STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR EDMUND G. BROWN JR.

Veterinary Medical Board
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MEETING NOTICE and AGENDA
MULTIDISCIPLINARY ADVISORY COMMITTEE

July 25, 2017
1747 N. Market Blvd. – 1st Floor Hearing Room
Sacramento, California

10:00 a.m. Tuesday, July 25, 2017

1. Call to Order/Roll Call/Establishment of a Quorum
2. Introductions
3. Review and Approval of April 18, 2017 Committee Meeting Minutes
4. Update from the Complaint Process Audit Subcommittee
5. Discussion and Consideration of "Extended Duty" for Registered Veterinary Technicians Regulations; Potential Recommendation to Full Board
6. Discussion and Consideration of Recommendations from State Humane Association of California and California Veterinary Medical Association Regarding Public and Private Shelters and Minimum Standards & Protocols for Shelter Medicine; Potential Recommendation to Full Board
7. Discussion and Consideration of Proposed Regulations Regarding the Compounding of Drugs Pursuant to the Enactment of Senate Bill 1193 (Hill, Chapter 484, Statutes of 2016); Potential Recommendation to Full Board
8. Discussion and Consideration of Proposed Amendments Regarding Drug Information to be Provided to Clients – Section 2032.1 of Title 16 of the California Code of Regulations; Potential Recommendation to Full Board
9. Discussion of Protocols for the Use of Sedatives in Emergency Situations; Potential Recommendation to Board
10. Public Comment on Items Not on the Agenda
    Note: The Committee may not discuss or take action on any matter raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting. (Government Code Sections 11125 and 11125.7(a).)
11. Future Agenda Items and Next Meeting Dates –
    - October 17, 2017 (Fresno)

    A. Multidisciplinary Advisory Committee Assignment Priorities
    B. Agenda Items for Next Meeting
12. Adjournment

This agenda can be found on the Veterinary Medical Board website at www.vmb.ca.gov. Action may be taken on any item on the agenda. The time and order of agenda items are approximate and subject to change at the discretion of the Committee Chair and may be taken out of order. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Committee are open to the public.

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*Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by the Committee prior to the Committee taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before the Committee, but the Committee Chair may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before the Committee to discuss items not on the agenda; however, the Committee can neither discuss nor take official action on these items at the time of the same meeting (Government Code sections 11125, 11125.7(a)).

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MISSION

The mission of the Veterinary Medical Board is to protect consumers and animals by regulating licensees, promoting professional standards and diligent enforcement of the practice of veterinary medicine.

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MEETING MINUTES
MULTIDISCIPLINARY ADVISORY COMMITTEE

April 18, 2017
Waterfront Hotel
10 Washington Street, Oakland, CA 94607

10:00 a.m. Tuesday, April 18, 2017

1. Call to Order/Roll Call/Establishment of a Quorum

Multidisciplinary Advisory Committee (MDC) Chair, Dr. Jon Klingborg called the meeting to order at 10:03 a.m. Veterinary Medical Board (Board) Executive Officer, Annemarie Del Mugnaio called roll; eight members of the MDC were present and thus a quorum was established. Diana Woodward-Hagle was not present.

2. Introductions

Members Present
Jon Klingborg, DVM, Chair
Allan Drusys, DVM, Vice Chair
William Grant, DVM
David Johnson, RVT
Jennifer Loredo, RVT, Board Liaison
Kristi Pawlowski, RVT
Jeff Pollard, DVM
Richard Sullivan, DVM, Board Liaison

Staff Present
Annemarie Del Mugnaio, Executive Officer
Louis Galiano, DCA Webcast
Kurt Heppler, Legal Counsel
Ethan Mathes, Administrative Program Manager
Candace Raney, Enforcement Manager
Tara Welch, Legal Counsel

Guests Present
Al Aldrete, DVM
Jonathan Burke, Department of Consumer Affairs
Nancy Ehrlich, RVT, California Registered Veterinary Technician Association
Valerie Fenstermaker, California Veterinary Medical Association
Erica Hughes, State Humane Association of California
Bonnie Lutz
John Pascoe, DVM, University of California, Davis
Ken Pawlowski, DVM, California Veterinary Medical Association

Cindy Savely, RVT, Sacramento Valley Veterinary Technician Association
Leah Shufelt, RVT, California Veterinary Medical Association
Cheryl Waterhouse, DVM, Veterinary Medical Board

3. Review and Approval of January 17, 2017 Committee Meeting Minutes

The MDC made minor changes to the January 17, 2017 meeting minutes.

- Dr. Allan Drusys moved and Dr. William Grant seconded the motion to approve the minutes as amended. The motion carried 8-0.

4. Update from the Complaint Process Audit Subcommittee

Dr. William Grant and Dr. Jeff Pollard met on April 6, 2017 in Sacramento to review closed cases. Report writing issues and expert witness training strategies were then shared with the Expert Witness training group in Sacramento on April 17, 2017.

Bonnie Lutz requested that the interpretation of regulations be considered as part of the Expert Witness training. Enforcement Manager, Candace Raney, offered to gather more details from Ms. Lutz to explore whetherthe application of various regulations by experts may be inappropriate.

5. Discussion and Consideration of "Extended Duty" for Registered Veterinary Technicians Regulations; Potential Recommendation to Full Board

The letter from the California Registered Veterinary Technicians Association (CaRVTA) included in the MDC's April 2017 meeting packet contained additional information on the list of "Suggestions for Extended Functions for Registered Veterinary Technicians (RVTs)" that CaRVTA originally submitted to the Board in October 2016.

The MDC asked several questions about CaRVTA's list including:

- What is the intended type of practice to which the list would be applied?
- Are the procedures taught in the RVT programs?
- Are the items in the list being tested on the national examination?
- Should some of these items be limited to veterinarians only?
- What supervision levels should be required?

Dr. Klingborg opined that some of the job tasks contain some form of a surgical component; therefore, should only be performed by a veterinarian.

Dr. Klingborg inquired about complaint data relative to RVTs versus Veterinary Assistants. Ms. Del Mugnaio noted that when the Board receives a complaint from a consumer, it is sometimes difficult to determine which individual in the veterinary clinic [i.e. RVT or Veterinary Assistant (VA)] performed a task(s), since consumers are not always sure of the credentials of the person treating their animal, nor are they able to observe all clinical procedures.

Nancy Ehrlich suggested changing the regulations to state that veterinarians may assign a task to an RVT or a VA, but those tasks requiring the skills of an RVT, should only be delegated to an RVT.

Ms. Lutz opined that this is a standard of care issue and the responsibility to delegate animal health care tasks should fall to the veterinarian. Ms. Lutz warned that addressing items specifically in regulations may allow individuals to perform specific tasks that they may not be qualified to perform.

Kristi Pawlowski referenced California Code of Regulations (CCR) section 2035, relating to the duties of the supervising veterinarian, stating that existing language identifies that the veterinarian is responsible for determining what tasks staff are capable of performing, and that this section addresses what the discussion on "Extended Duties for RVTs" is trying to achieve.

Dr. Grant agreed that any clarifying language should be kept general and expressed support for developing a subcommittee to develop the language.

Ms. Del Mugnaio clarified that the reason this item is before the MDC is because CaRVTA requested that RVT tasks are re-examined for other potential allowable tasks and that the tasks had not been reviewed in years. Ms. Del Mugnaio added that the recent RVT Occupational Analysis (OA) may be helpful in terms of identifying the knowledge, skills, and abilities that are expected upon graduation and licensure. Tasks outside of what is expected for a new practitioner may require advanced certification.

In response to Ms. Ehrlich's suggestion, David Johnson suggested addressing standard of care when assigning tasks to VAs. Jennifer Loredo agreed and suggested restriction of tasks by unlicensed personnel for more advanced procedures.

Ms. Ehrlich requested that the subcommittee, should it be formed, consider adding casting and splinting to the list of allowable RVT tasks under indirect supervision.

Ms. Del Mugnaio added that CCR section 2036.5(b) could be expanded to clarify that a supervisor shall not delegate a task to a VA that requires the formal training and skills of an RVT.

Dr. Klingborg clarified that the an animal shelter setting would be separate from the discussion and the focus would be primarily regarding the levels of supervision and the delegation of tasks to the appropriate individuals within private practice.

Dr. Ken Pawlowski expressed concern that the suggestion to clarify that a supervisor shall not delegate a task to a VA that *requires the formal training and skills of an RVT* might leave room for interpretation.

- Dr. William Grant motioned and Dr. Allan Drusys seconded the motion to form a subcommittee to review the extended functions of RVTs in private practice and evaluate whether "splinting and casting" could be performed by an RVT under indirect supervision.

Ms. Loredo suggested adding an amendment to CCR section 2036.5(b) to be more inclusive of advanced, invasive, high-risk tasks. From a consumer protection standpoint, Ms. Loredo felt that it was more important to restrict those tasks from VAs than it was to include them as RVT-only tasks.

Dr. Richard Sullivan requested that the subcommittee consider having RVTs obtain advanced training and certification to perform any extended functions.

Legal Counsel, Kurt Heppler, suggested amending the motion to have the subcommittee examine all of the applicable and relevant sections of regulations and statutes and report back regarding what areas would need to be changed to encompass extended RVT functions.

Dr. Grant amended his previous motion.

- Dr. William Grant motioned and Dr. Allan Drusys seconded the motion to form a subcommittee to review extended functions of RVTs in small animal practice, review existing regulations and statutes with regard to RVT tasks, consider whether "splinting and casting" could be performed by an RVT under indirect supervision, and consider adding language to be more restrictive of hig-risk, advanced procedures. The motion carried 8-0.

6. Review Legal Counsel's Guidance on the Federal Drug Mobility Act and its Impact on Registered Veterinary Technicians Transporting Controlled Substances for Emergency Treatment

Ms. Del Mugnaio stated that at the January 2017 MDC meeting, the MDC recommended expanding CCR section 2069 to include "pain management and sedation" to the list of emergency tasks that an RVT may perform.

The Board's new legal counsel, Tara Welch, reviewed the Controlled Substances Act (CSA) regarding provisions that allow an RVT to transport controlled substances under the direction of a veterinarian. Ms. Welch also reviewed the Federal Drug Mobility Act to determine if it had any bearing on an RVT Drug Enforcement Administration (DEA) registration.

Ms. Welch noted that the CSA requires a veterinarian to have a DEA registration if they are transporting controlled substances. The Federal Drug Mobility Act exempts the veterinarian from additional premises registration if the veterinarian is transporting controlled substances or administering controlled substances to a location other than their primary practice. When an RVT transports controlled substances to another location, the RVT is operating under the direction of a veterinarian and their DEA license.

Ms. Welch clarified that under the CSA, a Veterinary Assistant Controlled Substances Permit (VACSP) holder may be able to transport controlled substances under the direction of the veterinarian.

Dr. Allan Drusys expressed support for Ms. Welch's legal analysis and interpretation and opined that it also solves the issue of administering controlled substances for the purposes of sedation and/or anesthesia by and RVT in shelter settings under indirect supervision of the veterinarian.

Ms. Welch clarified that her legal interpretation was written from the standpoint of a private practice setting and the review of regulations and statutes, as they may apply to the shelter setting, would have to be performed separately.

Ms. Ehrlich reminded the Board that while the CSA may allow a VACSP holder to transport controlled substances, current regulations still do not allow VACSP holders to administer controlled substances outside of an animal hospital setting.

7. Discussion and Consideration of Recommendations from State Humane Association of California and California Veterinary Medical Association Regarding Public and Private Shelters and Minimum Standards & Protocols for Shelter Medicine; Potential Recommendation to Full Board

Erica Hughes, State Humane Association of California (SHAC), updated the Board on the outcome of the meeting with the California Veterinary Medical Association (CVMA) held in February 2017. The

two organizations identified a need to strengthen the relationship between shelters and veterinarians, as well as to understand why some shelters do not have premises permits.

SHAC and CVMA are still in the information-gathering stage and hope to be able to provide a joint recommendation by the next MDC meeting in July 2017.

Ms. Del Mugnaio noted that the Board's staff can send Ms. Hughes a list of the premises with permits (by county) to identify access issues. The list will also be sent to Dr. Drusys, who offered to geocode the locations on a map based on the list.

Mr. Johnson reviewed the discussion highlights (e.g. rabies vaccination, premises permits, RVTs as premises permit holders, etc.) since the issue was first brought before the MDC in December 2015. Ms. Hughes noted that many, if not all, of the highlights were addressed at the joint meeting and further research of the issues may dictate which of the discussion points will be retained or discarded.

Valerie Fenstermaker, CVMA, noted that the joint meeting primarily focused on the immediate problem of the vaccinations, parasite control upon intake, and the potential of written protocols under a supervising veterinarian.

8. Review and Consider Proposed Regulations Regarding the Compounding of Drugs Pursuant to the Enactment of Senate Bill 1193 (2016), Potential Recommendation to Full Board

Ms. Del Mugnaio noted that she and Dr. Sullivan met with the Board of Pharmacy on April 14, 2017 to explain the limited compounding provisions that the Board is trying to formulate for the purposes of veterinary medicine. The goal was to define veterinary in-office compounding as separate and apart from what a pharmacy and/or physician would perform. The discussion also included trying to find the best "beyond-use" date, specifically for sterile injectable compounded drugs.

The Board of Pharmacy expressed support for the Board regulating its own veterinary compounding. The Board will start off with a limited scope (e.g. training, quality assurance, supervision, simple compounding, limited sterile compounding with a conservative beyond-use date specification) and the Board of Pharmacy has agreed to provide guidance and expertise as needed.

Ms. Del Mugnaio noted there is a new United States Pharmacopeia (USP) 800 that will be introduced that will highly impact veterinarians' ability to compound chemotherapy and hazardous drugs.

Dr. Sullivan added that the Board of Pharmacy was concerned with the technical aspect of the language and opined that it will likely need to be refined in the future. Additionally, the Board of Pharmacy is concerned with stability of compounded drugs. The Board will need to document cases in which veterinary compounding was used to demonstrate that it is being performed safely and effectively.

Ms. Del Mugnaio noted that Business and Professions Code (BPC) section 4125 and CCR section 1711 are the Board of Pharmacy's laws and regulations, which clarify the requirements for pharmacies to conduct internal quality assurance. Quality assurance is confidential, performed in-house, and cannot be subpoenaed.

Dr. Klingborg added that there are three forms of drug stability studies that the Board of Pharmacy recognizes, two of which are experts and anecdotal information.

9. Discussion and Consideration of Proposed Amendments Regarding Drug Information to be Provided to Clients – Section 2032.1 of Title 16 of the California Code of Regulations; Possible Recommendation to Full Board

Dr. Sullivan updated the Board that the subcommittee, consisting of Dr. Pollard and himself, began developing proposed language with the assumption that the issue could be handled through regulations. However, the subcommittee decided to place their work on hold once the amendments to Senate Bill (SB) 546 were published as it includes similar language that appeared more prescriptive.

Ms. Del Mugnaio met with Bill Gage, Chief Consultant for the Senate Business Professions and Economic Development Committee (Committee) on SB 546. Ms. Del Mugnaio also noted that there will be a hearing on April 24, 2017 where she intends to provide preliminary comments to the Committee that the Board is in support of the Bill and is currently developing proposed regulatory language. By the next MDC meeting, there will likely be language that is ready to proceed through the legislative process via a Legislative Bill.

Dr. Grant expressed concern regarding the term "consultation" and suggested replacing it with the term "information".

Ms. Ehrlich noted that there was an amendment to SB 546 published on April 17, 2017; however, Ms. Del Mugnaio clarified that it is not part of the MDC agenda; therefore, it cannot be discussed.

- Dr. Richard Sullivan moved and Kristi Pawlowski second the motion to table the drug counseling item until the final amendments to SB 546 are published.
- Kristi Pawlowski withdrew her second to the motion.

Mr. Heppler suggested that the MDC continue work on the item until a final version of SB 546 is published and presented to the Board. The MDC collectively agreed and a motion was not needed.

10. Discuss Definitions and Scope of Responsibility for "Induction" of Anesthesia vs. Sedation – Section 2034 of Title 16 of the California Code of Regulations; Potential Recommendation to Board

Dr. Klingborg reviewed the highlights of the "induction" of anesthesia vs. sedation discussion since the last MDC meeting in January 2017.

Ms. Pawlowski expressed that there is significant difference in the definitions of "anesthesia" and "sedation" and opined that RVTs should not be performing either task without the animal first being examined by a veterinarian. RVTs also do not have liability insurance, nor are they able to obtain it because it is not legal for RVTs.

For the purposes of the discussion, an example of a "matted cat" needing sedating and being treated in an emergency situation was shared. Ms. Pawlowski expressed concern with allowing an RVT to diagnose, prescribe, and potentially sedate or induce anesthesia, without an examination or prior history, for the purpose of removing mats. Ms. Pawlowski suggested looking at referring these types of services to an emergency clinic and/or looking at why a relationship to refer the services to another facility with a veterinarian present does not exist.

In response to the "matted cat" example, Ms. Loredo argued that it may be considered an emergency situation when the cat is not just matted, but also covered in maggots, for example. Since a lot of facilities do not have access to RVTs and/or veterinarians, there appears to be an access issue.

Ms. Del Mugnaio suggested examining what is considered an "emergency" situation in a shelter setting.

Mr. Johnson suggested that "pain management" and "seizure control" be considered as additions to CCR section 2069.

Ms. Pawlowski referenced CCR section 2032.4, to remind the Board of the current anesthesia requirements under the Practice Act and opined that emergency anesthesia should require an examination by a veterinarian.

Dr. Klingborg suggested providing a recommendation to the Board to direct the MDC to research the expansion of emergency animal care in CCR section 2069.

Dr. Pollard pointed out that CCR section 2069(2) states "administration of pharmacological agents to prevent or control shock" could be interpreted as authority for RVTs to provide seizure control in emergency situations. Mr. Johnson shared that the original intent of that language was to allow RVTs to provide intravenous steroids and hook up the animal patient to Lactated Ringers.

Ms. Ehrlich suggested amending BPC section 4840.5 to establish the authority to amend CCR section 2069 to include "serious bodily injury", which may not be life threatening, but should be considered an emergency situation.

Mr. Heppler suggested focusing the discussion on CCR section 2069 and enabling statutes to clarify what constitutes as an emergency and a life threatening situation, regardless of setting.

Ms. Hughes and the MDC discussed the issue of liability when an RVT happens to anesthetize the animal patient when it was not their intention to do so. An example was shared that if an animal does not respond to the initial sedative, another sedative may be given which unintentionally leads to anesthesia. Beyond the intent and dosage, Dr. Grant stated that there are other variables that may affect the outcome of the induction of sedation/anesthesia, such as the physiological state of the animal patient.

Dr. Klingborg stated that he will report back to the Board how the agenda item evolved into emergency protocols and request the Board's guidance going forward.

11. Discuss Minimum Standards for Spay/Neuter Clinics

Dr. Grant suggested striking CCR section 2030.35(c)(3) regarding the "collection tank for disposal of waste material" since the intention of the language, as written for mobile clinics, does not apply in spay/neuter clinics.

Ms. Del Mugnaio noted that specialty clinics should not have a compliance issue noted regarding meeting minimum standards that are not applicable to the type of services provided at a given clinic. Ms. Del Mugnaio opined that there may not be a need to create separate minimum standards for spay/neuter clinics when inspections are specific to the type of services provided at a premises.

Regarding the requirement to establish a Veterinarian-Client-Patient Relationship (VCPR) on unowned animals, Ms. Del Mugnaio pointed out that the proposed language is not a standalone provision and applies in conjunction with other sections of the Practice Act.

The MDC identified CCR section 2030.35(e) regarding the "after hours emergency services" as not being specific to spay/neuter clinics, but applicable to fixed premises.

Dr. Klingborg identified two options:

1. Continue utilizing existing fixed premises minimum standards and allow inspectors to apply minimum standards as appropriate to each specialty clinic type.
2. Define minimum standards for each type of specialty practice.

Ms. Lutz expressed support for Option #1, but opined that there should be separate minimum standards for large animal practices.

- David Johnson moved and Dr. Richard Sullivan seconded the motion to reject the Minimum Standards for Spay/Neuter Clinics proposed regulatory language. The motion carried 8-0.

12. Discuss Minimum Standards for Mobile Specialists

Dr. Grant stated that issues were raised when trying to determine where to place the responsibility of patient care when cases are handed off to mobile specialists. After speaking with a number of medical doctors, veterinarians, and mobile specialists, Dr. Grant found that each case is so unique that it can be difficult to clearly define certain areas of responsibility between the primary veterinarian and the mobile specialist.

This is not an issue that can be resolved by regulation, but instead would be handled through the complaint process should animal harm occur.

13. Review, Discussion, and Possible Recommendation on Reciprocity Issues and License Eligibility for Veterinary Applicants Who Possess Work Experience in a Foreign Territory; Consider Equivalent Credentials of Board Certification (Business and Professions Code section 4848(b)(1))

Dr. Klingborg noted that the Board voted and passed a motion at the January 2017 Board meeting to clarify the Board's intent that veterinary clinical experience for purposes of reciprocity eligibility must be in another U.S. state, Canadian province, or United States territory.

The MDC was tasked with determining if special consideration should be afforded to individuals who are "Board certified" as an equivalent pathway to reciprocity eligibility.

The MDC expressed concerns that Board certified specialists (e.g. Dermatologists) tend to have experience in one particular area and there is currently no way to restrict a Board certified specialist from entering general practice (and performing surgery on animals).

Ms. Del Mugnaio pointed out that individuals with work experience in a foreign territory are not ineligible to practice in California, nor are they precluded from taking the California State Board examination and applying for licensure under the traditional pathway. There is currently no equivalent pathway for individuals with foreign experience.

Dr. Klingborg reviewed the list of six items under "Application of Current Laws and Issues" prepared by Ms. Woodward-Hagle.

- Dr. Richard Sullivan moved and Dr. Allan Drusys seconded the motion to recommend to the Board that it not consider recognizing veterinary specialty Board certifications as satisfying the clinical experience requirements for reciprocity eligibility. The motion carried 8-0.

14. Public Comment on Items Not on the Agenda

There were no comments from public/outside agencies/associations.

15. Future Agenda Items and Next Meeting Dates –

- July 25, 2017 (Sacramento)
- October 17, 2017 (Fresno)

A. Multidisciplinary Advisory Committee Assignment Priorities

Dr. Klingborg reviewed the list of existing MDC assignment priorities:

- Structure and Audit Enforcement Case Outcomes
- Minimum Standards for Alternate Premises
- "Extended Duties" for RVTs
- Drug Compounding Regulations
- Sedation vs Anesthesia
  - Emergency Protocols
- Drug Counseling

B. Agenda Items for Next Meeting – Minimum Standards for Small Animal Spay and Neuter Clinics

The Minimum Standards for Small Animal Spay and Neuter Clinics agenda item has been removed from the MDC's assignment priorities.

16. Adjournment

The MDC adjourned at 3:40 p.m.

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Extended functions for RVT subcommittee

Task 1: Central Line Placement

Existing regulations? *Relief hole *Suturing?

Curriculum? Yes – practiced in lab
Cosumnes River College
Carrington College

Tasks involved

- Sedation?
- Venipuncture
- Aseptic technique
- Suturing
- Bandaging

This procedure can be completed with a relief hole, as is already approved in the RVT-restricted tasks. No incision or severing of tissue is required.

Suturing to secure the catheter to the skin is performed, but not to appose tissue or close any incision.

Restricting this task to be performed by RVTs or veterinarians only will greatly reduce potential harm to the patient. RVTs have specific training in anatomy and physiology and are taught the potential pitfalls and dangers of intravenous access. It is especially important for those accessing the central circulation to understand the potential complications of said access including but not limited to: infection, hemorrhage, laceration of tissues, and others. Because the potential complications can be quite serious, restricting this task to RVTs or veterinarians only further protects the consumer by giving the consumer an avenue to pursue complaints with the Veterinary Medical Board

Task 2: Placement of nasogastric (NG) tubes, urinary catheters, tracheal tubes

Existing regulations? *Possibly Suturing

Curriculum? Yes (NG tubes)
Cosumnes River College
Carrington College
These are things they are taught in labs and practice (NG tubes are not practiced as widely)

Tasks involved

- Sedation
- Aseptic technique
- Suturing/stapling
- Knowledge of anatomy

Placement of NG tubes and urinary catheters require no incision or severing of tissue. Tracheal tube placement does require an initial surgery (performed by a licensed veterinarian), but replacement with a new, sterile tube and suctioning or other care of the tube, does not require any element of surgery.

Suturing to secure the tubes in place may be required, though many technicians and veterinarians may opt to use skin staples instead. For tracheal tubes, often sutures are placed around the tracheal rings cranial and caudal to the insertion point to facilitate changing the tube and aid in maintaining the opening in the trachea.

Restricting these tasks to be performed by RVTs or veterinarians only will greatly reduce potential harm to the patient: • NG tubes can be mistakenly place within the lumen of the trachea and advanced into the lungs. If the tube is then used to provide liquid nutrition, aspiration pneumonia may be induced, leading to a need for a prolonged hospital stay, and many more complications and expenses. RVTs are trained in

placement of these tubes, along with knowledge of anatomy and physiology, which attunes them to the potential complications and how they may be avoided. Additionally, placement of these tubes must be confirmed with properly positioned radiographs – a skill for which RVTs are specifically trained. • Urinary catheterization must be performed as aseptically as possible to avoid iatrogenic urinary tract contamination and infection. RVTs are trained in proper aseptic techniques and are better equipped than non-credentialed staff to avoid contaminating the urinary tract. Urinary catheterization can be fraught with complications including urethral or bladder rupture. RVTs are trained in the complications surrounding urinary catheterization and methods to avoid them. • Veterinarians place tracheal breathing tubes surgically and maintaining these tubes falls to veterinary team members. Because these tubes are placed to preserve a patient's airway in the face of trauma, inflammation, or upper airway obstruction, keeping them open is paramount to keeping patients breathing. Care of these tubes, particularly suctioning or swapping out tubes as part of regular tracheal tube maintenance, is a potentially dangerous procedure, which should only be undertaken by the most highly qualified staff members, which include RVTs. With their training in anatomy and physiology, and care and maintenance of life-sustaining apparatuses, RVTs are the ideal team members to provide tracheal tube care.

Task 3: CSF/Spinal taps:

The procedures are performed via needle puncture. No surgery is required.

Curriculum:
This is described and the procedure is discussed minimally. This is not taught in the current curriculum at Cosumnes River College or Carrington College. There is no hands-on practice.

No suturing is required.

Accessing the epidural or other spinal cord spaces is a high-risk procedure with numerous serious complications possible. Because of this risk, only team members with training in anatomy and physiology and a thorough knowledge of the potential complications of this procedure should be performing any collection of cerebrospinal fluid. Restricting this task to RVTs or veterinarians will provide more safety for patients and accountability for clients.

Task 4: Chest tube placement

Existing regulations? *Possibly suturing
Curriculum:
This is described and the procedure is discussed minimally. This is not taught in the current curriculum at Cosumnes River College or Carrington College. They do discuss how to properly care for and maintain a chest tube after it is placed. There is no hands-on practice.

There are many products available on the market that do not require any surgery or incisions for placement.

Suturing to secure the tube to the skin of the thorax may be required.

The thoracic cavity contains many vital structures, most notably the lungs. There are many potential complications associated with chest tube placement including laceration of lung tissue or of major vessels within the thoracic cavity. RVTs and veterinarians should be the only veterinary team members performing this task both to increase patient safety and provide accountability for clients in the event of an adverse event.

Task 5: Intraosseus (IO) catheter placement

Existing regulations? *Possibly a relief hole *Possibly suturing
Curriculum: both discuss but not much hands-on practical

Cosumnes River College
Carrington College

This is accomplished with a variety of needles, but no surgery is required. Occasionally a relief hole may be necessary, which is already an approved RVT-restricted task.

Depending on the technique used, suturing may be required to attach the IO catheter to the skin.

Placing catheters in the medullary cavity of bones to provide access to the systemic circulation should be restricted to RVTs and veterinarians only. There are several risks associated with IO catheters, including fractures and infection. By restricting this task to those staff members with training in and knowledge of anatomy and physiology, as well as the potential complications, the VMB will add safety protection for patients and consumer protection as well.

Task 6: Centeses (urinary bladder, abdominocentesis, thoracocentesis)
These procedures are done with needles and no surgery is required.

Curriculum: both discuss but not much hands-on practical for thoracocentesis, some abdominocentesis
Cosumnes River College
Carrington College

No suturing is required.

Centeses require accessing body cavities with a needle, an inherently dangerous procedure with many potential complications. RVTs and veterinarians have knowledge of anatomy and physiology that allows them to avoid potential complications, as well as recognize complications and intervene quickly and appropriately. Restricting this task to RVTs or veterinarians only will allow for the highest level of patient safety and will enhance consumer protection.

Task 7: Advanced nerve blocking techniques
Epidural administration, regional anesthesia, and local anesthesia are all accomplished via injection and no surgery is required.

Curriculum: both discuss but not much hands-on practical
Cosumnes River College
Carrington College

No suturing is required.

Advanced nerve blocks – such as epidurals, brachial-plexus blocks, sacrococcygeal blocks, and others – require injection of local anesthetics and/or opioid drugs into areas (including the epidural space of the spinal cord) to induce local anesthesia. As an anesthetic technique, these blocks should be restricted to RVTs or veterinarians only, just as general anesthetic induction is currently restricted. Overdoses of local anesthetics can be quite dangerous or even lethal; as such the administration of these agents should be restricted to those members of the veterinary team who have the knowledge to: correctly calculate drug doses; recognize adverse effects of local anesthetics; intervene promptly and appropriately in response to complications. Handling of opioids is already currently restricted to RVTs, veterinarians, or those assistants who hold Controlled Substance Permits (VACSP) and these agents are often used in nerve blocking techniques

Task 8: Casting and Splinting – Indirect Supervision

Existing regulations - direct supervision

Curriculum: because it is existing law, both colleges teach

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Intravenous Indwelling Catheters: Use & Care

Ann B. Weil, DVM, MS, Diplomate ACVA, and Jeff Ko, DVM, MS, Diplomate ACVA, Purdue University

Overview

Intravenous (IV) indwelling catheters are commonly used in dogs and cats for ease of various drug and fluid administration. They are placed in either peripheral or central veins and may be maintained for days if the site has been sterilely prepared and is inspected daily.

Uses

- Routine fluid administration
- Drug administration, including emergency drugs
- Administering blood products and colloids
- Measurement of central venous pressure
- Facilitation of blood draws in patients requiring multiple tests or with very poor vein access
- Total parenteral nutrition administration

Placement of an intravenous catheter ensures that the drug will be administered intravascularly. This is of particular importance when the intended drug is very irritating to tissues if administered perivascularly (eg, thiopental and chemotherapeutic agents).

Treatments that include frequent administration of drugs or those that involve large volumes can be facilitated by using an intravenous indwelling catheter. For drugs or fluids (like plasma or blood) that must be administered intravenously, IV catheter placement may be the only option for administration.

Types of Catheters

Peripheral—Through-the-needle catheter
Various sizes ranging from 18 gauge to 24 gauge are commonly used in small animal practice.

Central—Central catheters placed via Seldinger technique (or wire-guided)
Central catheters include through-the-needle catheters such as intracaths and wire-guided catheters. Wire-guided catheters allow multiple uses and administrations from a single device.

- Single lumen
- Double lumen
- Triple lumen

Various sizes ranging from 16 gauge to 22 gauge are commonly used in small animal practice. Central venous catheters are normally cleaner because they are less likely to be urinated or vomited on by the patient. They stay in place longer because they are less likely to be chewed out. Also, because they tend to be made of softer, more flexible materials (especially multiple lumen devices), they are less likely to cause phlebitis during long-term use.

Sites for Placement

Peripheral indwelling intravenous catheters are usually placed in the cephalic vein in the forelimbs of dogs and cats. In the hindlimb, they are most commonly placed in the lateral saphenous vein in the dog and the medial femoral vein in the cat. Peripheral catheter placement is not technically difficult and the device may be placed using physical or chemical restraint of the patient. Aseptic techniques should be used.

New Article Series

Patient Support is a new column that outlines optimum strategy and intervention for providing the best patient-centered veterinary care while pursuing curative medicine and surgery.

Central indwelling venous catheters are usually placed in the internal and external jugular veins. Insertion of central catheters is technically demanding. A sedative or general anesthetic may be required for placement in a healthy patient; chemical restraint is not necessary for ill or debilitated patients. A small volume of local anesthetic placed at the device site is very useful for maintaining patient comfort during the procedure. Aseptic techniques should be used.

Central catheters may be placed in peripheral veins for long-term use and improved security of device placement. In cats, the medial saphenous vein is frequently used for this purpose. The lateral saphenous vein is typically used in dogs and may also be used in cats.

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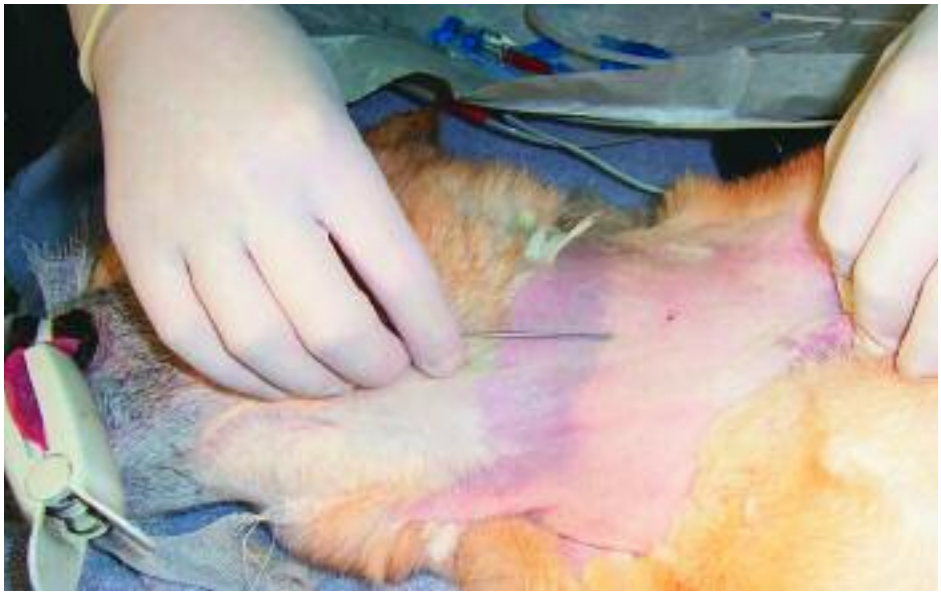
Placement & Security of Indwelling Catheters

Central

1. Place animal in lateral recumbency.
2. Clip area, being careful to avoid clipper burn.
3. Scrub the area using sterile technique.
4. Have another person restrain the animal and occlude the vein.
5. Scrub hands and put on sterile gloves.
6. Have another person flush the needle and the lumen of the central catheter while the sterile-gloved person holds the ports. The unsterile person may not touch anything inside the Arrow catheter packaging.
7. Drape the patient's neck to prevent inadvertent contamination of the catheter. *Draping is recommended but is not done in this series to allow for better visualization.*
8. Palpate the vein.
9. Tent the skin over the vein and use a surgical blade to make a small nick in the skin for insertion of the needle. A small amount of local anesthetic (2% lidocaine) may be placed prior to the skin nick.
10. Insert the needle, bevel up, with the needle going toward the heart.
11. When blood is observed flashing back into the needle catheter, feed the wire from the wire guide forward into the lumen of the needle catheter, while still holding the device. ***Do not move the needle catheter!***
12. Once the wire is advanced sufficiently into the vein, remove the plastic wire guide; then carefully pull the needle catheter back out over the wire. Be sure to hold the wire at all times.
13. *An alternative way of doing this is to place a through-the-needle catheter (a peripheral catheter), instead of using the needle catheter that comes with the jugular catheter package.* Using a peripheral through-the-needle catheter (after removing the stylette) may be easier and less likely to pierce the vessel wall while passing the wire.
14. Place a dilator over the wire and dilate through the skin and into the vein. The skin may need to be held and the dilator wedged through. When the dilator is pulled out, a small amount of blood should be observed from the hole. Pull the dilator completely off while still holding the wire in place. Apply pressure to the site to prevent blood loss.
15. Remove the cap from the brown port of the catheter and ensure it is not clamped off.
16. Measure how far you want to place your catheter (from insertion point to the heart). Alternatively, measuring the length of the catheter before the procedure is started will minimize the amount of time it takes to place the catheter and prevent



Introducing a jugular needle catheter into an anesthetized dog

Introducing a wire guide through the lumen of the needle with sterile technique

Threading a double-lumen jugular catheter through the wire guide and into the jugular vein

A jugular catheter in situ, sutured but not wrapped

blood loss during placement.

17. At this point, the wire should be coming out of the brown port and can be held while the catheter is fed over the wire into the vein to the desired length. Catheters are marked for ease of measurement. While holding the catheter in place, remove the wire.
18. Attach syringe of heparinized saline to the catheter and aspirate blood to ensure proper placement and to remove any air bubbles. Flush and clamp catheter, and place infusion cap on the end.
19. Suture to the skin through the plastic clamps. A "butterfly" of tape may be placed higher up and sutured as well.
20. Cover the site where the catheter enters the skin with betadine ointment and gauze.
21. Wrap the neck with soft padding, Kling, then Vet Wrap. The bandage should be firm, but never tight.

Peripheral

1. Place the animal in sternal recumbency if possible.
2. Clip the area where the catheter will be placed, avoiding clipper burn.
3. Gently scrub the area 3 times (Iodine versus chlorhexidine is discussed later).
4. Flush the catheter and t-set with heparinized saline (information on recommended heparin amount is provided later).
5. Restrain the patient and occlude the vein.
6. Insert catheter, bevel up, with the point of the needle headed toward the body.
7. When blood is observed in the catheter, feed the catheter forward. ***Do not advance the stylette!***
8. Remove the stylette when the catheter is threaded to the hub.
9. Attach the t-set and injection cap.
10. Wrap a long piece of 1/2-inch medical adhesive tape around the device; then around the leg.
11. Flush the catheter through the t-set to check for patency.

continues

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12. Dry the leg.
13. Place a Band-aid coated with betadine ointment where the catheter enters the skin.
14. Place 1-inch tape under the device and around the leg.
15. Wrap a short piece of 1/2-inch tape around the t-set and catheter to secure the t-set into the catheter.
16. Using another piece of 1-inch tape and starting at the top of the catheter, loop the t-set and tape to the leg.

Maintenance

Catheters should be flushed with heparinized saline or physiologic saline every 2 to 4 hours if the patient is not receiving fluids or a constant rate infusion of drugs. Opinions regarding the use of either heparinized saline or plain saline to flush intravenous catheters intermittently are contradictory. Some studies have shown that using heparinized saline decreases the likelihood of intraluminal clot formation and therefore prevents device malfunction. Others have shown that heparinized saline provides no significant advantages over regular sodium chloride for maintaining patency and preventing blood clot formation.[1] The concentration of heparin used with saline ranges from 2 IU/ml to 100 IU/ml. Some hospitals use premixed commercial heparin/saline while others use their own mixture of heparin/saline.

In humans, the concerns of using heparin as an antithrombotic agent for intravenous catheters include heparin-induced thrombocytopenia and allergic reactions to heparin. When a catheter is flushed repeatedly with solutions containing high concentrations of heparin, bleeding complications may result. This is of particular concern in small veterinary patients such as cats, toy breed dogs, or neonates. In our hospital, we prefer to use low concentration heparinized saline (2 IU per ml) and flush every 2 to 4 hours to maintain the patency of the catheter. Care must be taken to keep the catheter site clean and dry. At least daily inspection of the catheter site is very helpful in identifying problems early. Complications can be reduced by regular and timely changes of the dressing. For catheters that need to be maintained for longer durations (longer than 3 days), disinfectants such as chlorhexidine gluconate should be applied at the time of insertion and reapplied every 48 to 72 hours to prevent bloodstream infection.[2]

Catheters should be secured properly. Peripheral catheters are usually secured with 1/2- to 1-inch medical tape; central venous catheters are usually secured with sutures. Bandaging peripheral or central venous catheters too tightly or too loosely may cause significant problems. Excessively tight bandaging will cause local edema, while loose bandaging leads to malposition of the catheter and possible loss. It is important to periodically check the animal for either of these occurrences and make any necessary adjustments.

Many animals will require some method of restraint (Elizabethan collars, etc) to keep them from chewing out catheters. Another challenge is the security and proper placement of the injection cap or port to the hub of the catheter. A loosely attached injection cap or port will allow back flow of the blood or leakage of fluids, clotting of the catheter lumen, and ultimately cause malfunction of the catheter. Therefore, it is important to properly select and set the injection cap and port to best fit the catheter.

Complications

Intravenous catheter placement can result in serious complications including excessive bleeding, sepsis, thrombophlebitis, and thrombosis or air emboli.[3] Performing coagulation testing prior to central catheter placement is particularly warranted in critically ill patients with potential coagulation problems. Studies have compared the use of chlorhexidine gluconate or povidone iodine to disinfect the catheter insertion site and prevent bloodstream infection and sepsis. One study showed that site preparation with 2% chlorhexidine resulted in lower infection rates than did preparation with povidone-iodine or 70% alcohol.[4]

Some Signs of Catheter-Related Infection

- **Presence of purulence at catheter insertion site**
- **Elevation of body temperature over 38.5°C (101.3°F)**
- **Erythema or tenderness at insertion site**
- **Hypothermia with signs of shock**
- **Any elevation of body temperature associated with a positive blood culture**

Scheduled replacement of catheters has been proposed as a method of preventing infections. Studies of peripheral catheters show increased thrombophlebitis and bacterial colonization when a catheter is left in place longer than 72 hours.[5] Changing the device every 3 days may improve patient comfort and reduce infection rates.

It has been suggested that a fibrin sheath develops around the catheter within 24 hours, increasing bacterial attachment and replication and resulting in thrombus formation. This promotes further microbial adherence.[5] In humans, the diagnosis of catheter-related central vein thrombosis is based on visualizing an intravascular thrombus, incompressibility of the vein by probe pressure, or absence of spontaneous flow as detected by Doppler. The diagnosis of pulmonary emboli/air embolism requires pulmonary angiography or lung scanning.

Indwelling intravenous catheters are useful tools in veterinary practice. However, proper hygiene prior to insertion combined with good technique aids in preventing infections. Vigilance in monitoring and maintenance of indwelling catheters are keys to preventing further complications associated with their use.

See Aids & Resources, back page, for references, contacts, and appendices.

URETHRAL CATHETERIZATION

OF THE FEMALE DOG & CAT

Janet Aldrich, DVM, University of California-Davis

URETHRAL CATHETERIZATION is the passage of a urinary catheter from the external urethral orifice into the urinary bladder.

Benefits & Risks

Urinary catheters are used to quantify urine output and relieve the inability to empty the bladder. The primary risk is urinary tract infection from bacteria introduced during placement or ascending around or through the catheter. We recently reported the incidence of catheter-associated urinary tract infection as 10.3% in male and female dogs, with a mean duration of catheterization of 2 days.[1] This infection rate was lower than in previous reports, which we attributed to a standardized placement technique and catheter maintenance as described here. We found no association between gender and risk for catheter-associated urinary tract infection.

Technique

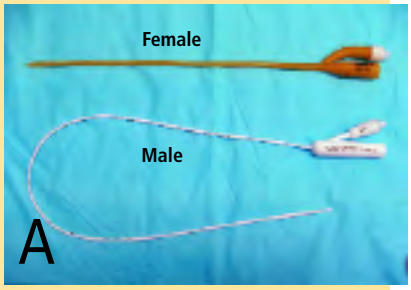
Various techniques have been described for placing urinary catheters in females. Most of these techniques include a speculum, light source, otoscope, and stylet.[2] In most of our patients we use a digital technique, also called a blind technique, that does not require a speculum, light source, or otoscope. Stylets are not routinely used. We prefer the technique described here for the following reasons:

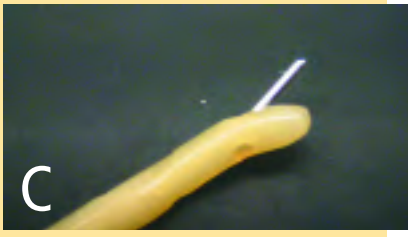
- We can position the patient in lateral recumbency, which is more comfortable than draping the rear legs over the end of the table as described for the instrument technique.
- Inserting a finger lubricated with sterile lidocaine jelly, rather than instruments, is more comfortable for the patient because it causes less distention of tissues.
- The positioning and local anesthesia with lidocaine jelly greatly reduce the need for sedation.
- Risk for tissue damage during insertion is reduced because stylets are used less often.

continues

What You Will Need

- We prefer Foley catheters (**Figure A**) because they are soft and pliable (decreased tissue trauma) and are self-retaining (no sutures needed).
- Use 5-French for small dogs, 8-French for medium dogs, and 10- to 12-French for large dogs.
- Multipurpose catheters, such as polypropylene and red rubber, can also be used; however, they must be sutured in place. Polypropylene catheters are made of semirigid plastic and although they are easier to introduce into the urethral opening, they are more likely to traumatize vestibular tissue and may damage the bladder if advanced too far. Our impression is that they are uncomfortable for the patient.
- Use 5- or 3.5-French catheters for cats and very small dogs. 5-French Foley catheters have a flexible stylet (**Figure B**). If a stylet is used, care must be taken that it does not become misdirected or dislodged during insertion. **Figure C** is the tip of a urinary catheter with a stylet. The stylet has become dislodged and is exiting through the side port rather than extending to the tip of the catheter. This misdirection of the stylet will preclude advancing the catheter tip into the urethra and repeated attempts to advance it can cause severe tissue injury.
- All in-dwelling urinary catheters should be attached to a sterile, closed collection system.





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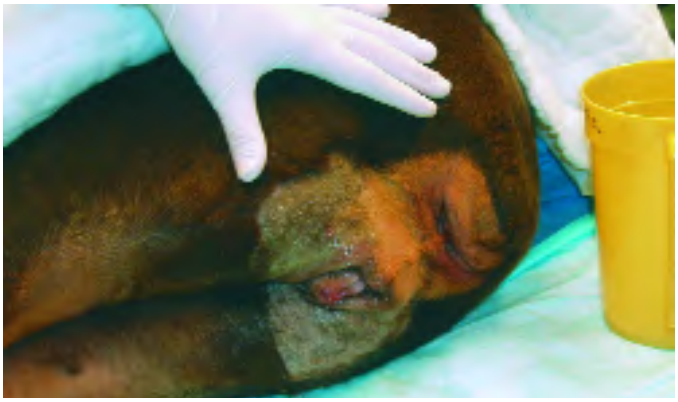
STEP BY STEP HOW TO PERFORM URETHRAL CATHETERIZATION

Patient Preparation

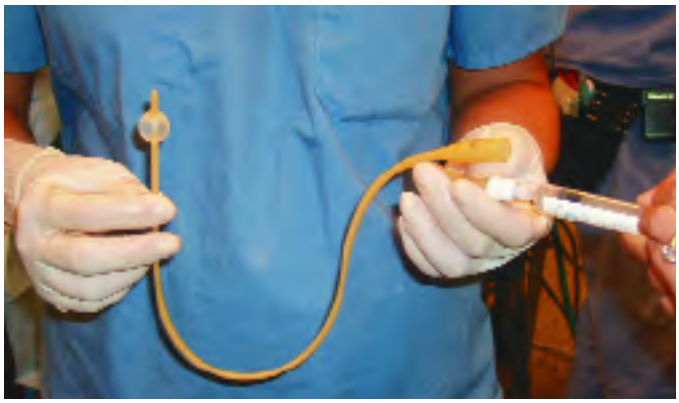


1 Position the patient comfortably in right lateral recumbency (for right-handed operators). Sedation is usually not needed in dogs because this position is comfortable and lidocaine jelly in the vestibule provides adequate pain control. Sedation is usually needed in cats. Clip, clean, and aseptically prepare the perivulvar area.

2 Flush the vestibule with 0.05% Nolvasan solution (6.3 ml Nolvasan in 250 ml sterile water). Instill enough 2% lidocaine jelly (0.5 to 2 ml, depending on patient size) into the vulva and vestibule to provide local anesthesia and lubrication. Place sterile drapes.

Catheter Insertion

Maintain sterile technique throughout the procedure. Operators should use the dominant hand for palpation. The procedure described here is for a right-handed operator.



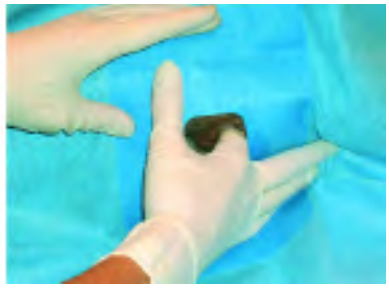
3 Inspect the catheter, estimate the length of catheter required to reach the bladder, and verify patency of the balloon.

Anatomy

The vagina is a canal extending from the vulva cranially to the cervix. It consists of two cavities, the most caudal is the vestibule, and the cranial cavity is the vagina. The urethral opening is covered by a soft mound of tissue and is located ventrally on midline in the vestibule, close to its junction with the vagina. The vestibular vaginal junction is palpable as a circular thickening that narrows the cavity.

PROCEDURE PEARL

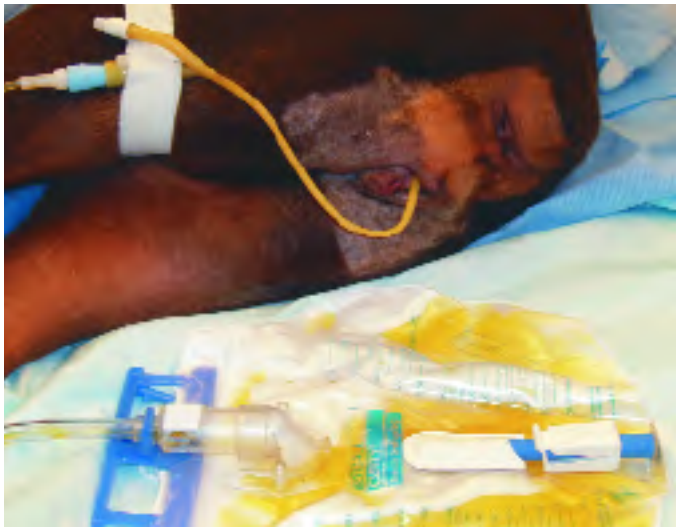
With practice, one can learn to advance a catheter without a stylet using the technique described in this article.



4 Insert a lubricated finger of the right hand between the labia of the vulva, direct the finger dorsally to avoid the clitoral fossa, then cranially to enter the vestibule. Slide the finger along the floor of the vestibule, on midline, and palpate the urethral opening at the junction of the vestibule with the vagina. The urethral opening is covered by a mound of tissue (papilla) that may be obvious or subtle. The junction of the vestibule and the vagina is a muscular thickening that is usually palpable as a narrowing of the lumen of the cavity to the extent that further advancement of the finger is impossible. Rather than an impediment, this anatomical landmark is usually helpful because the urethral opening is located just caudal to this junction. Inserting a finger into this opening prevents the catheter from advancing into the vagina rather than into the urethral opening.

5 Use the left hand to grasp the catheter near the tip, and gently insert it between the labia of the vulva and into the vestibule. Then place the finger of the right hand (which is within the vestibule) on the tip of the catheter and gently push it forward in very small increments to guide it along the ventral floor of the vestibule to the urethral opening. Do not expect to advance the catheter simply by pushing with the left hand: Gently advance it with the right finger while using the left hand to keep the catheter aligned. (Our students have compared this to advancing cooked spaghetti along a wet table.)

6 Position the tip of the catheter at the urethral opening and advance it in increments of a few millimeters until the catheter has entered the urethra. Verify placement in the urethra by palpating the tissue of the urethral papilla over the catheter. If the catheter has slipped over the papilla, it will continue to advance into the vagina but in that position the tissue cannot be palpated over the top of the catheter.



7 Once the catheter has entered the urethra, advance it until it rests in the bladder. Secure it by inflating the balloon for a Foley catheter, gently pull the catheter caudally to position its tip at the neck of the bladder, and attach a closed, sterile collection system. Secure the catheter to the rear leg or tail to prevent excessive traction on it. Maintain sterility of the closed system. See **Maintenance,** page 20.

Various strictures are present in some dogs. Most are cranial to the urethral opening and do not hamper catheterization. Rarely, the urethral opening is cranial to the stricture and the catheter must be directed through the stricture and then ventrally. In this case, the urethral opening cannot be palpated unless there is enough room for the finger to pass through the stricture. Nonetheless, blindly advancing the catheter along the correct path is often successful.

PROCEDURE PEARL

Once the catheter tip is in the bladder the balloon is filled with the recommended volume of saline to retain the catheter in the bladder.

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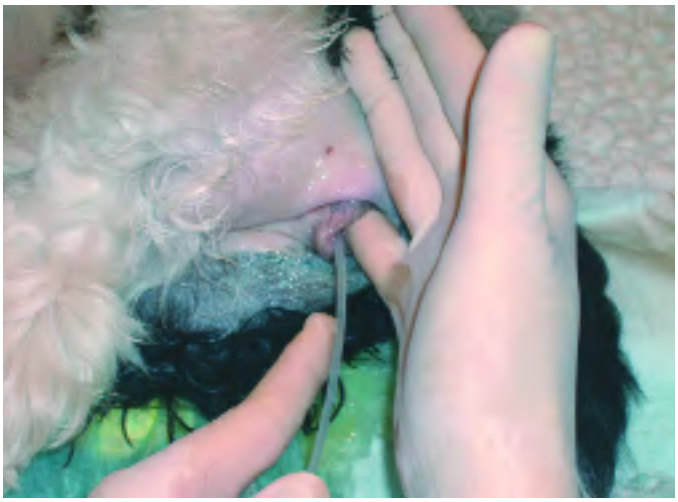
Guiding Catheter & Instrument Techniques

If the catheter cannot be placed within a reasonable time by using the digital technique, switch techniques.

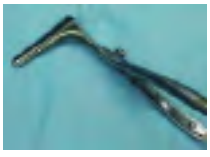
Guiding Catheter Technique

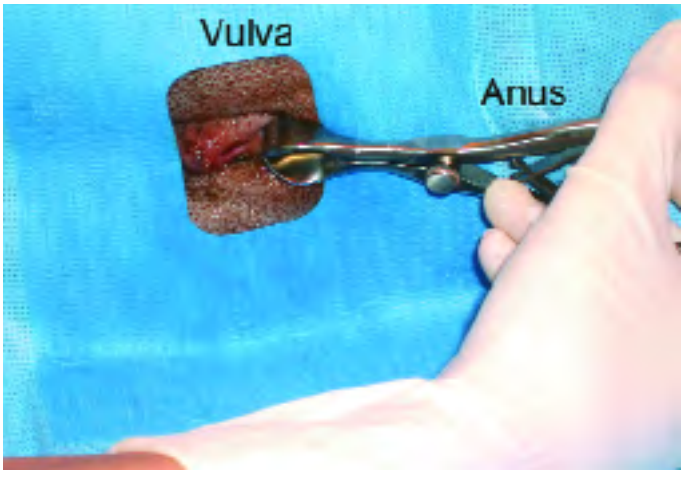


Polypropylene catheters are easy to insert but we prefer not to leave them in place because of the potential for tissue trauma and discomfort caused by their stiffness. In a difficult insertion, a polypropylene catheter can be used to locate the urethral opening; then a Foley catheter can be placed in the vestibule alongside it, using the polypropylene catheter as a guide. The polypropylene catheter is then removed.

Instrument Technique

A speculum is used to separate the urethral tissue so that the urethral opening can be seen with the aid of a light source such as a headlamp or penlight. Insert the speculum with the handles toward the anus. Standing out of the operator's way, an assistant should hold the speculum in an open position to allow the otoscope cone to be inserted through it. The catheter is then inserted through the cone into the urethral opening and then into the urinary bladder. A stylet through the catheter is required. The otoscope cone will not allow the distal portion of the Foley catheter to pass through, so the cone is removed from the otoscope but left in place on the catheter.



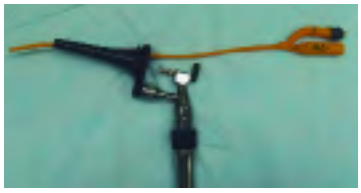


Maintenance

Maintain the sterility of the closed collection system according to published recommendations.[3]

- Educate personnel in correct techniques of catheter insertion and care.
- Catheterize only when needed.
- Stress hand washing before and after handling catheter and collection system.
- Insert catheter using aseptic technique and sterile equipment.
- Maintain closed, sterile drainage system.
- Maintain unobstructed urine flow.
- Obtain urine samples aseptically.
- Keep urine collection bag below the patient.

We inspect the catheter site daily. We also gently clean the catheter and labia with Nolvasan scrub and water daily, or anytime the catheter is visibly soiled.



It is not necessarily more difficult to place catheters in very small dogs and cats. While their size precludes palpation of the urethral opening, it also tends to direct a blindly inserted catheter along the correct pathway. Catheterization of female cats is generally easily done with the blind technique but usually requires a 3.5- or 5-French polypropylene tomcat catheter. The kitten shown here weighs 450 grams. We use 5-French Foley catheters in larger cats. The catheter is secured in place to the perivulvar area with a tape butterfly.

See Aids & Resources, back page, for references, contacts, and appendices.

Nasoesophageal & Nasogastric Tube Placement

1

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Karen M. Tobias, DVM, MS, DACVS
Brian Allett, DVM
University of Tennessee

Although Elizabethan collars are recommended, many patients do not tamper with NE tubes if they are secured to the patient in a comfortable location. In this dog, the NE tube is sutured to the skin caudolateral to the planum and on the forehead.

Early feeding of hospitalized veterinary patients is critical for prevention of malnutrition and recovery from systemic illness. Enteral nutrition may be preferred to parenteral nutrition when there is adequate GI tract function. Enteral nutrition helps maintain the structure and function of the GI tract and acts as an immunologic barrier. Recovery from such conditions as parvoviral enteritis is faster with enteral nutrition.[1] Patients should be given a chance to eat on their own before tube feeding is initiated.

Enteral nutrition is commonly delivered via a nasoesophageal (NE), nasogastric (NG), esophagostomy, gastrostomy, or enterostomy tube. NE and NG feeding tubes are relatively inexpensive, can be placed quickly and easily, do not require general anesthesia, and are generally well tolerated by cats and dogs (**Figure 1**). The small tube size allows patients to eat or drink around the tubes. Although NE and NG tubes are normally used for short-term feeding, they can be retained for several weeks[2]; however, unlike gastrostomy and enterostomy tubes, NE and NG tubes can be removed within hours of placement. Evidence that NG tubes can cause signs of reflux esophagitis is lacking (possibly because of their small size), despite the fact that they cross the lower esophageal sphincter.[3,4]

NE = nasoesophageal, NG = nasogastric

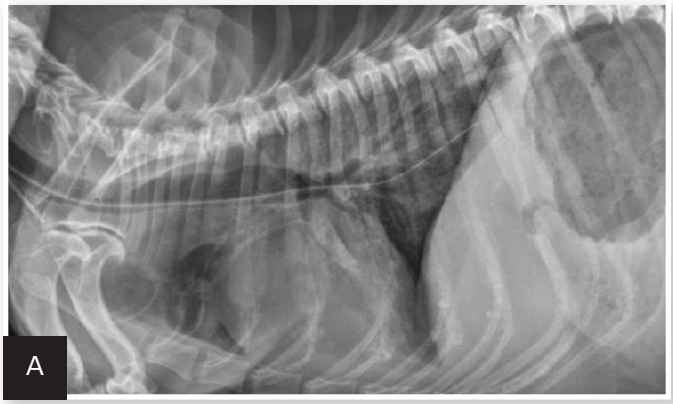
Care & Considerations

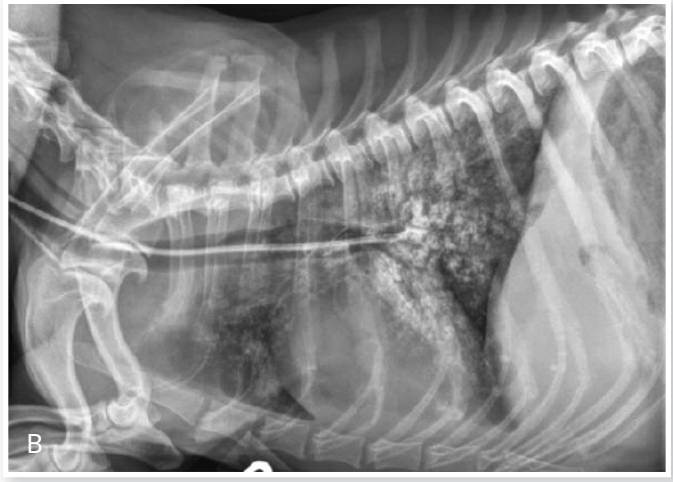
The small internal diameter of NE and NG tubes is a major limitation. When a 5- or 6-French tube is placed, supplementation is limited to a liquid enteral diet. If they can be used, larger tubes can accommodate a diluted, commercially homogenized recovery diet. Liquid diets can be delivered via constant-rate infusion (CRI) or intermittent bolus (see **Developing a Feeding Plan**, page 25). If a syringe pump is used for CRI, the fluid line should be changed daily to prevent clogging.

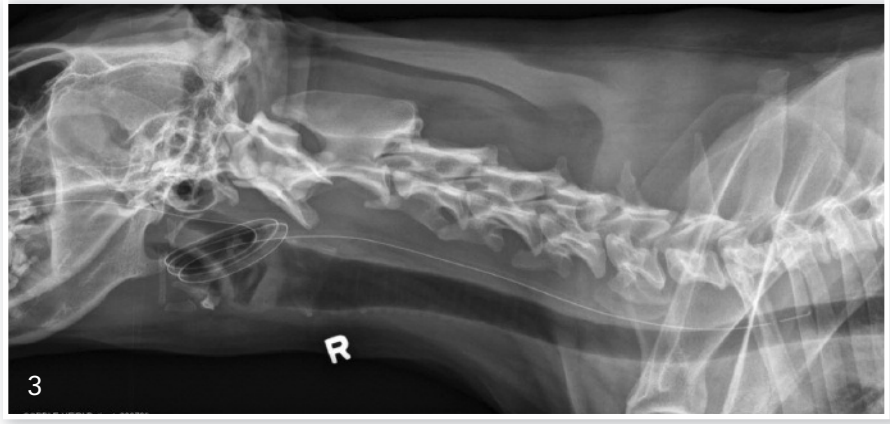
If bolus delivery is elected, the tube should be aspirated between feedings to confirm tube patency, GI motility, and adequate passage of the previous meal. If more than 20% of the previous meal is aspirated, prokinetic drug administration and reduced food intake are recommended. The diet should be warmed to near body temperature and slowly administered over 10 to 15 minutes. If vomiting, hypersalivation, or abdominal distention occurs during infusion, the volume and infusion rate should be decreased and feeding frequency increased. To prevent occlusion between feedings, the tube should be flushed and capped with a column of water remaining.

MORE ▶

2 **Inadvertent placement of an NG tube in the trachea and bronchus of a miniature dachshund (11 years of age). This dog had a severe pulmonary interstitial pattern secondary to infusion of 20 mL of sterile saline through the tube; it had no cough reflex during infusion (A). After injection of 3 mL of iohexol 240, positive contrast medium outlined the alveoli, particularly in the caudodorsal thorax, confirming tube misplacement (B). The following day, radiography confirmed that contrast medium and saline had been cleared from the lungs.**







Although this tube terminates in the esophagus, tube coiling in the nasopharynx and oropharynx will likely cause coughing or vomiting and subsequent oral expulsion of the tube end.

Contraindications & Complications

NE and NG tubes should not be placed in patients that are comatose, laterally recumbent, or dyspneic; lack a gag reflex; or have esophageal dysfunction or obstruction. Tubes should be placed with caution in patients with thrombocytopenia or coagulopathies to avoid uncontrollable nasal bleeding. Although vomiting sometimes contraindicates their use, NE and NG tubes have been successfully placed in vomiting patients; vomiting may be significantly reduced with NE or NG tube feeding.[1,3]

Potential complications of NE and NG tube placement and feeding include epistaxis, hypersalivation, vomiting, diarrhea, dacryocystitis, tube obstruction, or inadvertent tube dislodgement.

Evaluating Tube Placement

Tubes can be accidentally misplaced in the trachea (**Figure 2A**), nasopharynx, or nasal cavity, and subsequent feeding may result in aspiration pneumonia; therefore, appropriate placement should be confirmed before feeding is initiated. Various inexpensive methods can help verify tube location: laryngoscopic visualization of the tube entering the esophagus; suction to verify negative pressure; air infusion while auscultating the abdomen for borborygmus; infusion of sterile saline or nonionic contrast medium (**Figure 2B**), which sometimes elicits a cough with tracheal placement; or pH assessment of fluid aspirated from the tube.

Another quick way to assess placement is to attach the tube end to an airway gas analyzer (eg, capnograph). When the tube end is located in the esophagus or stomach, there is no capnographic waveform, respiratory rate, or end-tidal CO_2 detectable by the machine, which sets off its apnea alarm.[6] End-tidal CO_2 and respiratory rate are both measureable, and a capnographic waveform is elicited if the tube end is in the trachea, nasopharynx, or nasal cavity. Because an NE or NG tube could be coiled in the nasopharynx (**Figure 3**) or kinked and still terminate in the esophagus or stomach, survey or contrast radiography is recommended to verify placement. Use of a hyperosmolar, ionic iodinated contrast medium (eg, diatrizoic acid [Hypaque]) should be avoided, as its use in a tube improperly placed in the lungs can result in inflammatory reactions and pulmonary edema.

What You Will Need

- Sedative ± analgesic (eg, opioid) and local anesthetic
- 0.5% proparacaine hydrochloride or 2% lidocaine hydrochloride solution
- Water-based lubricant or 2% lidocaine gel
- 5-, 6-, or 8-French radiopaque polyurethane or silicone elastomer tube
- Skin marker
- 1-inch, white tape
- Skin stapler or 3-0 nylon suture on a straight needle
- Super or tissue glue (optional)
- 6-mL syringe
- 3–5 mL of sterile saline
- Elizabethan collar
- Nonionic radiographic contrast medium (eg, iohexol) or end-tidal CO_2 monitor

Developing a Feeding Plan

❑ Calculate resting energy requirement (RER) for the patient's current or ideal weight (if obese).
- For accuracy, use the formula: RER (kcal/day) = 70 × [body weight (kg)]$^{0.75}$
- RER may need to be adjusted to address underlying disease and is often multiplied by a factor of 1.25 to meet increased caloric requirements.

❑ If the patient is neither drinking nor on IV fluids, calculate fluid requirements.
- Daily mL of required water is approximately the same number as the daily RER kcal.

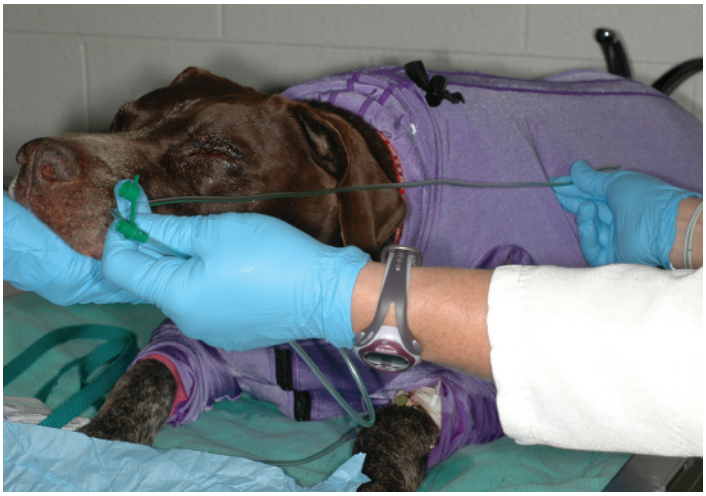
❑ Feed one-fourth to one-third of nutritional requirements on day 1; deliver via CRI or in 6–8 feedings.
- If there is risk for refeeding syndrome (see adjacent **Author Insight**), check electrolytes within 24 hours of initial feedings.

❑ Gradually increase volume and decrease frequency of feeding so the patient is receiving 100% of nutritional requirements in 3–4 feedings, or with CRI, by day 3 or 4.

Step-by-Step ■ Nasoesophageal or Nasogastric Feeding Tube Placement

Step 1

If the patient will be difficult to restrain during suture or staple placement (see **Step 5**, page 27), sedate before starting. Measure the distance from the tip of the patient's nose to the seventh or eighth intercostal space for placement of an NE tube (**shown**) or to the last rib for an NG tube. Mark the tube at the appropriate length. To determine when to expect the patient to swallow the tube, measure and mark the distance from nose tip to hyoid apparatus.



Author Insight **Anorectic patients receiving enteral feedings should be monitored for dramatic decreases in phosphate, magnesium, and potassium levels, which are clinicopathologic abnormalities associated with a rare metabolic disorder known as *refeeding syndrome*. Refeeding syndrome can result in hematologic, neuromuscular, neurologic, pulmonary, and cardiovascular complications and death.**

NE = nasoesophageal, NG = nasogastric, RER = resting energy requirement

Step 2

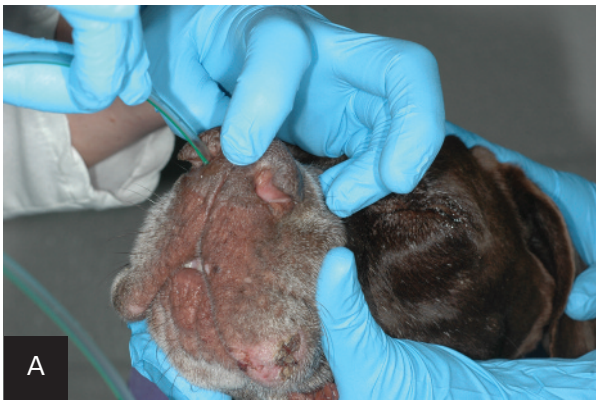
Tilt the patient's head upward and infuse 4–5 drops of 5% proparacaine hydrochloride or 2% lidocaine hydrochloride solution into each nostril. Wait several minutes for the local anesthetic to take effect. While waiting, lubricate the tube tip with a water-soluble or 5% lidocaine gel.

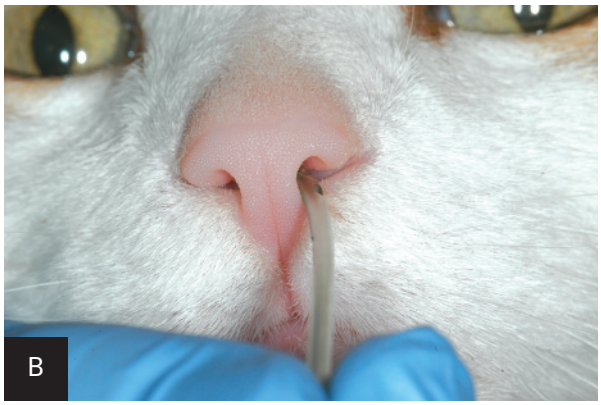
Author Insight **Premedicating both nostrils allows immediate passage into either of the nares once the anesthetic has taken effect.**

Step 3

Place the patient in a standing, seated, or sternally recumbent position with the neck slightly extended and the head in a neutral position. For dogs, push the nasal planum upward (**A**), and insert the tube up and over the ventral ridge at the proximal end of the nasal passage. Direct the tube ventromedially through the nostril into the ventral meatus. Quickly advance the tube into the nasal cavity. If the dog pulls away, release the tube immediately to prevent extraction.

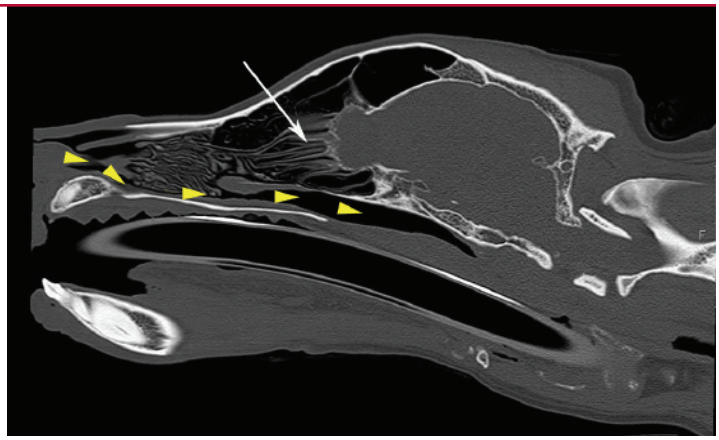
In cats, insert the tube in the medial aspect of either of the nares (**B**), and direct it caudoventrally.





Step 4

Advance the tube steadily into the nasopharynx. If there is resistance, withdraw the tube and redirect it ventrally to avoid the ethmoid turbinates. Hold the head in a normal position and allow the patient to swallow the tube.

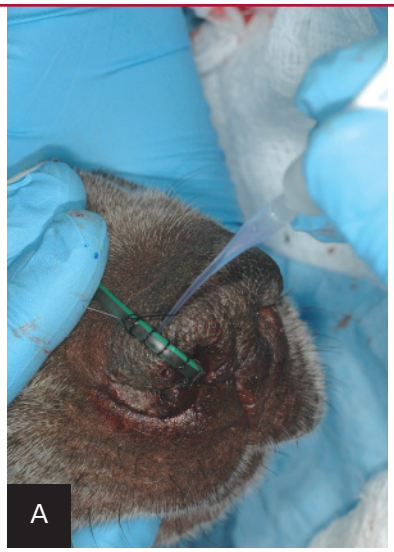


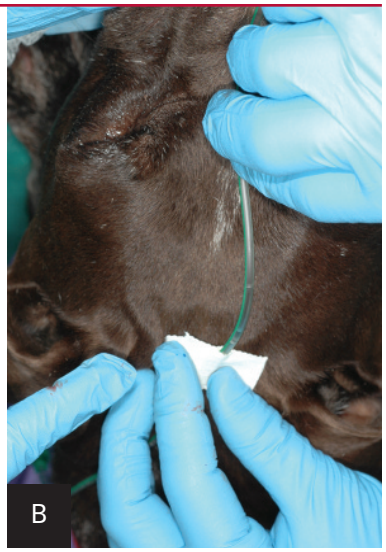
*Sagittal CT image of the nasal cavity of a dog. **Arrowheads** illustrate the path the tube must take. The tube must pass over the incisive bone and roots of the incisors before it can be directed through the ventral meatus, ventral to the ventral nasal concha (**arrow**) and ethmoid turbinates.*

Step 5

Once the tube is advanced to the appropriate mark, secure the remainder to the patient's head.

In dogs, use suture (± tissue glue) or skin staples to secure the tube near or along the nasal planum (**A**). At a point level with the forehead (dogs or cats) or the buccal pouch on the lateral face (dogs), place butterfly tape on the tube and staple or suture the tape to the skin (**B**). Place an Elizabethan collar and secure the tube on the neck under and behind the collar.



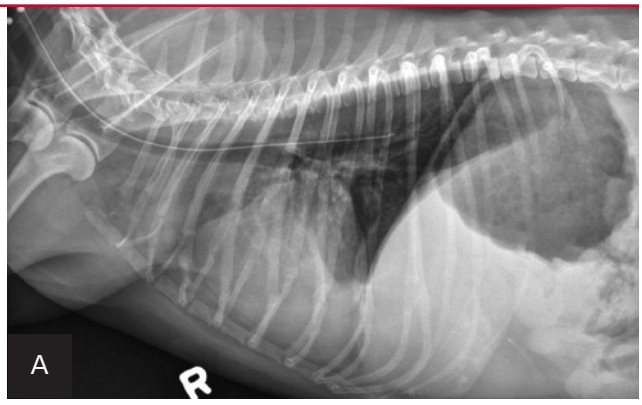


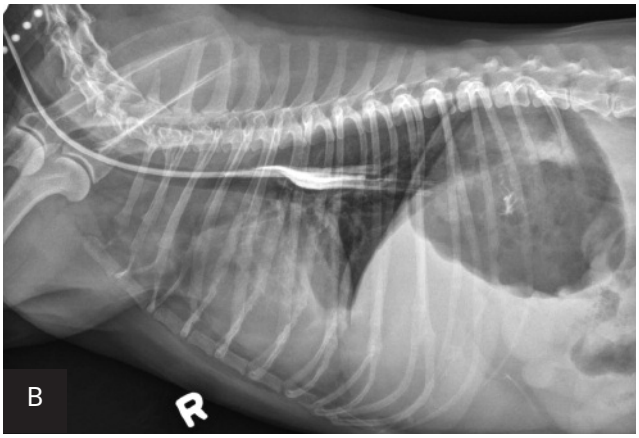
Author Insight **If a finger trap pattern is used, several drops of tissue glue can be placed along the suture to prevent slippage when the tube becomes wet (A).**

Step 6

Confirm initial tube placement by suctioning to verify presence of negative pressure, flushing with 3–5 mL of sterile saline and listening for a cough, or attaching the tube to an end-tidal CO_2 monitor.

Verify tube location with survey (**A**) or contrast (**B**) radiography. Inject 2–3 mL of iohexol or other nonionic, iodinated contrast medium into the tube, followed by 3–5 mL of air or sterile saline. Note how the contrast medium highlights the esophageal folds. ■ cb





In this dog, the proximal end of the tube is not associated with the trachea.

Author Insight **When an NE tube is placed appropriately, its end is located at the eighth intercostal space (approximately). Even properly placed tubes can appear to be in the airways, because the esophagus overlies the trachea and bronchi on caudal cervical and thoracic radiographs.**

See **Aids & Resources**, back page, for references & suggested reading.

NE = nasoesophageal, NG = nasogastric

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CEREBROSPINAL FLUID Collection & Analysis

Ladan F. Mohammad-Zadeh, DVM, and Allen F. Sisson, DVM, MS, Diplomate ACVIM (Neurology)

Analysis of CSF is an important diagnostic tool in veterinary medicine. It can be used to help differentiate between many diseases of the CNS, such as infectious and autoimmune meningitis, encephalitis/myelitis, and neoplasia. Analysis of CSF is indicated in any animal showing CNS signs if metabolic and toxic causes have been ruled out. To this end, it is crucial that a complete blood count, serum chemistry profile, and urinalysis and culture are obtained and interpreted before CSF is collected and analyzed. In addition, analysis for lead toxicity should be done if exposure is possible. Common metabolic causes for CNS signs in companion animals include hypoglycemia, uremia, and liver dysfunction.

Essentially, CSF is the ultrafiltrate that is produced when blood passes through the choroid plexus. Red cells, white cells, platelets, most of the proteins (immunoglobulins, albumin), and most drugs cannot pass through the choroid plexus. Therefore CSF is colorless and transparent. It is produced at a rate of 0.05 ml/min in dogs and 0.02 ml/min in cats. It circulates from the ventricular system to the subarachnoid spaces of the brain and spinal cord.

A CSF tap can be performed in any practice setting; barriers to the procedure usually include financial constraints of the client, skill and comfort level of the clinician, and the availability of in-house or laboratory personnel to analyze the sample on a timely basis. CSF can be obtained either via cerebellomedullary cisternal puncture or via lumbar puncture. The cisternal tap is technically easier to perform, but a lumbar puncture is better for the diagnosis of primary lumbar spinal cord disease. General anesthesia is required for this procedure, as it ensures limited movement of the animal and enables the clinician to manipulate the head and neck as needed. The following is a step-by-step explanation on performing a CSF tap.

continues

WHAT YOU WILL NEED

- Spinal needles. For most patients, a 22-gauge, 1.5-inch disposable spinal needle with a stylet can be used for cerebellomedullary cisternal taps. Needles 2 to 3.5 inches in length are used for lumbar taps and may be used for cerebellomedullary cisternal taps in large dogs. As an alternative, a 22-gauge, 1-inch regular needle or a butterfly with the tubing cut can be used for cats or small dogs.
- Clear glass or plastic collection tubes (nontreated)
- Culturette

CNS = central nervous system; CSF = cerebrospinal fluid

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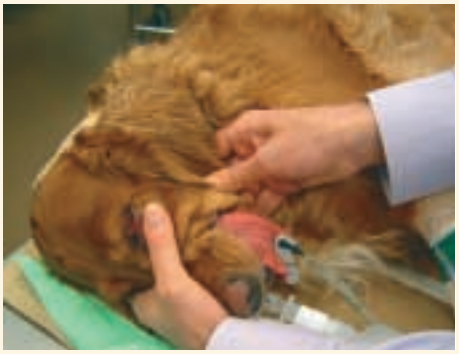
HOW TO COLLECT & ANALYZE CEREBROSPINAL FLUID

Cisternal Tap



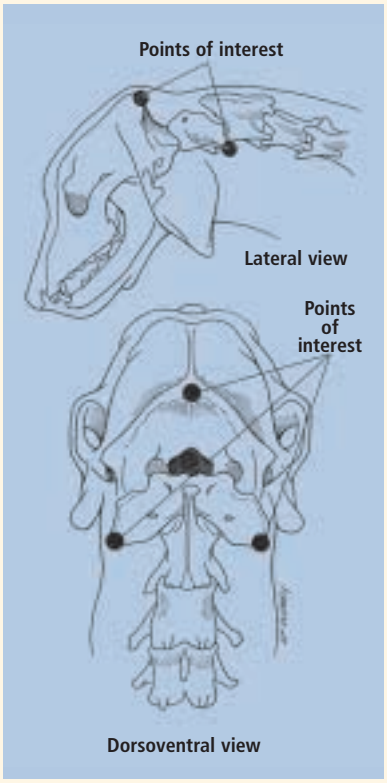
1 Position the patient in lateral recumbency. The nose should be flexed and the dorsum flush with the edge of the table. It is sometimes helpful to pull the ears down toward the face.

PROCEDURE PEARL

The pathologist should be informed of the CSF collection site, as protein content and cell counts can vary according to location.

2 Clip an area large enough to identify landmarks. For a cisternal tap, midline landmarks are the occipital protuberance and the dorsal spinous process of the axis (C2). Lateral landmarks are the wings of the atlas. Prepare the clipped area using aseptic technique. The clinician should wear sterile gloves for this procedure.

3 Palpate the wings of the atlas with the thumb and middle finger and palpate the occipital protuberance with the index finger, making a triangle. The middle of the triangle should approximate the cerebellomedullary cistern.

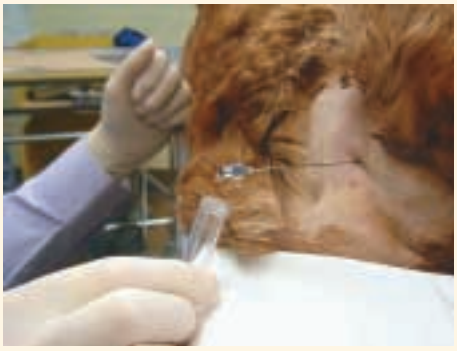


4 Insert the needle in the middle of the triangle. As the needle is advanced, a "pop" will be felt as it passes through the dorsal atlantooccipital membrane (dura) and then a slight loss of resistance will occur as it enters the subarachnoid space. The "pop" may be more difficult to appreciate in cats and small dogs.

PROCEDURE PEARL

Make only two attempts at a cisternal tap. If both attempts are unsuccessful, consider a lumbar tap or try again in 24 hours because each attempt at obtaining CSF could increase the risk for blood contamination.

5 Remove the stylet, and observe for CSF flowing into the needle. If this does not occur, replace the stylet and advance the needle 1 to 2 mm at a time, each time checking for CSF flow. A technician may occlude the jugular veins to enhance CSF flow, but proceed with caution: the increase in intracranial pressure may result in clinical deterioration if the animal has a tumor or other space-occupying mass.



6 Collect the CSF in a glass vial or plastic test tube. EDTA tubes are generally not necessary, as CSF should not clot. One to 2.0 ml of CSF in two tubes is sufficient for analysis.

PROCEDURE PEARL

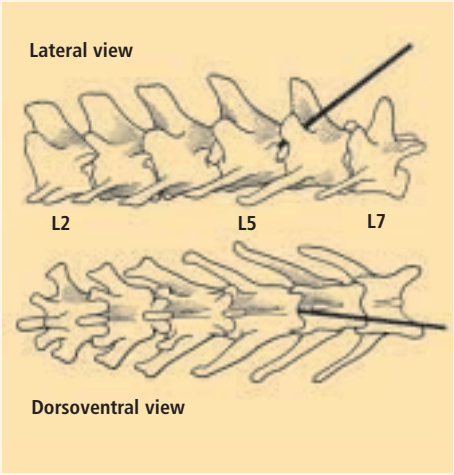
Occluding the jugular veins may enhance CSF flow.

CNS = central nervous system; CSF = cerebrospinal fluid

Lumbar Puncture

1 Position the patient in lateral recumbency with the dorsum flush with the table. The sternum should be elevated so that it is at the same level as the dog's vertebral column.

2 Landmarks for lumbar puncture include the dorsal spinous process of L6. The region should be clipped and prepared using aseptic technique.



3 Insert the needle just lateral to the most caudal aspect of the L6 spinous process. Angle the needle tip about 10 degrees cranially and about 3 degrees medially. Advance the needle slowly, with the needle tip just contacting the bone of the lateral aspect of the L6 dorsal spinous process as the needle is advanced. The goal is to enter the interarcuate space between L5 and L6 on the midline with the needle tip passing just cranial to the base of the L6 dorsal spinous process. Pelvic limb muscles often twitch visibly when the subarachnoid space is entered.

PROCEDURE PEARL
Do not attempt to aspirate with a syringe from the collection site.

It is possible in some cases to collect CSF from the dorsal subarachnoid space if very delicate technique is used; however, in most cases the needle is advanced through the spinal cord until bone is contacted on the floor of the vertebral canal. Then the needle is backed up 1 or 2 mm into the ventral subarachnoid space, where the fluid is collected.

In some very arthritic older dogs, it may be difficult to collect lumbar spinal fluid because of severe arthritic degeneration. The needle may have to be redirected several times with considerable force to overcome the friction encountered from arthritis.

4 Remove the stylet. If there is no CSF flow, replace the stylet and withdraw the needle a few millimeters at a time and check again for CSF flow. Jugular veins may be occluded to aid in flow. Some sources state that lumbar CSF can be aspirated with a syringe; however, we generally do not advocate this approach because it often leads to contamination of the sample with blood.

PROCEDURE PEARL
Hyperflexion of the neck may actually decrease the ability to gain access to the subarachnoid space.

PROCEDURE PEARL
Flexing the extended pelvic limbs cranially for the lumbar tap slightly expands the interarcuate space to allow passage of the needle. This requires flexing only the coxofemoral joints so that the cranial aspects of the dog's hocks are firmly pressing against the sternum.

Analysis

Normal CSF should be colorless, odorless, and clear. Remember, CSF should be collected in 2 tubes. One can be sent as is to a laboratory for quantitative protein analysis; the other should be sent for cytologic evaluation. Once in a collection tube, any cells in the CSF will be destroyed in a matter of hours due to the low oncotic pressure. This can be avoided by adding 2 drops of the patient's own serum to 1 ml of CSF.

Cell counts can easily be done in any practice using a simple glass hemocytometer. It is important to count both red and white blood cells.

A cursory cytologic examination of the fluid can be done in any clinical setting. A sedimentation chamber can be fashioned by cutting a plastic tube 1 inch from the top to form a cylinder. Apply Vaseline or paraffin wax around one of the edges of the cylinder and adhere it to a glass slide. Place 0.5 ml of CSF in the chamber and wait 30 minutes to allow any cells to settle on the bottom. Use a pipette to remove the supernatant, quickly air dry the slide, stain, and examine. Detailed information on cell counts, cytology, and protein analysis of CSF can be found in most clinical laboratory technique and clinical pathology textbooks.

Complications

Rapid flow of CSF through the needle. This could indicate increased intracranial pressure and could cause herniation. In cases of rapid flow, remove the needle and assess the patient's need for mannitol therapy (1–2 g/kg IV over 20 minutes).

Blood contamination. If whole blood is seen, the vertebral venous plexus—vessels that lie outside the spinal cord—may have been entered. If so, remove the needle and try again. A thin line of blood in otherwise-clear CSF may indicate that a surface vessel has been encountered; in these cases, the CSF may run clear after several seconds.

Figures for Step 3 (both methods) are reproduced with permission from *Small Animal Wound Surgery*, 2nd ed. Fossum T. St. Louis: Mosby, 2002, pp 1206-1207.

See Aids & Resources, back page, for references, contacts, and appendices.

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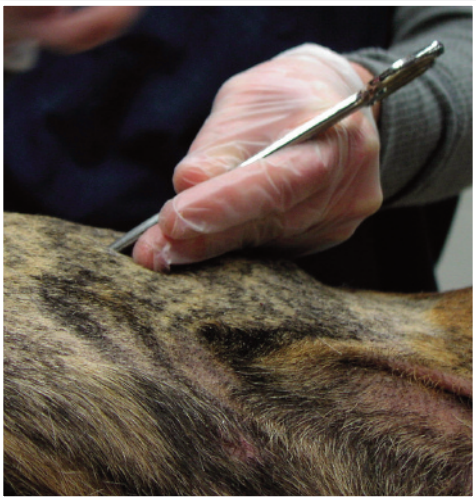
Chest Tube Placement

Lisa Powell, DVM, DACVECC
University of Minnesota



Chest tube placement (ie, tube thoracostomy) plays an important role in the management of severe pleural space disease. Chest tubes are indicated for managing unresolving pneumothorax, pyothorax, persistent pleural space disease requiring multiple thoracenteses, and postoperative thoracotomies.

Chest tube placement can often be performed under controlled conditions, with the patient sedated and intubated to allow regulation of breathing. Sometimes, however, a chest tube needs to be placed emergently or in a nonintubated patient and requires firm knowledge of the procedure.

In a noncrisis, adequate general anesthesia should be induced with placement of an endotracheal tube, allowing the patient to breathe on its own. If oxygenation is inadequate because of severe pleural space disease, gentle positive-pressure ventilation can be applied. In addition, an incision can be made into the chest cavity to relieve tension pneumothorax, with care to support ventilation, as the normal negative pressure within the chest is no longer present.

MORE ▶

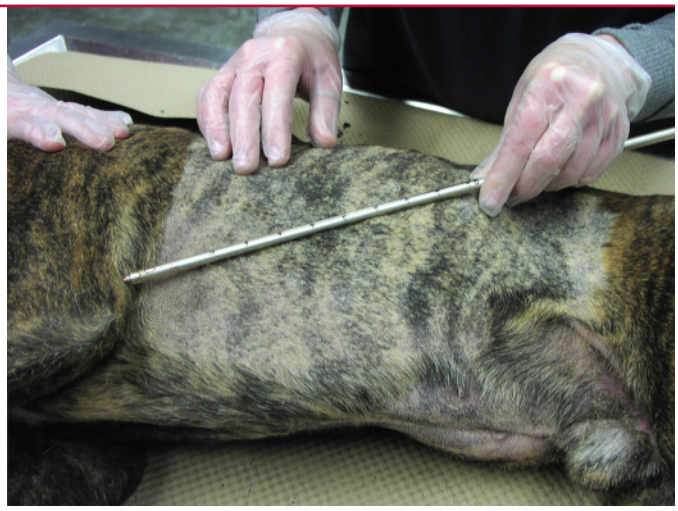
What You Will Need

- Thoracostomy tube (comparable in size to the diameter of the patient's mainstem bronchus as determined by lateral radiography)
- Sterile surgical pack (ie, blade, blade handle, needle drivers, suture scissors, drapes, straight Kelly hemostats)
- Suture material for skin closure and to secure tube (3-0 nylon for the skin, polydioxanone for tube)
- C-clamp for tube occlusion
- Christmas tree adapter, zip-tie, and 3-way stopcock for the end of the chest tube

Step-by-Step ■ Chest Tube Placement

Step 1

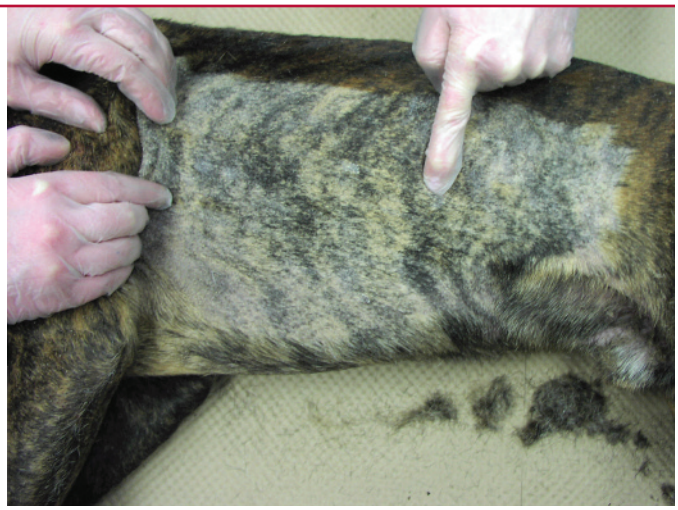
Once the patient is intubated and stable under anesthesia with adequate oxygen saturation readings, position the patient in lateral recumbency (either side) and widely clip the lateral thorax (from caudal to the thoracic limb to the caudal aspect of the last rib). Use an appropriately sized, sterile chest tube to measure the distance in centimeters from the anticipated skin incision (tenth intercostal space) to the ventral region just caudal to the thoracic limb. Place the chest tube on a sterile field, and prepare the thorax aseptically.



Author Insight **Maintain sterility while measuring the tube (ie, do not touch the thorax with the tube).**

Step 2

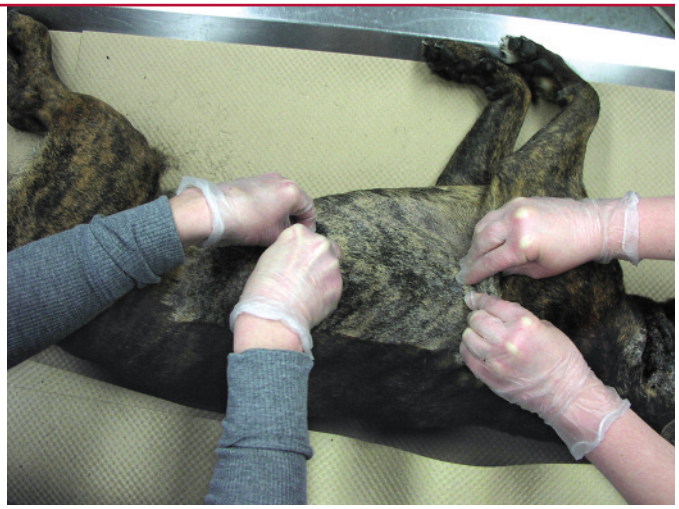
After identifying the tenth intercostal space, place sterile drapes and have an assistant pull the skin of the lateral thorax cranially, starting behind the thoracic limb, until the skin that had been over the tenth intercostal space is over the eighth intercostal space.



Author Insight **Ensure that all assistants wear sterile gloves.**

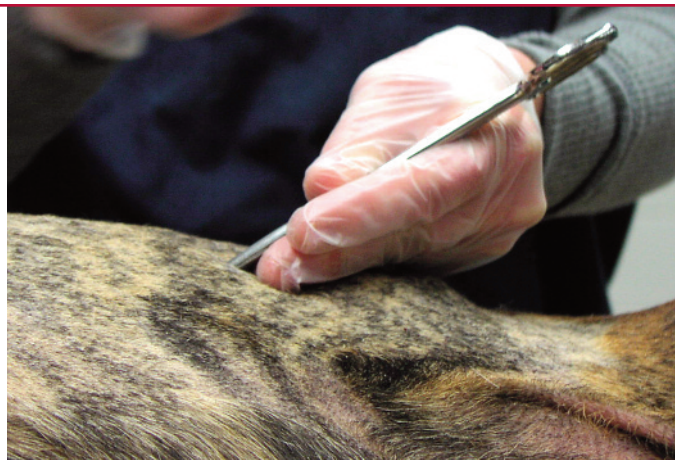
Step 3

While the assistant continues to pull the skin forward, make a skin incision in the center of the eighth intercostal space, midway between the sternum and spine. Ask the anesthetist to cease assisted ventilation in order to make a stab incision with a #10 blade through the skin incision into the chest cavity.



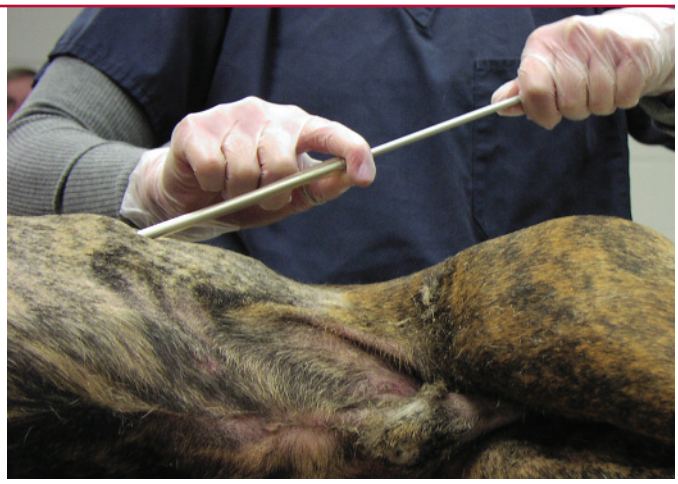
Step 4

Advance Kelly hemostats into the chest incision for localization, then advance the chest tube (with the trocar in place) cranially into the chest cavity. Once the tube has entered the chest cavity, remove the hemostats. Advance the chest tube (with the trocar still in place) cranially and ventrally into the chest; take care to avoid damaging underlying intrathoracic tissue.



Step 5

When approximately one-third of the tube is within the chest cavity, hold the end of the trocar in place, and advance the tube off the trocar and into the chest until the previously measured centimeter mark on the chest tube reaches the incision. Twist the tube several times to ensure there are no kinks.



Step 6

When the tube is in place, have the assistant release the skin, allowing a SC tunnel to form from the chest wall incision to the skin incision.

Step 7

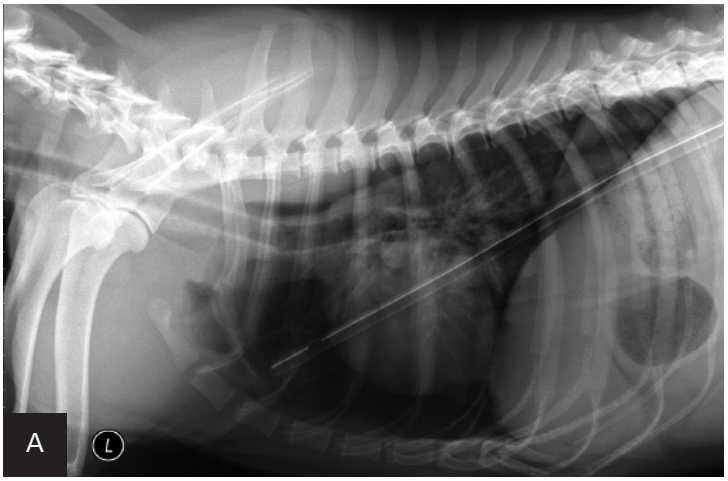
Place a Christmas tree adapter, connected to a 3-way stopcock, on the end of the chest tube, and use a zip-tie to secure the adapter. Using a large, Luer-tip syringe (35 or 60 mL), evacuate any remaining air or fluid from the pleural cavity. Then secure the chest tube by suturing the skin incision around the tube with a purse-string suture, followed by a finger-trap suture on the chest tube itself.

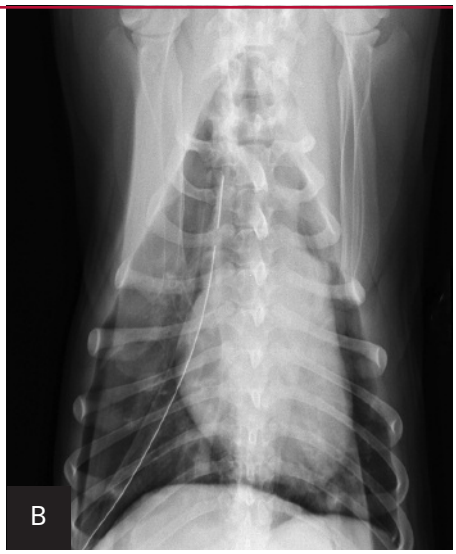
Author Insight **Once the trocar is removed from the tube, there is a continuous opening from the thoracic cavity to the air. Thus, if the patient is intubated, ventilation must be controlled. If the chest tube had to be placed without first intubating the patient, the tube should be occluded immediately by placing a C-clamp on the tube to avoid additional iatrogenic pneumothorax.**

MORE ▶

Step 8

Obtain thoracic radiographs to ensure correct tube placement, which should be directed cranially and ventrally with the tip located at the second to third intercostal space. There should be no bends or kinks in the tube. If necessary, replace the tube and obtain new radiographs to recheck tube placement.

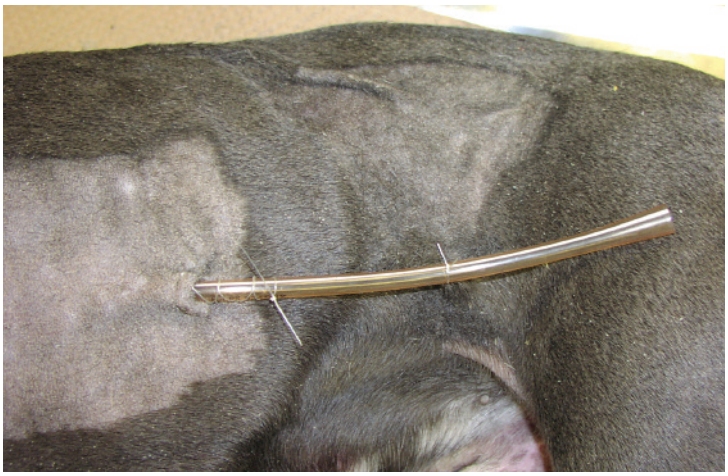




Author Insight **Both lateral (A) and VD (B) views of the thoracic cavity must be taken to verify proper tube placement.**

Step 9

Once correct placement is verified, secure the tube with an anchoring suture. Place this suture in the skin caudal to the chest tube incision by suturing with 2 knots on the skin, then encircling the chest tube and suturing 3 or 4 more knots over the tube. This allows tension to be evenly distributed between the tube and the skin. Cover the insertion site with antibiotic ointment and sterile gauze. Place a light wrap around the thorax to cover the insertion site and help keep the tube from dislodging. ■ cb



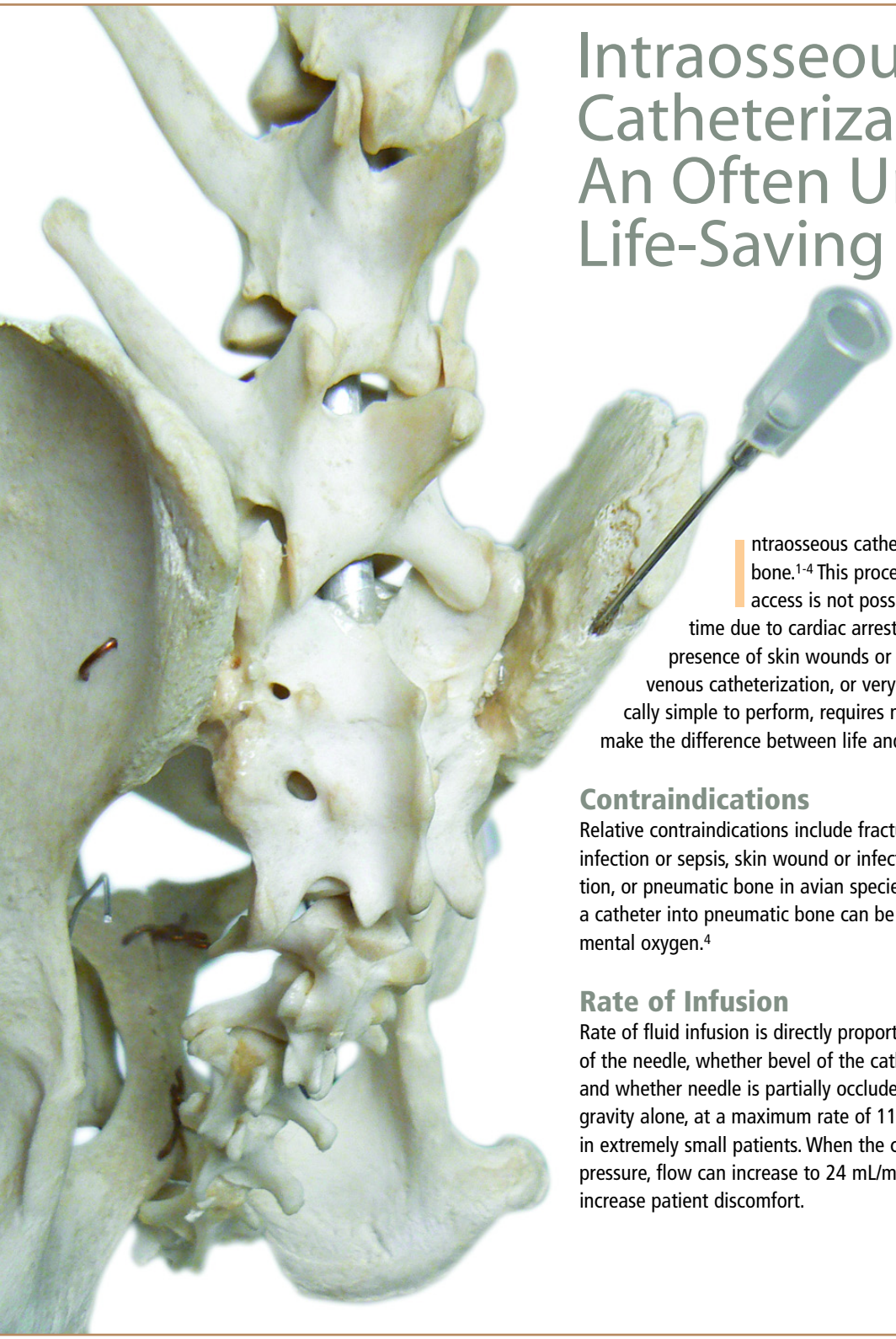
Tube Thoracostomy: International Insight

WSAVA Global Veterinary Community

- The "pound method" of placing a thoracostomy tube is no longer recommended, as underlying tissue damage and tube misplacement is more likely to occur.
- The patient should be anesthetized and intubated, if possible, before placing the chest tube for complete control of respirations when the chest is excised.
- Carmalt hemostats should not be used to clamp off the thoracostomy tube once it is placed in the chest cavity. Traumatic damage to the tube may occur, causing air leakage into the chest cavity after placement; an atraumatic C-clamp should be used instead.
- Once the chest tube is removed, the surgical site should be left to heal via second intention, and not sutured closed, as air leakage may occur under the skin for a period of time after the chest tube has been removed.

See **Aids & Resources**, back page, for references & suggested reading.

Elisa M. Mazzaferro, DVM, MS, PhD, Diplomate ACVECC, Wheat Ridge Veterinary Specialists, Wheat Ridge, Colorado



Intraosseous Catheterization: An Often Underused, Life-Saving Tool

Intraosseous catheterization involves placing a needle into a bone.[1-4] This procedure should be considered when vascular access is not possible or cannot be performed in adequate time due to cardiac arrest, hypovolemic shock, patient anatomy, presence of skin wounds or thrombosis over proposed sites of intravenous catheterization, or very small patient size. The technique is technically simple to perform, requires no specialized equipment or tools, and can make the difference between life and death in small animals.

Contraindications

Relative contraindications include fracture of the proposed catheter site, bacterial infection or sepsis, skin wound or infection over the proposed site of catheterization, or pneumatic bone in avian species. In avian species, however, placement of a catheter into pneumatic bone can be used to facilitate administration of supplemental oxygen.[4]

Rate of Infusion

Rate of fluid infusion is directly proportional to diameter of the needle, placement of the needle, whether bevel of the catheter is placed against the bony cortex, and whether needle is partially occluded with bony debris. Fluid can flow with gravity alone, at a maximum rate of 11 mL/min; however, this rate is much slower in extremely small patients. When the catheter is placed under 300 mmHg of pressure, flow can increase to 24 mL/min. In some cases, rapid infusion can increase patient discomfort.

continues

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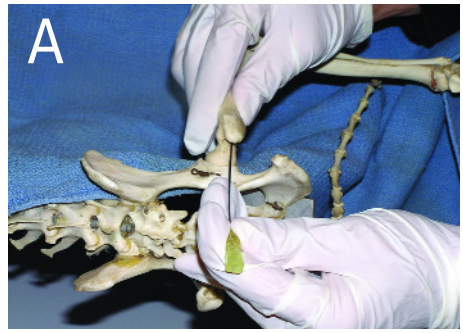
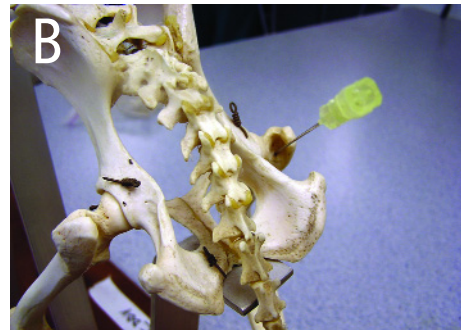
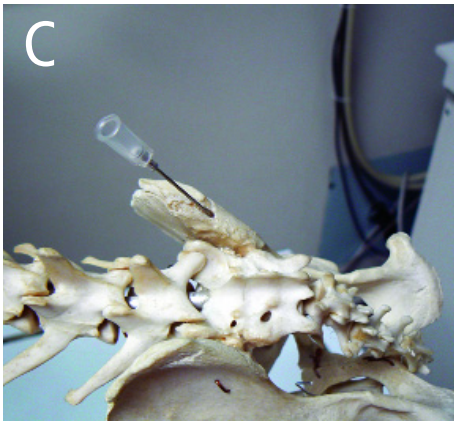
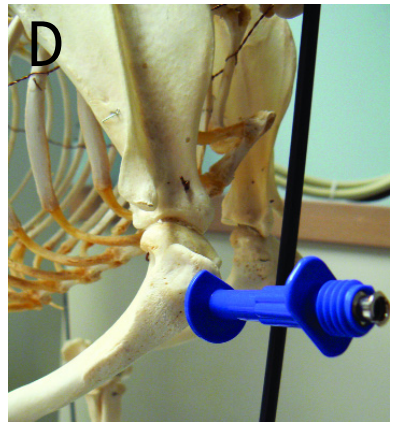
STEP BY STEP INTRAOSSEOUS CATHETERIZATION

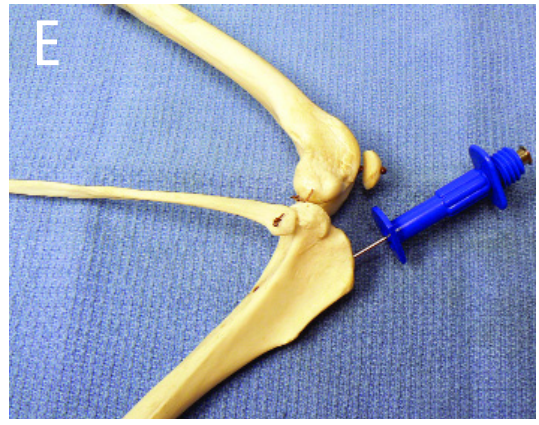
1 Locations for intraosseous catheter placement include the trochanteric fossa of the femur (**A** and **B**), the wing of the ileum (**C**), the proximal humerus (**D**), and the tibial tuberosity (**E**). The trochanteric fossa is easy to catheterize; the tibial tuberosity is an excellent place for catheterization of exotic species, including reptiles.







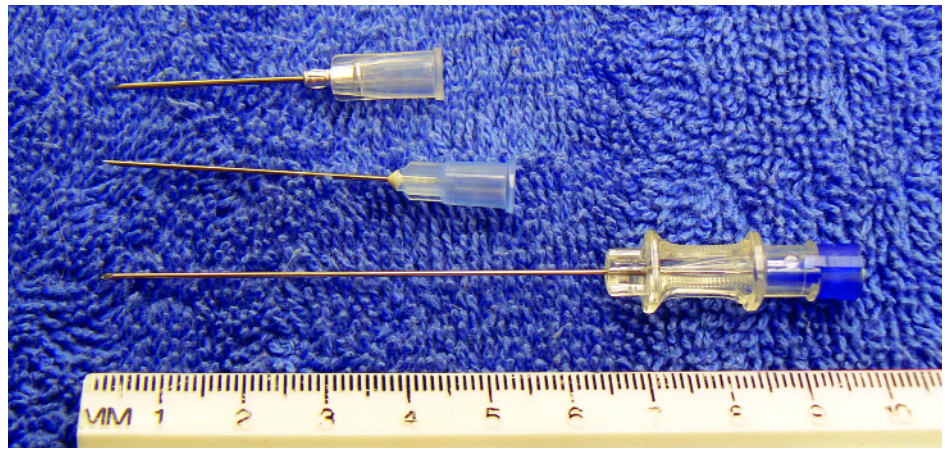




2 Supplies required include a clipper with clean blades, 4 × 4-cm gauze squares, antimicrobial soap and solution, local anesthetic, suture material, a T-set, and the catheter itself.

A variety of hypodermic needles or spinal needles can be used. In small or neonatal animals, 3/4- and 1 1/2-inch 22-gauge hypodermic needles or spinal needles (**shown**) can be used. Bone marrow needles can be used in large patients whose bones have already ossified; Smith Medical manufactures an intraosseous catheter that is appropriate for use in adult animals with ossified bones. Additionally, intraosseous drills (EZ-IO; vidacare.com) can be used to facilitate insertion of an intraosseous catheter in an ossified bone.

In smaller patients whose bones have not yet ossified, the shaft of the hypodermic needles can become clogged with bone debris during placement. You can avoid this by using a spinal needle with an outer needle and inner stylette, or you can place a piece of surgical wire in the shaft of the hypodermic needle to prevent clogging. If the needle does become clogged, you can simply remove the needle and replace it with an identical one through the hole that you have created.

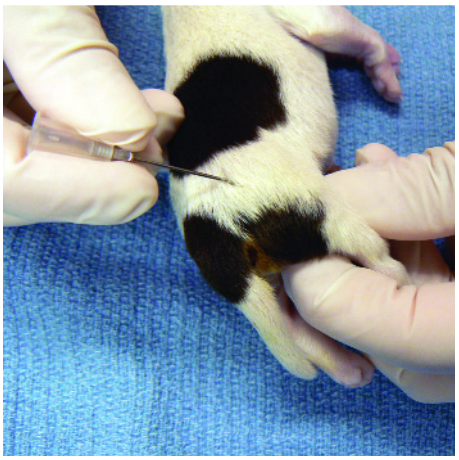


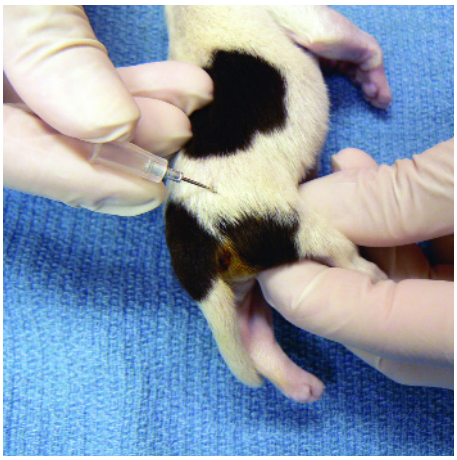
PROCEDURE PEARL

Avoid clogging the needle with bony debris by using a spinal needle with outer needle and inner stylette or by placing a piece of surgical wire in the hypodermic needle shaft.

Indications for Intraosseous Catheter Placement

- Extremely small body size
- Patient anatomy (eg, very short limbs)
- Exotic species
- Vascular collapse
  - Hypotension
  - Severe dehydration
  - Hypovolemic shock
  - Hypothermia
- Inaccessible IV catheter site
  - Wounds, edema, or infection over proposed sites
  - Thrombosis of vessels
  - Obesity



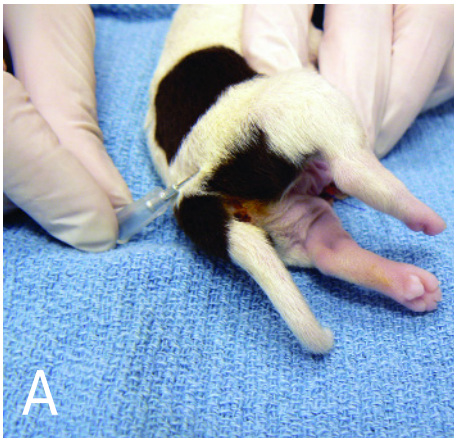


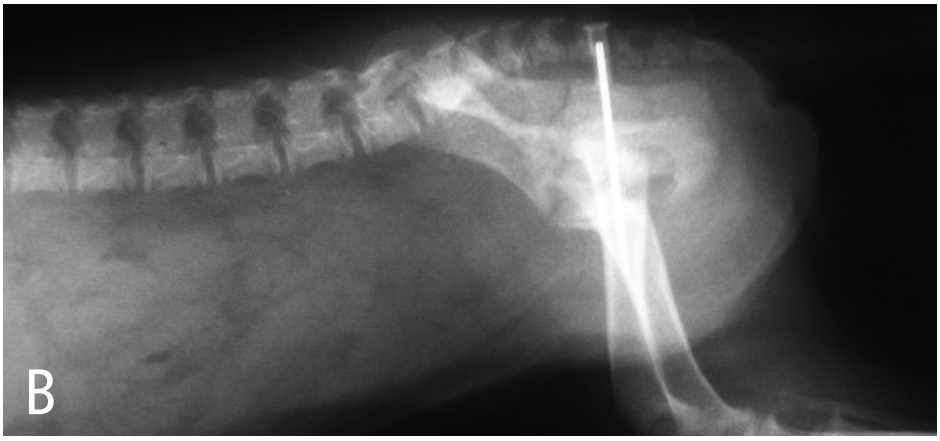
3 Clip and aseptically scrub the site of proposed catheter placement. A small amount of local anesthestic can be administered to the level of the periosteum to decrease discomfort associated with catheter placement.

A cadaver specimen was used to demonstrate the steps in this article; no aseptic preparation was needed.

4 Adduct the stifle so that it is pushed toward ventral midline and the trochanteric fossa is rotated laterally. This positioning helps decrease the risk of impaling the sciatic nerve. In smaller patients, the stifle can be held with your fingers or in the palm of your hand to provide support to push against during placement.

5 Push the tip of needle through the skin, and with a simultaneous pushing and twisting motion, push needle into the groove in the intertrochanteric fossa, through the periosteum, and into the shaft of the femur. You will feel resistance as the needle passes through the bone, then less resistance as it enters the shaft of the femur.





6 Once the needle is in place, you should be able to push the hub of the needle back and forth and move the leg (**A**). Aspiration of bone marrow also confirms placement. However, it is recommended that you check placement with radiographs (**B** and **C**).

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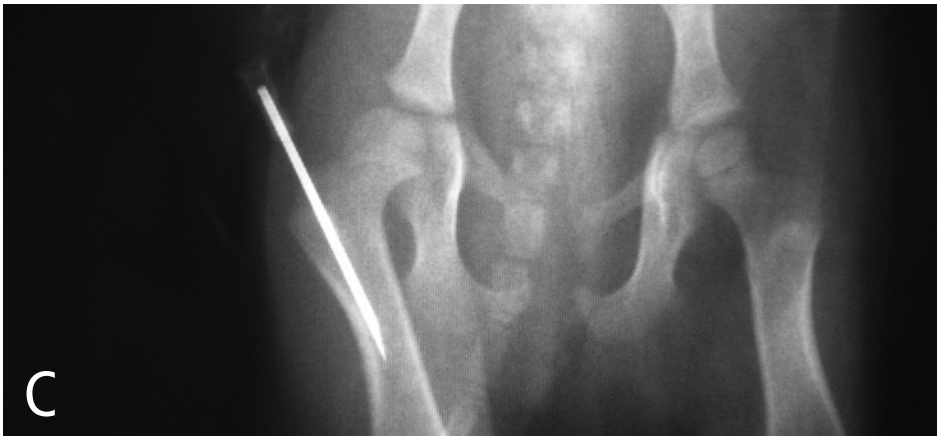

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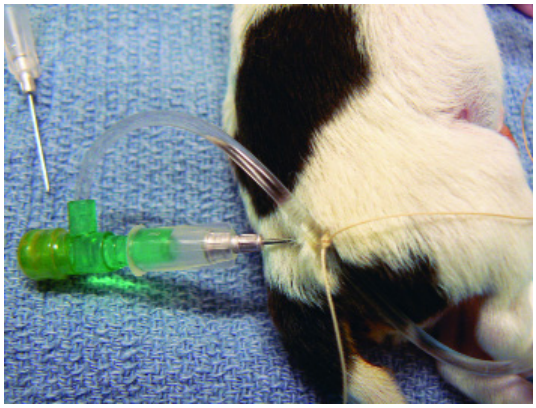
7 Insert a T-port into the hub of the catheter and flush the catheter with saline. Heparinized saline can be used in larger animals. However, nonheparinized saline should be used for very small animals to prevent coagulopathies. You should feel little resistance when flushing the catheter.

PROCEDURE PEARL
If fluid does not flow freely, rotate the needle 90 to 180 degrees; the bevel of the needle may be lodged against the wall of the cortex, thus causing an occlusion.

8 Secure the catheter in place. One method of doing so is to place a stay suture through the skin near the catheter hub, then suture the tubing of the T-port to the stay suture. A second method includes placing a piece of butterfly tape around the line of the T-port close to the catheter hub, then securing the butterfly tape to the skin with 2 sutures or surgical staples. Bandages can be cumbersome and become easily contaminated in very small patients, such as neonates or pocket pets.

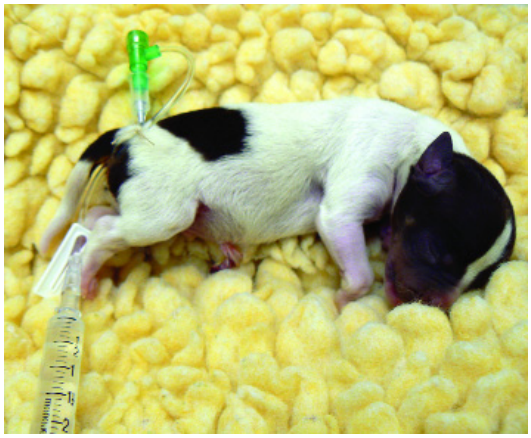


Contraindications for Intraosseous Catheter Placement

- Skin wound and/or infection over proposed catheter site
- Fracture of bone intended for catheterization
- Pneumatic bones
- Sepsis
- Metabolic bone disease

9 The catheter is now ready for use. Crystalloid and colloid fluids, blood products (including whole blood), drugs, and parenteral nutrition can be administered, even at very fast rates,[5,6] when necessary, through an intraosseous catheter. However, as mentioned earlier, rapid infusion rates can cause discomfort in some patients.

PROCEDURE PEARL
Nonheparinized saline should be used for very small animals to prevent coagulopathies.



Potential Complications of Intraosseous Catheter Placement

- Osteomyelitis
- Damage to epiphysis
- Fluid leakage into subcutaneous tissues
- Edema

See Aids & Resources, back page, for references, contacts, and appendices.

Article archived on cliniciansbrief.com

Abdominocentesis

Daniel D. Smeak, DVM, Diplomate ACVS, Ohio State University

PERCUTANEOUS SAMPLING OF PERITONEAL FLUID with a needle or small catheter, called abdominocentesis (sometimes also known as peritoneocentesis or abdominal paracentesis), is a simple, rapid, and safe diagnostic method. When physical examination or imaging indicates moderate to large amounts of peritoneal effusion in a patient, sampling the fluid for cytologic, microbiological, or biochemical analysis often helps the clinician to quickly make a diagnosis and then to initiate timely and appropriate therapy. Abdominocentesis is most often performed to determine whether a patient needs exploratory celiotomy, particularly for early diagnosis of peritonitis or serious injury.

Before considering abdominocentesis, determine the relative value versus the risk of a blind puncture, particularly when a large vascular abdominal mass, an enlarged vascular organ, or a disorder affecting a distended hollow organ (such as a pyometra) is suspected, or in patients with severe coagulopathies. In these instances, consider ultrasound-guided sample collection if available. Abdominocentesis is best performed after plain radiography unless a rapid diagnosis needs to be made in a deteriorating patient. Free peritoneal air on radiographs may help the clinician identify hollow organ rupture or peritoneal perforation.

PROCEDURE PEARL

Without prior imaging, any air introduced into the peritoneum during needle sampling can confuse the clinician, as it is impossible to determine if the free air is iatrogenic or caused by a ruptured hollow viscus or abdominal wall perforation.

In a large retrospective study of 129 dogs and cats with intraabdominal injury or disease, abdominocentesis had an overall diagnostic accuracy of 47% in dogs and cats (largely due to false-negative results), compared with 83% for catheter paracentesis, and 95% with diagnostic peritoneal lavage. The clinician must understand that false-negative results are reduced when larger amounts of free fluid are detected within the peritoneal space. False-negative results have also been reported with diseases confined to the retroperitoneal space and conditions resulting in only localized or walled-off fluid pockets. Diagnostic yield can be improved by ultrasound guidance to capture fluid within these pockets.

PROCEDURE PEARL

Abdominocentesis has a high false-negative rate, especially when only a small amount of free peritoneal fluid is available to sample.

What You Will Need

In General

- Clippers and blades
- Antiseptic scrub
- Sterile surgical gloves

Sampling Equipment

- 18- to 22-gauge 1.5-inch needles or 16- to 18-gauge over-the-needle catheters
- Luer tip syringes (3-12 ml depending on the patient's size and amount of fluid needed for testing)
- Sample containers
- Serum "red-top" tubes (for biochemistry analysis)
- EDTA "purple-top" tubes (for cytology, total protein content, red blood cell and total nucleated cell count)
- Culturettes for bacterial culture
- Glass slides for cytologic evaluation

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STEP BY STEP HOW TO PERFORM ABDOMINOCENTESIS

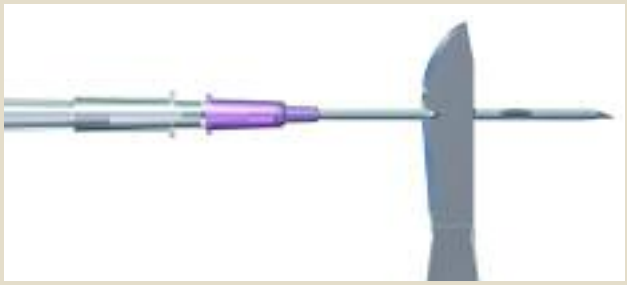
Positioning & Skin Preparation

Abdominocentesis is usually performed in conscious animals with physical restraint. If the patient is intractable, judicious use of chemical sedation should be considered.

1. Clip and prepare the ventral abdominal area for aseptic fluid collection.
2. Infiltrate the proposed sites with a local anesthetic agent if a larger over-the-needle catheter is chosen for sampling.
3. For simple abdominocentesis, stand the patient or position it in sternal recumbency. Access the most dependent site on the abdomen. Alternatively, nonambulatory or unruly patients can be positioned in left lateral recumbency. First puncture the right side to help avoid hemorrhage or contamination of the sample from accidental aspiration of the spleen.

PROCEDURE PEARL

I experience fewer "dry taps" when I use a 16-gauge over-the-needle catheter into which several staggered, side port holes have been added with a scalpel blade. Multiple side ports reduce obstruction from loose apposing tissue, particularly when small amounts of intraabdominal fluid are expected.

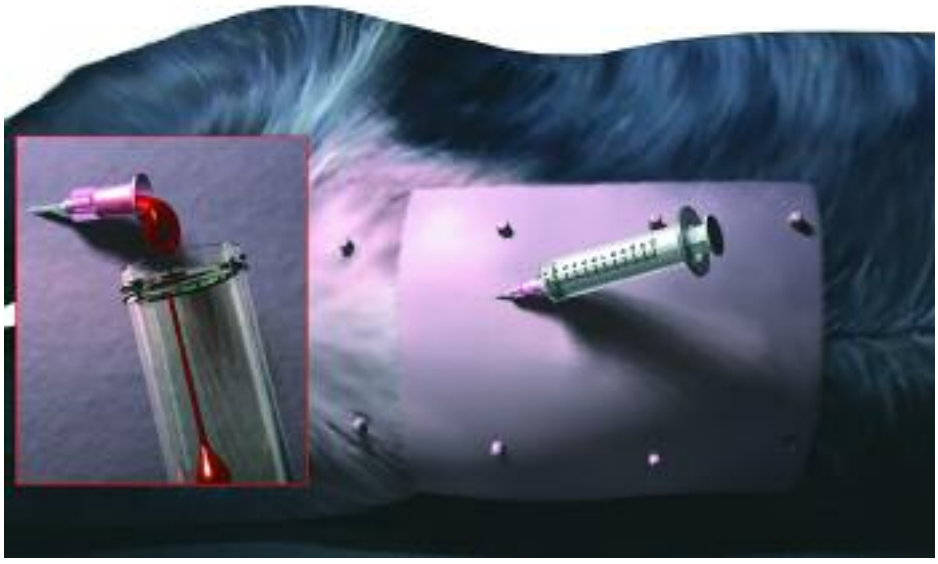


Creating side ports in an over-the-needle catheter. Four or five staggered holes are made with a sharp no. 10 scalpel blade. Be sure the holes are no larger than one third of the catheter circumference because larger holes may weaken the shaft and accidental breakage may occur when removing the catheter from the abdomen.

Productive Puncture Sites

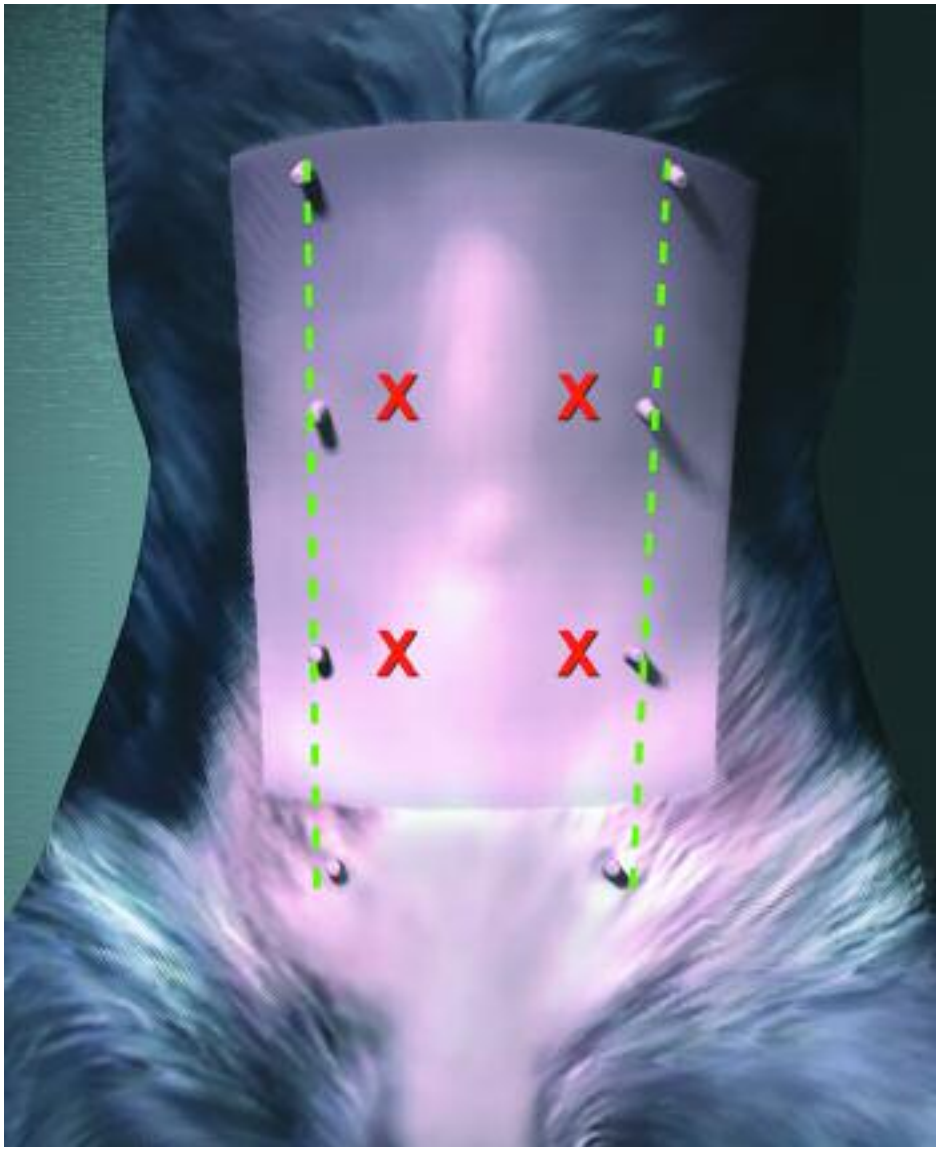
Simple Abdominocentesis

With the prepared animal in left lateral recumbency, insert the needle or fenestrated over-the-needle catheter just caudal to the umbilicus at or within 1 to 2 cm right of midline. Direct the needle toward the dependent side, slightly caudal toward the pelvis. The abdominocentesis shown here is positive. Fluid is flowing from the fenestrated catheter hub into a blood collection tube (**Inset**). If this approach is unsuccessful, attempt a second stick 2 to 4 cm cranial to the umbilicus on or slightly right of midline, with the needle angled in a slight craniodependent direction.



PROCEDURE PEARL

If simple abdominocentesis is unsuccessful and immediate results are important, a four-quadrant tap may be productive. … Four sites for needle placement are used with the umbilicus as the center point.



Four-Quadrant Abdominocentesis

If simple abdominocentesis is unsuccessful and immediate results are important, a four-quadrant tap may be productive. With the prepared animal in dorsal or left lateral recumbency, insert the needle or catheters described above. Four sites for needle placement are used with the umbilicus as the center point:

- Right cranial quadrant
- Left cranial quadrant
- Right caudal quadrant
- Left caudal quadrant

Avoid the caudal superficial epigastric vessels during needle or catheter puncture. Stay away from an imaginary line drawn longitudinally along the nipples. Red Xs depict suggested quadrant tap sites. The caudal superficial and deep epigastric vessels lie paramedian in the neighborhood of a longitudinal line drawn between the nipples (green dashed lines). These vessels should be avoided during puncture.

PROCEDURE PEARL

Hemorrhagic effusion generally does not clot—blood from inadvertent splenic aspiration generally does.

Puncture Technique (Any Site)

1. With gloved hands, gently insert the needle (without a syringe attached) through the abdominal wall, and observe for any fluid within the hub.
2. Slowly rotating the needle, not "blind jabbing," may help fluid to escape through the needle.
3. When using a fenestrated over-the-needle catheter, observe for fluid escape once the stylet has been removed.
4. Collect any fluid that flows from the needle in the appropriate container.
5. If no fluid is obtained, attach an appropriately sized syringe and apply very gentle suction.

PROCEDURE PEARL

Applying undue suction with a syringe increases the incidence of obstruction of the needle with tissue and subsequent false-negative results.

6. When one site is negative, repeat the needle puncture in another quadrant. A positive tap at any site completes the procedure.

Do not automatically accept that a negative abdominocentesis means little to no free abdominal fluid. Remember, between 5 and 6 ml/kg body weight of peritoneal fluid is

continues

required to achieve positive results with abdominocentesis in experimental dogs. If there is sufficient suspicion of abdominal effusion, ultrasound-guided needle sampling or diagnostic peritoneal lavage may be the next step. If diagnostic peritoneal lavage is planned, fluid can be infused and removed through the fenestrated over-the-needle catheter.

Complications

Complications from abdominocentesis are limited and uncommon. Inadvertent puncture of the caudal superficial epigastric vessels may cause significant ventral abdominal bruising. Blind puncture can lead to hemorrhage or hollow organ laceration, but this complication is rare provided the patient is properly restrained. The most common complication is contamination of the sample with hemorrhage, or sampling of a hollow viscus, such as the bladder or intestine, and this may contribute to misdiagnosis. False-positive results can be expected in about 5% to 10% of attempts.

Evaluation of Peritoneal Fluid

A representative fluid sample should be thoroughly analyzed. The test results must be combined with the clinician's assessment of the animal's clinical condition and, in many cases, compared with peripheral blood values to obtain an accurate diagnosis of intraabdominal disease. The following is a list of tests that can be requested from the sample depending on the clinician's index of suspicion for a particular disease process. Appropriate sample collection, handling, and preparation are essential to obtain an accurate diagnosis. Refer to Connally's article (**see Aids & Resources, back page**) for more information about sample preparation and which tests to consider for a variety of intraabdominal disease conditions.

See Aids & Resources, back page, for references, contacts, and appendices.

Peritoneal Fluid Evaluation

General Fluid Analysis

- Total protein
- Red and white cell count
- Specific gravity
- pH

Cytologic Evaluation

- White blood cell type and morphologic characteristics
- Foreign matter
- Intracellular organisms

Biochemical Analysis

- Glucose
- Creatinine
- Urea nitrogen
- Potassium
- Cholesterol
- Triglycerides
- Bilirubin
- Albumin
- Globulin
- Amylase and lipase
- Lactate
- Potassium
- PCO_2, PO_2

Culture & Susceptibility

- Aerobic and anaerobic bacterial culture

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COMING SOON

to these pages…

- **Complications:** Fluid Therapy
- **Patient Support:** Open Wound Care
- **Procedures Pro:** Artificial Insemination
- **Make Your Diagnosis:** Sudden Collapse
- **Ask the Expert:** Practice Promotional Strategies
- **What's the Take-Home?** Hip Dysplasia

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Chris Wong, DVM, VCA Sacramento Veterinary Referral Center, Sacramento, California

Thoracocentesis

Thoracocentesis is a technique used to remove fluid or air from the pleural space. It can be used as both a diagnostic tool and a therapeutic intervention.

Thoracocentesis aids in the diagnosis of many conditions including:

- Pyothorax
- Hemothorax
- Pneumothorax
- Chylothorax
- Bilothorax (a rare complication following trauma or liver surgery)[1]
- Malignant effusions
- Effusions secondary to primary heart disease.

Since the procedure may need to be performed differently depending on whether a patient presents with either a large or small change in pleural space volume, 2 different techniques are described.

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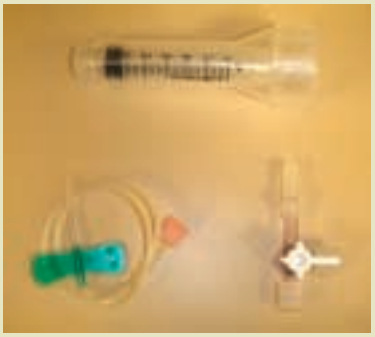
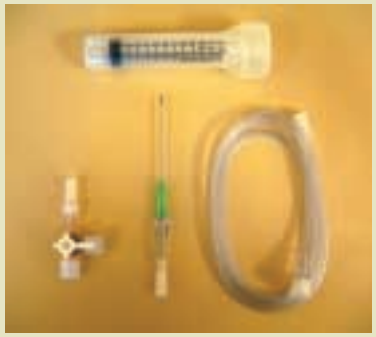
What You Will Need





To obtain a diagnostic sample

- **Cats and small dogs:** 19- to 23-gauge butterfly catheter, 3-way stopcock, 3-ml syringe, and 12- to 20-ml syringe
- **Medium or larger dogs:** 20- to 22-gauge 1.5- to 2.5-inch needle attached to an extension set, 3-way stopcock, 3-ml syringe, and 12- to 20-ml syringe

To perform therapeutic centesis

- **Cats and small dogs:** 20- to 22-gauge over-the-needle catheter attached to an extension set, 3-way stopcock, and a 20- to 60-ml syringe
- **Medium or larger dogs:** 14- to 16-gauge over-the-needle catheter attached to an extension set, 3-way stopcock, and a 20- to 60-ml syringe

For sample collection

- EDTA-containing glass tube
- Culturette
- Sterile glass collection tube

Risks & Contraindications

Risks

- Iatrogenic pneumothorax
- Hemothorax
- Intercostal artery laceration
- Lung laceration

Contraindications

- Severe coagulopathies
- Thrombocytopenia
- Only a small volume of fluid or air present

PROCEDURE PEARL

List the materials needed for thoracocentesis on an index card. During an emergency situation, your assistant can prepare the necessary supplies while you are evaluating the patient.

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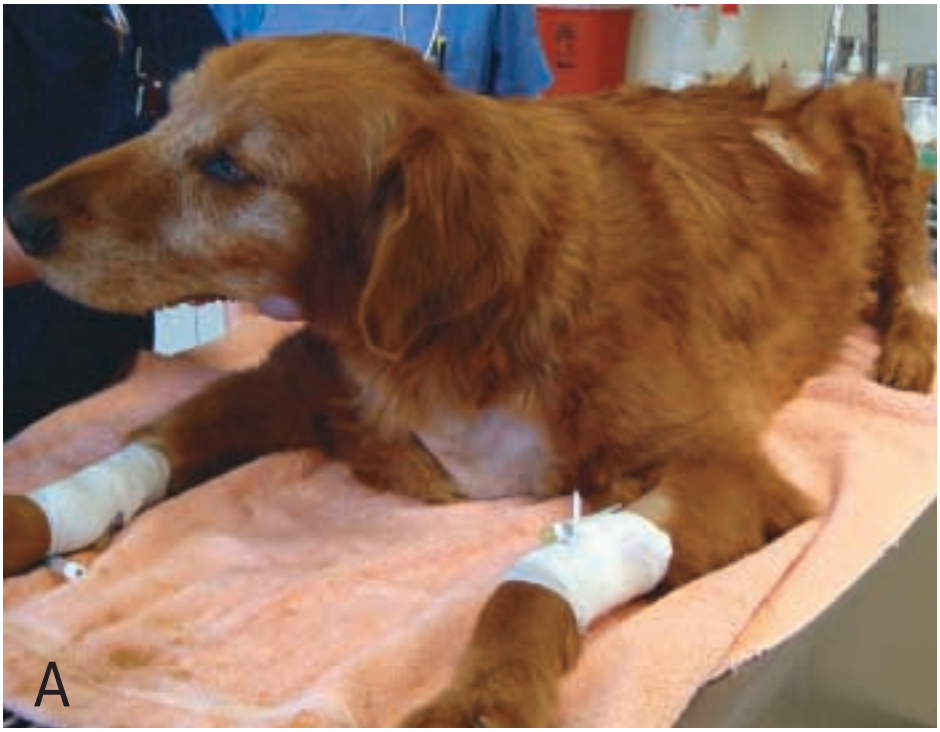
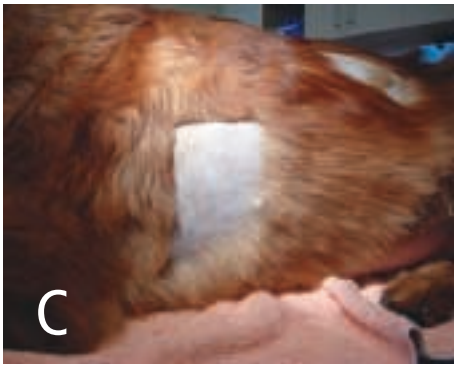
STEP BY STEP THORACOCENTESIS

Preparation





1 Most patients can be placed in sternal recumbency, which allows fluid to be positioned ventrally and air to be trapped dorsally (**A and B**). However, careful consideration should be given to compromised patients (eg, those with severe effusions or pneumothorax); they may be more comfortable standing, which allows the sternum to move freely and elbows to be abducted to accommodate greater chest excursions.

Sterile technique should be used. Shave the hair over the proposed site of puncture, keeping a 3-inch square area around the site (**C**). Disinfect the area with an iodophor- or chlorhexidine-containing antiseptic. For pneumothorax, aspirate between the 7th and 9th intercostal spaces in the dorsal third of the thoracic cavity. For fluid, aspirate between the 7th and 8th intercostal spaces in the ventral third of the thoracic cavity. (You will need to take care to avoid lacerating the internal thoracic artery that runs craniocaudally near the costochondral junction.)

PROCEDURE PEARL
If inexperienced, clip a much larger area of hair (generally from both sides of the chest wall): if you don't obtain an adequate sample from one site on the chest wall, this wide area allows you to move easily to a different rib space or another site.

Sedation

Sedation can be used in fractious patients, but the procedure is generally well tolerated with or without a local block. Opioids (see below) or an opioid/benzodiazepine combination (low end of opioid dose range with either diazepam [0.2 mg/kg IV] or midazolam [0.1 mg/kg IV]) can typically be administered safely to patients that require sedation. The opioid and benzodiazepine should be administered in separate syringes.

Opioid doses

- **Oxymorphone:** Dogs & cats—0.02 mg/kg SC or IM
- **Buprenorphine:** Dogs & cats—0.005 to 0.02 mg/kg SC or IM
- **Hydromorphone:** Dogs & cats—0.05 to 0.1 mg/kg SC or IM
- **Butorphanol:** Dogs & cats—0.2 to 0.4 mg/kg SC or IM

EDTA = ethylenediamine tetraacetic acid

Local Block Application

2 For diagnostic thoracocentesis, I apply a local block, but for most patients that need therapeutic thoracocentesis, local block application should be skipped in the interest of alleviating respiratory distress immediately.

Selecting the appropriate length and gauge needle attached to a syringe, draw up the necessary amount of lidocaine based on the patient's size (2 to 8 mg/kg maximum total infiltrative dose; 0.2 ml of 2% lidocaine should be more than sufficient for an average-sized cat and the maximum feline dose should not exceed 2 mg/kg).

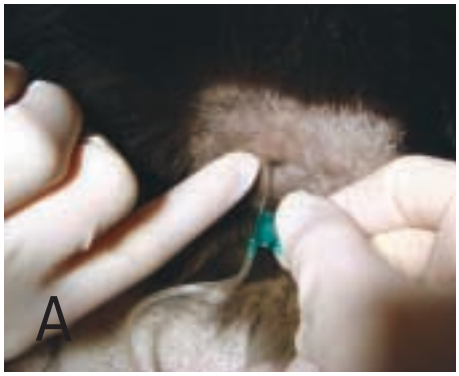
Insert the needle through the skin and intercostal muscles, perpendicular to the body wall, being careful to avoid the caudal aspect of the rib in front of the selected intercostal space.

Slow down as you approach the parietal pleura and alternate a small amount of positive and negative pressure on the plunger of the syringe while advancing the needle toward the pleural space.

Once pleural fluid or gas is obtained, note the depth of the needle, then withdraw it. Infuse the local anesthetic as you withdraw the needle through the intercostals and the skin.

PROCEDURE PEARL
Make sure the catheter and needle system stay firmly together while advancing the system through the chest wall into the pleural space.

PROCEDURE PEARL
Ultrasound can be used to find small pockets of effusion and may be a great adjunct to diagnostic thoracocentesis.



Diagnostic Thoracocentesis

3 Grasp the appropriate collection set and rest part of your hand or several fingers against the animal's lateral thoracic wall. This will help stabilize your hand in the event of sudden patient movement and decrease the incidence of iatrogenic trauma to the underlying lung.

Insert the needle perpendicular to the skin and advance it to the appropriate depth as was previously noted when infusing the local anesthetic (**A**). As you advance the needle, apply a small amount of negative pressure using a 3-ml syringe. Once fluid is obtained, reorient the bevel of the needle ventrally or laterally so that it sits parallel to the thoracic wall. This will prevent laceration of the lungs.

Collect fluid into EDTA and red-topped tubes for analysis. Once the fluid sample has been obtained, attach a length of extension tubing, 3-way stopcock, and large (12- to 20-ml) syringe to evacuate as much fluid from the thorax as is possible (**B**). Occasionally, pieces of fibrin, pleural tissue, or blood clots may obstruct the system. If this occurs, apply a small amount of positive pressure to the syringe plunger to clear the tip of the needle. Alternatively, apply a smaller syringe to the system to decrease excessive suction at the catheter tip. Ideally, no more than 5 cm of negative pressure should be applied to the syringe to avoid this complication.

Once you have obtained an appropriate sample, withdraw the needle parallel to the chest wall, but take care to avoid the caudal aspect of the rib. Record the total volume of material removed. Postprocedural radiographs are recommended.

PROCEDURE PEARL
Many patients have pleural space diseases detected on chest radiographs, which can also be a great help in determining where to perform a diagnostic thoracocentesis. Keep in mind that fluid and air can shift, however, since lateral radiographs are taken in lateral recumbency.

PROCEDURE PEARL
Place the thumbnail of your nondominant hand over the caudal aspect of the rib in front of the intercostal space you selected to act as a landmark and also to remind you to stay away from the intercostal vessels that run along the caudal aspect of the rib.

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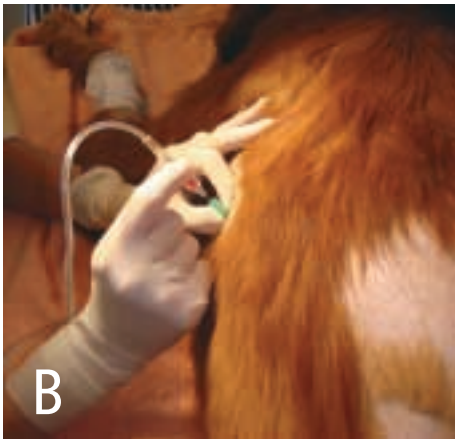
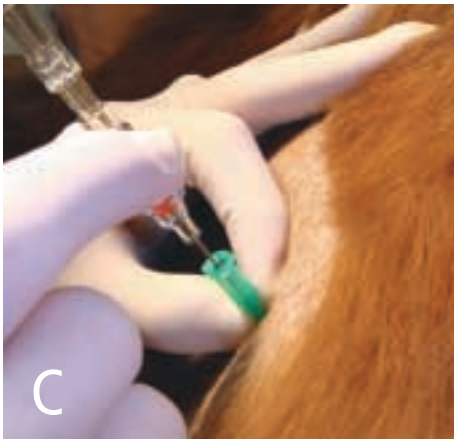




Therapeutic Thoracocentesis

4 Patients needing this procedure are typically dyspneic and may present with loss of airway sounds in the chest, dullness (fluid) or tympany (gas) upon percussion of the chest wall, rapid shallow respirations, and unwillingness to lie down. A quick ultrasound of the chest may give you useful information and locate pockets of thoracic effusion with minimal stress to the patient. Chest radiographs are the best way to evaluate the extent of pleural disease, but they may take valuable time (ultimately resulting in patient demise). Please use your best clinical judgment when deciding your course of action with these patients.

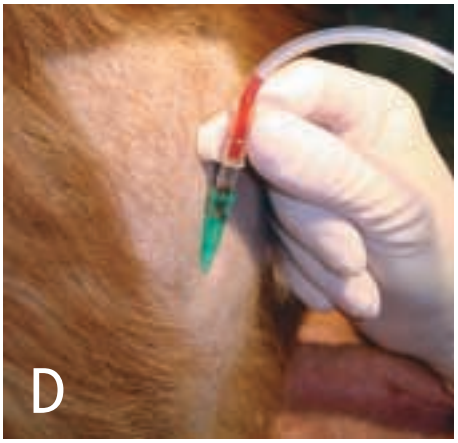
To begin, grasp the over-the-needle system. Rest your other hand or several fingers comfortably against the thoracic wall. Grasp the shaft of the catheter near the tip with the thumb and index finger of your nondominant hand.

Have an assistant connect the extension set with the 3-way stopcock and syringe to the end of the needle. Insert the needle/catheter system through the skin and intercostal muscles perpendicular to the thoracic wall (**A**).

Advance the needle to the predetermined depth (**Step 2**) or until you typically feel a "pop," which indicates puncture of the pleura (**B**). Have an assistant apply 1 to 4 mm of negative pressure on the plunger of a 20- to 60-ml syringe as you advance the needle into the pleural space. Once fluid or air is aspirated, advance the needle 3 to 5 mm further into the pleural space; then direct the bevel of the needle or catheter parallel to the thoracic wall to avoid lacerating the underlying lung.

PROCEDURE PEARL

If you start to obtain frothy material at any time during the procedure, you should withdraw the system quickly. Frothy material may indicate a punctured lung lobe and air in the chest.



Push the catheter off the needle in the direction that you want to aspirate (**C**); then remove the needle and reattach the extension set system to the end of the catheter. The tip of the needle or catheter can be moved dorsally to remove air, and ventrally to remove fluid (**D**).

As described in the previous section, collect appropriate samples, drain the chest, and then remove the catheter carefully. Record the volume of material obtained and take postprocedural thoracic radiographs.

PROCEDURE PEARL

If the catheter does not advance smoothly, you may not have it completely in the pleural space. Back the system out and hold it perpendicular to the chest wall. Advance the system under minimal suction until fluid or gas is obtained. This time advance the system just a little further into the chest so the tip is completely in the pleural space. Redirect and advance the catheter portion. If this doesn't work, then you may have barbed the tip on the way in. Remove the whole system and begin again with a new system.

See Aids & Resources, back page, for references, contacts, and appendices.

The 90-90 Flexion Bandage

Daniel D. Lewis, DVM, DACVS
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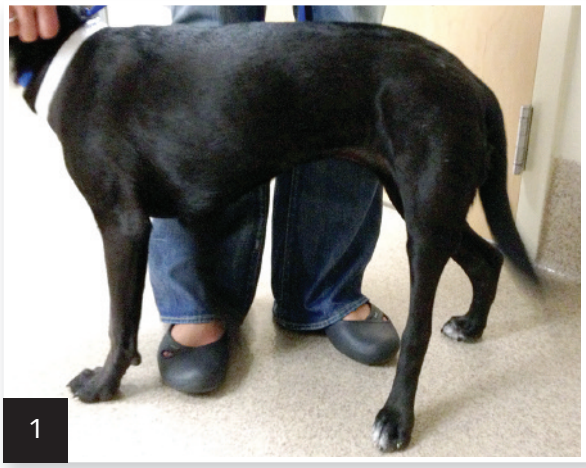
Quadriceps contracture (ie, quadriceps tie-down) can be a devastating sequela to stabilization of femoral fractures. It is a severe manifestation of fracture disease that occurs most frequently in skeletally immature dogs and cats that sustain physeal or other fractures involving the distal femur. In cases of quadriceps contracture, the involved pelvic limb becomes permanently fixed in rigid extension, impeding ambulation (**Figure 1**). Some cases of quadriceps contracture are unavoidable, such as those resulting from vascular compromise of the quadriceps muscle group sustained during a traumatic incident that caused the fracture. Other cases can be attributed to faulty fracture management.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With quadriceps contracture, the involved pelvic limb becomes permanently fixed in rigid extension.

Previous Methods & Application

Previously, distal femoral fractures were frequently managed in a closed fashion by placing the limb in coaptation, which positioned the stifle and hock joints in extension, predisposing the patient to develop quadriceps contracture. With advancement in orthopedics, open anatomic reduction and stable fixation became standard for most femoral fractures; however, some patients still developed quadriceps contracture even when appropriate surgical techniques were applied. Many animals maintain the repaired pelvic limb in extension after anesthesia and appear painful and uncooperative when manual flexion of the affected stifle and hock is attempted.

A Different Approach

Aron and Crowe described application of the 90-90 flexion bandage, which maintains the stifle and hock joints in 90° of flexion to decrease the occurrence of quadriceps contracture following open stabilization of femoral fractures.[1] Prolonged coaptation is contraindicated following open fracture reduction, as a splint or bandage provides no appreciable mechanical stability to internal implants placed during surgery, and prolonged immobilization of involved limb segments promotes development of fracture disease. The 90-90 flexion bandage maintains the quadriceps muscle group in an extended position transiently during the early postoperative convalescent period.

As originally described, the 90-90 flexion bandage was maintained for a mean of 11 days (range, 7–21 days)[1]; however, the author has found maintaining the splint for 48 to 72 hours to be sufficient. After bandage removal, most patients begin placing weight on the affected limb, can maintain the affected stifle positioned in a normal standing angle (ie, 135°), and are amenable to manual flexion of the involved stifle.

MORE ▶

What You Will Need

- Bandage scissors
- Nonadherent adhesive bandage (Tegaderm +Pad, 3m.com)
- Tongue depressor
- Roll of porous white adhesive tape (Zonas, jnj.com)
- 1–2 rolls of cast padding (multiple brands, bsnmedical.com)
- 1–2 rolls of stretch bandage (Curity, covidien.com)
- 1–2 rolls of adhesive elastic tape (Elastikon, jnj.com)

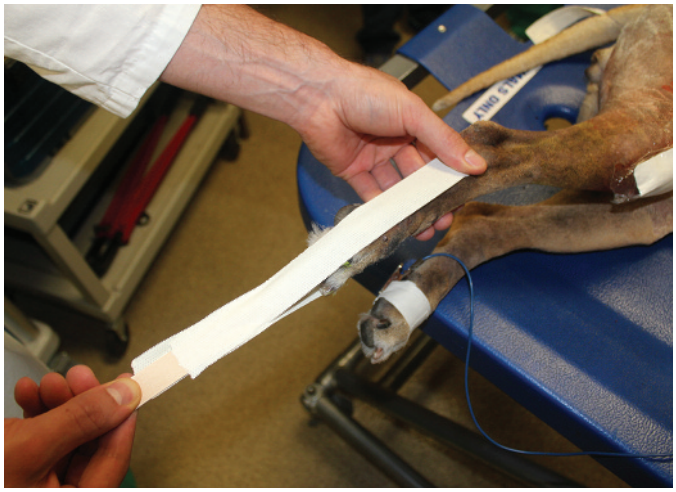
Step-by-Step ■ 90-90 Flexion Bandage

Step 1

Confirm acceptable reduction and fixation with postoperative radiographs, and apply the bandage while the patient is still anesthetized. Place a nonadherent adhesive bandage over the surgical wound and position the patient in lateral recumbency.

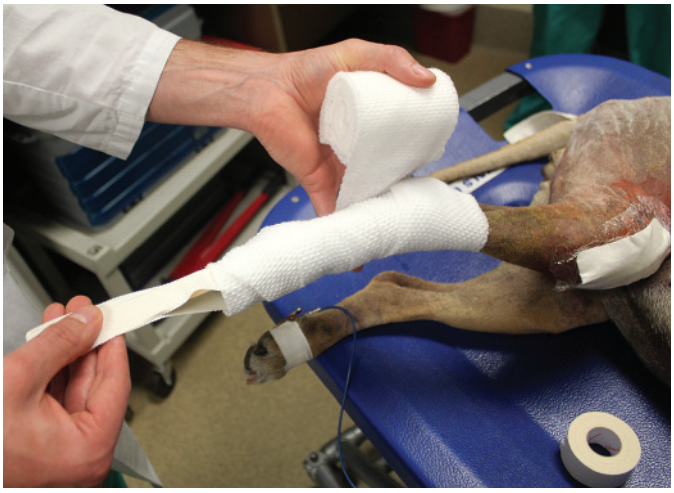
Step 2

Apply strips of porous white adhesive tape to the medial and lateral aspects of the paw; several centimeters of tape should extend beyond the digits. Place a tongue depressor between the adhesive surfaces of the tape so the stirrups can be easily separated later.



Step 3

Apply 3–4 layers of cast padding to the paw. The cast padding should extend from, but not beyond, the distal ends of the digits.

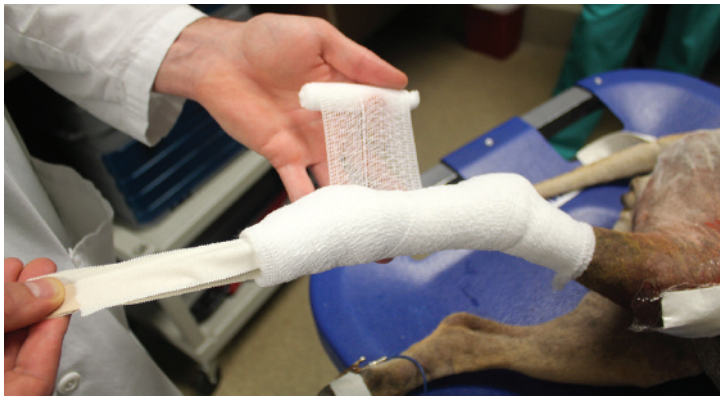


Author Insight

Extend the cast padding proximal to the hock to secure the bandage to the limb; alternately, the bandage can be terminated just distal to the hock.

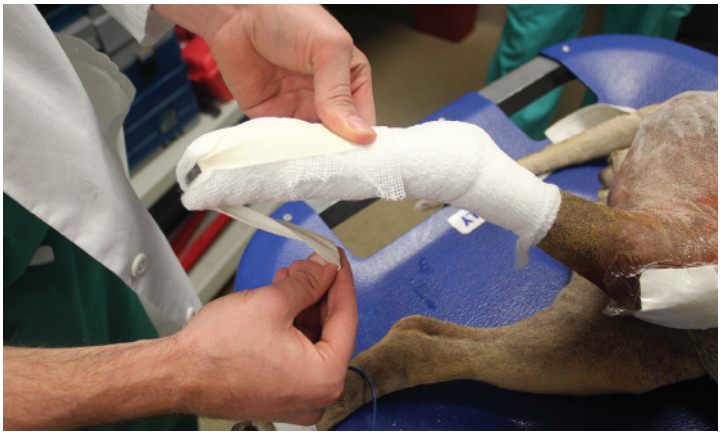
Step 4

Apply 2–3 layers of stretch bandage over the cast padding with firm, even tension; a 2–3-mm margin of cast padding should be visible at the proximal extent of the bandage.



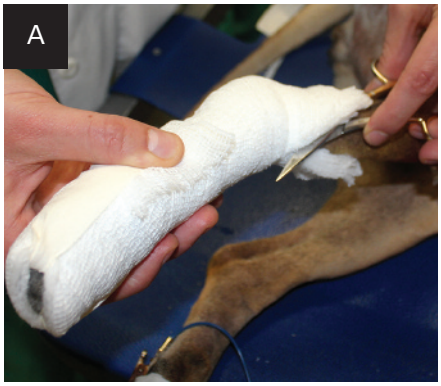
Step 5

Separate the stirrups and double back the strips of porous white tape on their respective sides of attachment, securing the adhesive surface to the stretch bandage.



Step 6

As the hock is flexed, the bandage material over the cranial aspect of the talocrural joint will bunch, which can cause pressure necrosis of nearby skin. Use bandage scissors to incise the bandage material over the cranial aspect of the distal crus and hock (**A**) until this region is tension free (**B**).



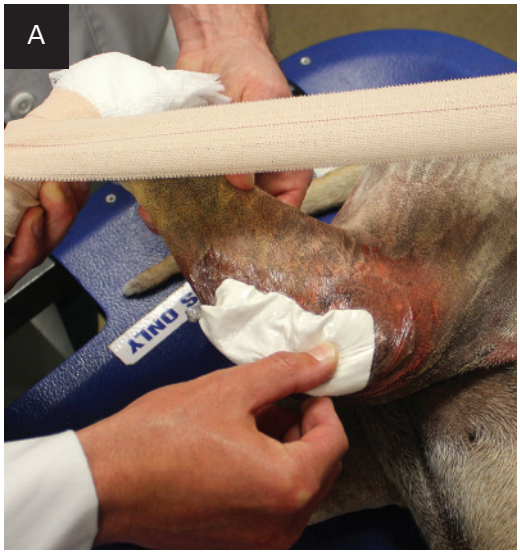
Author Insight **Extending the bandage above the hock can reduce irritation from the adhesive that was placed circumferentially around the distal crus.**

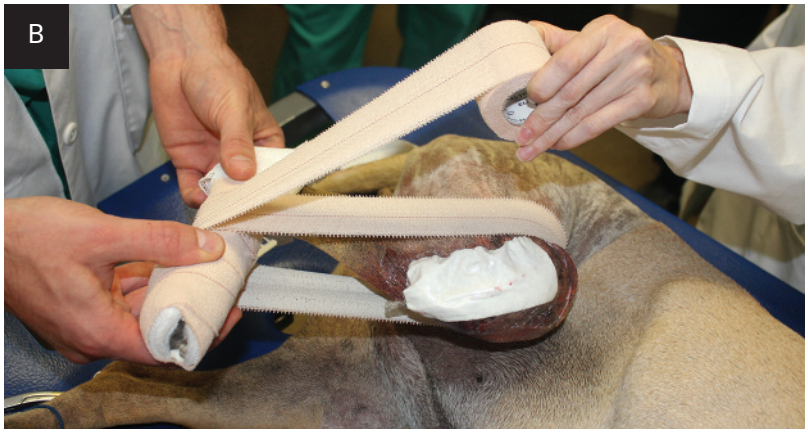
MORE ▶

Step 7

While wrapping the adhesive elastic tape over the region of the thigh, pull the skin distally over the cranial aspect of the thigh. Once the adhesive elastic tape is in place, the skin is released and the tape will be positioned more proximal on the thigh and less likely to slip over the stifle (**A**).

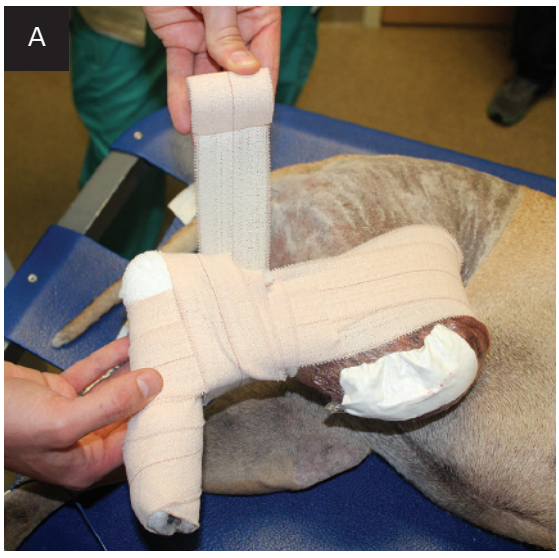
Wrap adhesive elastic tape around the paw several times circumferentially (cranial to medial to plantar to lateral). Next, wrap the adhesive elastic tape over the cranial surface of the thigh as proximal as possible, then back around the hock. Repeat the process several times (**B**).

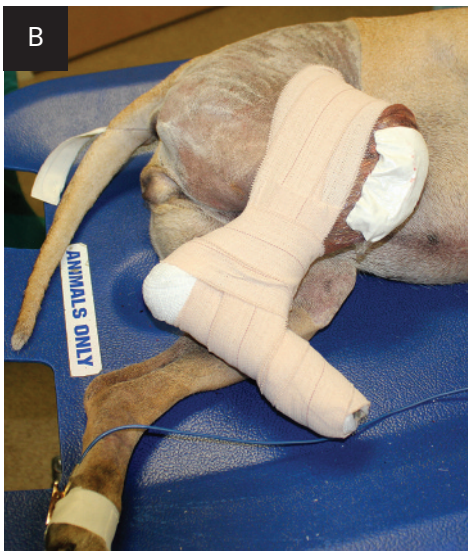




Step 8

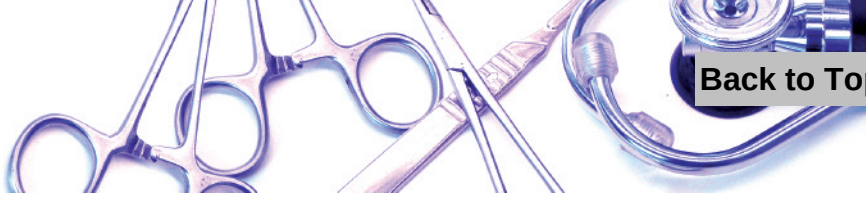
Wrap an additional segment of adhesive elastic tape circumferentially around the distal crus to secure the first application of adhesive elastic tape in place (**A**) and help maintain the limb in flexion (**B**). ■ cb





See **Aids & Resources**, back page, for references & suggested reading.

Peer Reviewed



Mirae C. Wood, DVM, &
James L. Cook, DVM, PhD, DACVS & DACVSMR
University of Missouri

Applying a Spica Splint

Although spica splints are used infrequently, they can be a helpful means of external coaptation in patients with selected musculoskeletal abnormalities. Spica splints are most commonly used for temporary immobilization of the shoulder or elbow following open or closed fracture reduction, particularly when surgery is delayed or the patient requires transport before fixation.

Spica splints are rarely used for primary management of humeral fractures because of the availability of more viable treatment options. However, spica splinting may be considered in a young animal with a greenstick fracture of the humerus.

APPLICATION

Proper application and management are critical to ensure safe use of the spica splint, so named for the method of attaching the splint to the body by a "spica" or figure-of-8 bandage shape. In dogs and cats, however, the bandage is modified so it is only half of a figure-of-8. During application, the bandage material begins at the digits and continues proximally around the torso. The splint should extend over the scapula (or hip) to the dorsal midline and be secured around the contralateral shoulder or hip. Although the spica splint is most often applied to the thoracic limb, it can be used for reduction of the pelvic limb. However, bandaging the pelvic region can be difficult, especially in male dogs.

Because extensive manipulation is required, the patient should be heavily sedated or under general anesthesia. Additional wounds should be treated appropriately and covered with a dressing before the splint is applied. Although the torso is included in the bandage, tape stirrups should be placed to prevent it from slipping, possibly obscuring assessment of the digits.

After the splint has been applied, ambulation may be cumbersome, so appropriate assistance (eg, sling support) should be provided.

COMPLICATIONS & MONITORING

Because spica splints are generally well padded and used only for a brief period, there is minimal opportunity for complications. Also, because the splint must be secured firmly around the torso, slippage is less common. The patient should still be monitored closely, however, for abrasions or bandage sores in the axillary or inguinal region.

With extended use, joint contracture or loss of range of motion can occur, especially when the spica cast is used for fracture management. During bandage application, care must be taken to avoid compressing the patient's thorax and compromising respiratory function, especially in patients with preexisting thoracic trauma (eg, pneumothorax, pulmonary contusions).

CONTINUES

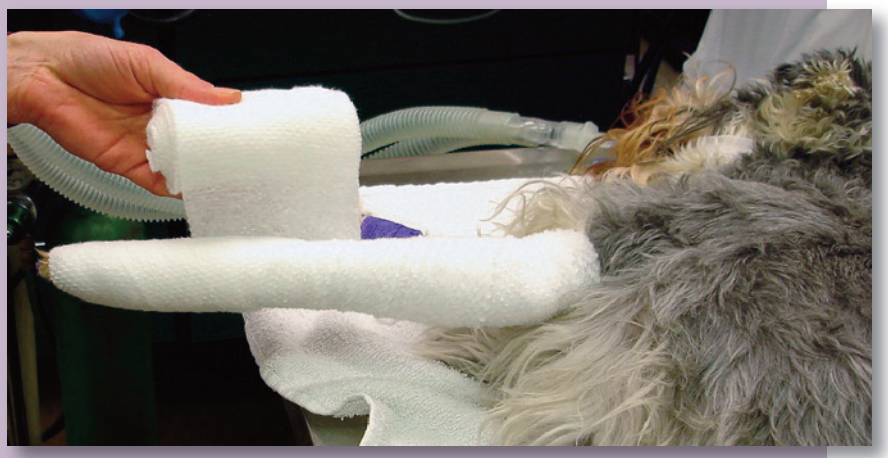
WHAT YOU WILL NEED

- Cast padding
- Rolled gauze
- Cast material (eg, fiberglass, thermoplastic material) or splint rod
- Casting gloves
- Bandage tape or self-adhesive stretch tape

STEP-BY-STEP APPLYING A SPICA SPLINT

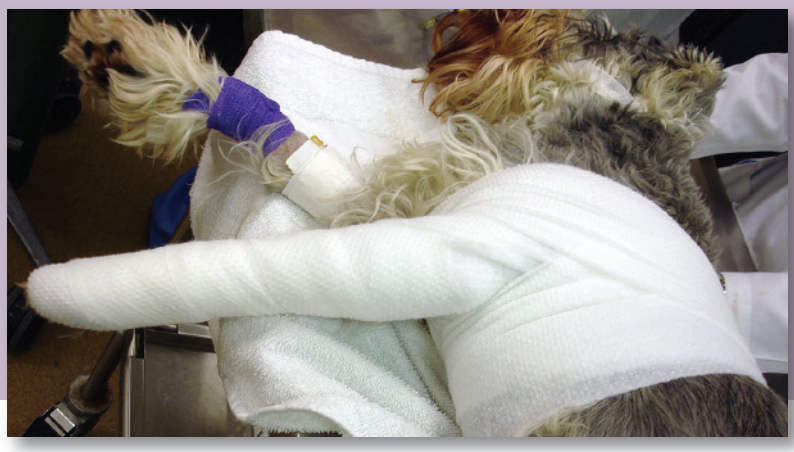
STEP 1

Place the patient in lateral recumbency with the affected limb uppermost. Wrap adhesive tape stirrups on the medial and lateral aspects of the affected limb, and apply cast padding (4- or 2-inch), beginning at the level of the second and fifth digits. Leave the toenails of digits 3 and 4 exposed for monitoring. Apply the padding tightly, allowing no wrinkles or twists and overlapping the previous layer by 50% with each successive layer.



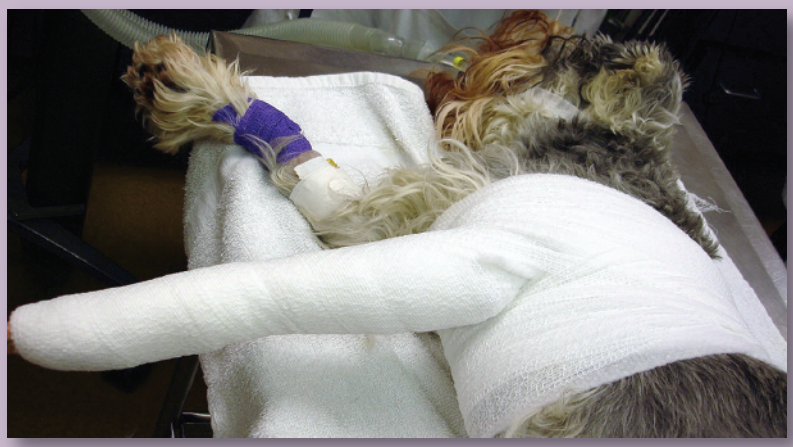
STEP 2

Wrap the padding around the patient's torso several times, caudal to the contralateral limb and alternating cranially and caudally to the affected limb.



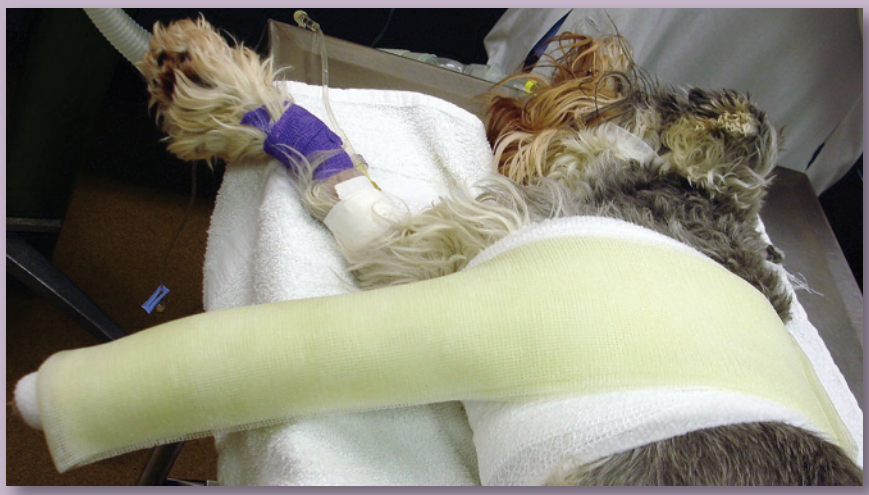
STEP 3

Apply rolled gauze in the same manner as the cast padding. To achieve a smooth bandage with uniform tension, apply at least 2 to 3 layers of gauze using even pressure. The gauze compresses and conforms to the cast padding but does not provide sufficient strength to immobilize the joints.



STEP 4

Reinforce the bandage with casting material or a splint rod. Conform the material or rod to the bandaged limb from the toes to the dorsal midline. If thermoplastic material is applied, use 4–8 layers, depending on the size of the patient and degree of rigidity required.



AUTHOR INSIGHT

Because thermoplastic material (eg, Vet-Lite, runlite.com/vet-lite) can be remolded following application, its use is advantageous in cats and small dogs. In large dogs, multiple layers of thermoplastic material may be required to achieve the necessary rigidity.

AUTHOR INSIGHT

To prevent the underlying bandage from becoming wet, place plastic wrap over the gauze before applying the casting material. After the cast material cures, remove the plastic wrap and complete the bandaging process as described.

STEP 5

Apply another layer of rolled gauze to hold the splint in place (**5A**). Completely cover the bandaging with bandage tape or self-adhesive stretch tape (**5B**). If the splint is constructed properly, the limb and torso are immobilized and move as a single unit.

AUTHOR INSIGHT

If the patient goes outdoors, the owner should cover its toes with a protective boot (eg, Medipaw, medivetproducts.com) or an IV fluid bag to prevent the bandage from becoming soiled.

See **Aids & Resources**, back page, for references & suggested reading.

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Laura E. Peycke, DVM, MS, Diplomate ACVS, Texas A&M University

Effective Casting Techniques

What You Will Need

- Scissors
- Adhesive tape (1 inch)
- Tongue depressor
- Primary, secondary, and tertiary layers for initial bandaging (cast padding, stretch bandages, flexible wrap)
- Toilet paper
- Fiberglass cast material
- Latex gloves (nonsterile)
- Cast saw

PROCEDURE PEARL

Because casting often requires manipulation of the fractured limb, anesthesia is strongly recommended. Superficial wounds should be clipped and cleaned and primarily covered with a nonadhesive dressing. Fractures with significant soft tissue trauma are generally not amenable to casting, unless frequent changes are done. Clip medium to long hair to ensure a snug fit of the cast.

Casting is a commonly used technique for external coaptation or fixation in veterinary medicine and surgery. Casts are primarily used to provide rigid support of an injured limb and are typically molded around a fractured distal extremity to provide relatively motionless stability for bone fragments during the healing process. Healing occurs by secondary bony union and callus formation. As long as the joints above and below the fracture are included within the cast, bending and rotational forces are counteracted and adequate rigid stability is usually achieved. Compressive and distractive forces are not neutralized in most cases. Therefore, indications for casting include minimally displaced, closed, simple fractures of the radius, ulna, tibia, fibula, metacarpus, metatarsus, and phalanges.

Casting can be used successfully when a fracture depends on its intact paired bone to provide support (eg, fractured radius and intact ulna, isolated metacarpal/metatarsal fracture). Fracture ends should have at least 50% anatomic reduction in 2 orthogonal radiographic planes. Casting can also be used as adjunct support with internal fixation when necessary. Situations in which casts are not indicated include comminuted and significantly displaced fractures in which casting cannot neutralize forces present, fractures above the elbow or stifle, and distal radius/ulna fractures in toy or small-breed dogs.

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STEP BY STEP APPLYING A CAST






1 Apply 2 tape stirrups (1/2- to 1-inch adhesive tape) to opposite sides of the distal limb. The stirrups should extend from a point at or above the carpus or tarsus and to approximately 6 inches below the digits. These will be laid over the bandage at a later time to prevent distal slipping of the cast. A tongue depressor can be placed between the stirrups to facilitate separation prior to application.

PROCEDURE PEARL
A tongue depressor can be placed between the stirrups to facilitate separation prior to application.

2 A minimum of 2 layers of snugly placed cast padding is applied next. Excessive use of padding, however, can lead to inadequate cast rigidity and cast loosening. With all layers of the bandage and cast, the nails of middle distal phalanges should be accessible to check for swelling. Begin at the distal-most aspect of the limb and allow for at least 50% overlap of the material. Padding over pressure points must be even to prevent casting pressure sores. If additional padding is desired over bony prominences (such as the elbow or calcaneus), foam or a padded donut is recommended.

3 Stretch bandage (Conform Stretch Bandages; Kendall, www.kendall-healthcare.com; or Kling; Johnson & Johnson, www.jnjfirstaid.com) is applied over the cast padding. This material should be applied evenly and compressively, but not pulled excessively tight. Two to 3 layers should be sufficient to hold the cast padding.

6 Gloves should be worn during wetting and application of the fiberglass material. The material is rolled onto the most distal portion of the desired area. A small amount of bandaging material should be visible distally, but the cast should encompass the distal paw, leaving only the distal portion of the middle 2 toenails exposed. At least 2 to 3 rotations should be done to anchor the material. The material should overlap itself no less that 50% and wrinkles in the material should be avoided. Additional wraps can be done at the level of the joint to provide additional support. Use at least 2 layers of cast material in small- to medium-sized animals and a minimum of 3 to 4 layers in large animals.

4 Toilet paper or other nonadherent material can be used to provide a layer that does not stick to the casting material. Toilet paper has an advantage because it does not require removal after cast application. When reapplication of the original cast is desired, this layer makes it possible to remove the cast easily from the stretch bandages beneath it.

PROCEDURE PEARL
Other nonadherent materials, such as polyethylene film (food wrap), can be used in this step, but materials that do not breathe should be removed after the cast is bivalved and prior to applying the final bandaging layer.

5 Commonly used fiberglass casting materials are made of a polyurethane-resin–impregnated fiberglass tape that is packaged in roll form (Vetcast Plus Veterinary Casting Tape, 3M, www.3m.com; Delta-Lite S, BSN Medical, www.bsnmedical.com). The material is strong, lightweight, and easy to apply. Widths typically vary from 2 to 4 inches. Wider material generally improves the strength of the cast, but the material must be appropriate to the animal's size. The fiberglass is porous and stretches to conform to the shape of the limb. The polyurethane resin is activated after the tape is immersed in room temperature water. The material typically sets up in 5 to 7 minutes. During all steps of bandage and cast application, the limb should be maintained in a neutral standing position. Fiberglass casting materials are usually radiolucent, so postcasting radiographs are recommended.

PROCEDURE PEARL
To optimize the ability of a cast to neutralize fracture forces, the cast should cover the joint above and the joint below the fracture site.

PROCEDURE PEARL
Gloves should be worn during wetting and application of the fiberglass material.

continues

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7 Once the cast has hardened (at least 5 minutes after application), a cast cutter is used to cut the cast longitudinally into 2 halves (sagittal plane). These halves facilitate quick removal during emergency or routine cast changes.

8 Stretch bandaging material should be applied tightly enough to keep the cast in place. Strips of adhesive tape can be used to keep the halves together. One layer of material should be adequate to keep the cast securely together.

9 Stirrups should be removed from the tongue depressor and directed proximally onto the cast.

10 Bandaging tape (Vetrap; 3M, www.3m.com) should be applied last. Anchor the material with at least 2 layers distally and continue proximally. The material should overlap by at least 50% and should fit snugly over the cast to help keep it in place. As long as the toenails remain accessible, a layer of cotton elastic cloth tape (Elastikon; Johnson & Johnson, www.jnj.com) can be used to preserve the distal portion of the cast material.

PROCEDURE PEARL

During bandage and cast changes, do not remove the stirrups from the hair coat. Simply cut the stirrups flush with the distal extremity and replace the adhesive tape stirrup on top of the existing tape.

Postapplication Care

The cast should be evaluated within 24 to 48 hours of placement. Weekly rechecks are recommended and radiographic reevaluation is typically recommended after 4 to 6 weeks. The cast can be left in place (without changing) for a maximum of 4 weeks for adult animals, as long as owners are able to keep the cast clean and dry and the animal is comfortable and using the limb well. Cast changes may be needed more frequently in young, rapidly growing animals. Logically, leaving the cast in place for as long as possible without change is best for rigid stabilization and prevention of excessive movement. If superficial abrasions or wounds were present at the time of cast placement, the first cast change should not exceed 5 to 7 days.

Potential Complications

Warn owners about complications such as dermatitis and recommend frequent (weekly) evaluations. Owners should be instructed to evaluate for abrasions created by the cast ends and for toe swelling. If any confusion exists, a card can be marked or a measurement taken to document the original distance between toenails. The owners should understand that any abrasions or increase in distance between toes requires immediate evaluation by a veterinarian.

To protect the distal portion of the cast, an empty IV bag or plastic household bag can be placed over the foot when the animal is taken outside. The bag should be removed immediately once the animal returns inside. If the cast becomes damp, a hair dryer can be used to dry the area.

If acute reluctance to bear weight, foul odor, loosening of the cast, or licking and chewing at the cast is noted, immediate (same day) evaluation is crucial. When replacing the cast, the original cast halves may be used, but particular attention to fit and integrity of the material is important. When in doubt, replace the casting material. General anesthesia is recommended for the first 2 to 4 weeks if a cast change is necessary (especially if a new cast is required). ■

See Aids & Resources, back page, for references, contacts, and appendices.

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The Ehmer Sling in Canine Orthopedic Surgery

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Walter C. Renberg, DVM, MS, DACVS
Kansas State University

Case Selection & Management

Proper case selection for Ehmer or Figure-8 sling use is critical to a successful outcome. The Ehmer sling was designed to maintain the head of the femur in the acetabulum after closed reduction of a craniodorsal coxofemoral luxation, to prevent weight bearing, and to limit hip motion during healing. It should not be used in dogs with ventral coxofemoral luxation, which should be treated with hobbles to prevent limb abduction.

Best results are obtained in dogs with acute luxations <24 hours in duration with temperaments amenable to confinement and continual bandage care. Ehmer slings should not be applied to dogs with luxations of >1 week duration, luxations associated with fractures of the adjacent acetabulum, poor hip comformation (hip dysplasia), or dogs that are unable to ambulate on the contralateral limb. Ehmer slings can be difficult to apply in obese or chondrodystrophic dogs. Ehmer slings may be useful after internal fixation of acetabular or femoral head and neck fractures to temporarily prevent weight bearing.

Success of Ehmer sling application is enhanced by appropriate technique during reduction. Hip radiographs must be taken and evaluated before reduction to identify dogs with acetabular fractures or ventral luxations and are not candidates for Ehmer sling application. Reduction should be attempted in anesthetized dogs with craniodorsal hip luxations. Reductions are best accomplished by a manipulative sequence composed of external rotation of the affected limb while simultaneously providing distal traction to the limb and countertraction to the inguinal area. While traction is maintained, the limb should be internally rotated and simultaneous distal pressure to the greater trochanter applied to facilitate reduction. After reduction and before sling application, the coxofemoral joint should be put through multiple complete range-of-motion exercises while medial pressure is applied to the greater trochanter to clear the acetabulum. Orthogonal radiographs of the affected hip should be performed and evaluated after Ehmer application to confirm reduction of the coxofemoral joint.

Aftercare

Daily examination of the hip and Ehmer sling determines effectiveness of the sling for maintenance of internal rotation, flexion of the coxofemoral joint, and limb abduction. Loss of internal rotation, hip flexion, or abduction are indications for immediate sling replacement. The position of the greater trochanter in ventral relationship to a line that connects the ilial wing and ischiatic tuberosity should be palpated daily to confirm continued hip reduction, and the joint should be palpated through a shortened

What You Will Need

- 1 to 2 rolls of 2-inch wide porous, nonelastic adhesive tape.

Author Insight

Best results are obtained in lean, calm dogs with acute luxations <24 hours in duration.

continues

range of motion to confirm continued smooth function. The flank, abdomen, and distal limb are examined daily for sores, inflammation, and edema. If pressure sores or wounds develop, modify the sling or remove it immediately. Monitor the abdominal band in male dogs for urine contamination and irritation of the underlying skin.

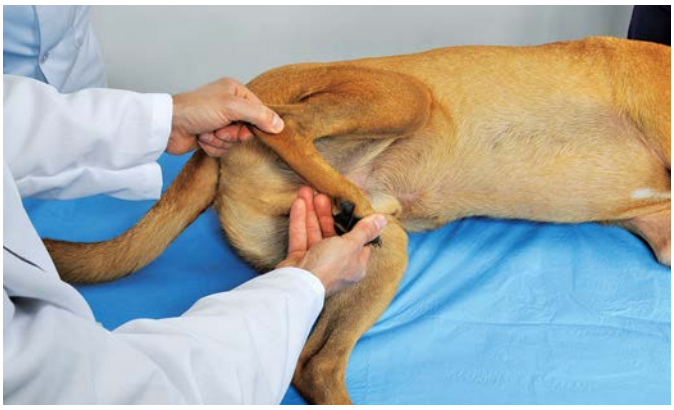
Maintain the Ehmer sling for a minimum of 7 to 10 days (maximum, 14 days) and remove only after coxofemoral reduction is confirmed by repeated orthogonal radiographs. Reluxation rates of 15% to 71% have been reported after closed reduction[1]; however, the specific reluxation rate after closed reduction and Ehmer sling application has not been reported. Owner evaluation scores are better after closed reduction than after femoral head and neck excision, extracapsular suture stabilization, and De Vita pinning.[2] Direct comparisons of recurrence rates or owner satisfaction between closed reduction, Ehmer sling, and more recently developed techniques (eg, toggle pin, rod repair) have not yet been reported.

Dogs should be kept under cage confinement for the period of Ehmer sling application and for a minimum of 4 weeks after removal. Voluntary use of the limb by the patient should begin within 1 or 2 days as stiffness decreases, then gradually increase on a daily basis following removal of the sling. Gentle physical rehabilitation consisting of daily hip range-of-motion exercises can be initiated 4 to 6 weeks after sling removal. Controlled leash walks or underwater treadmill therapy may also be beneficial to restore normal use and function.

STEP-BY-STEP ■ EHMER SLING APPLICATION (AFTER CLOSED HIP REDUCTION)

STEP 1

Place the dog in lateral recumbency with the affected limb up. Flex the limb, and place it in slight internal rotation. Two to 3 layers of cast padding may be placed around the metatarsal area initially but can lead to increased incidence of bandage slippage.



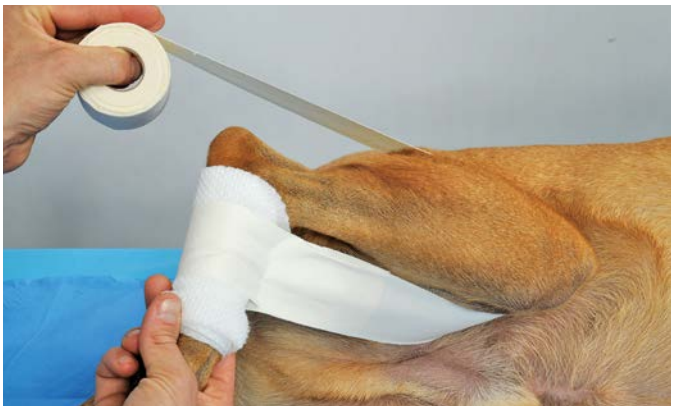
STEP 2

Place the adhesive tape on the metatarsal area by placing it around the caudal surface with the adhesive side of the tape against the limb or initial wrap. Wrap the tape so the adhesive sides meet cranially and do not completely encircle the metatarsal. Take care not to place the tape tightly or completely around the metatarsus.

Images courtesy of Wiley-Blackwell. Reprinted from: Swaim SF, Renberg WC, Shike KM. *Small Animal Bandaging, Casting, and Splinting Techniques*. 1st ed. Ames, IA: Wiley-Blackwell; 2011:100-104.

STEP 3

Bring the tape up the medial aspect of the crus and around the cranial aspect of the thigh proximal to the stifle with the adhesive side against the animal.



Author Insight

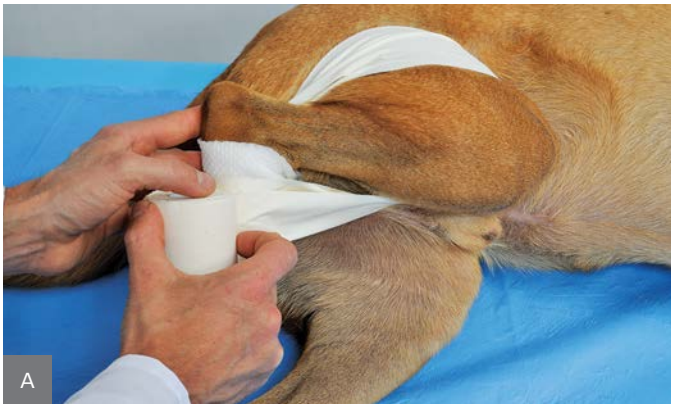
Preoperative hip radiographs *must* be taken and assessed to exclude dogs with acetabular fractures, femoral head fragments, and dogs with ventral luxations.

STEP 4

Continue to wrap tape around the caudal aspect of the crus and onto the medial side of the hock to finish caudally on the metatarsal area (**A**). When this portion of the bandage is completed, the lateral aspect of the j3 should be visible and internal rotation should be maintained. Steps 3 and 4 are repeated several times to strengthen and reinforce the bandage (**B**).

Author Insight

Perform daily examination of the hip and Ehmer sling to assess continued hip reduction and lack of bandage complications.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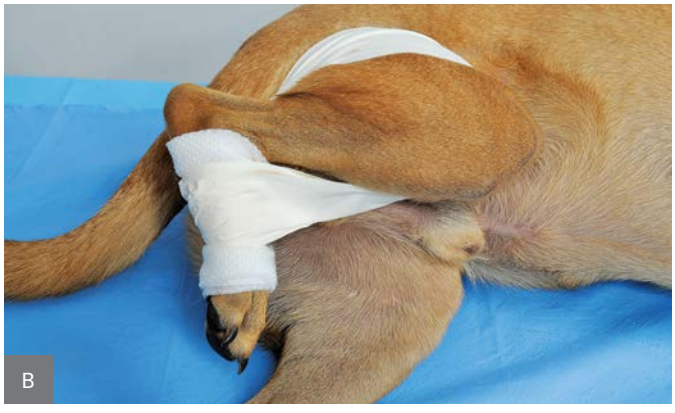
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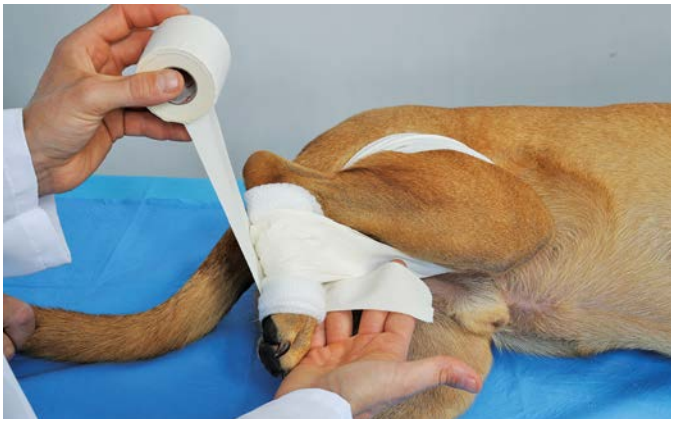
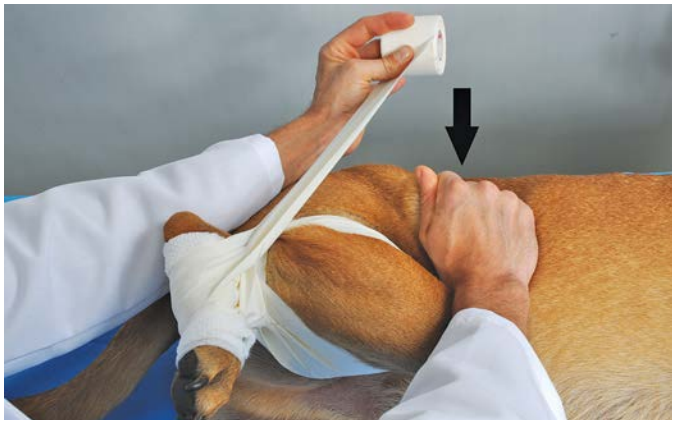
STEP 5

An abdominal support portion of the sling is necessary to maintain hip flexion and limb abduction and begins with the tape applied at the metatarsal region as described in Step 3.



STEP 6

Bring tape up the lateral aspect of the limb and then over the dorsum of the animal, cranial to the tuber coxae, with the adhesive side against the animal. To avoid shifts of loose skin that might let the limb extend as the animal stands, pull skin of the flank ventrally (**arrow**) before applying tape.

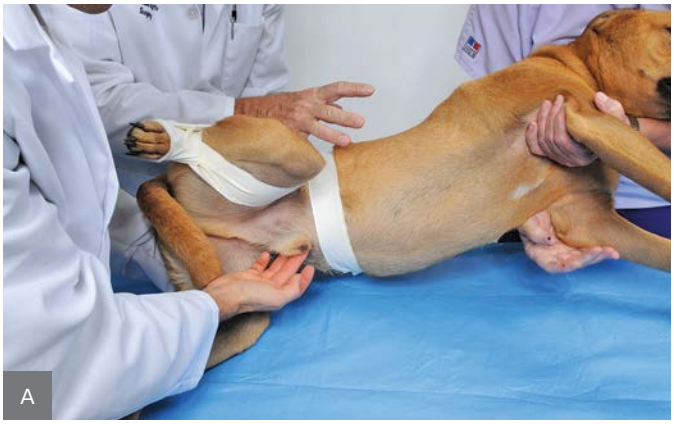


STEP 7

Continue to tape around the opposite side of the animal and abdomen. Place tape cranially to the prepuce on male dogs (**A**). Repeat Steps 5, 6, and 7 several times to strengthen and reinforce the sling. When the sling is complete, the limb should be abducted and flexed, with slight internal rotation (**B**). ■ cb

Author Insight

Before application of the splint, mild external rotation of the hip should be performed to assess the degree of stability. Dogs with excessive laxity or easy luxation are not candidates for Ehmer sling application.



A

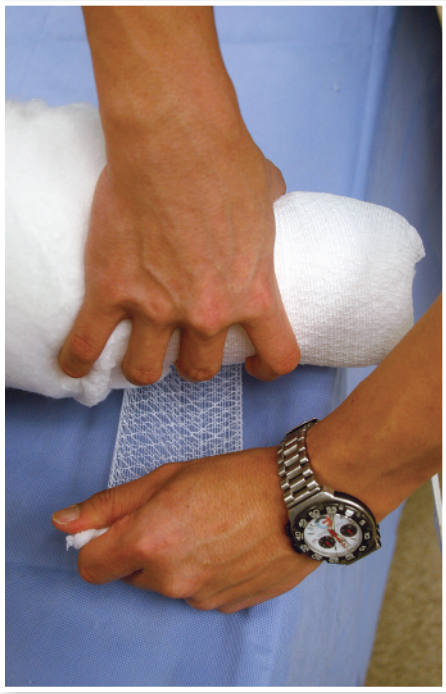
B

References

1. Basher, AWP, Walter MC, Newton CD. Coxofemoral luxation in the dog and cat. *Vet Surg.* 1986;15(5):356-362.
2. Evers P, Johnston GR, Wallace LJ, et al. Long-term results of treatment of traumatic coxofemoral joint dislocation in dogs: 64 cases (1973-1992). *JAVMA.* 1997;210(1):59-64.

Robert Jones Bandage

Stanley E. Kim, BVSc, MS, DACVS
University of Florida



Application of a traditional Robert Jones bandage can simply provide transient support of injuries distal to the elbow and stifle in dogs and cats. This bandage is commonly used for initial treatment of antebrachial and crural fractures and for fractures, instability, and luxations of the distal extremities.

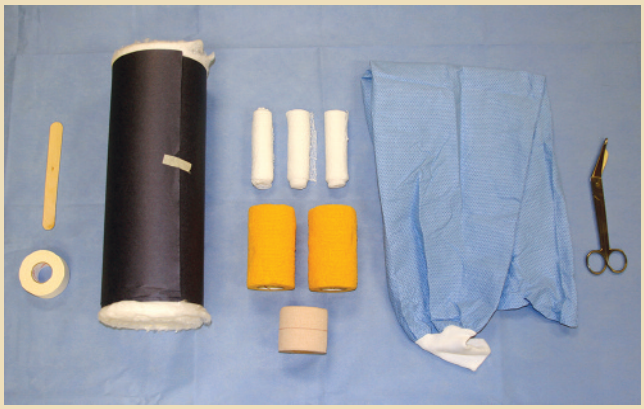
When the bandage is applied correctly, compression is evenly distributed to underlying tissues. The compression and the bulk of the bandage address pain by providing early stability to the traumatized area.[1,2] This bandage is also beneficial for minimizing or preventing local tissue edema and hemorrhage.[1,2] The bandage should be maintained until definitive repair can be performed.

Although closed reduction of fractures is not necessary before application of the Robert Jones bandage, limb alignment should be as close to normal as possible.

MORE ▶

What You Will Need

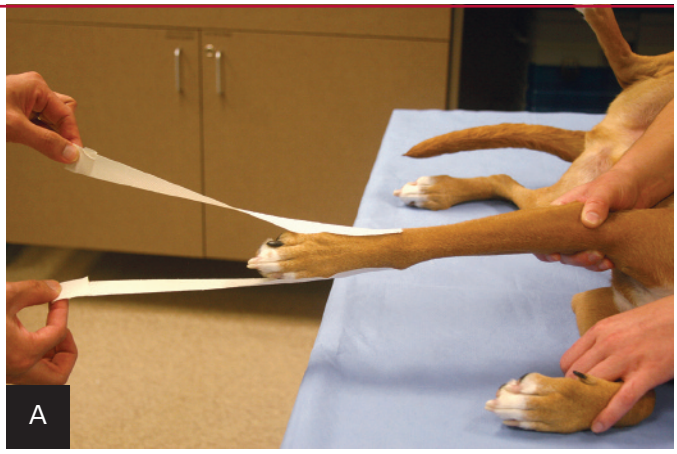
- White adhesive tape (1-inch wide)
- Tongue depressor
- 12-inch roll of cotton (for medium to large dogs) or 3–4 rolls of 2- to 4-inch cast padding (for cats and small dogs)
- 2–3 rolls of 3- to 6-inch roll gauze
- 1–2 rolls of self-adherent elasticized wrap
- Bandage scissors
- 2-inch adherent elastic tape (optional)
- Clean disposable surgical gown sleeve (optional)



Step-by-Step ■ Robert Jones Bandage

Step 1

Place the patient in lateral recumbency with the affected side facing up. Dress any wounds that will be covered by the bandage with an appropriate contact layer. Apply strips of white adhesive tape as stirrups to the medial and lateral surfaces of the limb, extending from the carpus or tarsus to 4–6 inches beyond the digits (**A**). Fold the ends of the stirrups to create tabs, and place a tongue depressor between the strips of tape (**B**).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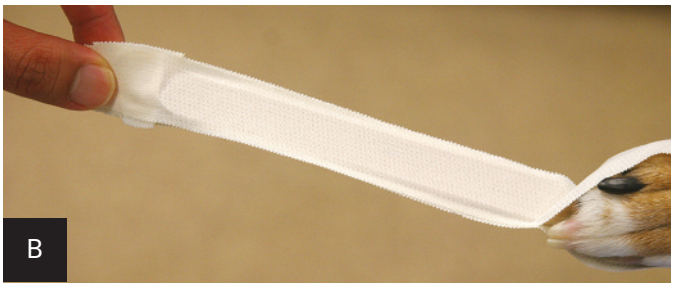
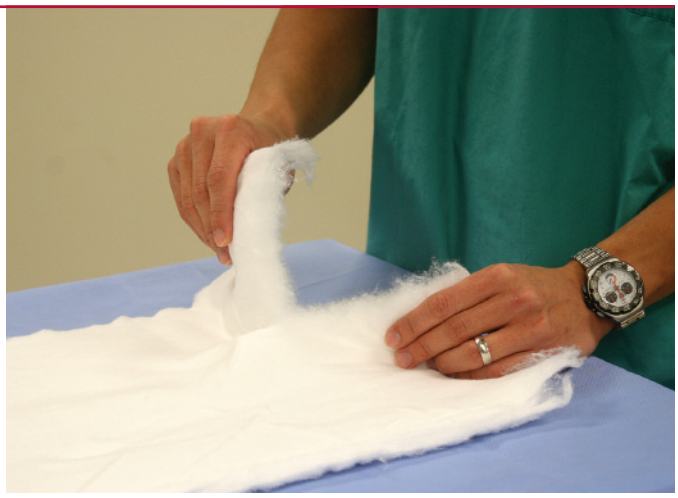

B

Step 2

Unravel the roll of cotton and remove the paper. Because the 12-inch roll of cotton is too wide for effective application in all except the largest canine breeds, it should be torn longitudinally in half or thirds to create narrower strips of padding. Afterward, evenly reroll the cotton.



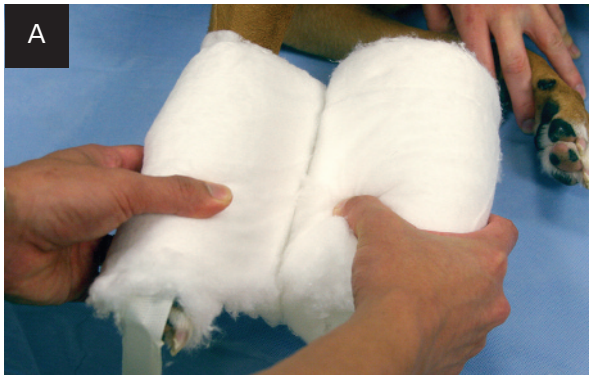
Anesthetic Considerations

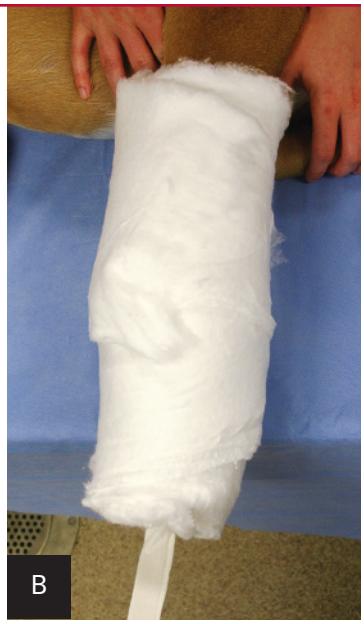
Sedation or general anesthesia may be required. Pure mu-agonist opioids such as hydromorphone (0.05–0.2 mg/kg IM, IV, or SC) or methadone (0.1–0.5 mg/kg IM, IV, or SC) are preferred analgesics that also have some sedative properties. An opportune time to apply a Robert Jones bandage is after radiography, which also frequently requires chemical restraint.

Step 3

Apply the roll of cotton (or cast padding for cats and smaller dogs) with the limb in full extension. Application always starts at the level of the digits; only the nails of digits 3 and 4 should be visible when the bandage is started and finished (**A**). Orient the cotton roll so the outer layer of cotton unrolls onto the limb.

Apply the cotton distally to proximally up the limb, using firm even pressure. Layers should overlap by 50%; avoid folding or wrinkling to prevent uneven distribution. Extend the padding to the level of the mid-humerus or midfemur (**B**). The cotton will tear if the pressure is too great.





Author Insight **With each successive layer, monitor the position of the toes, as the distal limb can become rotated and cause excessive supination or pronation. If this is observed, apply the next layer in the opposite direction to reorient the distal limb appropriately (eg, from distolaterally to cranially to proximomedially if the paw appears supinated).**

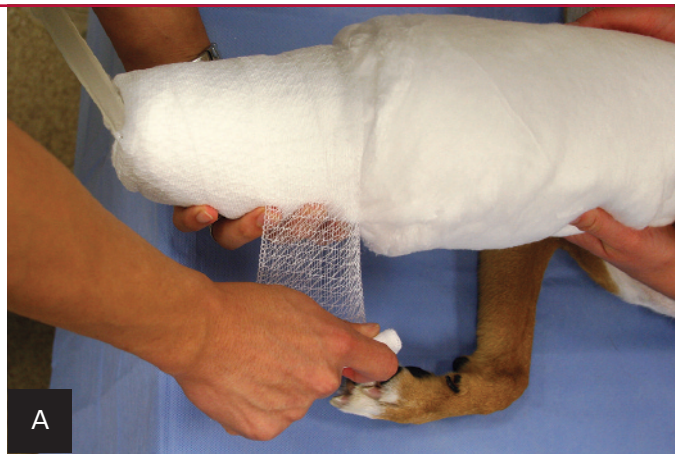
Step 4

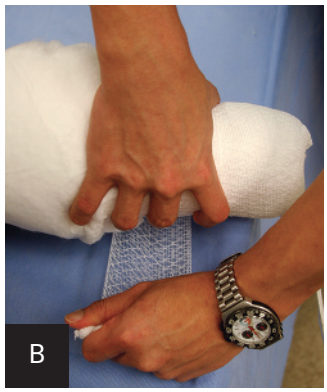
Use the roll gauze to secure and compress the cotton layer. As previously explained, application starts distally and progresses proximally by overlapping the gauze by 50% on each successive turn. To achieve adequate compression, pull the roll gauze tightly against the countertraction being applied to the limb by the supporting hand during both the cranial (**A**) and caudal (**B**) passes. This should compress the cotton layer by ~50%. Apply 2–3 layers of roll gauze.

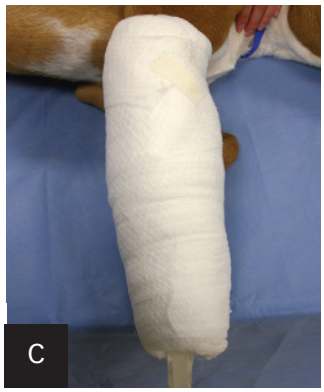
The roll gauze should capture the entire length of the cotton, including the proximal and distal margins; however, the gauze should not contact the skin (**C**). Make sure the roll gauze does not become bunched or twisted and cause a line of compression.

Author Insight **Overtightening the bandage can be difficult in medium to large dogs; rather, undertightening and subsequent slippage are more common.**

MORE ▶

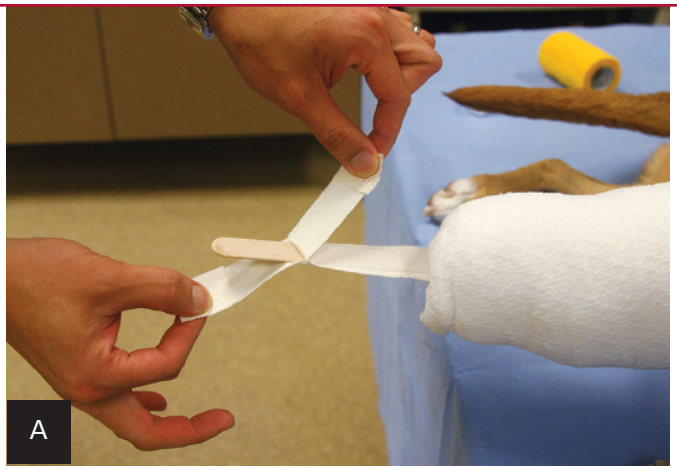


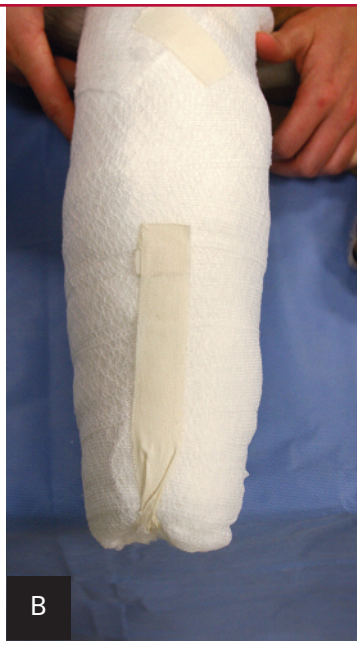




Step 5

Separate the white tape strips at the tabs and remove them from the tongue depressor (**A**); twist the tape strips and apply them to the respective surfaces of the roll gauze layer (**B**).



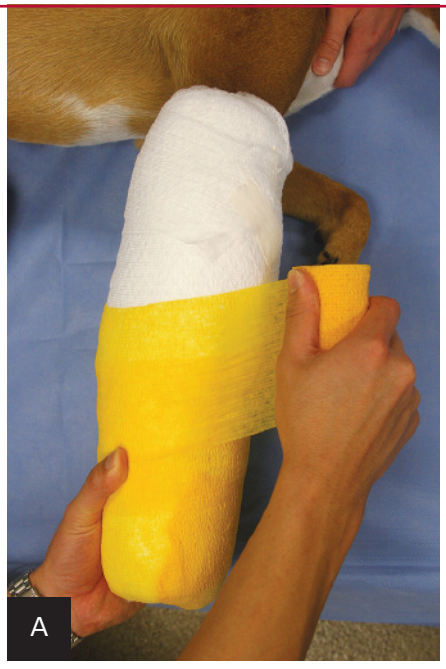


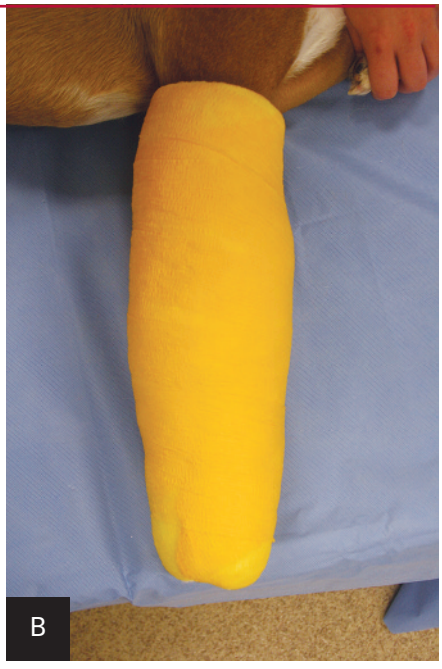
Step 6

Apply the self-adherent elasticized wrap from distal to proximal, with 50% overlap of the layers (**A**). Unraveling and rerolling the wrap to avoid overtightening the bandage is unnecessary. Fine-tune the degree of compression before finishing the final layer, but always apply each layer firmly and evenly.

The outer layer should capture the gauze and cotton layers but not contact the skin proximally. This layer should be taut over the entire bandage (**B**).

Check the bandage every few hours for slippage or loosening. The cotton layer can stretch with motion; the bandage is too loose if a gap between the proximal aspect of the bandage and the skin is visible.





Author Insight **Pinging the bandage with a finger should result in a sound similar to tapping a ripe watermelon. As a precaution, monitor the patient's toes for swelling, which can occur (although rarely) if the bandage is too tight.**

Step 7

Optional: Apply adherent elastic tape distally as a durable layer in areas where the bandage may rub against the floor during weight-bearing (**A**). A sleeve from a disposable surgical gown can be used as a water-resistant barrier to protect the bandage from becoming wet or soiled (**B**). ■ cb


A


B

Author Insight **Although reinforcement of the Robert Jones bandage with metal or plastic materials has been described, the author does not find this necessary as long as adequate bulk and compression are achieved.**

See **Aids & Resources**, back page, for references & suggested reading.

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RVT and Animal Shelter Subcommittee Research Report Outline

B&P 4840

(a) Describes RVT **and** assistants are approved…"under the *supervision* of a veterinarian"….Not otherwise defined. We feel a premise permit should be a prerequisite.
(b) As discussed at the last MDC meeting and also in our directions from Dr. Klingborg, the term "written order" as used in the context of this article needs to be better defined to address how animal health care services are provided in a shelter setting. Legislative change would be required to better define it here so it is best to define it within the sections of CCR Article 4 - Practice, possibly in CCR 2034 or 2036 Animal Health Care Tasks Definitions.

B&P 4840.2

This article addresses unauthorized practices. (b) Specifically states that diagnosis and prognosis is prohibited. Diagnosis is further defined in B&P 4825.1 (a).

We need to somehow address the issue that exams and diagnostic tests are performed (i.e parvo etc) prior to an examination by a veterinarian or subsequent euthanasia. These tests are performed to protect the health and well-being of every other animal and the personnel within the shelter.
The issue of appliances/splints needs discussion.

B&P 4840.5

This article defines and authorizes emergency aid with those specific tasks listed in CCR 2069 We may need to look at the phrase " may only be continued under the direction of a licensed veterinarian" to see if any clarification is needed for a shelter setting

B&P 4853

(a) and (b) describe premises. Should include animal shelters (or limit to those who are animal control jurisdictions or who have contracts to provide animal sheltering services).
Could RVTs hold an "animal shelter premise license"?

CCR 2032.1

This section defines the Veterinarian-Client -Patient Relationship (VCPR). At the end of (a) where is states "or the owner is unknown" do we need a special reference to impounded shelter animals which may be owned or whose owners are not forthcoming? Do we need to add a reference to animals seized under the provisions of PC 597?

CCR 2032.4

CCR 2036(b) in conflict with PC 597.1 (2) relative to administration of controlled substances/anesthesia by ACO and RVT? Is it not anesthesia as defined in CCR 2032.4?

CCR 2035

This section defines the duties of the supervising veterinarian, In (c) it states that " the supervising veterinarian shall have examined the animal patient prior to the delegation of an animal health care task"

This is a major issue with regards to how animal health care tasks are performed in a shelter setting and needs to be reviewed and modified.

CCR 2069

This is one of the original RVT task sections and it has worked well over the years. It has direct application in a shelter setting. It has not been updated in many years. With the current standards of practice for both shelter medicine and private practice, it would be appropriate to add an additional treatment type for "pain management"

In addition to the points that we have raised in the above articles and regulations, these other issues require consideration:

1. Sedation/anesthesia of animals in a shelter setting for the purpose of:
   (a) Grooming severely matted hair coats
   (b) Cleaning wounds
   (c) Bandaging
   (d) Splinting
   (e) Removing foxtails from the eye

2. Sedation of animals in the field - (this is different than chemical capture by ACOs)

3. Vaccination upon entry into a shelter setting which is considered best practice in today's shelter environment

4. Diagnostic testing upon entry into a shelter setting or when herd health management practice would call for it.

5. Treatment of commonly recognized animal shelter disease symptoms (cough, upper-respiratory signs, diarrhea, endoparasites) prior to an examination by a veterinarian.

6. How long may an animal be treated under a written protocol before a veterinarian would be required to examine the animal? Redefine CCR 4840.5 to include shelter impounds?

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HIGH-PRIORITY SHELTER-RELATED ISSUES – 7/18/17

1. Veterinary Care on Intake: Unregistered shelter staff ("unregistered assistants") should be permitted to perform the following animal health tasks on impounded animals immediately on intake regardless of whether a veterinarian is present:

a. Perform a physical exam

b. Administer vaccines (e.g. distemper, parvo, Bordetella for dogs and FHV-1, FCV, and FPV for cats)

c. Administer medicine for prophylactic treatment of parasites

d. Cats: Test for FeLV/FIV and screen for ringworm, etc.

2. Controlled Substances

Shelter staff who have been trained to administer sodium pentobarbital pursuant to 16 CCR 2039 should also have authorization to administer a pre-euthanasia sedative when needed to euthanize the animal humanely (e.g. for feral/aggressive/frightened animals or when doing an intracardiac injection). Note: The California Attorney General has held that it is a violation of the our anti-cruelty laws to perform an intracardiac injection on a conscious animal if the animal may first be rendered unconscious in a humane manner or, if in light of all the circumstances, the procedure is unjustifiable. (Note that 16 CCR 2036.5(a) authorizes veterinary assistants to administer controlled substances under indirect supervision.)

3. Sodium Pentobarbital/Euthanasia Reg: 16 CCR 2039

a. Shelter staff should be authorized to euthanize wildlife (CA's native creatures such as raccoons) and wild animals (e.g. zebras, alligators or other non-native species) as well as domestic animals.

b. The requirement that a person must have taught euthanasia for at least three years before being eligible to be a certified trainer must be revised (because it only allows people from out of state to qualify).

4. Authority of RVTs in Shelters – Business and Professions Code section 4840(b)

RVTs who work at SPCAs and humane societies incorporated under Corporation Code section 10400 should be included in B&P Code section 4840(b).

5. Rabies Vaccines:

Shelter staff should be authorized to administer rabies vaccines to impounded dogs and cats when they are redeemed by owners without a veterinarian having examined the animal.

5. Indirect Supervision

Question: Do shelters need a different definition of "indirect supervision" than that provided in the regs? What does "at such times as good veterinary medical practice requires" mean in a shelter setting? (Note: "Indirect supervision" means: (1) that the supervisor is not physically present at the location where animal health care job tasks are to be performed, but has given either written or oral instructions ("direct orders") for treatment of the animal patient; and (2) the animal has been examined by a veterinarian at such times as good veterinary medical practice requires, consistent with the particular delegated animal health care task and the animal is not anesthetized as defined in Section 2032.4.)

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CVMA CALIFORNIA VETERINARY MEDICAL ASSOCIATION

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June 27, 2016

Annemarie Del Mugnaio, Executive Officer
Veterinary Medical Board
1747 N. Market Boulevard, Suite 230
Sacramento, California 95834-2987

Dear Ms. Del Mugnaio:

At the request of the Veterinary Medical Board (VMB), the California Veterinary Medical Association (CVMA) formed a Premises Task Force to review premises permit laws and regulations as they relate to all species and practice types. As part of its charge to provide recommendations for a variety of practice types, the task force discussed the delegation of health care tasks to registered veterinary technicians in a shelter setting.

The CVMA invited veterinarians who work in shelters, shelter directors and a representative from State Humane Association of California to our last two task force meetings to discuss the unique issues associated with the delegation of tasks in a shelter setting. The issues identified were:

- The limited availability of veterinarians during shelter operating hours,
- The difficulty of establishing a Veterinarian-Client-Patient relationship for each animal,
- The need to perform certain procedures on animals upon intake at the shelter for the health and wellbeing of the individual animal and the shelter population as a whole,
- Protocols that would allow treatment for animals that are sick or injured when a veterinarian is not available to examine the animal.

As an outcome of these discussions, the task force developed a proposed regulation which would allow registered veterinary technicians to perform certain tasks on animals under indirect supervision following a veterinarian's written orders.

The CVMA Board of Governors approved the proposed regulation at its June, 2016, meeting and requests that this proposal be included in the agenda for the July meeting of the Multidisciplinary Advisory Committee.

We feel that this proposal addresses the primary issues that shelter personnel face when dealing with a large population of animals and the inability to have a veterinarian on site at all times. The regulation is intended to provide a guideline for what tasks a registered veterinary technician may perform under the direct written order of a veterinarian and to allow shelter veterinarians and staff the flexibility to provide care under specific circumstances.

The CVMA is pleased to submit the enclosed recommendation for consideration.

Sincerely,

Ken Pawlowski, DVM
CVMA President

The California Veterinary Medical Association Premises Task Force proposed regulation to the Veterinary Medical Board Multidisciplinary Advisory Committee

Section 2035.5 Duties of Supervising Veterinarian and Animal Health Care Tasks for Registered Veterinary Technicians in the Shelter Setting

(a) Notwithstanding subsection (c) of 2035 and pursuant to 4840(b), limited medical care may be provided in a shelter setting by a registered veterinary technician for the specific purpose of controlling infectious and zoonotic disease, controlling acute pain, and preventing environmental contamination if all the following are met:

(1) The supervising veterinarian has direct knowledge of the animal population and examines the animal(s) at such time as good veterinary medical practice requires consistent with the particular delegated animal health care tasks.

(2) The supervising veterinarian establishes written orders for:

(A) Vaccination and prophylactic control of endo- and ecto-parasites on intake

(B) Treatment of medical conditions based on an animal's symptoms

(3) Treatment rendered under subsection (2) may only be continued under the direction of a licensed veterinarian

(b) Emergency animal care may be rendered by a registered veterinary technician pursuant to section 2069.

(c) An RVT shall not diagnose, perform surgery or prescribe pursuant to section 4840.2.

(d) The supervising veterinarian shall maintain whatever physical presence is reasonable within the facility to ensure that the requirements in (a)-(c) are met.

(e) Animals that have been adopted and returned to the shelter by the owner for treatment of a medical condition must be examined by a veterinarian prior to treatment or dispensing medication pursuant to 2032.1.

Current Law:

4840. Authorized services by technicians and assistants

(a) Registered veterinary technicians and veterinary assistants are approved to perform those animal health care services prescribed by law under the supervision of a veterinarian licensed or authorized to practice in this state.

(b) Registered veterinary technicians may perform animal health care services on those animals impounded by a state, county, city, or city and county agency pursuant to the direct order, written order, or telephonic order of a veterinarian licensed or authorized to practice in this state.

(c) Registered veterinary technicians may apply for registration from the federal Drug Enforcement Administration that authorizes the direct purchase of sodium pentobarbital for the performance of euthanasia as provided for in subdivision (d) of Section 4827 without the supervision or authorization of a licensed veterinarian.

4840.2 Unauthorized Practices

(a) Surgery

(b) Diagnosis and prognosis of animal diseases

(c) Prescribing of drugs, medicines and appliances

2035. Duties of Supervising Veterinarian.

(a) The supervising veterinarian shall be responsible for determining the competency of the R.V.T. or unregistered assistant to perform allowable animal health care tasks.

(b) The supervising veterinarian of a R.V.T. or unregistered assistant shall make all decisions relating to the diagnosis, treatment, management and future disposition of the animal patient.

(c) The supervising veterinarian shall have examined the animal patient prior to the delegation of any animal health care task to either an R.V.T. or unregistered assistant. The examination of the animal patient shall be conducted at such time as good veterinary medical practice requires consistent with the particular delegated animal health care task.

2069. Emergency Animal Care.

Emergency animal care rendered by registered veterinary technician. Under conditions of an emergency as defined in Section 4840.5, a registered veterinary technician may render the following lifesaving aid and treatment to an animal:

(1) Application of tourniquets and/or pressure bandages to control hemorrhage.

(2) Administration of pharmacological agents to prevent or control shock, including parenteral fluids, shall be performed after direct communication with a licensed veterinarian or veterinarian authorized to practice in this state. In the event that direct communication cannot be established, the registered veterinary technician may perform in accordance with written instructions established by the employing veterinarian. Such veterinarian shall be authorized to practice in this state.

(3) Resuscitative oxygen procedures.

(4) Establishing open airways including intubation appliances but excluding surgery.

(5) External cardiac resuscitation.

(6) Application of temporary splints or bandages to prevent further injury to bones or soft tissues.

(7) Application of appropriate wound dressings and external supportive treatment in severe burn cases.

(8) External supportive treatment in heat prostration cases.

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BPC 4826.5. *Notwithstanding any other law, a licensed veterinarian or registered veterinary technician under the supervision of a licensed veterinarian may compound drugs for animal use pursuant to Section 530 of Title 21 of the Code of Federal Regulations and in accordance with regulations promulgated by the board. The regulations promulgated by the board shall, at a minimum, address the storage of drugs, the level and type of supervision required for compounding drugs by a registered veterinary technician, and the equipment necessary for the safe compounding of drugs. Any violation of the regulations adopted by the board pursuant to this section shall constitute grounds for an enforcement or disciplinary actions. (SB 1193 (Hill, Chapter 484, Statutes of 2016).)*

Proposed Regulations:

Article 11 Compounding in a Veterinary Premises.

2090. Definitions.
(a) "Compounding" means any of the following activities performed in a registered veterinary premises by a licensed veterinarian that has established the veterinary-client-patient relationship for the patient(s) or a registered veterinary technician under the direct or indirect supervision of that veterinarian:
(1) Altering the dosage form or delivery system of a drug.
(2) Altering the strength of a drug.
(3) Combining components or active ingredients.
(4) Preparing a compounded drug preparation from chemicals or bulk substances.
(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.
(c) "Expiration date" means the date, or date and time, determined from the date the preparation is compounded, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored other than for quarantine purposes.

2091. Veterinary Drug Compounding.
(a) A veterinarian shall ensure the safety and efficacy of a compounded drug preparation, including, but not limited to, avoiding known drug incompatibilities and inappropriate complications.
(b) A veterinarian shall not perform drug compounding when the complexity of the drug compounding exceeds the veterinarian's knowledge, skill, facilities, or available equipment.
(c) Sterile compounding shall be for immediate use except in the following conditions:

(1) A dilution of the ingredients is essential for the safe administration of the preparation.
(2) There are no other human or animal drugs that satisfy the need of this preparation.
(3) There is a historical documentation of the need, safety, and efficacy of the preparation.
(d) Only drugs approved by the United States Food and Drug Administration shall be used as the ingredients in a sterile compounded drug preparation.

2092. Policies and Procedures.
(a) A veterinary premises that engages in compounding drug preparations shall develop and maintain a written policies and procedures manual, which shall include:
(1) A list of each of the requirements of subdivisions (b) and (e) and sections 2093 and 2094.
(2) Policies and procedures for the training of a registered veterinary technician who may perform compounded drug preparations.
(3) Policies and procedures for a quality assurance program established pursuant to section 2095.
(b) For each compounded drug preparation, a master formula document shall be maintained and include all of the following:
(1) Active ingredients to be used.
(2) Equipment to be used.
(3) Expiration date of the preparation.
(4) Inactive ingredients to be used.
(5) Specific compounding steps to be used to prepare the drug.
(6) Instructions for storage, handling, and administration of the compounded preparation.
(c) The master formula document may be included in the policies and procedures manual maintained pursuant to subdivision (a).
(d) If the compounded drug preparation is not routinely compounded, a master formula record for the preparation may be kept in the medical record of the patient.
(e) For each compounded drug preparation prepared for a patient, the following information shall be recorded in the patient's medical record:
(1) Name or initials of the veterinarian that made or supervised the making of a compounded drug preparation and the name or initials of the registered veterinary technician, if any, who made the compounded drug preparation.
(2) Expiration date of the compounded drug preparation.
(3) Directions for its storage and administration.
(4) Name, amount, and strength of the compounded drug preparation.
(5) Date the drug preparation was compounded.
(6) Proper storage of the compounded drug preparation.
(f) The veterinarian performing or supervising the compounding of drug preparations is responsible for the following:

(1) Training and supervision of the registered veterinary technician who is compounding the drug preparation.
(2) Proper storage of the drugs used in compounding and the compounded drug preparations.

2093. Expiration Dates.
(a) For non-sterile compounding, the expiration date shall not exceed either of the following:
(1) 180 days from the date the preparation is compounded.
(2) The shortest expiration date of any ingredient in the non-sterile compounded drug preparation.
(b) For sterile compounding, the expiration date shall not exceed either of the following:
(1) 30 days from the date the preparation is compounded.
(2) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation.
(c) The expiration date may be extended if [INSERT CIRCUMSTANCES].

2094. Labeling of Compounded Preparations.
All labeling of any compounded drug preparation shall comply with subdivision (b) of section 2032.2.

2095. Quality Assurance.
(a) A veterinary premises that engages in compounding drug preparations shall establish a quality assurance program which documents and assesses medication errors to determine cause and an appropriate response.
(b) The purpose of the quality assurance program shall be to assess errors that occur in the compounding of drug preparations, as well as to evaluate and document adverse reactions of animal patients to compounded drug preparations.
(c) When a veterinarian determines that a medication error has occurred, the veterinarian shall as soon as possible communicate to the client or the client's representative the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
(d) Records generated for and maintained as a component of the ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a veterinary premises's quality assurance program and records maintained as part of that system by the board or the California State Board of Pharmacy as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the veterinary premises. Nothing in this section shall be construed to prohibit a client or client's representative from accessing records of the animal patient.
(e) Reports of drug contraindications and adverse reactions may be included in the quality assurance documentation.

2096. Inspection Authority and Enforcement.
(a) The California State Board of Pharmacy and the California Veterinary Medical Board shall have authority to inspect any veterinary premises engaged in compounding to ensure compliance.
(b) The Veterinary Medical Board is charged with enforcing the provisions of this Chapter

Board of Pharmacy

Order of Adoption (CLEAN)

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a

transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

(d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

(e) “Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) “Compounding Aseptic Containment Isolator (CACI)” means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile

preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(m) "Displacement airflow method" means a concept which utilizes a low pressure differential,

high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

(n) “Dosage unit” means a quantity sufficient for one administration to one patient.

(o) “Equipment” means items that must be calibrated, maintained or periodically certified.

(p) “First air” means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(q) “Gloved fingertip sampling” means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

(r) “Hazardous” means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

(s) “Integrity” means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.

(t) “Lot” means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

(u) “Media-fill test” means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

(v) “Non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of

intervening sterilization of that ingredient.

(w) “Parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.

(x) “Personal protective equipment” means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

(y) “Potency” means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.

(z) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber’s practice environment.

(ab) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

(ac) “Process validation” means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(ad) “Product” means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(ae) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(af) “Segregated sterile compounding area” means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

(ag) “Strength” means amount of active ingredient per unit of a compounded drug preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

(f) Where a pharmacy does not routinely compound a particular drug preparation, the master

formula record for that preparation may be recorded on the prescription document itself.

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation;

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) 180 days for non-aqueous formulations,

(E) 14 days for water-containing oral formulations, and

(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.
(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. Recordkeeping for Compounded Drug Preparations.

(a) For each compounded drug preparation, pharmacy records shall include:

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States

Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug product preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug Preparations.

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled

strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and~~ 4127, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug preparations shall be stored, used, maintained,

and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.
(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.
(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile Compounding

1751. Sterile Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.
(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2,

Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:
(1) Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.
(2) Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).
(4) There shall be a refrigerator and, where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 ~~and 4127.7~~, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile Compounding Recordkeeping Requirements.

(a) In addition to the records required by section 1735.3, any pharmacy engaged in any

compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

(1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

(6) Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(9) Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(10) Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

(11) Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records

indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy that compounds sterile drug preparations shall include the following information on the labels for each such preparation:

(a) The telephone number of the pharmacy. The telephone number is not required on the label for sterile drug preparations administered to inpatients within the hospital.

(b) Instructions for storage, handling, and administration.

(c) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.3. Sterile Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation

of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

(b) For lot compounding, the pharmacy shall maintain written policies and procedures that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies

and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen sterilization methods.

(2) End-product evaluation, quantitative, and qualitative testing.

(d) Policies and procedures shall be immediately available to all personnel involved in compounding activities and to board inspectors.

(e) All personnel involved must read the policies and procedures before compounding sterile drug preparations. All personnel involved must read all additions, revisions, and deletions to the written policies and procedures. Each review must be documented by a signature and date.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

1751.4. Facility and Equipment Standards for Sterile Compounding.

(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO

Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow

patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile Compounding Attire.

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask,

facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) Personal protective equipment must be donned and removed in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

(5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 Sterile Compounding Consultation; Training of Sterile Compounding Staff.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations.

(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The quality assurance program shall include at least the following:

(1) Procedures for cleaning and sanitization of the sterile preparation area.

(2) Actions to be taken in the event of a drug recall.

(3) Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure,

each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package

containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.10. Sterile Compounding Reference Materials.

In any pharmacy engaged in compounding sterile drug preparations, there shall be current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5 Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

(1) furnished by a registered pharmacist;

(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;

(4) labeled on the outside of the container with a list of the contents;

(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy

may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

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Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section -1753.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

Virginia Herold
Executive Officer
California State Board of Pharmacy

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Veterinary Drug Counseling Draft Language

[Language reflects negotiations on SB 546]

(a) Each time a veterinarian initially prescribes, dispenses, or furnishes a dangerous drug, as described in Section 4022, to an animal patient, the veterinarian shall offer to provide the client, or his or her authorized representative, a consultation that includes the following information:

(1) The name and description of the dangerous drug.

(2) Route of administration, dosage form, dosage, duration of drug therapy, the duration of the effects of the drug, and common severe adverse effects associated with the use of a short acting or long acting drug.

(3) Any special directions for proper use and storage.

(4) Actions to be taken in the event of a missed dose.

(5) If available, precautions and relevant warnings provided by the drug's manufacturer, including common severe adverse effects of the dangerous drug.

(b) A veterinarian shall provide along with the consultation veterinary drug resource information, when available, if requested by the client, or his or her authorized representative.

(c) A veterinarian may delegate the task of providing the consultation and veterinary drug resource information to a registered veterinary technician or veterinary assistant who is employed by and working under his or her supervision.

(d) The consultation may be provided to the client, or his or her authorized representative in person, or through other electronic means by the veterinarian, a registered veterinary technician or veterinary assistant who has access to the animal patient's record.

(e) If a consultation is refused by the client, that fact shall be recorded in the client's record.

(f) If a consultation is provided by the veterinarian or his or her registered veterinary technician or veterinary assistant, that fact shall be recorded in the client's record.

(h) (1) In every fixed veterinary premises, there shall be a notice prominently posted in a conspicuous location indicating that the consultation specified in subdivisions (a) and (b) must be offered to the client, or his or her authorized representative. The heading of the notice shall read "NOTICE TO CONSUMERS".

(2) The notice shall inform clients about the following consumer rights:

(A) The right to be offered a consultation by the veterinarian or his or her registered veterinarian technician or veterinary assistant, as directed by the veterinarian.

(B) The right to request veterinary drug resource information.

(3) The notice shall be cited as the Lizzie's Law for Veterinary Pharmacy.

(4) If the safety or health of any animal patient is at risk, consistent with Section 4800.1, the board may adopt a regulation requiring additional information to be included ~~on~~ in the notice.

1707.2 Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
(1) upon request; or
(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.
(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
(A) whenever the prescription drug has not previously been dispensed to a patient; or
(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.
(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice: of his or her right to request consultation; and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.
(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.
(c) When oral consultation is provided, it shall include at least the following:
(1) directions for use and storage and the importance of compliance with directions; and
(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.
(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:
(1) the name and description of the medication;
(2) the route of administration, dosage form, dosage, and duration of drug therapy
(3) any special directions for use and storage;
(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
(5) prescription refill information;
(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with 207 known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
(7) action to be taken in the event of a missed dose.
(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code.
Reference: Sections 4005, 4076 and 4122, Business and Professions Code.

1707.3. Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery.

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

Authority cited: Sections 4005, 4121 and 4122, Business and Professions Code. Reference: Sections 4005, 4074, 4121 and 4122, Business and Professions Code.

1707.6

Notice to Consumers

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster -sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi -screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12 -point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely

with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.
Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.
The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code.
Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

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From: [redacted]
To: [redacted]
Subject: Plumb"s Letter and Sample Pharmaceutical Literature
Date: Saturday, May 27, 2017 11:13:54 PM
Attachments: Plumb"s Letter.pdf
Cephalexin Client Friendly Guide.pdf

May 27, 2017
Dear Members of the California Veterinary Medical Board:
I hope the enclosed information is formally shared with veterinarians. It is a modern, more informative, client friendly practice of veterinary medicine and respects the consumers right to be informed.
As you know this is what the Lizzie Initiative for Pet Protection advocates for.

Since the information is digitally available, and hundreds of client friendly medication guides will become available in printable form this summer, it is high time to stop leaving the consumer in the dark about their pet's medications.
Salomon Stupp
The Lizzie Initiative for Pet Protection

[redacted]

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May 3, 2017

Salomon Stupp

P.O. Box 2215

San Anselmo, CA 94979

Mr. Stupp,

Thank you for your interest in Plumb's Veterinary Drugs, this letter will serve as a brief explanation of this product.

Plumb's Veterinary Drugs is a cloud based veterinary drug reference used in both the veterinary and pharmacy industries.

Professionals in these fields can access drug information including dosages, interactions, precautions/warnings, client friendly drug information and more. Veterinary and Pharmacy professionals use a web browser on a computer to access this resource, however, it can also be accessed on a mobile device via our iOS and Android app. The Plumb's Veterinary Drugs content is regularly updated, so that these professionals have the most up-to-date drug information available.

This resource is currently used by over 20,000 professionals across the veterinary and pharmacy industries.

This Summer, we will be expanding our client friendly handouts to add printable Veterinary Medications Guide which can be given directly to clients. (Sample attached.) Some of this information is available now to copy and paste from the drug monograph to print for clients.

For additional information on Plumb's Veterinary Drugs, please visit plumbsveterinarydrugs.com

If we can be of additional assistance, please do not hesitate to contact us.

Best regards,

Rodney Hoose

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Plumb's Account Manager
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Cephalexin

*(sef-a-**lex**-in)*

Category: Cephalosporin Antibiotic

Other Names for this Medication: Keflex®, Rilexene®

Common Dosage Forms: Veterinary: 75 mg, 150 mg, 300 mg, and 600 mg chewable tablets. **Human:** 250 mg and 500 mg tablets; 250 mg, 333 mg, 500 mg, and 750 mg capsules; 125 mg/5 mL (25 mg/mL) and 250 mg/5 mL (50 mg/mL) oral suspension.

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This information sheet does not contain all available information for this medication. It is to help answer commonly asked questions and help you give the medication safely and effectively to your animal. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- Can be given with or without food, but gastrointestinal side effects might be prevented if given with food. If your pet vomits or acts sick after receiving the drug on an empty stomach, try giving the next dose with food or a small treat. If vomiting continues, contact your veterinarian.
- Most common side effects are diarrhea, vomiting, and loss of appetite.
- Be sure to give as long as your veterinarian has prescribed, even if your animal seems better.
- Cephalosporin antibiotics have an odor that resembles cat urine, but this is normal.

How is this medication useful to your pet?

In dogs and cats, cephalexin can be useful to help treat infections of the skin, respiratory tract, and urinary tract.

The FDA (U.S. Food & Drug Administration) has approved this drug for use in humans and dogs, but it is not officially approved for use in other species. The FDA does allow veterinarians to prescribe and use human products containing this drug in animals in certain situations. You and your veterinarian can discuss why this drug is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given to my pet?

Many things might affect how well this drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- Other drugs can interact with cephalexin, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.
- Tell your veterinarian about any conditions or diseases your pet may have now or has had in the past.
- If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it worked or didn't work.
- If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this drug.
- Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your pet has developed in the past.

When should this drug not be used or be used very carefully?

No drug is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this drug in your animal.

This drug **SHOULD NOT** be used in patients:

- That are allergic to it or drugs like it (eg, other cephalosporins).

This drug should be used **WITH CAUTION** in patients:

- That have severe kidney disease.

If your animal matches either of these, talk to your veterinarian about the possible risks of using the medication versus the benefits that it might have.

What are the side effects of the drug?

Side effects that usually are not serious include:

- Diarrhea, vomiting, and loss of appetite.

You don't have to be overly concerned if you see any of these unless they are severe, worsen, or continue to be a problem. Contact your veterinarian if this happens.

Side effects that may be serious or indicate a serious problem:

- Complete loss of appetite in cats can sometimes cause severe liver problems.
- Fever, rashes, trouble breathing, and anemia, which may be allergic reactions to the drug.
- Severe skin irritation may occur in certain cats.

If you see any of these, contact your veterinarian immediately.

If my pet gets too much of this drug (an overdose), what should I do?

Vomiting is the most likely adverse effect after an overdose, but larger overdoses of cephalexin can be serious and can cause anemia and damage to the kidneys and nervous system. If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24-hours a day include: ASPCA Animal Poison Control Center (888-426-4435) and Pet Poison HELPLINE (855-764-7661); a consultation fee is charged for these services.

How should this drug be given?

For this medication to work, give it exactly as your veterinarian has prescribed. It's a good idea to always check the prescription label to be sure you are giving the drug correctly.

- Cephalexin can be given with or without food, but If your pet vomits or acts sick after receiving the drug on an empty stomach, try giving the next dose with food or a small treat. If vomiting continues, contact your veterinarian.
- Liquid forms of this medication must be measured carefully and stored in the refrigerator and need to be shaken well before giving. Your veterinarian or pharmacist can help by providing special measuring spoons or syringes. Liquid forms of this drug should be discarded 14 days after mixing.
- If you have difficulty getting your animal to take the medicine, contact your veterinarian or pharmacist for tips to help dosing and reduce the stress of medication time for both you and your animal.

- This medication can be given for various lengths of time. Be sure you understand how long the veterinarian wants you to continue giving this medication. Prescription refills may be necessary before the therapy will be complete. Before stopping this medication, talk to your veterinarian, as there may be important reasons to continue its use.

What should I do if I miss giving a dose of this medication?

If you miss a dose, give it when you remember, but if it is close to the time for the next dose, skip the dose you missed, and give it at the next scheduled time. After that, return to the regular dosing schedule. Do not double-up or give extra doses.

How should I store this medication?

- Store tablets and capsules in their original prescription bottle or an approved dosage reminder (ie, pill minder) container at room temperature. Liquid forms (suspension) should be stored in the refrigerator; any unused suspension should be thrown out after 14 days.
- If your veterinarian or pharmacist has made (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- Keep away from children and other animals.

Can handling this medication be hazardous to me, my family, or other pets?

There are no specific precautions required when handling this medication unless you are allergic to it. Wash your hands after handling any medication.

How should I dispose of this medication if I don't use it all?

- Do not flush this medication down the toilet or wash it down the sink. If a community drug "take-back" program is available, use this option. If there is no take-back program, mix the drug with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash. Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

- Use of this drug may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

If you have any other questions or concerns about this medication, contact your veterinarian or pharmacist.

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Explore expanding 2069 and 4840.5 to allow RVTs to provide sedation under urgent but not necessarily life-threatening circumstances.

Drusys & Klingborg

This agenda item originally started as a discussion of exploring the scope of authority of RVTs or VAs in a shelter setting in regards to sedation or anesthesia. Through lengthy discussions, we have moved away from changing any anesthesia regulations and instead want to focus on looking at 2069 and 4840.5 as it pertains to the use of sedatives or other medications for serious, but not necessarily life-threatening issues such as seizures, badly matted cat with infected skin, Husky who has bitten a cage and has his jaw stuck, etc.

BPC 4840. Authorized services by technicians and assistants

(a) Registered veterinary technicians and veterinary assistants are approved to perform those animal health care services prescribed by law under the supervision of a veterinarian licensed or authorized to practice in this state.

(b) Registered veterinary technicians may perform animal health care services on those animals impounded by a state, county, city, or city and county agency pursuant to the direct order, written order, or telephonic order of a veterinarian licensed or authorized to practice in this state. In accordance with §4836, and pursuant to direct orders or written protocol of a California licensed veterinarian employed by the impounding agency, a registered veterinary technician may sedate impounded animals for the relief of pain and suffering and render non-surgical aid to animal patients in the absence of a licensed veterinarian.

(c) Registered veterinary technicians may apply for registration from the federal Drug Enforcement Administration that authorizes the direct purchase of sodium pentobarbital for the performance of euthanasia as provided for in subdivision (d) of Section 4827 without the supervision or authorization of a licensed veterinarian.

Other reference statutes:

BPC 4840.5 Emergency aid

Under conditions of an emergency, a registered veterinary technician may render such lifesaving aid and treatment as may be prescribed under regulations adopted by the board pursuant to Section 4836. Such emergency aid and treatment if rendered to an animal patient not in the presence of a licensed veterinarian may only be continued under the direction of a licensed veterinarian. “Emergency” for the purpose of this section, means that the animal has been placed in a life-threatening condition where immediate treatment is necessary to sustain life.

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BPC 4836 Regulations defining tasks of technicians and veterinarians

(a) The board shall adopt regulations establishing animal health care tasks and an appropriate degree of supervision required for those tasks that may be performed only by a registered veterinary technician or a licensed veterinarian.
(b) The board also may adopt regulations establishing animal health care tasks that may be performed by a veterinary assistant as well as by a registered veterinary technician or a licensed veterinarian. The board shall establish an appropriate degree of supervision by a registered veterinary technician or a licensed veterinarian over a veterinary assistant for any tasks established under this subdivision and the degree of supervision for any of those tasks shall be higher than, or equal to, the degree of supervision required when a registered veterinary technician performs the task.
(c) The board may adopt regulations, as needed, to define subdivision (c) of Section 4840, including, but not limited to, procedures for citations and fines, in accordance with Section 125.9.

2069. Emergency Animal Care.
Emergency animal care rendered by registered veterinary technician.

Under conditions of an emergency as defined in Section 4840.5, a registered veterinary technician may render the following life saving aid and treatment to an animal:

(1) Application of tourniquets and/or pressure bandages to control hemorrhage.
(2) Administration of pharmacological agents to prevent or control shock, including parenteral fluids, shall be performed after direct communication with a licensed veterinarian or veterinarian authorized to practice in this state. In the event that direct communication cannot be established, the registered veterinary technician may perform in accordance with written instructions established by the employing veterinarian. Such veterinarian shall be authorized to practice in this state.
(3) Resuscitative oxygen procedures.
(4) Establishing open airways including intubation appliances but excluding surgery.
(5) External cardiac resuscitation.
(6) Application of temporary splints or bandages to prevent further injury to bones or soft tissues.
(7) Application of appropriate wound dressings and external supportive treatment in severe burn cases.
(8) External supportive treatment in heat prostration cases.
(9) Administration of a drug or drugs to manage the pain or to sedate an animal for examination or to prevent further injury. Such a task shall only be performed after direct communication with a veterinarian licensed or otherwise authorized to practice in this state In the event that direct communication cannot be established, the registered veterinary technician may administer the drug or drugs in accordance with written instructions as established by his or her employing veterinarian, or, in the case of a sanctioned rodeo or other sporting event, the veterinarian charged with the responsibility to provide treatment to the animals at the rodeo or event.

Authority cited: Sections 4808 and 4836, Business and Professions Code.
Reference: Section 4840.5, Business and Professions Code.

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Multidisciplinary Advisory Committee Assignments

July 2017

EXISTING PRIORITIES – Currently being addressed by MDC

1) **Evaluate Structure and Audit Enforcement Case Outcomes**
    a. **Complaint Process/Audit Taskforce**

2) **Develop minimum standards for alternate premises (large animal, equine mobile, public and private shelter medicine, ambulatory, etc.)**
    a. **Shelter Medicine Subcommittee**

3) **Pursue "Extended Duty" for Registered Veterinary Technicians.**
    a. **RVT “Extended Duty” Subcommittee**

4) **Develop regulations to implement the authorization for Veterinarians and RVTs under direct supervision to compound drugs.**

5) **Emergency Protocols with Sedatives**
    a. **Emergency Protocols Subcommittee**

6) **Drug Counseling/Risks and Side Effects**