

ESTERISOL™ VETERINARY INSTRUCTION MANUAL

esterisol™

Esterisol™ is indicated for chemical sterilization in healthy male dogs over three months of age.



Instruction Manual for Administering Esterilsol™

For questions or assistance please call 443.451.7140.

Indications:

Esterilsol™ is indicated for chemical sterilization in healthy male dogs over three months of age.

Physical Exam:

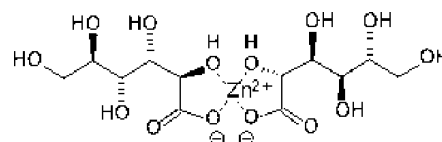
The veterinarian should perform a routine physical exam before and subsequent follow-up exams after the sterilization procedure and must pay particular attention to palpation of the testis. The first post treatment physical examination should be conducted 2-3 days post injection. The second post injection exam should be conducted on day 10.

Pre-Treatment Examination:

1. Medical/Health history
2. Estimated age
3. Ambulatory status
4. Body weight
5. Rectal temperature
6. Scrotal and inguinal skin area
7. Testicular palpation and examination of penis (check for TVT)
8. Heart and respiratory rate
9. Examination of thorax, forelegs, neck (hydration, integument, shoulder and neck muscle mass, prescapular lymph nodes, inducible cough)
10. Examination of hind legs, perineum, abdomen (popliteal and inguinal lymph nodes, tail, perineum, testis, penis, abdominal palpation, integument)
11. Examination of head (mandibular lymph nodes, eyes, mouth and mucous membranes, ears, nose, and integument)

Upon successful injection of Esterilsol™, please complete a post-treatment examination including:

1. General attitude
2. Appetite
3. Ambulatory status
4. Palpation of testis
5. Rectal temperature
6. Scrotal and inguinal integument



Contraindications:

Do not use Esterilsol™ in dogs under 3 months of age or dogs that have the following conditions:

- Undescended testicles (cryptorchid).
- A disease or malformation of the testicle (including fibrosis of the testicles or epididymides).
- A history of allergic reaction to any of the components of the drug.
- Pre-existing scrotal irritation or dermatitis.
- Infected bite wounds.
- Testicular cancers of any kind.
- TVT

Warning:

Human warnings; Keep this and all drugs out of reach of children. Not for human use. Wash the skin with soap and water and flush eyes with water if contact occurs. Flush mouth with water and drink plenty of water if accidental ingestion occurs. Contact a physician if accidental exposure by any route (oral, skin, injection).

Materials and Method:

Esterilsol™ is a sterile injectable aqueous solution. Esterilsol™ is sold in single dose vial of 2 mL for private practice veterinarians or a multi-dose 20 mL vial for government and NGO use. The solution contains no preservatives, therefore only sterile hypodermic needles should be used to remove the solution from the vial. The drug does not need to be refrigerated. One dose of Esterilsol™ injected with strict observance of the following guidelines will permanently sterilize the male dog safely, effectively and efficiently. Withholding food from the dog for 12 hours before administering the drug is recommended.



Dosage and Administration:

1. Calculating Exact Dose of Esterilsol™

Dosage is calculated by measuring the maximum width of each testicle with an approved caliper which gives the corresponding dosage. Esterilsol(tm) should not be used in male dogs with testicles measuring less than 10mm or greater than 27mm.

Calculate the dose of Esterilsol by measuring the widest part of the testicle:

Range of Testicular Width (Mm)	Dose Per Testis (ml/cc)
10 - 12	0.2
13 - 15	0.3
16 - 18	0.5
19 - 21	0.7
22 - 24	0.8
25 - 27	1.0

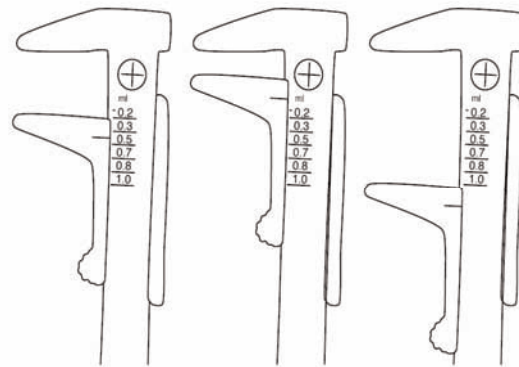


Diagram A Diagram B Diagram C

2. Example Dosage Calculation:

When the veterinarian measures the width of the left testicle to be 17mm and the right testicle measures 15mm then the appropriate dose would be 0.5ml for the left testicle and 0.3ml for the right testicle.

3. Testicular Measurement:

- Check to see that the caliper is clean.
- With the dog lying on its back, measure the width of each testicle by placing the testicle inside the two measuring points and then slide the ruler until it rests gently against the testicle.
- Read the dose corresponding to the measurement by noting the position of the indicator line on the sliding ruler. If the indicator line exceeds the dosage line, use the next higher dose (See Diagram A).
- The testicle is too small for injection if the indicator line does not fall on or below the minimum position marked on the caliper (See Diagram B).
- The testicle is too large for injection if the indicator line falls beyond the maximum position for the 1.0 ml dose marked on the caliper (See Diagram C).



3. Esterisol™ Administration Technique:

- a) After passing the physical examination and approval of the dog as a candidate for the procedure, the veterinarian determines whether the male dog needs chemical restraint or standard humane manual restraint, at his/her discretion. If chemical restraint is necessary, restrain the animal using xylazine and ketamine, or a similar approved sedative/tranquilizer that the veterinarian chooses and is familiar with the affects. It is highly recommended that for the first 10 dogs, the veterinarian use chemical restraint to make it easier to handle the dogs while learning this new procedure.
- b) After placing the dog in dorsal or dorsal-lateral recumbency on the surgery or exam table, measure the width of each testis at the widest part using the caliper as explained above. Stabilize and hold the testis in one hand and the caliper to measure with the other hand. Set the caliper to slide over the widest part of the testis and note the dosage for the respective testicle, then repeat for other testicle. Do not squeeze the caliper into the scrotal tissue.
- c) Remove dirt and debris from the scrotum with a mild surgical soap or solution; such as chlorhexidine diacetate diluted 1:10 (The scrotum should not be scrubbed with abrasive sponges or brushes and use of alcohol or strong iodine solution should be avoided because it may irritate the scrotal skin of some animals and stimulate a cycle of biting and licking.) Standard Surgical Prep of the inguinal/scrotal skin area is neither recommended nor necessary. After cleaning the scrotal area, the veterinarian should take the opportunity at this time to re-evaluate the testis again and carefully palpate the testis one final time for fibrotic tissue, tumors, cryptochidism, inguinal hernia, etc. If there is chronic inflammation of the scrotal skin and/or bacterial or fungal infections the veterinarian may at his/her discretion postpone the Esterisol™ procedure until these infections have been properly treated and returned to normal. Chronic fleabite allergies and other dermatological conditions (e.g. mange) of the scrotal skin that have resulted in a habit or “vice” of chronic licking and biting must be noted and followed closely post injection. Do not inject a dog with a bite wound in the scrotal/inguinal area. Treat the wound first and when resolved, reschedule the dog for the procedure.
- d) **A 1 mL cc syringe with a 28 gauge, 1/2 inch or 1 inch needle** is recommended for injection of the drug. The length of the needle is dependent on the size of the testicle. Larger testis may require a longer needle, at the discrimination of the veterinarian. First use a **separate sterile needle** to aspirate the volume of Esterisol™ calculated from previous measurement into two sterile 1mL/cc syringes for both right and left testis. Then remove and discard the wet needle used in aspiration and loading. The next step is to place a **new sterile needle** on both syringes after loading syringes with appropriate dose. Again stabilize the testis with one hand and inject with the opposite hand.

CAUTION: Inject each testis with a new separate sterile needle. Using the same needle for the two testes may lead to infection. To summarize, the veterinarian will need **THREE NEW STERILE NEEDLES** to administer the drug properly: **one needle to aspirate and load both syringes with the drug, and two more new needles placed on both syringes in preparation for injection.**



Materials and Methods for the Application of Esterilsol™



1.



2.



3.



4.



5.



6.



7.

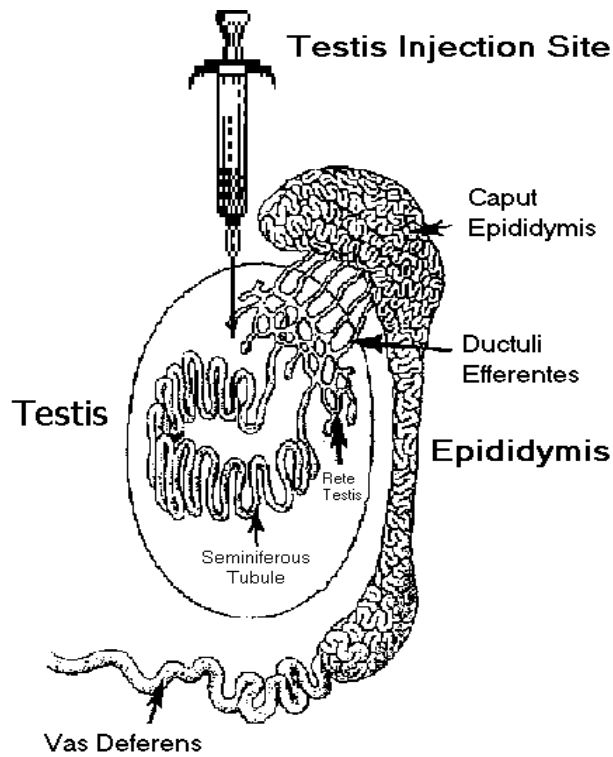


8.

4. Proper injection technique is as follows:

- a) Inject Esterilsol™ into the dorsal cranial portion of the testis beside the caput (head) epididymis so that the drug not only diffuses into the testis and rete testis but also into the caput epididymis (see Fig 1). This will prevent maturation of sperm and cause atrophy of the ductuli efferentes and rete testis that prevents passage of sperm to the caput epididymis, thereby achieving sterilization by shutting down sperm maturation and transportation.

Figure 1.



4. Injection Technique (continued)

- b) Do not inject the drug into the scrotum, subdermally or intradermally into the scrotal skin. The skin of the scrotum should be pulled tightly over the testis by the hand stabilizing the testis because loose scrotal tissue over the testis may lead to injection into the scrotum.

Inject Esterilsol™ into the Dorsal Cranial portion of the testis.



Figure 2.



Figure 3.



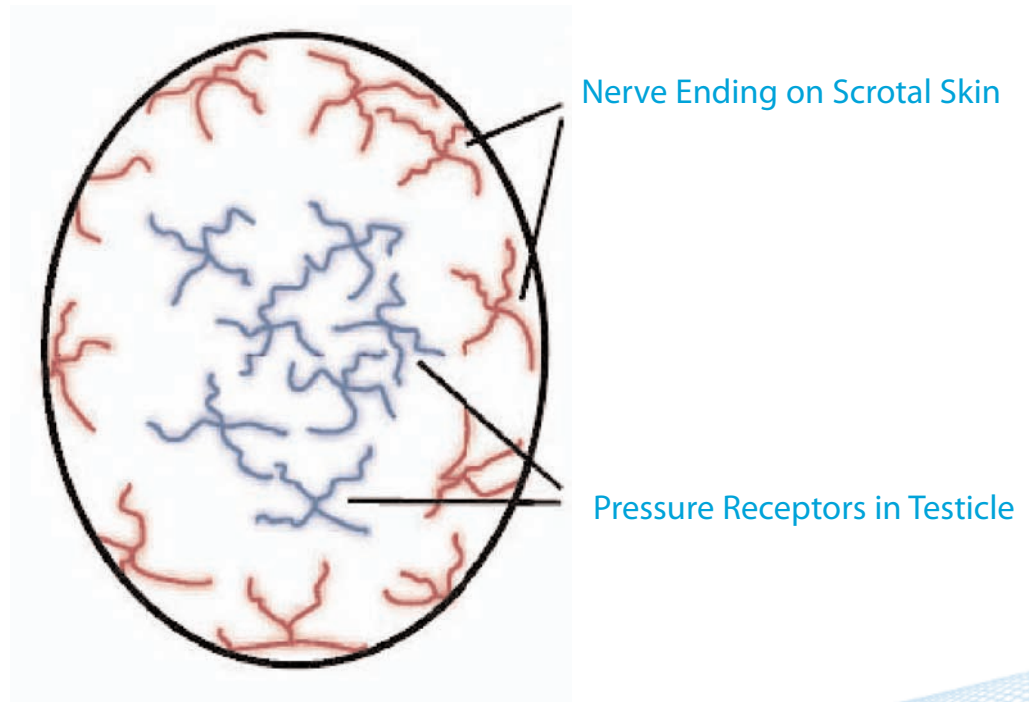
Figure 4.

- c) Humanely restrain the dog to reduce movement. Insert the needle (28 gauge, 1 1/2 inch) into the dorsal cranial portion of the testis (see Figs. 2, 3). Expect only a mild pain prick reaction from the dog as the needle passes through the scrotal skin. When needle has been placed into the testis and during injection continue humane restraint if the dog is not sedated. Depth of the needle will vary with the size of the testicles, but the tip of the needle must be long enough to deposit the drug near the center of the testicle (figure 4).

CAUTION: if the veterinarian injects the drug into the wrong site, he/she must stop the procedure.



- d) Do not use excessive injection pressure to force the drug into the testicle. The nerve endings on the scrotal skin will not cause pain to the animal if a fine gauge needle is used. **Inject slowly, greater than 5 seconds per testicle to avoid the Pressure Receptors in the testicle from contracting and forcing the Esterilsol™ outside of the testicle.**



CAUTION: Esterilsol™ solution left on the scrotal skin may cause an ulcer and must be wiped or removed immediately.

- e) If resistance is felt, discontinue the injection. All male dogs should be disqualified from this procedure if the drug is abnormally difficult to inject into the testis.



- f) After normal slow easy injection, remove needle quickly and check for leakage. If there is ANY Esterilsol™ solution leaking out of the injection site, remove from skin by wiping immediately with mild surgical soap or solution.
- G) It is recommended that the veterinarian develops his or her own reliable system of notes, records and methodology to calculate the correct dosage for both testicles and a reliable method for injecting each testicle with the proper single dose.

CAUTION: if the veterinarian injects the same testicle twice by error, he or she should stop the procedure

Recommendations

Post Injection Care:

After the injection is completed, expect some dogs to vomit (if you have sedated the dog with xylazine there is a higher chance of vomiting) for up to four hours, and advise the owner; dog owners should be advised the vomiting (if it occurs) is almost always transitory. However if the vomiting is prolonged, anti-emetics may be used at the veterinarian's discretion. It is recommended to withhold food from the animal 12 hours prior to the treatment.

Expect some dogs to have mild to moderate pain for up to one-week post injection, but peaking on day 2-3 post injection. Expect all dogs to have mild swelling of the testicles post injection. The swelling should peak 3-7 days post injection.

If there has been an improper injection and leakage or prolonged drug/skin contact, an ulcer will form 2-3 days post injection. Often a potential ulcer will begin with only a red spot at the injection site 1-2 days post injection and then develop into 1-2 cm ulcer 2-3 days post injection. Most ulceration will occur 2-3 days post injection.

Esterilsol does not contain any preservatives, discard any unused product 24 hours after first needle insertion to avoid any potential complications due to possible product contamination.





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