Join us as we work towards a day when there truly are no more homeless pets!

## We now offer Non-Surgical Neutering for Dogs! Zeutering is the new way to safely and permanently neuter your male dog using a simple injection.

### What is Zeuterin?

• Zeuterin is a safe, FDA –approved injectable solution used to permanently sterilize dogs 3 months of age and older. Dogs are lightly sedated for the procedure, no general anesthesia or surgery is required. The testicles remain in place but are no longer able to produce sperm.

### How is this different from Surgical Castration?

ZEUTERIN	SURGICAL CASTRATION
Light sedation recommended	General anesthesia required
Testicles remain in place	Testicles surgically removed
Discomfort limited	Pain mild to severe (controlled with medication)
Testosterone reduced by ~50%*	Testosterone reduced ~100%*
*testosterone may have protective value against some types of cancer (prostate, bone, bladder), may reduce future weight gain	*greater reduction in testosterone may reduce male sexual behaviors more (mounting, marking), although AGE at "alteration" is more influential
Testicles may still be at risk for future tumors, although these are generally benign	Testicles removed, so no risk of testicular tumors
Prostate size only reduced ½ as much as surgical castration	Lower future risk of prostate inflammation and enlargement
Cannot be done if scrotal skin or testicles are abnormal or if testicle size is less than 1cm or more than 3cm wide	Recommended if testicles are abnormal
Identified as "sterilized" by a green "Z" tattoo	Identified as sterilized by lack of testicles as well as green line tattoo
Activity restricted for 3 days, bathing OK	Activity restricted for 10-14 days, bathing prohibited
THERE IS 1 IN 100 RISK of tissue reaction to injection,	There is a 1 in 1000 chance that infection or excessive
which will require surgical castration 3-5 days later (at no	swelling will require further treatment or additional
charge)	surgery after surgical castration

### What should I expect after the Zeuterin procedure?

- It is NORMAL for the testicles to have mild to moderate swelling which peaks at 48 hours and can last a few weeks. In most cases this will not bother the dog, but you may see him sit or walk "funny" during this time. Activity should be restricted for 3 days and he should be encouraged to lay on soft surfaces and avoid laying on wet surfaces. A recheck exam is required (at no charge) if licking or chewing at scrotum is noted (not normal).
- **93% of dogs show no pain**, but if it is noted, it is most common in the first 3-5 days. We will be dispensing Vetprofen for the first 3 days, because it is has both an anti-inflammatory and anti-pain activity.

#### Zeuterin Script – First Coast No More Homeless Pets

#### Client: I want to get my dog neutered.

Great, we now offer a non-surgical method of sterilization called Zeuterin. Zeuterin is an injectable solution used to permanently sterilize your dog. Your dog will be lightly sedated for the procedure, no general anesthesia or surgery is required. The testicles remain in place but are no longer able to produce sperm. When would you like to book your appointment?

#### Client: Can you tell me more about Zeuterin - what is it?

Zeuterin is a non-surgical method of sterilization that involves an injection into each of your dog's testicles that will make him permanently sterile.

You can go to our website and click on "Fix My Pet" then choose the second option for Zeuterin and read more details about the procedure and even watch a 6 minute video that shows everything from start to finish.

#### How does Zeuterin work?

The solution that is injected into the dog's testicles causes permanent scarring down of testicular tissue which renders them sterile.

#### Client: Do you still offer traditional surgical neuters?

Yes, there is an additional cost of \$20.00. Would you like me to schedule your appointment now? Would you prefer the surgical neuter or the less invasive method?

#### What are the benefits to using the Zeuterin?

- Your dog will not have to go under general anesthesia
- Faster recovery time typically only 3 days versus 10-14 days for surgical neuters
- No incision to be concerned about
- Safe for older pets or those with history of seizures because they are not going under general anesthesia

# Client: Are my dog's bad habits going to change (marking, humping, aggressiveness) – is it going to calm him down?

Just like with surgical castration, these behaviors are not necessarily modified after being neuter/zeutered. If you have a young dog, neutering him will not calm him down – exercise and obedience are what you need to focus on with him.

#### Client: Will my dog still be able to reproduce?

Like with surgical castration, your dog still has sperm in his system for 30 days after the procedure so we advise that you keep your pet away from intact females for 30 days after the procedure.

#### **CLIENT INFORMATION SHEET**

### Zeuterin™ (pronounced "zū-tur-in") Injectable Solution for Dogs

#### (Zinc gluconate neutralized by Arginine)

This summary contains important information about Zeuterin<sup>™</sup>. You should read this information before your dog is injected with Zeuterin<sup>™</sup>. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information, if you want to know more, or have questions about Zeuterin<sup>™</sup>.

Zeuterin<sup>™</sup> injectable solution is a safe, non-invasive method used to sterilize male dogs 3 months of age and older. It is currently labeled in the US for dogs 3-10 months of age, although labeling for all dogs over 3 months is expected in Spring 2013. Zeuterin<sup>™</sup> is given as a single injection with a fine needle into each testicle. The injection should be given only by or under supervision of a licensed veterinarian trained in the proper injection technique.

#### What happens after my dog is injected with Zeuterin<sup>™</sup>?

The effectiveness of Zeuterin<sup>™</sup> was demonstrated in a field study. In this study, 99.6% of the 224 dogs injected became sterile. Zeuterin<sup>™</sup> may not kill all the sperm present at the time of injection in dogs. As with castration or a vasectomy, you should keep your dog away from females in heat for at least 60 days after the injection if you want to ensure no pregnancies.

Unlike surgical castration, dogs treated with Zeuterin<sup>™</sup> become sterile without surgical removal of the testicles and, therefore, the male hormone, testosterone, is not completely eliminated. Zeuterin<sup>™</sup> may not prevent diseases associated with male hormones, such as prostatic disease or testicular or perianal tumors in dogs, but may reduce the increased risk of other diseases associated with castration such as prostatic cancer.

As with surgical castration, Zeuterin<sup>™</sup> may not eliminate male behavior such as roaming, marking, aggression, or mounting in dogs.

### What are the possible side effects that may occur in my dog after an Zeuterin™ injection?

Zeuterin<sup>™</sup> may cause some side effects. Local and systemic reactions were observed in the field study at a rate of about 1.1%.

Local reactions included testicular swelling (normal reaction to the injection), pain (dogs may resist sitting or may sit with both hind legs open), biting and licking at the scrotum, swelling of the prepuce and irritation, dermatitis, ulceration, infection, dryness or bruising of the scrotum.

Systemic reactions included an increase in the white blood cell count, vomiting, anorexia (loss of appetite), lethargy (tiredness or abnormal attitude), and diarrhea.

Most reactions were seen within the first 7 days after the injection. Pain was most commonly seen in the first 2 days. Vomiting was most commonly seen on the day of the injection (within 1 minute and 4 hours after the injection). You should withhold food for 12 hours prior to injection to help prevent vomiting.

Mild, temporary swelling of the testicles is an expected reaction to the injection which you will notice within 24 - 48 hours after the injection. Your dog's testicles may remain slightly enlarged but non-painful for a few months after the injection.

To minimize the occurrence of adverse reactions, such as scrotal irritation, inflammation or infection, it is critical that you closely monitor your dog's activity post-injection and that you take all precautions necessary to prevent injury to the testicles and to prevent your dog from licking or biting the scrotal area.

#### For the first few days after injection:

1.Restrict your dog's exercise to leash walking.

2.Do not allow your dog to run, jump, or engage in play activity.

3.Do not allow your dog to lay on hard or wet surfaces.

4.Do not allow your dog to lick or bite the scrotal area.

You should contact your veterinarian immediately if you notice that your dog is biting or licking the scrotal area or if you see any signs of redness, discharge or broken skin in the scrotal area.

To report suspected adverse events and/or obtain a copy of the MSDS or for technical assistance, call Ark Sciences, Inc. at 1-800-345-4735. Adverse events can also be reported to the FDA by telephone at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

Ark Sciences, Inc. New York, NY 10019 U.S.A.



## Owner name:

Pet name:

I am the owner/guardian of the animal identified above and have been informed of the option to zinc neuter the animal as a part of the post-approval field study on permanent, non-invasive neutering for dogs (approval study already complete).

I understand that:

- This is an animal drug formula that is approved for use in the US by the FDA. Current label states 3-10 months of age, but expected to change to "all dogs" spring 2013.
- This drug was produced in the US at the manufacturing facility that follows Good Manufacturing Practices (GMP) and facility is awaiting FDA approval in 2012.
- Adverse reactions can occur, please refer to the Client Information Sheet that should be provided to you.

I fully agree to:

- Allow the animal identified above to be part of the post-approval field study.
- Make the animal available to the veterinarian at the specified time if necessary for recheck.
- Follow post-treatment instructions of the veterinarian given at the time of the procedure.

I understand that:

- A green "Z" tattoo will be placed on the skin near the scrotum.
- Sedation will be used and there is a slight risk of adverse reactions depending on the individual patient.
- I understand that there is a 1 in 100 risk that my pet will develop a tissue reaction which will require surgical castration later at no charge. I understand that I must monitor my pet closely for excessive licking for the first 5 days.
- There is no charge for the Zinc Gluconate product itself, but the fee is for the exam, sedation and ancillary procedures.
- If owner requests, FCNMHP will surgically castrate my dog after 30 days but before 6 months at no charge.
- If my dog does not qualify for the Zeuterin procedure, I give permission for FCNMHP to surgically castrate my dog. Yes <u>No</u> (please initial)

I hereby agree to hold FCNMHP and Ark Sciences harmless from any negative or adverse reaction that may result to my animal from participation in the study and agree that I shall not bring any cause of action against Ark Sciences for any loss, claim or damage resulting from the participation of my animal/s in the study.

Owner's Signature

## ZEUTERIN TREATMENT Form Date of injection:\_\_\_\_\_

## **ORGANIZATION: FCNMHP**

PROBLEMS WITH INJECTION OF RIGHT TESTIS? (N0) \_\_\_\_\_ YES: \_\_\_\_\_

PROBLEMS WITH INJECTION OF LEFT TESTIS? (N0) \_\_\_\_\_ YES: \_\_\_\_\_

NOTES of TREATMENTS, OUTCOMES:

## DAY THREE FOLLOW-UP

Clients are asked to watch for pain, licking, biting at scrotum, reluctance to sit, and seeing a red area that is developing on the scrotum. These would all be signs of an adverse reaction (possible ulcer forming) and early treatment is advised.

1. PHYSICAL CHECK-UP \_\_\_\_\_
2. PHONE FOLLOW-UP \_\_\_\_\_
3. PICTURE TAKEN \_\_\_\_\_



Join us as we work towards a day when there truly are no more homeless pets!

## **Zeuterin After Care Instructions**

## What should I expect after the Zeuterin procedure?

- It is NORMAL for the testicles to have mild to moderate swelling, which peaks at 48 hours and can last a few weeks. In most cases this will not bother the dog, but you may see him sit or walk "funny" during this time. **Activity should be restricted for 3 days** and he should be encouraged to lay on soft surfaces and avoid laying on wet surfaces.
- Biting or chewing is not expected, if it is seen, you should bring your pet back to our clinic for a recheck exam that day (as this could be a sign of an issue). If you are not able to get back to us that day, you should put an e-collar on your dog to prevent additional chewing or licking until you can get to the clinic.
- 93% of dogs show no pain, but if it is noted, it is most common in the first 3-5 days. We will be dispensing **Vetprofen** for the first 3 days, because it has both an anti-inflammatory and anti-pain activity.
- If there is ANY redness, pain, or ulceration after 3 days, we recommend a recheck. The most common adverse reaction (1.1%) is scrotal irritation, but ulcerations or (rarely) draining tracts can occur. These are better treated early if they are seen.

## When should I feed my dog and give the pain medication?

- Because the procedure or sedation may cause vomiting /nausea, we **recommend feeding a small meal and/or small amount of water** at dinner time today. If drooling or vomiting occur, remove food and water and offer again in the morning.
- Your dog has received the first dose of pain medication today. We recommend giving the next dose of Vetprofen with breakfast tomorrow as long as there is no further vomiting.

## PLEASE CALL 904-735-2770 IF YOU HAVE QUESTIONS OR CONCERNS.

## Day 3 Update – We Want To Hear From You!

Congratulations! Your dog has just been *Zeutered*, the gentle, non-surgical Neuter! As part of our careful attention to the health of your dog we are asking for your help:

THREE days after your pet has been Zeutered, please turn your pet over to look for any signs of redness, irritation or ulcer (small hole) on the scrotum.

Then call 904-735-2770 and let us know:

1. Everything looks great OR

2. You need to bring your dog in for a re-check.

If you have to leave a message, please note your name and your dog's name. Thanks for helping us take the best care of your pet!

## Zeuterin: Non-Surgical Neutering for Dogs- FCNMHP Staff Information Sheet

## What is Zeuterin? STAFF INFORMATION!

- FDA- approved Zinc solution which is injected into each testicle in order to permanently sterilize dogs. The current label states 3-10 months of age, but expected to be licensed in US for all dogs by spring 2013. Is licensed in other countries for all dogs now.
- Zinc solution leaves the body within 72 hours, but results in permanent scarring down of testicular tissue. Over time, testicles may feel smaller and more firm.
- Surprisingly, the injection itself is non-painful (watch if you do not believe), is done with a very fine needle and can be done under light sedation only. The noise of the tattoo bothers the dogs more than the injection!

## Why is FCNMHP offering this alternative?

- It is a safe, non-invasive way to sterilize male dogs without surgery or general anesthesia and is expected to result in fewer complications.
- It is expected to free up time for us to accomplish more female surgeries, thus have a greater impact on local pet overpopulation.
- It is a great alternative to those pet owners who object to surgical castration because of the removal of the testicles or because of general anesthesia and will eventually be offered as an outpatient procedure.
- Like "early age spay/neuter", injectable neutering can revolutionize how we think of sterilization and will widen the possibilities for population control. Also like "early-age" spay/neuter, you will hear a lot of misconceptions coming from the veterinary and even the animal welfare side until more education and acceptance occurs.

### How will Zeuterin option affect our current protocols?

- Zeuterin will be offered as the "default" procedure for neutering dogs at our current pricing. Owners may elect surgical castration instead, but the fee will be \$20 higher starting Nov 12<sup>th</sup>.
  Prior to Nov 12, Zeuterin will be discounted \$20 relative to regular neuter fee. (do not discount license fees!)
- Appointments will be made as usual, with the client being informed at that time of our protocol and pricing changes and their options. For further information, they will be referred to our website for the Zeuterin video and more detailed information. Or to <u>www.arksciences.com</u> until our website is updated.
- At check-in, the client will chose injectable or surgical sterilization and will sign the appropriate release form. At check-out, the client will, of course, receive different after care instructions. Most likely, "Zeutered" dogs will be able to go home before lunch.
- As usual, any complications will be treated at no charge. In addition to this we will offer to surgically castrate the dog for free within 6 months if owners change their mind for any reason.

#### What should our clients expect after the Zeuterin procedure?

- It is NORMAL for the testicles to have mild to moderate swelling which peaks at 48 hours and can last a few weeks. In most cases this will not bother the dog, but you may see him sit or walk "funny" during this time. Activity should be restricted for 3 days and he should be encouraged to lay on soft surfaces and avoid laying on wet surfaces.
- Biting or chewing is not expected, but as with surgical castration, if it is seen, an e-collar is required.
- 93% of dogs show no pain, but if it is noted, it is most common in the first 3-5 days. We will be dispensing Vetprofen (instead of Tramodol) for the first 3 days, because it is more of an anti-inflammatory.
- If there is ANY redness, pain, or ulceration after 3 days, we recommend a recheck. The most common adverse reaction (1.1%) is scrotal irritation, but ulcerations or (rarely) draining tracts can occur. These are better treated early if they are seen.

#### What are the pros and cons of Zeuterin compared to surgical castration?

- Pros (for the dog): safe, non-invasive (think of the scalpel, cutting, blood, bruising and sometimes excessive swelling after castrations), no skin- irritating surgical clipping or scrubbing, quick, light, reversible sedation similar to what we use to take xrays instead of general anesthesia, less pain expected
- **Pros (for us):** quicker procedure (once we get practiced), fewer supplies, no pack or suture used, less autoclaving, eventually may not even admit into a kennel (no cleaning), go home sooner
- **Pros (for general health):** it is thought there is a benefit to retaining some testosterone in the body- (medical jury still out); it is a fact that castrated dogs are at higher risk for prostate cancer (2-4x higher risk), may help retain cognitive function as ages, neutering *slightly increases* chances for these conditions: transitional cell carcinoma, osteosarcoma, hemangiosarcoma, obesity/diabetes. Therefore, retaining 50% of testosterone may reduce this increased risk.
- Cons (for the dog): may have a few days of swelling, +/- pain, scrotal dermatitis, or rarely, adverse reactions such as ulcerations or draining tracts. Worse case scenario, we may have to go back and remove testicles if draining tract is severe (likely less of a risk than having to do scrotal ablation post- castration due to excessive bruising or swelling)
- **Cons (for us):** initially, learning about it, more paperwork with forms (will streamline), more explaining new stuff to clients; have to look for tattoo to prove "zeutered"
- Cons (for general health): still a risk of testicular tumor, although in dogs is almost always benign and easily diagnosed on exam; prostatic hyperplasia (enlargement) with 50% of testosterone, as with surgical castration, may not eliminate male behaviors such as marking, mounting (more related to age when Zeutered or castrated), aggression is only expected to be effected if it involves presence of females.
- **Dogs not eligible for Zeutering:** cryptorchid; existing scrotal skin disease, abnormal testicles, testicles WIDER than 30mm or smaller than 10mm