



## **Neutersol<sup>®</sup>**

### **Summary Position Statement**

The Alliance for Contraception in Cat and Dogs is pleased that Abbott Animal Health has announced plans to market Neutersol<sup>®</sup>. The first non-surgical sterilant to achieve FDA approval, Neutersol is the only product to sterilize male dogs via injection rather than surgery. Indications are that the product will be priced to provide significant cost savings compared to castration, further increasing the potential of this new tool for use by animal welfare organizations.

ACC&D believes that Neutersol has the potential to expand the reach of dog sterilization programs. In addition, ACC&D believes that utilization of Neutersol is an important precedent to set the stage for future generations of non-surgical sterilants for male and female cats and dogs.

As part of a public/private partnership with Abbott, ACC&D has offered to serve on an advisory board to support focus on the abilities of this product to offer value to the animal welfare community. As part of this partnership ACC&D looks forward to developing and implementing special projects and events to

- demonstrate effective field use of Neutersol, and publicize results achieved
- stimulate animal welfare utilization of this new tool, and
- contribute to understanding about Neutersol use and client experience through follow-up and other evaluation

ACC&D has asked Abbott Animal Health to donate doses of Neutersol for use in these animal welfare projects and events.

ACC&D is excited to support the first non-surgical sterilant for dogs in the US and we encourage inquiries from organizations and individuals who wish to be part of making this introduction a success for the animals. For our full position statement and further background on Neutersol see [www.acc-d.org](http://www.acc-d.org)



## **Neutersol®**

### **Full Position Statement**

#### Background

The Alliance for Contraception in Cats and Dogs (ACC&D) was founded with the focused purpose of expediting the introduction of non-surgical sterilants for dogs and cats, and supporting the distribution of products suitable for the humane control of cat and dog populations.

When Neutersol was approved by the FDA as safe and effective for use in the U.S., it became the first non-surgical sterilant for companion animals to receive regulatory approval anywhere. Though approved for male puppies from 3-10 months of age, Neutersol has been used effectively off-label for adult dogs. Neutersol was available in the United States from mid 2003 for less than two years. In early 2005, the patent holder severed the contract with Addison Laboratories, the marketing company, and sought another partner. In November 2006, it was announced that Abbott Animal Health will reintroduce Neutersol in the U.S., though timing of the relaunch has not been announced. Neutersol has seen limited use outside the United States to date with the exception of Mexico which has recently completed a successful field trial sterilizing 10,000 adult dogs.

#### Benefits of Neutersol compared to surgical sterilization: Neutersol:

- 🐾 provides permanent sterilization (99.6% effective) with injection rather than surgery.
- 🐾 does not require specialized surgical facilities, equipment or supplies. This allows Neutersol to be used in the field, or in areas where facilities are not available or adequate for the volume of procedures.
- 🐾 provides increased operating efficiencies which include the reduction of veterinary and staff time, reduction of drug and supply inventory required for surgical neutering procedures.
- 🐾 can be more affordable than surgery in most cases, and dramatically less expensive in some cases.
- 🐾 can be used to expand the number of male dogs sterilized, overall, and by efficiently treating a large number of dogs in a short period of time, in large scale sterilization events.
- 🐾 eliminates the risks of anesthesia and post-surgical complications, reduces stress of stays in the hospital associated with surgical neutering, and minimizes aftercare and therefore client compliance with post-surgical instructions.
- 🐾 provides an alternative when medical issues may make anesthesia and surgery contraindicated.
- 🐾 provides an alternative for owners who are not willing to castrate their dogs due to opposition to anesthesia or surgery, for cultural reasons, or those who believe it will make their dog less of a 'male'.
- 🐾 provides a convenient option, offering treatment as an outpatient and with no overnight stay.



Challenges to successfully reintroduce Neutersol include:

- ❖ Neutersol results in variable testosterone reduction in puppies, and may not reduce testosterone at all in adult male dogs. The FDA has stated that as with surgical castration, secondary male characteristics such as roaming, marketing, aggression and mounting may be displayed in animals who have received the Neutersol injection.
- ❖ ACC&D recommends—and may pursue—research to better understand the behavioral differences between Neutersol-treated, castrated, and intact dogs. Recent research has suggested that long held assumptions that aggression is reduced in castrated males may not be accurate. (1)
- ❖ Most veterinarians and the public believe that castration reduces risk of canine prostate cancer. Recent research (2) has shown that castrated dogs are actually more prone to developing prostate cancer. Castration may reduce the risk of prostatitis and benign prostatic hypertrophy, both conditions which can be treated medically if needed. Clarity is needed about the comparative impact on a dog's future likelihood of getting prostate cancer.
- ❖ Precise injection technique is critical to avoid injection site reactions. Scrotal irritation and ulcers may be unavoidable in 1-2% of dogs, and require follow up topical treatment or in some cases, castration. ACC&D recommends additional research in this area to evaluate how to minimize these reactions.
- ❖ Complete sterility may take up to 60 days to achieve in post pubescent males.
- ❖ FDA approval has not yet been sought for male dogs outside the 3-10 months of age profile. However, Neutersol has been used successfully off-label in adult dogs and younger puppies.
- ❖ Perceptions in the veterinary/shelter community about issues associated with Neutersol will need to be overcome. Perceptions primarily relate to historic pricing, injection site reactions and the unresolved question about subsequent levels of testosterone in treated dogs. This will require a completely transparent educational program.
- ❖ Given the above issues, the need for adequate levels of consumer education/marketing and veterinary/shelter detailing to explain and sell this product will be a challenge for an animal health company to provide.

ACC&D Proposed Role in the Relaunch of Neutersol

ACC&D was founded to fill critical gaps in development, introduction and implementation of non-surgical tools for pet contraception. We believe in the potential of public/private partnerships to advance the effective introduction of an animal health product, as demonstrated by nonprofits advancing technology in human health care. We are committed to helping facilitate a successful U.S. re-launch of Neutersol, the first non-surgical pet sterilant available anywhere. We also feel that the greatest potential impact for use will be in nations with less infra-structure to provide surgical neutering.

As part of a public/private partnership with Abbott, ACC&D has offered to serve on an advisory board to support focus on the abilities of this product to offer value to the animal welfare community. As part of the reintroduction of Neutersol, ACC&D looks forward to developing and implementing special projects and events to:



- demonstrate effective field use of Neutersol, and publicize results achieved
- stimulate animal welfare utilization of this new tool, and
- contribute to understanding about Neutersol use and client experience through follow-up and other evaluation

ACC&D has asked Abbott Animal Health to donate doses of Neutersol for use in select animal welfare projects and events.

ACC&D is excited to welcome back the first non-surgical sterilant for dogs in the US and we encourage inquiries from organizations and individuals who wish to be part of making this introduction a success for the animals.

### Summary

ACC&D believes that Neutersol has the potential to expand the reach of sterilization programs and plans to help facilitate that impact. In addition, ACC&D believes that utilization of Neutersol is an important precedent to set the stage for future generations of non-surgical sterilants for male and female cats and dogs. ACC&D is excited to welcome back the first non-surgical sterilant for dogs in the US and we encourage inquiries from organizations and individuals who wish to be part of making this introduction a success for the animals

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Both of the studies below were presented or referenced in presentations by speakers at the Third International Symposium of the Alliance for Contraception in Cat and Dogs (ACC&D) in November 2006.

(1) Deborah L. Duffy, Ph.D. and James A. Serpell, Ph.D., Center for the Interaction of Animals & Society, School of Veterinary Medicine, University of Pennsylvania, Behavioral Effects of Spaying/Neutering in Domestic Dogs presented Nov. 2006.

(2) E Teske, EC Naan, EM van Dijk, et al., 2002. Canine prostate carcinoma: epidemiologic evidence of an increased risk in castrated dogs. Molecular and Cellular Endocrinology. 197:251-255.