

## DOGSPIRAL



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### Product Profile and Position Paper

Dogspiral is an intrauterine device (IUD). It was developed by two veterinarians in Bosnia as a less invasive alternative to sterilization for female dogs. It became commercially available for dogs worldwide in 2014 via sales over the Internet.

Data on the safety and efficacy of the Dogspiral IUD is extremely limited; data on other intrauterine devices and expert input raise concerns about Dogspiral safety and ease of use.

# Dogspiral

## INTRAUTERINE DEVICE FOR FEMALE DOGS

### INTRODUCTION

This paper profiles Dogspiral, an intrauterine device (IUD) commercialized in 2014, and provides ACC&D's position on this product. The inventors of Dogspiral envision wide application in dogs, ranging from pets to free-roaming populations who lack access to surgical sterilization. The same IUD design has also been used in client-owned horses, and a patent was sought for human use (personal communication, Birgit Contzen, 17 January 2017; WIPO 2017a). There is extremely limited data on the safety and efficacy of Dogspiral and other canine IUDs at this time.

IUDs have a long history of contraceptive use in females, both human and non-human. According to popular legend, Arab traders inspired the modern IUD. Legend has it that they inserted small stones into the uteruses of their camels to prevent pregnancy during long desert treks. The story was originally a tall tale to entertain delegates at a scientific conference on (human) family planning; although it was later repeated as truth, it has no known historical basis (Planned Parenthood 2002).

Devices to be inserted into the human uterus were invented in Germany in 1909. They were made of silkworm gut. They worked, but often led to infections, which was a very serious side effect before penicillin became widely available in 1945, because such infections invariably caused death. During the 1920s and 1930s, contraceptive researchers in Germany, China, and Japan created ring-shaped devices of gut, gold, and silver, but infection still remained a serious problem (Planned Parenthood 2002). Varied designs and materials have since been studied, modified, and successfully commercialized, and today the IUD is reported to be the most popular method of non-permanent contraception for married or in-union women worldwide, with 14% using it (United Nations 2015).

Although animal research (not in dogs) led to the development of human IUDs, for many decades this contraceptive method was, for the most part, not considered for non-human animals (there are exceptions, primarily for livestock). Published research on an earlier canine-specific IUD (Biotumer, Buenos Aires, Argentina) is found in just two articles (Nagle et al., 1997; Volpe et al., 2001). There is no evidence that the Biotumer product is presently available, and Dogspiral is the only known commercially available IUD currently being promoted for dogs.

### PRODUCT DESCRIPTION

Dogspiral is a contraceptive device marketed for female dogs; it was developed by veterinarians Dr. Tilen Klevisar and Dr. Almir Karabegovic, based in Bosnia and Herzegovina, and launched in 2014. It is

implanted within the uterus non-surgically via the vaginal canal. Dogspiral is being marketed internationally over the Internet and has a small but multi-country (primarily European) user base.

A patent application for the Dogspiral IUD design was filed with the World Intellectual Property Organization in 2014 (WIPO 2017a). The proposed patent was for a design for use in female animals and humans, and consisting of an array of materials (copper, silver, and copper/gold) covering a stainless steel spiral coil. The International Preliminary Report on Patentability, published in 2017, concluded that the design is not sufficiently novel to warrant a patent (WIPO 2017b). Lack of a patent does not, however, preclude commercial sale.

The following section content is based on information available on the company website (DogSpiral NDa), in an instruction sheet (Klevisar 2015), and in an online video accessible from the company website (YouTube 2015). *ACC&D cannot verify the accuracy or data behind the claims and instructions provided by the company.*

The company promotes the following attributes of this product (Dogspiral NDb; Klevisar 2015):

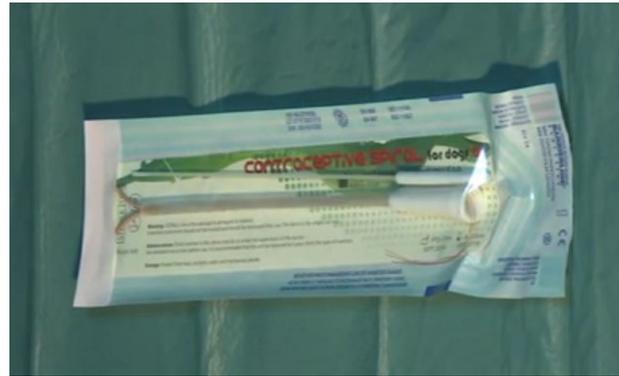
- “The procedure can be performed with mild sedation, or if necessary with anesthesia” (Klevisar 2015).
- The endocrine system is not disrupted so female dogs continue to have estrus and an unaffected social and sexual life (with the exception of pregnancy).
- The IUD can stay in the uterus for up to ten years (*ACC&D note: this claim draws from human study data, not canine studies with this or other IUDs.*)

Instructions for insertion are available in an instruction sheet and an online video accessible from the product website (Klevisar 2015; YouTube 2015). No further training is promoted by the developer/manufacturer.

Instructions state that “insertion and removal of the IUD should only be performed by a qualified veterinarian in a properly equipped room” (Klevisar 2015). In brief, using sterile gloves and aseptic technique, the company instructs the veterinarian to place a sedated (or, if necessary, anesthetized) dog in dorsal recumbency, grasp and visualize the cervix, gently insert a catheter through the cervix, and advance an insertion rod into the catheter. The company advises that the veterinarian check the correct position of the IUD by tightening the nylon thread that protrudes from the vagina, then cut the thread near the cervix to prevent removal during coitus. Finally, the instruction sheet recommends “an annual check-up at the vet to determine whether the IUD is still in the uterus.”

Dogspiral is sold in three different sizes: Small (dogs up to 5 kg), Medium (dogs 5–15 kg), and Large (dogs over 15 kg) (Dogspiral NDa). The copper and silver-plated options are promoted on the website.

The website lists several contraindications to Dogspiral use: During pregnancy, with dogs under one year of age, if a sexually transmitted disease is present, with chronically sick animals, if the dog has an allergy to components of the IUD, and with the English Bulldog breed (Dogspiral NDb).



*Photo credits: Dogspiral website (L); Dogspiral instruction sheet (R).*

## MECHANISM OF ACTION

In human medicine, two types of IUDs are available. The copper IUD does not contain hormones and is approved for use for up to 10 years. The hormonal IUD releases progestin and is approved for a shorter period of use (ACOG 2017). Dogspiral is more comparable to the first IUD in that it does not contain hormones; in humans, the non-hormonal IUD prevents fertilization of the egg by the sperm (ACOG 2017).

According to product instructions (Klevisar 2015), the Dogspiral IUD works based on:

- 1) The presence of a “foreign body coil” in the uterus, which causes a mild aseptic inflammation and changes the uterine lining in such a way to prevent implantation of a fertilized egg. In addition, there is an increase of neutrophils (one of several types of white blood cells), which phagocytose (engulf) the sperm, thus impairing fertilization, plus an increase of prostaglandins.
- 2) The electrochemical properties of the copper or silver plating. The instructions explain that copper and silver are very reactive because they discharge very lightly positively charged ions, which attract the negatively charged sperm, reduce their mobility, and kill them. The instructions add that these metals also act as antivirals, bactericides, and fungicides, with an effect localized to the uterus, fallopian tubes, and cervix.

*The Dogspiral instructions do not list references for claims regarding the IUD’s mechanism of action, nor canine-specific applicability. ACC&D cannot verify the accuracy or data behind the claims.*

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## SAFETY AND EFFECTIVENESS

There are no peer-reviewed or published studies on Dogspiral. References to safety in company materials extrapolate studies in humans to those in dogs; product-specific safety and efficacy data are anecdotal. The two peer-reviewed publications found in a literature review used a canine IUD with a different design and manufacturer (Nagle et al., 1997; Volpe et al., 2001). The following discussion of safety and efficacy therefore draws from Dogspiral company claims, data from the two published dog IUD studies, and veterinary expert opinion.

The Dogspiral website claims that its IUD with a copper/silver finish offers 99.9% reliability in dogs (Dogspiral NDa), although this is not substantiated by product-specific data. The IUD has reportedly been used successfully in over 300 dogs since 2012 (personal communication, Tilen Klevisar, 15 January 2017). This includes monitoring 30 treated free-roaming female dogs at a feeding ground in Bosnia and Herzegovina. No pregnancies or complications were observed, though no formal data was collected (personal communication, Tilen Klevisar, 22 January 2017). The inventors additionally monitored 76 client-owned dogs, consisting of various breeds and ages and residing in nine European countries, who were treated between February 2014 and January 2017; those implanted more than a year ago have received an annual follow-up evaluation. Among these, two lost the IUD. The developers reported “No Abnormality Detected” based on physical and vaginal examinations of the dogs and a conversation with owners (personal communication, Birgit Contzen 24 July, 17 August, 2017).

Dogspiral has not undergone any regulatory approval by any nation (such as the Food and Drug Administration in the United States), during which efficacy and safety claims would be evaluated. In the European Union and the United States, veterinary medical devices do not require regulatory review and approval to be marketed, a process required for a pharmaceutical or immunological contraceptive (e.g., an intratesticular injection or contraceptive vaccine) (EMA 2016; U.S. FDA 2016).

As noted above, published data on IUDs in dogs are limited to two studies of the Biotumer IUD, described below. It is important to note that the Biotumer design differs from the Dogspiral IUD in its composition materials and design (United States Patent 2000), and thus findings should not be extrapolated to Dogspiral.

The first study implanted five adult dogs of varied sizes, who were then euthanized to acquire information on measurements of internal organs and appropriate size for the IUD. Based on these learnings, 30 bitches in different stages of estrous (proestrus, estrus, anestrus) were subsequently implanted and observed for 12–36 months. The researchers observed no changes in behavior, frequency of estrus, or frequency of matings among treated dogs; they reported that the product was 100% effective in preventing pregnancy, even among dogs who received the IUD in proestrus or estrus and were immediately exposed to male dogs (Nagle et al. 1997).

A subsequent study evaluated the implant in nine bitches of different breeds, ages (3–6 years), and sizes (3–70kg). All were in proestrus or estrus and received the implant under anesthesia (versus sedation).

None of the nine treated dogs became pregnant during the two-year period that they were monitored and bred. One Bulldog showed persistent estrus and had to have the device removed 24 days after implantation. Reportedly, 24 hours after removal, the bitch stopped showing signs of estrus. The IUD was found to be safe and effective in the other eight dogs (Volpe et al. 2001).

### Expert Assessment of Canine IUD Safety and Effectiveness

ACC&D contacted multiple Board-certified small animal theriogenologists (reproductive specialists) to assess Dogspiral. While these experts have not used this product, their knowledge of canine anatomy prompted consistent concerns about use of an IUD in a dog, and specifically Dogspiral's instructions for insertion. Concerns include, but are not limited to:

- The anatomy of the canine reproductive tract makes insertion of an IUD very difficult in general, and particularly challenging outside of proestrus and estrus. Dogspiral does not address timing of insertion relative to the dog's estrous cycle as a consideration for safety, or practicality.
- No guidance is provided on how to confirm that the IUD has passed the cervix and is actually in the uterus (versus the cranial vagina), and it is possible that the IUD as inserted per instructions would not enter the uterus. The Biotumer IUD articles reference special equipment (cervical distender, cerviscope) to aid with insertion; Dogspiral instructions do not.
- The instruction to "grasp the cervix" carries risk of damage to the cervix and/or vagina, and "pull up to the labia" carries risk of tearing surrounding tissue (mucosa, submucosa, muscles).
- The risk of developing uteropathy based on evidence that foreign body reactions can occur in the uterus in bitches (Nomura 1994, 1995, 1997).

### AVAILABILITY

The fact that the Dogspiral IUD does not require regulatory review or approval means that its availability is not country-specific. The company reports that it is currently selling the IUD to veterinarians or directly to pet owners who have a veterinarian willing to use Dogspiral (personal correspondence, Birgit Contzen, 17 August 2017).

### ACC&D POSITION

The ACC&D's mission is to advance non-surgical fertility control so as to effectively and humanely reduce the number of unwanted cats and dogs. Data on device insertion, rate of loss, effectiveness over time, and short- and long-term safety are required before Dogspiral can be adequately evaluated. Because there are no comprehensive, peer-reviewed, and/or published safety or efficacy data available for this product, ACC&D as a scientific body cannot adequately evaluate this device, and therefore cannot develop a recommendation regarding its use.

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## REFERENCES

- American College of Obstetricians and Gynecologists, The (ACOG). Long-Acting Reversible Contraception (LARC): IUD and Implant. 2014. <https://www.acog.org/Patients/FAQs/Long-Acting-Reversible-Contraception-LARC-IUD-and-Implant>. Accessed August 30, 2017.
- Dogspiral NDa. Dogspiral contraceptive device for dogs. [www.dogspiral.vet/English/](http://www.dogspiral.vet/English/). Accessed February 15, 2017.
- Dogspiral NDb. What is dogspiral? <https://www.dogspiral.vet/English/What-is-Dogspiral/>. Accessed February 15, 2017.
- European Medicines Agency (EMA). The European regulatory system for medicines A consistent approach to medicines regulation across the European Union. [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Leaflet/2014/08/WC500171674.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2014/08/WC500171674.pdf). Accessed September 13, 2017.
- Klevisar, T. 2015. Dogspiral instructions. [https://www.dogspiral.vet/cm4all/iproc.php/Dogspiral\\_instructions.pdf?cdp=a](https://www.dogspiral.vet/cm4all/iproc.php/Dogspiral_instructions.pdf?cdp=a). Accessed February 15, 2017.
- Nagle, CA, Turín, E, Nagle, HA, et al. Anticoncepcion en perras mediante la insercion no-quirorgica de un dispositivo intrauterine (DIU). *Veterinaria Argentina* 1997;14:414–420.
- Nomura, K. Histological evaluation of canine deciduoma induced by silk suture. *The Journal of Veterinary Medical Science*. 1995;57:9–16.
- Nomura, K. Induction of a deciduoma in the dog. *The Journal of Veterinary Medical Science*. 1994;56:365–369.
- Nomura, K. Induction of canine deciduoma in some reproductive stages with the different conditions of corpus lutea. *The Journal of Veterinary Medical Science*. 1997;59:185–190.
- Planned Parenthood. 2002. A History of Birth Control Methods. <https://web.archive.org/web/20080517045452/http://www.plannedparenthood.org/resources/research-papers/bc-history-6547.htm>. Accessed July 27, 2017.
- United Nations. Trends in Contraceptive Use Worldwide 2015. 2015. <http://www.un.org/en/development/desa/population/publications/pdf/family/trendsContraceptiveUse2015Report.pdf>
- United States Food & Drug Administration (U.S. FDA). How FDA regulates veterinary devices. <https://www.fda.gov/animalveterinary/resourcesforyou/ucm047117.htm>. Accessed August 15, 2017.
- United States Patent. 2000. Intrauterine device for use as a contraceptive means in female dogs and methods of insertion thereof (US 6119696 A). <https://www.google.com/patents/US6119696>. Accessed August 5, 2017.

- Volpe, P, Izzo, B, Russo, M, Iannetti, L. Intrauterine device for contraception in dogs. *The Veterinary Record* 2001;149:77–79.
- World Intellectual Property Organization (WIPO). 2017a. (WO2016032406) Insert for humans and animals and the process for producing the same. <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016032406>. Accessed August 5, 2017.
- World Intellectual Property Organization (WIPO). 2017b. Patent Cooperation Treaty: International Preliminary Report on Patentability. [https://patentscope.wipo.int/search/docservicepdf\\_pct/id00000036847334/IPRP1/WO2016032406.pdf](https://patentscope.wipo.int/search/docservicepdf_pct/id00000036847334/IPRP1/WO2016032406.pdf). Accessed August 5, 2017.
- YouTube. Dogspiral, Contraceptive spiral for dogs, 2015. <https://www.youtube.com/watch?v=Irf5kruT8>. Accessed February 15, 2017.