**DexStent-TN Implantable Self-Expandable Nitinol Stent**

**Instruction for Use**

Please read carefully!

**CAUTION:** U.S. Federal Law restricts this device to sale by or on the order of a veterinarian. For veterinary use only. Not for human use.

**INTENDED USE:** The DexStent-TN implantable stent system is designed for the palliative treatment of tracheal collapse in dogs.

**DESCRIPTION:** The DexStent-TN stent system consists of a braided self-expandable Nitinol stent which is preloaded, sitting compressed on the top end between the inner and outer catheter/sheath of the delivery system. The compressed stent expands back to its original dimensions when the outer catheter/sheath is retracted during the placement procedure. A special feature of this stent/delivery system is the stent can be reconstituted when only partially deployed. It allows the operator to re-sheath the stent which improves the accuracy during the positioning process. In addition, the delivery system has a removable safety latch that prevents the accidental deployment of the stent.

**CONTRAINdications:** The DexStent-TN stent systems are generally contraindicated in situations presenting a reasonable probability of tissue or organ damage. This device is not currently indicated for use in animals other than dogs.

**ADVERSE EFFECTS:** Bleeding or injury to the tracheal wall may occur with the use of tracheal stent devices.

**WARNings:**
- Use of the DexStent-TN should be restricted to specialists who are familiar with, and have been trained to perform, the procedures for which this device is intended.
- The product is supplied sterile; if the pouch is opened or damaged compromising the sterile barrier, please discard the product. This product cannot be re-sterilized or re-used.
- The DexStent-TN is designed for single use only. Dextronix Inc. ("Dextronix") makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of the stent or the delivery system.
- In addition, Dextronix assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.
- The stent delivery system is a delicate mechanical assembly, deliberate misuse by bending, twisting or any other severe physical manipulation will void the warranty.
- Do not use the DexStent-TN stent system for purposes other than those indicated.

**PRECAUTIONS:** The DexStent-TN device is a delicate scientific instrument and should be treated as such. Always observe the following precautions:
- Protect the catheter tip of the delivery system from impact and excessive force.
- Do not cut, crease, knot, or otherwise damage the outer catheter of the delivery system.
- Do not handle the stent.
- During use, ensure that the placement of the delivery system does not preclude air flow through the trachea.
- When inserting the delivery system assure that the intra-thoracic and cervical trachea of the patient are positioned in a straight line to allow unrestricted passage of the delivery system.
- Do not advance the delivery system against significant resistance. If kinking of the delivery system occurs while inside the patient, CAREFULLY REMOVE the delivery system and do not use. If kinking occurs outside of the patient, remove the delivery system and do not use.

**INSTRUCTIONS FOR USE:**
- The patient is placed under general anesthesia and is intubated with a sterile endotracheal tube. The tube should be as large as possible to allow insertion of the stent delivery device. A bronchoscopic Y-port can then be attached to the endotracheal tube enabling passage of the delivery device while minimizing excessive release of anesthetic gas. The remainder of the procedure is then best performed under fluoroscopic guidance. The patient is then placed in lateral recumbency (left, right). The patient’s head, neck and thorax should be aligned to make the cervical trachea as straight as possible. A sterile drape can be used under the endotracheal tube to limit contamination during stent placement.
- Remove the DexStent-TN from its sterile packaging when in a sterile field. Prior to placing within the patient the stent deployment mechanism should then be tested to ensure that it is working properly. The stent can be re-constrained on the delivery device until it reaches the peel-away safety-latch at approximately 90% of its full deployment length.
- The stent delivery system is then inserted though the Y-port and endotracheal tube. The delivery device should pass freely and without restriction to ensure proper stent placement.
- The delivery device should be advanced to the level of the carina. **DO NOT place the stent directly in the carina.** Optimal placement is approximately 0.5 to 1cm orad of the carina. Using both hands, the stent sheath is slowly pulled back while holding the cannula steady. At times, a push-pull technique (push the stylet in while pulling the cannula towards the operator) may be necessary when first deploying the stent to ensure that the distal end of the stent remains in the proper location.

Excessive movement of the stent once starting deployment can result in tracheal injury. If the placement is not appropriate, reverse the procedure and reconstitute the stent.
- If the placement and deployment are optimal, the distal aspect of the stent will engage the trachea and remain in place. As more of the stent is deployed, the stent becomes fixed in place and is less likely to move.
- Continue deploying the stent throughout a majority of the trachea. Closely monitor the location of the stent relative to the endotracheal tube. The endotracheal tube cuff may need to be deflated and the endotracheal tube withdrawn to allow full deployment of the stent.
- Once reaching the peel-away safety-latch, the stent can still be reconstituted and removed. When the stent placement is appropriate, remove the peel away safety-latch and fully deploy the stent. The delivery device is then withdrawn from the patient.
- The stent placement should ideally be checked with bronchoscopy. The stent should be tightly adhered to the tracheal wall without gaps or fissures. If a focal area of poor apposition is identified, the identified location can optionally be ballooned to achieve better confirmation. Small erosions in mucosa are frequently seen following placement, but bleeding should minimal.

**STORAGE AND HANDLING:** Products should be stored in a dry place with the temperature not exceeding 54 degrees Celsius (54 °C/129°F) in their original cardboard box.

**PRODUCT SPECIFICATIONS:**

**Model** DexStent-TN  
**Catalog Number** 231047

One stent per delivery system  
Maximum shaft outer diameter: 10F (3.3 mm)  
Usable length of shaft: 47 cm

**LIMITED WARRANTY AND DISCLAIMER FOR DEXTRONIX IMPLANTABLE PRODUCTS ONLY:** Subject to the conditions and limitations set forth below, Dextronix Inc., warrants that its permanent and temporally implantable products will be free from defects in material or workmanship while in place in the pet/companion animal in whom it is originally implanted. Dextronix Inc. will furnish, without charge, a replacement for any product that it determines to have failed to function within normal tolerances because of a defect in materials or workmanship. The responsibility of Dextronix Inc. under this Limited Warranty is specifically conditioned upon each of the following conditions being met:

a. The product must have been implanted prior to the "USE BEFORE" date marked on the package.

b. The product was new and unused and has not been implanted before and has not been re-sterilized.
c. The product was purchased from Dextronix Inc. or through a Dextronix Inc. authorized distributor.
d. The product has not been damaged or altered by improper handling, use or placement.
e. The explanted product must be returned to Dextronix Inc. within thirty (30) days after removal from the patient and must be accompanied by data documenting the failure of the product. In the event that the removal of the implant is impractical, Dextronix Inc. will accept alternative objective evidence of failure such as e.g. x-ray imagery.
f. The replacement product must be a product supplied by Dextronix Inc.
g. All claims must be submitted in writing with required data to Dextronix Inc., Attention: Customer Service.

**GENERAL WARNING:** All of Dextronix Inc. products are –for veterinary use only- in companion animals (pets). They are not intended for human use and Dextronix Inc. refuses any responsibility for misuse or misbranding of its implantable and non-implantable products. All of Dextronix implantable products are for single use only and Dextronix refuses any responsibility for the consequences of re-use and/ or re-sterilization of its implantable products. In addition, Dextronix Inc.’s implantable products are implanted in an extremely hostile environment of the pet/ companion animal body. The implanted products may fail to function for a variety of causes not limited to medical complications, body rejection phenomenon, allergic reaction, fibrotic tissue, mechanical fatigue and wear out due to mechanical induced stress during usage. Implantable pacing leads and stents may fail by breakage, breach of manufacture, and testing prior to sale. Implantable products may be damaged before, during, or after insertion by improper handling, placement, other intervening acts and/ or wear and tear during use. Consequently, no representation is made that insertion by improper handling or cessation of function of the product will not occur or that the body will not react adversely to the implantation of implantable products or that medical complications (including perforation of the heart or fracture of leads or stents will not follow the implantation) or that the product will, in all cases, restore adequate bodily functions.

**ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:**

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