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: Dextronix retrieval baskets for the ureteroscopic removal of stones from the urinary tract.

DESCRIPTION: Dextronix retrieval baskets consist of 3 main components: the handle, shaft and basket: The basket is formed of biocompatible Nitinol wires, which are joined to the handle and run into a flexible shaft (catheter tube). The basket can be opened and closed by moving the mobile handle. During normal use, the glue at the crossing of the wires cannot be torn inside the catheter tubing. The glue serves as stabilization of the basket and insures a non-traumatic insertion of the basket, as the edges of the catheter tubing are covered.

INDICATION:
The grasping and removal of stones present in the urinary tracts through the thin channel of an ureteroscope. Tipless Dextronix retrieval baskets have been developed for the use inside the kidney, especially inside the renal calyx in combination with flexible endoscopes. Dextronix retrieval baskets with tip are only dedicated for the use inside the ureter in combination with stiff or semi- flexible endoscopes. Dextronix retrieval baskets may only be employed by veterinarians who are trained and experienced in urological endoscopic procedures, especially stone therapy.

The instrument may not be used if either the product or the packaging is damaged or defective. If this should be the case, please return the packaging with the product to Dextronix immediately.

WARNINGS:
- Some of the foreign bodies to be removed are too firmly embedded or too large – fluoroscopy or radiography is recommended to determine the size of the stone. Do not employ Dextronix urological retrieval baskets when the foreign body is too large for endoscopic retrieval and at the same time inappropriate for laser treatment.
- This product could present a biological hazard after it has been used. Therefore, handle and dispose of the product in accordance with the recognized medical guidelines and the relevant legislation and directives.
- If resistance should be encountered while inserting or withdrawing the instrument, stop attempting to move the instrument and determine the cause of the resistance. Persistent resistance could lead to damage on the instrument and injury to the patient. Suitable measures should be taken to alleviate the resistance.

CONTRAINDICATION:
Urological Retrieval baskets may not be employed if the stone is too large to be removed by endoscopic means. The retrieval baskets may not be used on incidence of acute infections in the case of ureteritis or in event of ureteral malformation or in the case of ureteral stenosis, for difficult extraction through the ostium or when ureters cannot be safely dilated.

POSSIBLE COMPLICATIONS/RISKS
Resulting from the application of the retrieval basket for example: perforation, avulsion, haemorrhage, oedema, entanglement, fixation of the basket to a concrement that is impossible to move.
The well known general complications that are encountered during the insertion of catheters into the upper urinary tract, for example: perforation of the ureter, irritation of the ureter, injury to the mucosa, hematuria, discomfort during urination.

Preparation
- Remove the sealed package from the cardboard box. Check the packaging to ensure that it is intact and undamaged.
- Remove the product –while still being in the dispenser - from the sealed package.
- Draw the instrument out of the dispenser by pulling carefully. Light twisting of the adapter relatively to the dispenser is supportive. Make sure that you pull on dispenser and adapter (not the handle).
- Check the product for damage and proper functioning. The empty basket should be opened and closed several times by moving the slider on the handle (2-3 times). Store the product in a sterile location for application.

WARNING:
- Do not activate the mobile handle of the instrument while the basket is in the dispenser.
- It is unnecessary to adjust the instrument before it is used as it is mounted in such a manner by the manufacturer that it will function optimally.
- The catheter tube must not be kinked. Do not loosen the Luer Lock connection.
- Only retract empty baskets. Tests with a foreign body in the basket could lead to irreparable damage in the instrument, making later application impossible.
• Do not try to pull the tip of the basket inside the catheter tubing by stretching the catheter as this could damage the basket and/or make the use of the instrument impossible.

• Do not try to pull the crossing of the basket wires inside the catheter tubing by stretching the catheter, as this could damage the basket and/or make the use of the instrument impossible.

INSTRUCTIONS FOR USE – STONE CAPTURE:

Dextronix retrieval baskets may only be employed by veterinarians who are familiar with and experienced in the insertion techniques and the instruments that are normally employed for this procedure. Various techniques may be applied. However, the veterinarian should apply the technique that is most suitable for the situation of the particular patient in question.

• Inspect the instrument both prior to application and during the invention.

• Make sure that the basket is closed. For this purpose retract the mobile handle (A) to the stop.

• Gently push the closed instrument into the working channel of the ureteroscope, until you observe the emergence at the distal end of the channel.

• Slowly push the tip of the retrieval basket alongside or beyond the stone under direct sight control or fluoroscopic guidance.

• Open the basket with the mobile handle (A). Bring the open basket into the position above the stone by moving the entire handle. A gradual turning of the entire handle (not at the Luer lock), as well as a slight forward and backward movement of the entire instrument will facilitate the capturing of the stone.

• As soon as the stone has been captured, partially close the basket by withdrawing the mobile handle (A), in order to grasp the stone tightly while the basket is being removed. DO NOT PROCEED WITH EXCESSIVE FORCE!

CAUTION: Do not use excessive force during the withdrawal of the retrieval basket and the stone. Maintain the grasping position to keep the stone in the same position. The ureteroscope and the retrieval baskets must be removed at the same time in the case of stones that are too large to be retrieved through the ureteroscope channel.

WARNING:

• The retrieval basket can no longer be used if the wires of the basket are bent or kinked. Do not attempt to straighten the bent wires.

• Dextronix Retrieval baskets are not designed for application in combination with lithotripters or electro-surgical instruments, as the Nitinol wires could be damaged in such processes.

• The basket may never be closed completely as long as it is located in the urinary tract regardless of whether the basket contains a stone or not. The closing of the basket could lead to severe injury to the mucosa of the urinary tract due to pinching or tearing.

• When pushing/pulling the slider, always wait at least 3 seconds between two cycles for minimizing permanent deformation of the basket.

• If the user pulls the tip of the basket inside the catheter by stretching the catheter tubing, it will be nearly impossible to push the basket out again as the radial forces of the wires are too great.

• Dextronix- Retrieval baskets are only suitable and approved for single use. As catheter and bonding connections do not withstand repeated sterilization, DO NOT USE MORE THAN ONCE, RECYCLE NOR RE-STERILIZE!

LOOSENING THE HANDLE: The stone retrieval basket is designed to be used once only. Tipless Dextronix retrieval baskets of size 1.3FR, as well as all of the Dextronix retrieval baskets with tip can be disassembled and assembled alike. Thus, the veterinarian is able to disconnect the handle with the catheter shaft from the core (the basket) and to withdraw it. Outside of the body, the instrument can be re-assembled afterwards. The descriptions for disassembling and assembling can be found in ANNEX 1 (tipless, 1.3FR) and ANNEX 2 (with tip).

Attention: Tipless Dextronix retrieval baskets of sizes 1.9FR to 3.0FR cannot be disassembled without being destroyed.

DELIVERY:

• Every Dextronix- Retrieval basket is packaged in a dispenser and is supplied sterile (ETO).

• The sterility of the instrument and its components is only guaranteed as long as the individual package remains unopened and intact, and the expiry date is adhered to.

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.
LIMITED WARRANTY AND DISCLAIMER: Subject to the conditions and limitations set forth below, Dextronix Inc. warrants that its products will be free from defects in material or workmanship. 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 used prior to the “USE BEFORE” date marked on the package.

b. The product was new and unused and has not been inserted 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 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.

THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR USE, WHICH ARE SPECIFICALLY DISCLAIMED, EXCEPT AS EXPRESSLY PROVIDED IN THIS LIMITED WARRANTY. DEXTRONIX INC. SHALL NOT BE RESPONSIBLE OR LIABLE FOR ANY DIRECT CONSEQUENTIAL OR INCIDENTAL DAMAGES CAUSED BY DEVICE MALFUNCTION, FAILURE, OR DEFECT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

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 single use products.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

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ANNEX 1: Disassembling and assembling of Dextronix retrieval baskets 1.3FR

Disassembling of a retrieval basket with tip
If the veterinarian desires to disassemble the handle of a tipless Dextronix retrieval basket 1.3FR during surgery, following actions should be taken:

- Loosen the knurled screw on the slide by turning it anti-clockwise. Thus, the core wire (basket with pulling wire) is disconnected from the handle.
- Retract the handle together with the catheter shaft from the core wire and out of the patient’s body. The core wire remains inside the body.

Warning: Make sure that the catheter shaft is neither kinked nor damaged in another way during disassembling.

Assembling of a retrieval basket 1.3FR
If the veterinarian desires to re-assemble the tipless Dextronix retrieval basket 1.3FR afterwards, this is possible outside the body, as long as the components are still intact:

- Push the slide to the handle’s distal end and insert the core wire, starting with its twisted side, inside the catheter shaft until the basket gets in contact with the shaft.
- Fix the core wire by tightening the knurled screw on the slide (turn clockwise).
Open and close the basket repeatedly for testing the proper function of the instrument.

**Warning:** Make sure that the catheter shaft is neither kinked nor damaged in another way during assembling.

**ANNEX 2: Disassembling and assembling of Dextronix retrieval baskets with tip**

**Disassembling of a retrieval basket with tip**
If the veterinarian desires to disassemble the handle of a Dextronix retrieval basket with tip during surgery, following actions should be taken:

- Loosen the knurled screw on the slide by turning it anti-clockwise. Thus, the core wire (basket with pulling wire) is disconnected from the handle.
- Retract the handle together with the catheter shaft from the core wire and out of the patient’s body. The core wire remains inside the body.

**Warning:** Make sure that the catheter shaft is neither kinked nor damaged in another way during disassembling.

**Assembling of a retrieval basket with tip**
If the veterinarian desires to re-assemble the Dextronix retrieval basket with tip afterwards, this is possible outside the body, as long as the components are still intact:

- Insert the core wire, starting on the pulling wire side, inside the catheter shaft until the basket gets in contact with the shaft.
- Push the slide over the core wire. The use a pair of tweezers or of a pincer can facilitate insertion of the wire in the slide.
- Push the slide to the handle’s distal end, make sure that the basket is still in contact with the shaft and fix the core wire by tightening the knurled screw on the slide (turn clockwise).

Open and close the basket repeatedly for testing the proper function of the instrument.

**Warning:** Make sure that the catheter shaft is neither kinked nor damaged in another way during assembling.