allwin® Medical Devices

U-Perc Nitinol Stone Basket

Description:
U-Perc Nitinol Stone Basket

Configuration:
See brochure

Intended use:
U-Perc Nitinol Stone Basket is used for stone extraction during percutaneous nephrolithotomy (PCNL.)

Contraindications:
Not suited for use as a lithotripter basket.

Complications:
Some possible complications may include, but are not limited to, the following:

- Perforation
- Evulsion
- Edema
- Entrapment
- Hemorrhage
- Inability to disengage from irretrievable object

Caution:
Federal (USA) law restricts this device to sale by or on the order of a physician.

Warning/ Precaution:

- Manipulate the handle prior to use to ensure smooth functioning of the device. Avoid contact with electric instruments.
- Only physicians trained in stone manipulation should perform this procedure. A variety of techniques can be employed; however the physician should employ the technique with which he/she is most comfortable.
- For single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Do not use if package is opened or damaged.
- Check compatibility with working channel of endoscope.
- Storage temperature between 5ºC to 30ºC.

Potential Biohazard:
Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.

Instruction for Use:

- Insert U-Perc through the working channel of the endoscope for capturing calculi.
- Once the calculus is entrapped in the basket, gradual pull is requested so that there is no mucosal damage.
- Fluoroscopic visualization is advantageous.
- If unsuccessful, further attempts may be made by repeating previously described procedure.
- Simultaneously, withdraw the instrument and the endoscopes from the area of interest.

Do not reuse, reprocess & resterilize:
Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

Read Instruction | For Single Use Only | Do not Re-Sterilize | Use By | Sterile unless package is opened or damaged | Caution : Federal (USA) law restricts device to sale by or on the order of a physician

STERILE EO Sterilized using ethylene oxide | Keep out of sunlight | Keep Dry | Not made with natural rubber latex | CE 2460

EC REP
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