



Urological Stone Extraction Baskets

IFU No. IVX/RE/US/7.5.3-04, Version A/2

DEVICE DESCRIPTION

Urological stone extraction baskets are 3- or 4-wire nitinol baskets which consist of a basket set, outer tube set, handle and guide nozzle. The device is available in a range of French sizes, lengths, and basket diameters.

INTENDED USE

Urological Stone Extraction baskets are intended to be used endoscopically to grasp, manipulate and remove calculi and other foreign objects from the urinary tract.

CONTRAINDICATIONS

None Known

POTENTIAL COMPLICATIONS

The following complications are possible with the use of the stone extraction devices, but may not be limited to:

- Pain
- Bleeding
- Infection
- Non-Retrieval of Stone
- Tissue Perforation
- Tissue Avulsion
- Entrapment of Basket around stone requiring surgical removal.

WARNINGS

1. This device is provided sterile and intended for single use only. Attempts to

reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.

2. If the package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use.
3. Do not use this device for any purpose other than the stated intended use.

PRECAUTIONS

1. This device is intended for use by physicians trained and experienced in urological procedures. Standard urological techniques should be employed.
2. Sterile if the package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile.
3. Upon removal from the package, inspect the product to ensure no damage has occurred.
4. This device is conductive. Avoid contact with any electrified instrument.
5. Using without guide nozzle may damage the stone extraction baskets.
6. If the stone is too large to be removed under endoscope, or cannot be inside the basket, do not use this device.
7. Do not use excessive force to manipulate this device. Damage to the device may occur.

INSTRUCTIONS FOR USE

1. Remove the stone extraction basket from its outer package and move the thumb lever on the handle to the "Close" position to close the basket.
2. Place the guide nozzle securely into the endoscopic cap on the scope.



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3. With the guide nozzle in place, carefully insert the stone extraction basket into the scope.
4. Under direct visualization, locate the stone and advance the stone extraction basket to a location just proximal to the stone. Slide the thumb lever on the handle to the “Open” position to deploy the basket near the stone and maneuver the stone extraction basket until the stone is within the basket.
5. Once correctly positioned, draw the basket down around the stone and slide the thumb lever into the “Close” position.
6. Maintaining position of the stone within the basket, retract the scope and basket.

Upon completion of procedure, dispose of device per institutional guidelines for biohazardous medical waste.

STORAGE

- Store in a dry location, away from extreme temperature and direct sunlight.
- The expiration date is indicated on the box and pouch. Do not use after the expiration date.

SYMBOL EXPLANATION

 Sterilized using ethylene oxide	 Date of manufacture	 Use-by date
 Do not use if package is damaged	 Batch code	 Single use
 Consult instructions for use	 Keep away from sunlight	 Keep dry
 Catalogue number	 Do not resterilize	 Manufacturer
 EU Authorized representative	 CE Mark	 Caution



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