Tricep[™] Hooked Prong Grasping Forceps

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Tricep Hooked-Prong Grasping Forceps are used endoscopically to entrap and remove stones from the ureter or kidney.

Contraindications

None known.

Warnings

- For single use only. Do not reuse, reprocess or resterilize.
- Use of this device should be restricted to use by or under the supervision of physicians trained in urologic endoscopic procedures. Care should be exercised to prevent perforation or trauma of the linings and associated tissue of vessels or ducts.
- Some stones may be too large to be removed endoscopically with stone retrieval forceps. To avoid stone impaction, fluoroscopy or x-ray should be used to determine the size of the stone; do not use the Tricep Hooked-Prong Forceps if the stone is too large to be removed endoscopically or held in the forceps.
- Do not rotate open forceps in ureter.
- This device must not come in contact with any electrified instrument.
- This device should not be directly fired upon by a pulsed dye laser.
- Warnings can be found in the product labeling supplied with each device.

Potential Adverse Events

Adverse events generally recognized with the use of stone retrieval basket devices include, but are not limited to:

- Ureteral Perforation
- Ureteral Evulsion
- Hemorrhage
- Kidney Perfoation
- Edema

Precautions

- Kinks in the sheath will hinder the mechanical operation of the forceps.
- It is recommended that the ureter be pre-dilated before endoscopy and stone retrieval to prevent stone impaction when retracting the stone.
- Some stones may be too large to withdraw the forceps and stone fully into the sheath. Do not
 exert excessive force to withdraw forceps and stone into sheath. Carefully maintain forceps
 position to hold the stone in place.
- Precautions can be found in the product labeling supplied with each device.
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.