

# Leslie Parachute™ Multi-Wire Stone Sweeping Device

## Prescriptive Information

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

### Intended Use/Indications for Use

The Leslie Parachute Multi-Wire Stone Sweeping Device is used endoscopically to entrap and remove stones from the ureter.

### 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. The Leslie Parachute™ Multi-Wire Stone Sweeping Device is for single patient use and has no user serviceable parts.
- Some stones may be too large to be removed endoscopically with a stone retrieval basket. To avoid stone impaction, fluoroscopy or x-ray should be used to determine the size of the stone; do not use the Leslie Parachute Multi-Wire Stone Sweeping Device if the stone is too large to be removed endoscopically or held in the basket.
- 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
- Entrapment of calculi too large to be removed
- Ureteral evulsion
- Hemorrhage
- Kidney perforation
- Inability to disengage from irretrievable stone
- Edema

### Precautions

- Kinks in the sheath will hinder the mechanical operation of the basket.
- It is recommended that the ureter be pre-dilated before endoscopy and stone retrieval to prevent stone impaction when retracting the stone.
- Stones may be too large to withdraw the basketed stone fully into the sheath. Do not exert excessive force to withdraw basketed stone into sheath. Carefully maintain basket 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.

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