

Stone Cone™ Nitinol Urological Retrieval Coil Prescriptive Information

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

Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. DO NOT REUSE, REPROCESS OR RESTERILIZE. Reuse, reprocessing or reesterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or reesterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Intended Use/Indications for Use

The Stone Cone Coil is intended to be used endoscopically to entrap and remove calculi and other foreign objects from the urinary tract.

Contraindications

None known.

Potential Complications

Potential complications generally recognized with the use of stone retrieval devices included, but are not limited to:

- Perforation
- Entrapment
- Evulsion
- Hemorrhage
- Edema
- Stone migration
- Stone impaction

Warnings

1. This device is restricted to use by or under the supervision of a physician trained in urological endoscopic procedures.
2. Exercise care to prevent perforation or trauma of the linings and associated tissue.
3. Some objects may be too large to be removed endoscopically with the stone retrieval coil. Use fluoroscopy or x-ray to determine the size of the stone prior to instrumentation. Do not use the device if the stone is too large to be removed endoscopically. To do so may result in stone impaction and patient injury.
4. Do not attempt to sweep a stone fragment that is too large to be removed through the narrowest lumen of the relevant anatomy.
5. This device must not come in contact with any electrified instrument.
6. Do not directly fire upon the device with a laser.
7. When using in conjunction with a holmium laser, do not set holmium laser energy above .8 Joules or power setting over 8 Watts.
8. If resistance is encountered while attempting to withdraw the coil DO NOT EXERT EXCESSIVE FORCE. To release the object from the device, advance the sheath to straighten the coil and remove the device.
9. Do not rotate the Stone Cone™ Coil clockwise while the device is deployed. To do so may result in entrapment of ancillary equipment (i.e. guidewires, laser fibers, or other foreign objects).

PRECAUTION: Before using, inspect the blister pouch for any breach of the package to ensure a sterile product and inspect product for any damage. If seal has been broken or product is damaged DO NOT USE. Immediately return package and product to Boston Scientific.

PRECAUTION: Refer to the Directions for Use supplied by the manufacturer of the laser fiber.

WARNING: To minimize risk of device breakage or patient injury, do not fire laser directly on any part of the Stone Cone Coil.

WARNING: Do not set holmium laser energy above .8 Joules or power setting over 8 Watts.

WARNING: If resistance is encountered while attempting to withdraw the coil DO NOT EXERT EXCESSIVE FORCE. To release the object from the device, advance the sheath to straighten the coil and remove the device.

WARNING: Do not rotate the Stone Cone Coil clockwise while the device is deployed. To do so may result in entrapment of ancillary equipment (i.e. guidewires, laser fibers, or other foreign objects).