

# INSTRUCTIONS FOR USE



## Flexor Tendon Sheath Retractor and Suture Retriever/Sheath Dilator

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

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### INDICATIONS

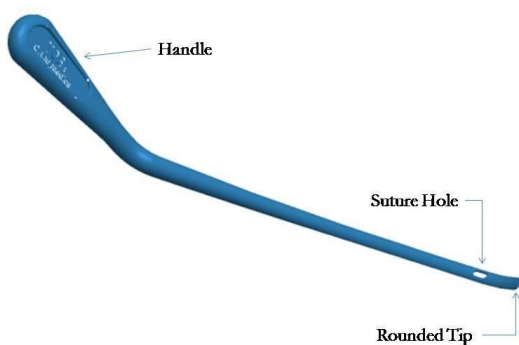
Flexor Tendon Sheath Retractor and Suture Retriever/Sheath Dilator kit is indicated for use in the repair of lacerated digital flexor tendons.

Flexor Tendon Sheath Retractor and Suture Retriever/Sheath Dilator are NOT intended for implantation

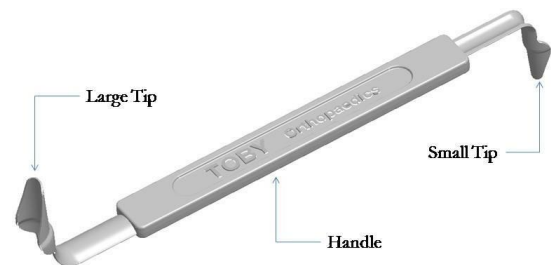
### DESCRIPTION

Flexor Tendon Sheath Retractor and Suture Retriever/Sheath Dilator kit includes one Sheath Retractor with a large and small tip and one Suture Retriever/Sheath Dilator sized to fit inside an empty flexor sheath or between the sheath and its tendon.

### NOMENCLATURE - COMPONENTS



SUTURE RETRIEVER/SHEATH DILATOR

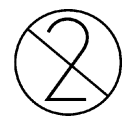


SHEATH RETRACTOR

### STERILIZATION

Flexor Tendon Sheath Retractor and Suture Retriever/Sheath Dilator kit is sterilized for single use only. Do not re-sterilize the tools.

**CAUTION: SINGLE USE ONLY**



### HOW SUPPLIED

The instruments are supplied sterile in a dual-compartment pouch.

### CONTRAINDICATIONS

None are known.

### CLINICAL HISTORY

These instructions are based upon current experience. The physician may wish to vary the procedure in accordance with clinical judgment.

## SHELF LIFE

The instruments have a shelf life of 5 years from the date of manufacture.

## INSTRUMENTS

### Sheath Retractor

1. The Flexor Tendon Sheath Retractor (FUNNEL) is a device made of a transparent polymer for ease of visualization of the surgical process where it is used in the tunneling of severed tendon ends through the tight pulleys of the flexor tendon sheath. The FUNNEL relies on the fact that tendons are relatively compressible, such that their cross-sectional areas can be reduced when they are compressed circumferentially.
2. The FUNNEL includes large 4mm and small 2.5mm members to accommodate most flexor tendon pulleys. The FUNNEL also works as a retractor for the flexor tendon sheath to allow for easy access to the surgical repair site of a lacerated tendon by exposing the tendon substance while retracting the flexor tendon sheath and protecting it from inadvertent suturing or damage.

### Suture Retriever/Sheath Dilator

1. The Suture Retriever/Sheath Dilator (RETRIEVER) is a device made of a flexible thermoplastic material and is designed for the atraumatic retrieval of sutures within the flexor tendon sheath. The tip on the distal end of the shaft is curved slightly upward to facilitate insertion into the tendon sheath. The tip has a concave lower surface and convex upper surface. The tip is tapered in thickness from 0.7mm distally to 3.5mm proximally with a hole in the more distal region, which accommodates the suture. The RETRIEVER has a handle for ease of manipulation.

## APPLICATION OF TOOLS

1. The RETRIEVER is advanced through the empty flexor sheath in a retrograde direction, from the site of the distal flexor stump to the site of the proximal flexor stump.
2. The proximally retracted flexor tendon stump is sutured, leaving the suture ends long

enough for retrieval. (The surgeon may elect to leave the needle attached to the suture)

3. The free ends (with or without the needle) of the suture are passed into the hole on the tip of the RETRIEVER.
4. The RETRIEVER is pulled distally to retrieve the suture (and needle) through the sheath.
5. The FUNNEL is placed at the entrance of the flexor tendon sheath prior to pulling on the free ends of the suture. The suture ends are pulled; the tendon is pulled into the sheath with the FUNNEL in place to ease the tendon into the sheath.
6. To dilate a contracted flexor tendon sheath, the RETRIEVER is advanced through the sheath with a controlled force to dilate the sheath. *Once the RETRIEVER is placed through the tendon sheath, it may be alternatively pulled with a controlled force from the tip to advance the RETRIEVER and dilate the contracted sheath.* The RETRIEVER is left in place for a few minutes to distend the flexor tendon sheath, taking full advantage of the visco-elastic properties of the tissue.

**CAUTION:** • Exercise care to avoid damaging the sheath when using the RETRIEVER as a sheath dilator.

• Do not use if package is damaged



• NOT Intended for Implantation



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