

# INSTRUCTIONS FOR USE

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

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

### **DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY**

*There is no express or implied warranty, including any implied warranty of merchantability or fitness for a particular purpose, on Toby Orthopaedics product(s) described in this publication. Under no circumstances shall Toby Orthopaedics be liable for any direct, incidental, or consequential damages other than as expressly provided by law. No person has the authority to bind Toby Orthopaedics to any representation or warranty except as specifically set forth herein.*

*Descriptions or specifications in Toby Orthopaedics printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express or implied warranties.*

### INTENDED USE

The intended use of the sheath dilator (blue tool) is to enlarge a tendon sheath in a non-traumatic fashion. The intended use of the transparent funnel-sheath retractor is to facilitate the re-sheathing of an enlarged swollen lacerated tendon end back into its sheath.

### 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.

### STERILIZATION

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

### HOW SUPPLIED

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

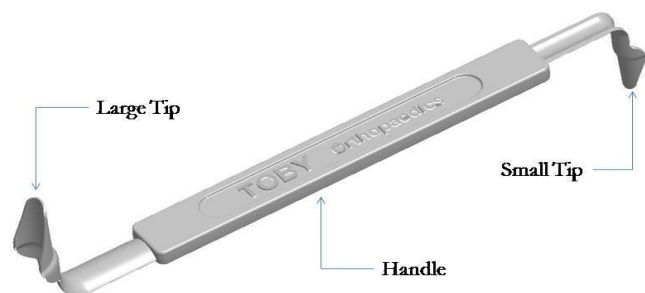
### CONTRAINDICATIONS

None are known.

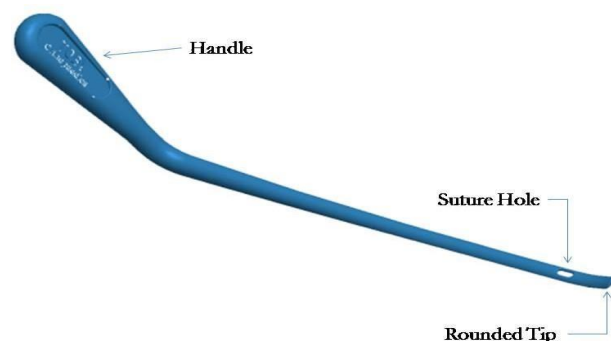
### CLINICAL HISTORY

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

### NOMENCLATURE - COMPONENTS



SHEATH RETRACTOR



SUTURE RETRIEVER/SHEATH DILATOR



## 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. 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 viscoelastic properties of the tissue.

## CAUTIONS:

- **Single Use Only**



- **Do not use if package is damaged.**










- **Keep dry.**











- **Not Intended for Implantation.**
- **Exercise care to avoid damaging the sheath when using the retriever as a sheath dilator.**

**CE 2797**

## Symbols Legend

	Single use
	Medical Device
	Keep dry
	Do not use if package is damaged.
 www.tobyortho.com	eIFU
	Sterile
	Refer to Instructions for Use

	Unique Device Identifier
	Manufacturer
	European Conformity, (CE) Mark
	Date of manufacture
	EU authorized representative
	Lot number
	Reference catalogue number

 Toby Orthopaedics, Inc.  
6355 SW 8th Street, Unit 101  
Miami, FL 33144 USA  
Phone: 305.665.8699  
sales@tobyortho.com

 Atlantico Systems, Ltd.  
34 Oldfield  
Kingston  
Galway  
Ireland