Flexor Tendon Repair Tool Sheath Retractor & Suture Retriever/Sheath Dilator SURGICAL TECHNIQUE GUIDE

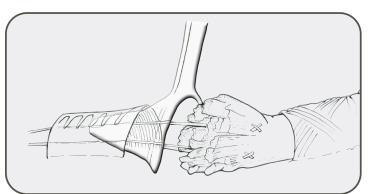


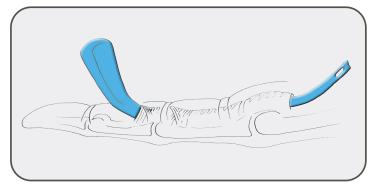


TOBY® FLEXOR TENDON SHEATH RETRACTOR & Suture Retriever/Sheath Dilator FACILITATE YOUR REPAIR WITHOUT DICTATING YOUR METHOD

Retrieve suture

Dilate contracted pulleys





Compress and tunnel the tendon into its pulley

Acting as a funnel shoehorn, the novel transparent retractor allows for smooth passage of the tendon to the repair site.

- Atraumatic tendon placement back into its sheath.
- Minimization of soft tissue trauma.
- Reduced surgical time and frustration.

The versatile suture retriever is designed for smooth passage through the delicate flexor sheath, and can also be used as sheath dilator.

- Easier suture retrieval.
- Dilation of contracted flexor tendon sheath.
- Primary tendon repair in acute and delayed presentation.

INTENDED USE

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

INDICATIONS

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

DESCRIPTION

The 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.

Suture Retriever/Sheath Dilator sized to fit inside an empty flexor sheath or between the sheath and its tendon.

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.

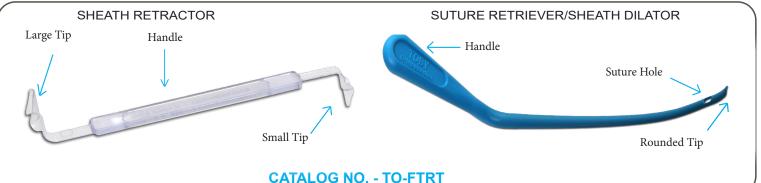
SHELF LIFE

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

CAUTION:

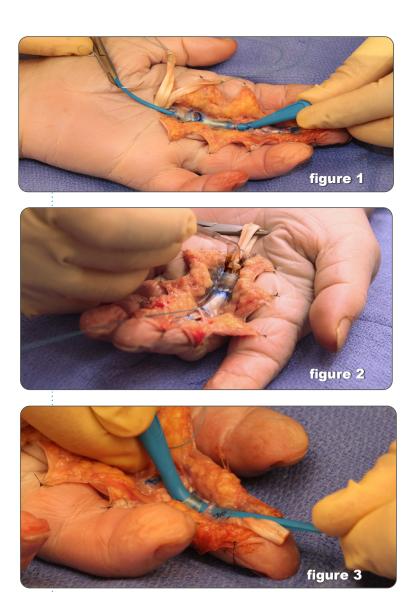
- Single Use Only.
- Not Intended for Implantation.
- Exercise care to avoid damaging the sheath when using the RETRIEVER as a sheath dilator.

NOMENCLATURE - COMPONENTS



APPLICATION OF TOOLS

- 1. The Retriever is advanced throught 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 enought 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 (see figure 1).
- 4. The RETRIEVER is pulled to pass the suture (and needle) throught the sheath.
- 5. The transparent 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 (see figure 2).
- To dilate a contracted flexor tendon sheath, the RE-TRIEVER is advanced throught the sheath with a controlled force, pushing on the handle or pulling from the tip of 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 (see figure 3).





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Federal law restricts this device to sale by or on the order of a Physician.

This surgical technique is intended as an educational tool to assist a properly licensed medical professional in the usage of Toby Orthopaedics products, and is not meant to replace professional judgment as to product usage and technique.

Prior to use, medical professionals should consult the product's Instructions for Use (Doc. 60000001) and rely on their own training and experience.

