

Furlow

Disposable Insertion Tool

REF M00635400020

Rx ONLY

REUSE WARNING

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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.

DEVICE DESCRIPTION

The Furlow Disposable Insertion Tool (Figure 1) is a single-use, sterile surgical tool that is used to facilitate prosthesis cylinder insertion during implant procedures of the BSC Inflatable Penile Prosthesis (IPP), which is used in the treatment of both chronic and organic erectile dysfunction (impotence).

The Furlow Disposable Insertion Tool is used to:

- Guide cylinder advancement from the corporal insertion site distally within the corpora cavernosa to the glans of the penis during the BSC IPP implantation procedure.
- Assist in penile cylinder selection.

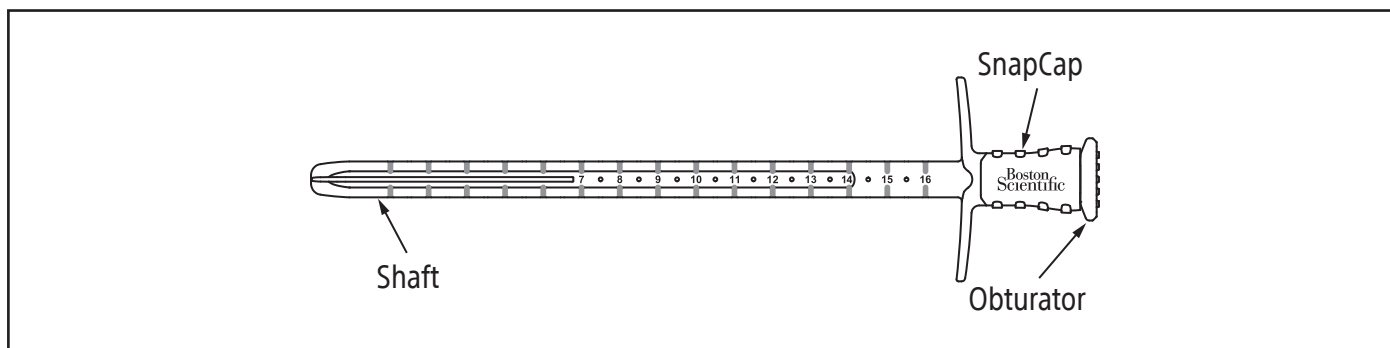


Figure 1. Furlow Disposable Insertion Tool

Contents

(1) One Furlow Disposable Insertion Tool

Operating Principle

The Furlow Disposable Insertion Tool performs the following functions to facilitate the BSC IPP placement procedure:

1. Facilitating IPP cylinder placement: The Furlow Disposable Insertion Tool is used to position and drive the Keith Needle (included with the BSC IPP), which has been previously threaded with traction sutures, through the glans of penis. The traction sutures are then used to assist in distal positioning of the IPP cylinder(s).
2. Sizing aid: External sizing indications on the tool's surface may be used to gauge the insertion depth of the corpora, which may facilitate physician selection of IPP.

Materials

The Furlow Disposable Insertion Tool is constructed of VALOX Resin HX420HP and DOW HDPE DMDA-8920 HEALTH+, which are smooth, biocompatible thermoplastic materials chosen to provide high strength and rigidity.

User Information

This device is to be used only by physicians who are trained in performing IPP surgical procedures. This Instructions for Use is not intended to be a complete reference.

INTENDED USE / INDICATIONS FOR USE

The Furlow Disposable Insertion Tool is a single-use manual surgical instrument intended to facilitate selection of the appropriate BSC IPP cylinder and insertion of the cylinder into the corpora cavernosa.

Clinical Benefit Statement

The Furlow Disposable Insertion Tool facilitates the selection of the appropriate BSC IPP cylinder and the insertion of the cylinder into the corpora cavernosa.

CONTRAINDICATIONS

None known.

WARNINGS

- Do not use this device in a manner which may cause tissue trauma.
- Pre-existing penile or corporal scarring may make surgical use of the device complicated or impractical.
- Failure to evaluate and promptly treat tunical trauma and perforations may result in a substantial worsening of the condition, and may lead to infection and/or loss of tissue.

PRECAUTIONS

- The Furlow Disposable Insertion Tool is provided sterile and intended for single use only. DO NOT RESTERILIZE.
- Do not use beyond the Use By date indicated on the package, which may cause a loss of sterility and increase the risk of infection.
- This device is to be used only by physicians who are knowledgeable regarding implantation of a penile prosthesis. This Instructions for Use is not intended to be a complete reference.
- This device is not designed to be implanted.
- Inspect the package for damage. If the package integrity is compromised, do not use the Furlow Disposable Insertion Tool as sterility may have been compromised.
- Use caution when using this device with other surgical instruments that may damage the tool.

ADVERSE EVENTS

Possible complications include, but may not be limited to:

- Allergic reaction
- Inflammation
- Infection
- Perforation
- Tissue damage
- Bleeding

HOW SUPPLIED

Device Details

The Furlow Disposable Insertion Tool is provided sterile using a e-beam sterilization process.

The device is provided in a tray that is packaged inside a single sterile barrier.

- Do not use if package is damaged or unintentionally opened before use.
- Do not use if labeling is incomplete or illegible.
- Do not use the device if past the Use By date.

Handling and Storage

This product has no special handling or storage requirements.

OPERATIONAL INSTRUCTIONS

Procedure

The Furlow Disposable Insertion Tool is used to assist cylinder advancement from the corporal insertion site distally within the corpora cavernosa to the glans of the penis. Furlow Disposable Insertion Tool needle loading (Figure 2) and needle deployment positions (Figure 3) are indicated by noticeable, tactile detents for positive positioning of the obturator during the needle loading and needle deployment.

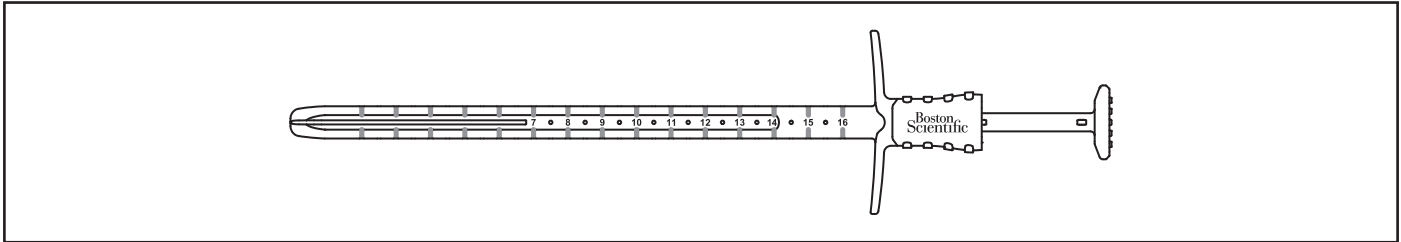


Figure 2. Needle Loading Position

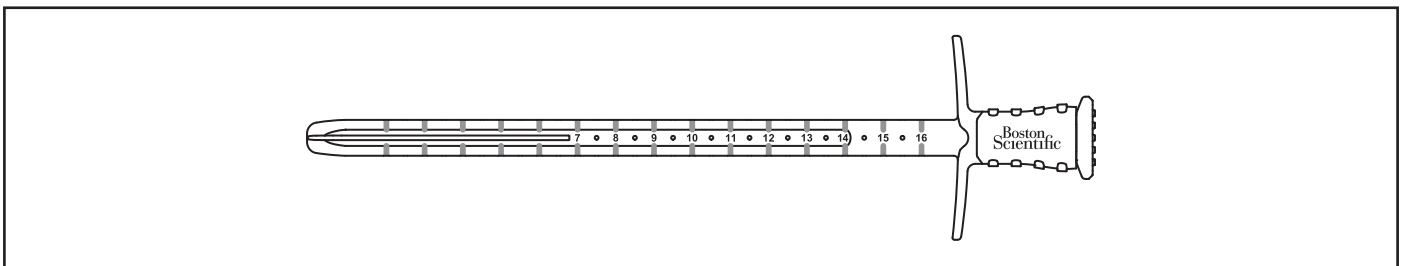


Figure 3. Needle Deployment Position

Needle loading for the obturator corresponds to the position with the obturator fully retracted (Figure 4). During obturator retraction, a first click indicates displacement of the obturator from the fully-deployed position. A second click is felt when the obturator is fully retracted and in the needle loading position.

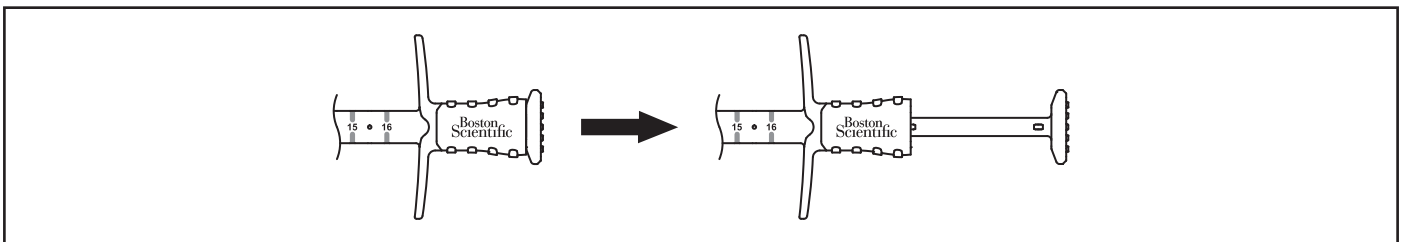


Figure 4. Retracting Obturator for Needle Loading

Note: The obturator cannot be fully removed from the tool assembly.

Once in the needle loading position, the Keith needle (included with the BSC IPP) can be loaded into the Furlow Disposable Insertion Tool. To load the Furlow Disposable Insertion Tool, place the blunt end of the needle into the tool and draw the suture into the tool slot (Figure 5).

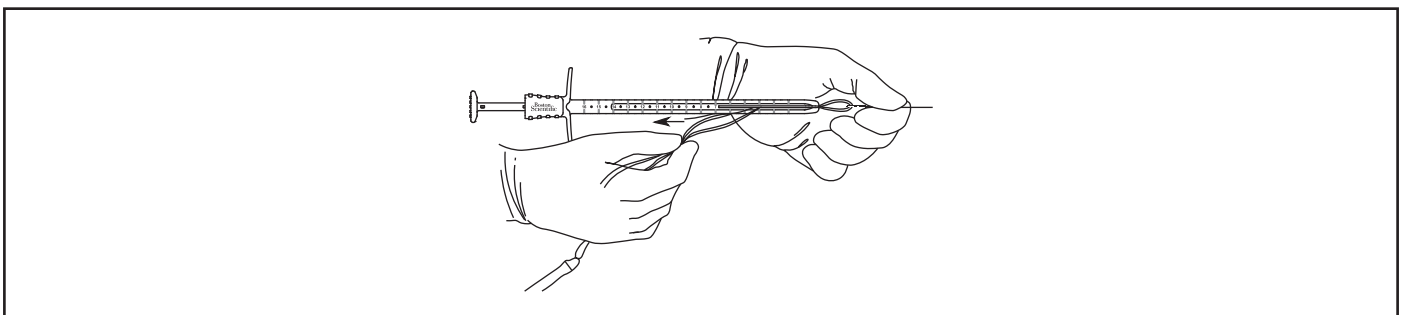


Figure 5. Load Keith Needle

Completely retract the suture into the slot, pulling the needle fully into the barrel of the tool.

Needle deployment for the obturator corresponds to the position with the obturator fully inserted inside the shaft (Figure 6). During needle deployment, a first click indicates displacement of the obturator from the needle loading position. A second click is felt when the obturator is fully displaced to the needle deployment position. The needle deployment position allows for the Keith needle (included with the BSC IPP) to be passed through the glans of the penis.

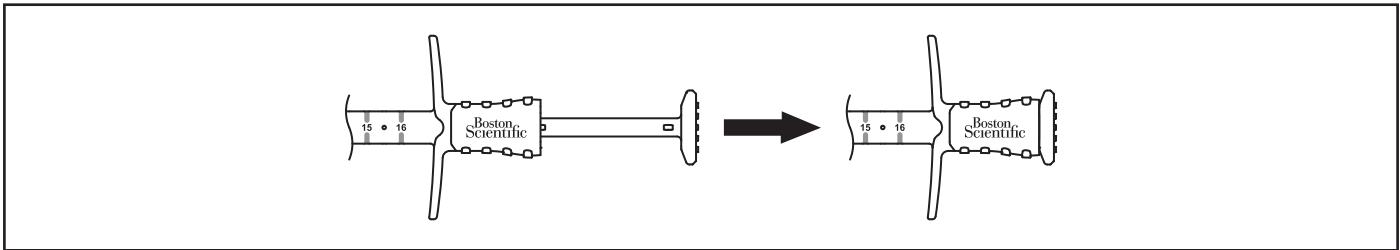


Figure 6. Fully Inserting Obturator for Needle Deployment

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

PATIENT COUNSELING INFORMATION

Prior to use of this device, brief the patient on any contraindications, precautions, adverse events, and post-procedure instructions outlined in this document that are of relevance to the patient.

WARRANTY

For device warranty information, visit (bostonscientific.com/warranty).

VALOX is a trademark of Sabic.

DOW and HDPE DMDA-8920 HEALTH+ are trademarks of Dow.

All other trademarks are the property of their respective owners.

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at bostonscientific.com/SymbolsGlossary.



Contents



Open Here



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