

INSTRUCTIONS FOR USE FOR GORE SUTURE PASSER INSTRUMENT

The GORE Suture Passer Instrument (SPI) is composed of a thumb ring, connecting nut, handle, sleeve, and needle with suture grasper.

The complete device, as well as the assembled needle and sleeve, is supplied **NON-STERILE**, with protective tubing covering needle. The device must be sterilized before use.

INDICATIONS

The GORE SPI is intended for use in the transmural closure of laparoscopic wound sites and laparoscopic fixation of prosthetic materials used in the repair of hernia defects or soft tissue deficiencies. The SPI has applications in abdominal laparoscopy, gynecological laparoscopy, and pelviscopy.

CONTRAINDICATIONS

The GORE SPI or any of its parts are not for implantation.

WARNINGS

Do not bend the needle or sleeve assembly. If the needle/sleeve is bent or damaged, replace with new assembly.

Incomplete needle retraction into the sleeve during use may cause breakage of the needle tip.

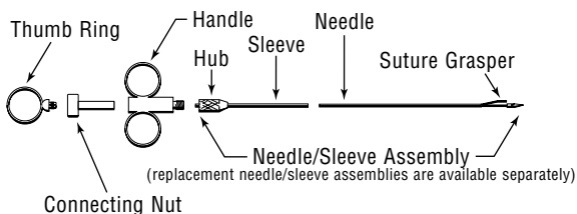
Extreme care should be used during insertion to avoid inadvertent puncture of any internal organs. Procedures should be performed only by qualified and trained physicians familiar with laparoscopic surgical techniques.

Should the needle inadvertently come loose or a portion break, falling into the body cavity, retrieve the part with graspers.

PRECAUTIONS

This is a reusable device, packaged non-sterile, and should be properly cleaned and sterilized prior to each use.

The entire needle/sleeve assembly should be changed periodically when the needle becomes dull or the needle/sleeve assembly is bent or damaged.



METHODS OF USE

1. Ensure the SPI has been sterilized.
2. Inspect the SPI for any damage. **Do not bend the needle or sleeve assembly. If the needle/sleeve is bent or damaged, replace with new assembly.**
3. Ensure both the sleeve and the needle are secure prior to use.
4. Depress the thumb ring to expose the suture grasper on the needle.
5. Place the suture at the distal end of the suture grasper.
6. Pull the thumb ring upward to draw the suture into the sleeve.
7. Insert the SPI into the body cavity. Advance the SPI through the abdominal tissue and into the body cavity under laparoscopic visualization.
8. Depress the thumb ring to release the suture.
9. Grasp and retain the suture with a laparoscopic instrument.
10. Retract the needle completely into the sleeve.

11. Withdraw the SPI, redirect, advance through abdominal tissue and into the body cavity.
12. Depress the thumb ring to expose the suture grasper on the needle, regrasp the suture at the distal end of the suture grasper and pull the thumb ring upward to draw the suture into the sleeve. Withdraw the SPI.
13. Tie the suture.
14. Repeat steps 2-13 for additional suture placement as desired for closure of laparoscopic wound site or fixation of prosthetic materials.

ASSEMBLY OF THE SUTURE PASSER INSTRUMENT

1. Insert needle through sleeve, making sure needle is flush with top of sleeve. Tighten sleeve on handle (**Figure 1**).
2. Insert connecting nut into the handle. Insert end of needle into orifice of thumb ring so that the needle is seated completely in the thumb ring in a vertical, upright position (**Figure 2**).
3. Tighten the connecting nut onto the thumb ring. Extend and retract the needle prior to use (**Figure 3**).

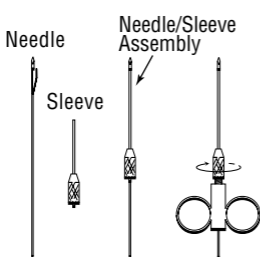


Figure 1

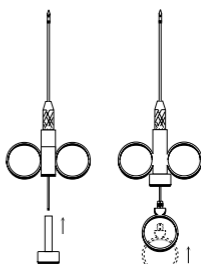


Figure 2

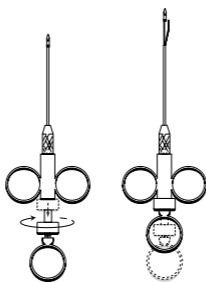


Figure 3

CLEANING METHODS

1. Following each patient use and for routine cleaning, completely disassemble.
2. Soak disassembled parts for a minimum of two minutes in a warm enzymatic solution prior to cleaning.
3. Wash the disassembled parts using a low sudsing detergent with a neutral pH by either mechanical or manual methods. Use a soft brush when doing manual washing.
4. Following washing, rinse thoroughly using tap or distilled water.
5. Thoroughly dry the disassembled parts using mechanical methods or a soft, absorbent, lint-free towel.
6. Assemble device. Place the protective tubing over the needle to avoid inadvertent puncture. Place device in appropriate packaging and sterilize.

NEEDLE/SLEEVE REPLACEMENT

1. Disengage the needle by loosening and removing the connecting nut and thumb ring.
2. Remove the needle/sleeve.
3. Replace with new needle/sleeve.

STERILIZATION METHODS

This is a reusable device, packaged non-sterile, and **must be sterilized prior to each use**. The device must be packaged in materials appropriate for the sterilization method used. Do not sterilize the device in the original packaging materials. Sterility of the repackaged and sterilized product is the responsibility of the health care institution.

Both the device and protective tubing may be sterilized using steam. The device may be sterilized assembled or disassembled.

STEAM

Using a validated gravity displacement steam sterilizer, autoclave at or above these minimum requirements:

250° F (121° C) for 30 minutes

270° F (132° C) for 15 minutes

DEFINITIONS



Attention, See Instructions for Use

REF Catalogue Number



Batch Code



European Authorized Representative



Non-Sterile



Quantity



AB0486-ML3



W. L. Gore & Associates, Inc.

3300 E. Sparrow Avenue
Flagstaff, Arizona 86004
USA

Order Information 800/528-8763
 520/526-3030
Technical Information 800/437-8181
 520/779-2771

EU REP European Authorized
 Representative

W. L. Gore & Associés, S.A.R.L.

Z.I. de St Guénault
4, Rue Jean Mermoz
F-91031 Evry Cédex
FRANCE

Tél.: +33 / 1-60-79-60-79
Fax: +33 / 1-60-77-56-50
Numéro vert: 0800 / 141702



The product contained in this package is covered under one or more of the following patents: U.S. Patent 368,776 and 5,772,672.

MADE IN JAPAN.

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