INSTRUCTIONS FOR USE FOR:

GORE

SUTURE PASSER

- en **English** • GORE Suture Passer Instrument
- bg **Български** • Инструмент за зашиване GORE
- cz **Čeština** • Nástroj GORE pro zavádění šicího vlákna
- dk **Dansk** • GORE suturpasser
- nl **Nederlands** • GORE draadgeleider
- ee **Eesti** • Haavaõmblusniidi paigaldamisvahend GORE
- fi **Suomi** • GORE -ommellangan kuljetusinstrumentti
- fr **Français** • Passeur de suture GORE
- de **Deutsch** • GORE Nahtführungsinstrument
- gr **Ελληνικά** • Εργαλείο διέλευσης ραμμάτων GORE
- hu **Magyar** • GORE varratbehelyező eszközhöz
- it **Italiano** • Strumento passa-suture GORE
- lt **Lietuvių** • GORE siūlo vediklis
- no **Norsk** • GORE sutursetterinstrument
- pl **Polski** • Instrument do przesuwania szwów GORE
- pt **Português** • Passador de fios de sutura GORE
- ro **Română** • Instrument port-ac de sutură GORE
- sk **Slovenčina** • Nástroja GORE Suture Passer
- es **Español** • Pasador de suturas GORE
- se **Svenska** • GORE suturpasserinstrument

INSTRUCTIONS FOR USE FOR

GORE Suture Passer Instrument

The GORE Suture Passer Instrument is composed of a thumb ring, connecting nut, handle, sleeve, and needle with suture grasper. The GORE Suture Passer Instrument is composed of titanium alloys, stainless steel, and polymeric materials.

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 Suture Passer Instrument 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 GORE Suture Passer Instrument has applications in abdominal laparoscopy, gynecological laparoscopy, and pelviscopy.

CONTRAINDICATIONS

The GORE Suture Passer Instrument 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.

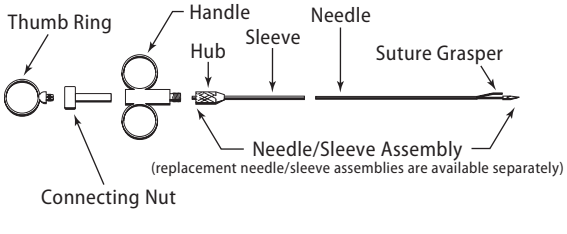
Extreme care should be used during insertion to avoid inadvertent puncture of any internal organs. Procedures should be performed only by qualified and trained physicians familiar with laparoscopic surgical techniques.

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 GORE Suture Passer Instrument has been sterilized
2. Inspect the GORE Suture Passer Instrument 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 GORE Suture Passer Instrument into the body cavity. Advance the GORE Suture Passer Instrument 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 GORE Suture Passer Instrument, 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 GORE Suture Passer Instrument.
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 hub of needle/sleeve assembly onto 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)**.

NEEDLE/SLEEVE REPLACEMENT

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

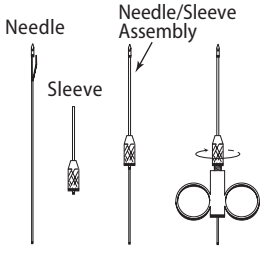


Figure 1

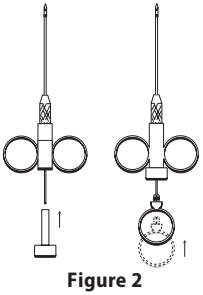


Figure 2

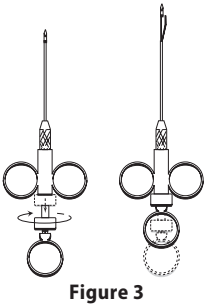


Figure 3

DISCLAIMER

W.L. Gore & Associates, Inc. has validated the cleaning and sterilization methods and cycles described below. This device is supplied non-sterile and health care personnel are ultimately responsible for ensuring that cleaning and sterilization conditions can be obtained in their own facilities. W.L. Gore & Associates, Inc. does not accept responsibility or liability from a lack of cleanliness or sterility of any device that should have been cleaned and sterilized by the end user.

WARNINGS	The GORE Suture Passer Instrument contains a needle that is extremely sharp. Handle the device carefully to avoid accidental puncture. Do not use high acidic (pH< 4) or high alkaline (pH>10) products for disinfection or cleaning since these can corrode metal and cause discoloration. Disassembly of the device is required to achieve adequate cleaning and decontamination.
Limitations on reprocessing	Repeated cleaning, decontamination, and sterilization has minimal effect on the GORE Suture Passer Instrument. End of life is normally determined by wear and damage due to use. The needle will dull after repeated use. Replacement needles and sleeve assemblies are available.
Safety precautions	Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated devices (Reference ANSI/AAMI ST79).
Point of use:	Prior to any transportation, place device in a puncture resistant container. It is recommended the GORE Suture Passer Instrument be kept moist and do not allow blood and/or bodily fluids to dry on the instrument.

CLEANING METHODS

Preparation for cleaning:	Disassemble the device by reversing the assembly instructions above. Ensure the protective sleeve is removed from the needle.
Cleaning: Automated	**Pre-Cleaning** 1. Remove gross contaminates by immersing the device parts in warm temperature (95°F [35°C] or below) pH neutral proteolytic enzymatic detergent solution for five minutes and then scrub cannulas, mating surfaces, and crevices with brushes where possible. 2. Rinse with warm potable water (95°F [35°C] or below) **Automatic Washing Cycle** Equipment – Washer/disinfector Detergent – pH neutral proteolytic enzymatic detergent and pH neutral Non-enzymatic detergent. Follow washer/disinfector manufacturer's instructions. 1. Load the GORE Suture Passer Instrument parts into the washer such that all the features are accessible to cleaning and liquids are able to drain. Secure instrument/parts into place. 2. Run automatic cycle with the following minimum cycle parameters (temperatures to be based on chosen enzyme and detergent manufacturer's recommendations). • Two minute potable water prewash < 113°F (45°C) • Five minute Enzyme treatment at 100°F to 140°F (38°C to 60°C) • Two minute detergent wash at 140°F to 167°F (60°C to 75°C) • One minute hot potable water rinse 113°F (45°C) minimum • Ten second hot purified water (RO, DI, or distilled) rinse 140°F (60°C) minimum • Ten minute air dry at 240° (116°C)
Cleaning: Manual	Equipment: ultrasonic cleaner, neutral proteolytic enzymatic detergent , soft brush, tap water, purified water. 1. Immerse the device parts in pH neutral enzymatic detergent solution (< 95°F [35°C]) for five minutes. Follow manufacturer instructions for detergent solution. 2. Scrub surfaces, cannulas, mating surfaces, and crevices several times with brushes. 3. One minute warm potable water rinse < 113° F (45° C). 4. Sonicate for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent solution compatible with ultrasonic cleaners. Follow detergent manufacturer's instructions. 5. Rinse thoroughly with warm potable water < 113°F (45°C) for two minutes 6. Check GORE Suture Passer Instrument for visible soil. Repeat cleaning if necessary. 7. Final rinse with purified water (RO, DI, or distilled) for one minute.

Drying	Dry the device using a clean lint-free cloth and/or pressurized air. Instruments need to be thoroughly dried prior to storage.
Inspection	If visible soil remains, repeat the cleaning steps above. Inspect GORE Suture Passer Instrument parts for any visible damage, nicks, scratches, etc. Replace any damaged or worn parts (needle and sleeve assemblies are available for replacement).

STERILIZATION METHODS

This is a reusable device, packaged non-sterile, and must be sterilized prior to each use. Sterilization is the responsibility of the health care institution.

Preparation for Sterilization	The device may be sterilized assembled or disassembled, with or without the protective sleeve on the needle. A standard sterilization wrap/packaging material may be used per manufacturer's instructions. Do not sterilize the device in the original packaging materials.
Sterilization: Gravity	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 Dry for 30 minutes
Sterilization: Dynamic air removal (Pre-Vacuum)	Using a validated pre-vacuum steam sterilizer, autoclave at or above these minimum requirements 270°F (132°C) for 5 minutes 273°F (134°C) for 3 minutes Vacuum dry for 30 minutes
Storage	Follow protective sterilization wrap / packaging manufacturer's instruction for storage. The end user is responsible for ensuring the sterility of the device.

DEFINITIONS


Caution


Consult Instructions for Use

REF Catalogue Number

LOT Batch Code

EC REP European Authorized Representative

QTY Quantity


Non-Sterile


Manufacturer

℞ Only CAUTION: USA Federal Law restricts the sale, distribution,or use of this device to, by, or on the order of a physician.

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GORE
Creative Technologies Worldwide

Manufacturer

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