

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed Suture Passer


Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **STERILE**

Explanation of Icons


 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

 Product Code

 Do Not Reuse

 See Instructions For Use

Suture Passer Description

A "Suture Passer" is actually a set of three devices: one Carter-Thomason suture passer, one 5mm suture passer guide, and one 10-12mm suture passer guide. The Carter-Thomason suture passer is a ring-handled suture-grasping device that is intended to pass suture through soft tissue.

Indications for Use

Reprocessed Suture Passers are intended to pass sutures through soft tissue during endoscopic/laparoscopic surgery.

Warnings

- Package is provided sterile by method of ethylene oxide gas and is for single patient use only. Do not use if there is any evidence of damage to the package.
- Prior to use, read and follow the instructions of this insert as well as those of the instruments to be used during the procedure.
- Minimally invasive surgery should only be performed by qualified physicians trained in the techniques of the procedures. A thorough understanding of endoscopic/laparoscopic principles and techniques is required in order to minimize the risk of patient injury.
- The suture passer jaws can injure internal tissues. Do not use the suture passer in procedures where the position of the needle tip cannot be clearly ascertained.
- The suture passer jaws must be closed completely in order to form a needlepoint for insertion through tissue. Insertion through tissue without pressure on the plunger ring may cause the jaws to open, resulting in loss of the suture or inadvertent tissue capture.
- The suture passer tip can injure personnel if contacted by the pointed end of the jaws. The suture passer tip should be protected at all times when the suture passer is not in use.

Precautions

- Store instrument in a cool dry place.
- Use sterile techniques to remove the suture passer from its package and place on sterile surface. Replace the device if it is dropped outside of the sterile field.
- Ensure that the correct size suture passer guide is used for the trocar incision. Use of the incorrect size suture passer guide could compromise performance of the suture passer device.
- Do not hit the jaws of the suture passer on the suture passer guide when inserting the suture passer, as damage to the jaws may result.

Adverse Reactions

None.

Directions for Use

The package label is detachable and may be affixed to the medical record of the patient.

Suture Passer:

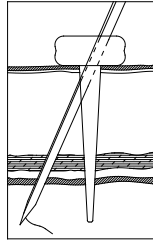
The suture passer has two operating positions: jaws open and jaws closed.

1. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
2. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument was not used, return the instrument and package to Stryker Sustainability Solutions.
3. Do not attempt to resterilize.
4. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted. Return the instrument and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for surgery.
5. To open the needlepoint tip, pull back on the plunger ring.
6. Lay suture in the jaw opening nearest the hinge.
7. Close the jaws over the suture by releasing the plunger ring. This forms a needlepoint tip.
8. Push the needlepoint tip (holding the suture) through the target tissue by pushing distally on the handle while maintaining a slight pressure on the plunger ring to keep the tip closed.
9. When desired, open the jaw to release the suture.
10. Close the jaw and remove the suture passer.
11. Reinsert the suture passer near the first entry point.
12. Repeat steps 1-3 to retrieve the suture and complete the stitch.

Trocar Wound Closure Surgical Technique

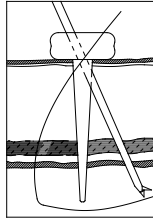
Step 1:

- Insert the suture passer guide with the holes aligned cephalad to caudad.
- Use the Carter-Thomason suture passer to push suture material through the Suture passer guide, fascia, muscle, and peritoneum into the abdomen.
- Drop the suture, and remove the suture passer.



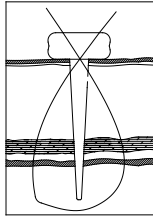
Step 2:

- Push the suture passer through the opposite side of the Suture passer guide, and pick up the suture.



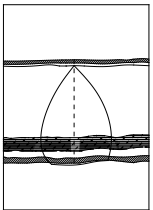
Step 3:

- Pull the suture up through the peritoneum, muscle, fascia, and guide.



Step 4:

- Remove the Suture passer guide and tie.



Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.