

Reprocessed by



## 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


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 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

**REF** Ascent 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:***

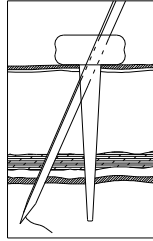
The suture passer has two operating positions: jaws open and jaws closed.

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 Ascent Healthcare 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 Ascent Healthcare 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**

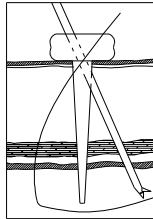
**Step 1:**

- 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.



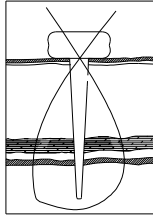
**Step 2:**

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



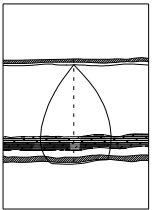
**Step 3:**

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



**Step 4:**

- Remove the Suture passer guide and tie.



**Warranty**

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. 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.