

**REF 75926**

Carter-Thomason CloseSure System®

**REF 733776**

Carter-Thomason CloseSure System XL®



Instructions for Use (English)

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## DEVICE DESCRIPTION

The **Carter-Thomason CloseSure System®** is available in two configurations consisting of the following components:

**[REF] 75926:**

- one (1) Carter-Thomason® Suture Passer (CTSP)
- one (1) 5 mm Pilot® Guide
- one (1) 10/12 mm Pilot Guide

**[REF] 733776:**

The **Carter-Thomason CloseSure System XL®** consists of the following components:

- one (1) elongated CTSP
- one (1) elongated 10/12 mm Pilot Guide
- one (1) elongated 15 mm Pilot Guide

The CTSP is a sterile, single-case use, hand-held suture grasping device that is designed to pass suture through soft tissue.

**CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.

## INDICATION FOR USE

The CTSP is intended to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery. It is to be used only by surgeons trained in endoscopic/laparoscopic surgery.

## PRECAUTIONS

- A surgeon should not begin clinical use of the CTSP without a full understanding of the directions for use.
- The CTSP is not recommended for use in surgical procedures where the position of the needle tip cannot be clearly determined.
- The jaws of the instrument must be closed completely in order to form a needle point to pass suture through tissue. Passage of the CTSP through tissue without pressure on the thumb ring may result in losing grasp of the suture or the inadvertent capture of tissue.
- The suture passer jaws can injure internal tissues and/or any personnel in contact with the pointed end of the instrument. The suture passer jaw should be protected at all times with the protective cap when the instrument is not in use.

## CARTER-THOMASON SUTURE PASSER INSTRUCTIONS FOR USE

The suture passer has two operating positions: Jaws Open and Jaws Closed (see illustrations).

1. To suture, open the needle point tip to grasp suture by pulling back on the thumb ring. We recommend the use of Vicryl Size 0 braided Sutures. (CSI approved suture material via validations)
2. Place suture in the jaw depression opening nearest the hinge point.
3. Close the jaws around the suture by releasing the thumb ring, thus forming a needle point.
4. Pass the needle point with the suture through tissue by pushing distally on the handle while maintaining a gentle pressure on the thumb ring to keep the needle tip closed.
5. Open the jaw to drop the suture.
6. Close the jaw and remove the suture passer.
7. With the jaws closed, reinsert the suture passer in proximity to the first entry point.
8. Open jaws to retrieve suture by pulling back on thumb ring.
9. Close jaws by releasing the thumb ring to form a needle tip.
10. While removing the suture passer (suture in place) maintain gentle pressure on the thumb ring.

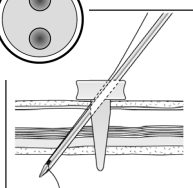


**TROCAR WOUND CLOSURE SURGICAL TECHNIQUE**

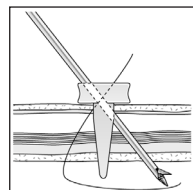


**Step 1**

Insert Pilot® Guide into trocar wound with holes aligned perpendicular to the trocar wound.

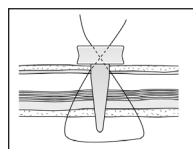


With the jaws in the closed position push suture through Pilot Guide, fascia, muscle, peritoneum and into the abdomen. Drop suture and remove suture passer.



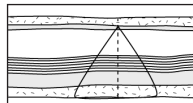
**Step 2**

With the jaws in the closed position push suture passer through opposite side of Pilot Guide. Pick up suture.



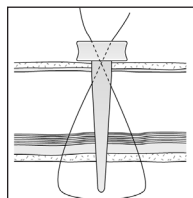
**Step 3**

Pull the suture up through the peritoneum, muscle, fascia, & Pilot Guide.

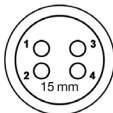


**Step 4**

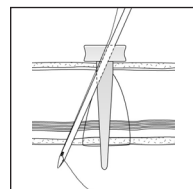
Remove Pilot Guide. Tie suture to complete the closure.



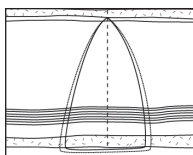
**If using the 15 mm Pilot Guide,** position the guide with holes 1 and 2 aligned perpendicular to the trocar wound.



Perform Steps 1-3 using the holes labeled 1 and 2.



With another piece of suture, repeat Steps 1-3 using holes labeled 3 and 4.



Remove Pilot Guide. Tie each suture to complete the closure.

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### EXPLANATION OF SYMBOLS



Catalogue Number



Distributor



Batch Code



Do not use if package is damaged



Use-by date



Sterilized Using ethylene oxide



Caution



Do not re-use



Do not resterilize



Consult instructions for use



Not made with natural rubber latex

[www.coopersurgical.com/ifu](http://www.coopersurgical.com/ifu)



Manufacturer



Medical Device

**R<sub>x</sub>Only**

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

This product is protected under one or more of the following U.S. Patents: 5,899,911 • 6,183,485

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 **regard.**

CooperSurgical®



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