

REF 351277

Carter-Thomason® SG with SureGrasp™ Technology

Instructions for Use (English)



DEVICE DESCRIPTION

The Carter-Thomason® SG with SureGrasp™ Technology is available in one configuration consisting of the following components:

CTI-1015SG:

- one (1) Carter-Thomason SureGrasp Suture Passer (SGSP)
- one (1) 10/12 mm Pilot® Guide
- one (1) 15 mm Pilot Guide

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

The Pilot Guide is a single use device that is designed to work with the SGSP for placement of the suture through soft tissue.

CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Dispose of in accordance with all applicable Federal, State, and local Medical / Hazardous waste practices.

INDICATION FOR USE

The SGSP 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 SGSP without a full understanding of the directions for use.
- The SGSP is not recommended for use in surgical procedures where the position of the needle tip cannot be clearly determined.
- The grasping fingers of the instrument must be closed completely in order to form a needle point to pass suture through tissue. Release button on the SGSP to draw suture completely into mechanism.
- The SGSP needle point can injure internal tissues and/or any personnel in contact with the pointed end of the instrument. The SGSP needle point should be protected at all times with the protective cap when the instrument is not in use.

CARTER-THOMASON SUREGRASP™ SUTURE PASSER INSTRUCTIONS FOR USE

The SGSP has two operating positions: Fingers Open and Fingers Closed (see illustrations).

1. To suture, open the finger grasping mechanism by pressing on the plunger on the handle of the guide. We recommend the use of Vicryl Size 0 braided sutures (CSI approved suture material via validations).
2. Place suture in the finger mechanism.
3. Close the grasping fingers by releasing the plunger.
4. Pass the needle point with the suture through tissue by pushing distally on the handle.
5. Open the grasping fingers to drop the suture by pressing on the plunger.
6. Close the grasping fingers by releasing the plunger and remove the SGSP.
7. With the grasping fingers in the closed position, reinsert the SGSP in proximity to the first entry point.
8. Open the grasping fingers to retrieve suture by pressing on the plunger on the passer handle and grasp the suture.
9. Close the grasping fingers by releasing the plunger.
10. Remove the SGSP with the suture in place.

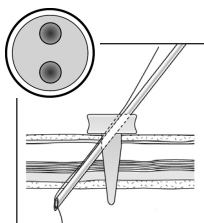


Grasping Fingers Open



Grasping Fingers Closed

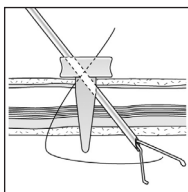
TROCAR WOUND CLOSURE SURGICAL TECHNIQUE



Step 1

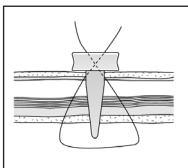
Insert Pilot® Guide into trocar wound with holes aligned perpendicular to the trocar wound.

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



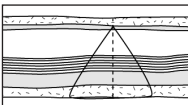
Step 2

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



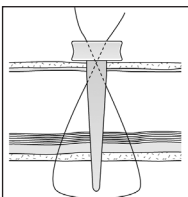
Step 3

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

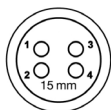


Step 4

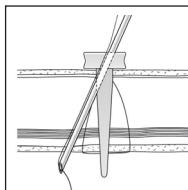
Remove Pilot Guide. Tie suture to complete the closure.



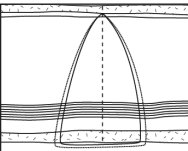
If using the 15 mm Pilot Guide, position the guide with holes 1 and 2 (using image below as a guide) aligned perpendicular to the trocar wound.



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



Reorder Number



Batch Code



Use-by date



Sterilized Using Ethylene Oxide.
Contents sterile unless package
has been opened or damaged.
Do not use if sterile barrier has
been breached.



Do not re-use due to risk
of septicemia



Do not use if package is
damaged



Consult instructions
for use

www.coopersurgical.com/ifu



Manufacturer



Not made with natural
rubber latex.



Do not resterilize



Caution

R_xOnly

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

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Patents: 5,899,911; 6,183,485

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Made in the USA



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