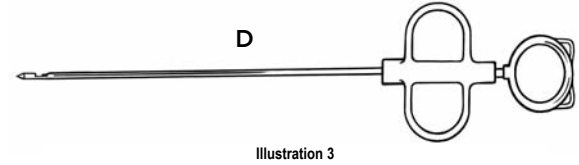
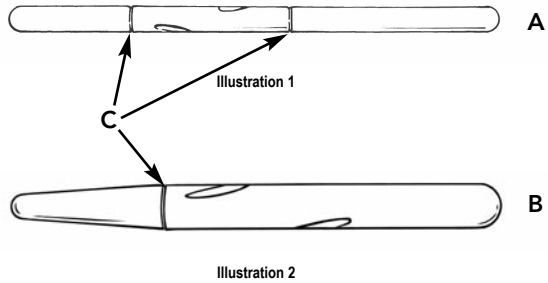




Lap Assist™ DCS

INSTRUCTIONS FOR USE.....3

LapAssist™ DCS



A
Guide Rod

B
Dilating Guide Rod

C
Circular Groove

D
Suture Passer

E
Trocar



Figure 1

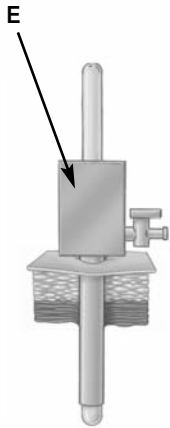


Figure 2

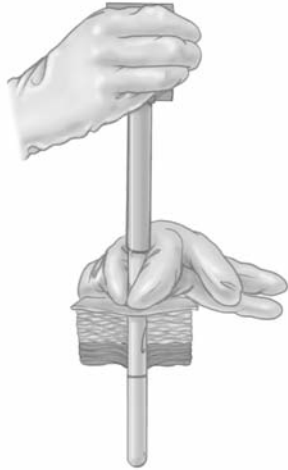


Figure 3



Figure 4

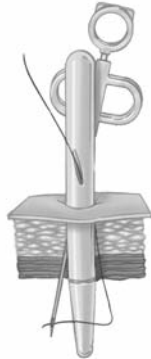


Figure 5



Figure 6

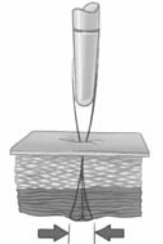


Figure 7

SYMBOL DEFINITIONS:



Do not re-use



Consult *Instructions for Use*.

STERILE EO

Sterilized using ethylene oxide.

MADE IN THE U.S.A.

CONTENT



Peel

REF

Catalog number



Use by date

LOT

Lot number



Manufacturer

PN SSI part number. TN SSI tracking number. IC SSI internal code. ID SSI internal code.

DESCRIPTION:

The LapAssist™ DCS (Dilating and Closure System) is a device for trocar wound dilation and closure. The device is sterile, single use and consists of one guide rod with guide holes (Illustration 1) or one dilating guide rod with guide holes (Illustration 2) and one suture passer instrument (Illustration 3)

that are designed to be used as a system. The guide rod or dilating guide rod/suture passer (GR/SP) is a manually operated device designed to maintain pneumoperitoneum, dilate trocar wounds and carry suture through soft tissue to effectively close large operating ports.

INDICATIONS FOR USE:

To dilate and close soft tissue layers (fascia, muscle and peritoneum) of a trocar wound during laparoscopic surgery.

WARNINGS:

This product is intended for single use only and cannot be re-sterilized after use.

CAUTIONS:

A surgeon should not use the GR/SP devices without a full understanding of the instructions for use.

This product is designed to be used as a system.

The GR/SP devices are not recommended for use in surgical procedures where the position of the needle tip cannot be clearly determined.

Passage of the GR/SP devices through soft tissue without pressure on the thumb ring plunger may result in losing grasp of the suture or undesirable capture of tissue layers.

The needle tip of the suture passer can injure internal tissues and/or any personnel in contact with the needle tip end of the instrument. The needle tip should be protected at all times when the instrument is not in use.

PRODUCT SPECIFICATIONS:

The dilation and closure system and its accessories are supplied sterile. Do not use if the package is opened or damaged as sterility may be compromised.

INSTRUCTIONS FOR USE:

Insertion

1. Select appropriate size guide rod to accommodate trocar port size.
2. Insert guide rod or dilating guide rod.
 - a. Guide rod and dilating guide rod can be inserted directly into trocar wound. (See Figure 1)

b. Guide rod can also be inserted through the trocar. (See Figure 2) Insert guide rod through the trocar until flush with top of trocar. Begin to remove trocar from wound, when guide rod becomes visible hold guide rod in place and complete trocar removal. (See Figure 3)

3. Position guide rod until circular groove reaches level of peritoneum.

Suture Placement

4. Grasp suture with suture passer by depressing plunger.

5. While depressing plunger, insert suture passer with suture through hole in guide rod. (See Figure 4)

6. Observe entrance into abdominal cavity to avoid injury to surrounding structures.

7. Release plunger to release suture.

8. Remove suture passer.

9. Re-insert suture passer through opposite guide hole being careful not to rotate guide rod. (See Figure 5)

Figure 5)

10. Place suture into suture passer and hold suture by depressing plunger.

11. Remove suture passer with suture attached. (See Figure 6)

Removal

12. Remove guide rod. (See Figure 7)

13. Apply tension to suture and press wound to assure full closure of wound.

14. Observe wound from inside to assure closure and hemostasis.

Closure

15. Tie suture.

16. Check wound to confirm proper fascia closure.

DISCLAIMER OF WARRANTIES:

Synovis Surgical Innovations (SSI), a division of Synovis Life Technologies, Inc., warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written, or oral, including, but not limited to, any implied warranties of merchantability or fitness. As a result of biological differences in individuals, no

product is 100% effective under all circumstances. Because of this fact and since SSI has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after it leaves its possession, SSI does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. SSI will replace any device, which is defective at the time of shipment. No representative of SSI may change any of the foregoing or assume any additional liability or responsibility in connection with this device.



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