

Figure 4

7. Disconnect the loading cartridge and withdraw the blunt cannula over the wire guide to expose the suture ends. Discard the cartridge and cannula.

Remove the 18 gage introducer needle over the wire guide and expose suture ends, maintaining slight tension on the suture to prevent bunching.

NOTE: Normally, the sutures are left in place for two weeks to enable the tract to mature. (Figure 4)

8. With the wire guide still in position, apply light traction to the sutures by attaching hemostats to secure the anterior wall of the hollow viscus against the abdominal wall.
9. The wire guide may now be used to facilitate passage of fascial dilators and introduction of a procedural catheter.
10. While maintaining traction on the suture anchors, wrap the ends of the suture around 2x2 gauze rolls and secure in place. Apply a standard wound dressing around the insertion site.

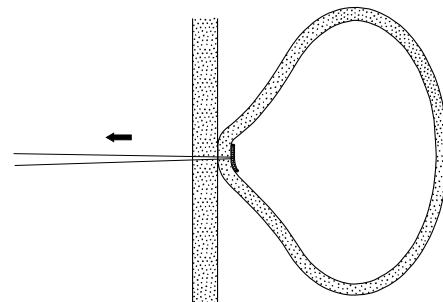
NOTE: The suture anchors may be left in place for two weeks while tract formation occurs. Cutting the suture end at the skin level releases the anchors into the organ allowing its passage via the gastrointestinal system.

ACKNOWLEDGEMENT

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Enterostomy Suture Anchor Set

Suggested Instructions for Use



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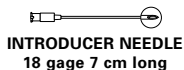
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These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care.

ENTEROSTOMY SUTURE ANCHOR SET

ORDER NUMBER: GIAS-100-CHAIT



INTRODUCER NEEDLE
18 gage 7 cm long

AMPLATZ ULTRA STIFF WIRE GUIDE
TFE coated .035 inch (0.89 mm) 80 cm long



LOADING CARTRIDGE CONTAINING SUTURE ANCHORS
(2 each)



COONS DILATOR
8.0 French appropriate length

INTENDED USE

Used for anchoring the wall of a hollow viscus to the abdominal wall prior to introduction of interventional catheters. Supplied sterile in peel-open packages. Intended for one-time use.

SUGGESTED INSTRUCTIONS FOR USE OF THE ENTEROSTOMY SUTURE ANCHOR SET

1. Insufflate the hollow viscus with air through a nasogastric tube or enema balloon catheter. Use of glucagon to control bowel peristalsis is recommended.
2. **NOTE: Ultrasound is useful in determining anatomic structures before needle introduction. For gastrostomy, it is important to identify the liver, spleen, and gallbladder before introduction. For cecostomy, identify the gallbladder and urinary bladder before initial puncture.**
3. Localize the puncture site and administer local anesthesia with a 27 gage needle into the subcutaneous tissue and down to the peritoneum using fluoroscopic control. Attach a Luer slip 10 cc syringe, half filled with (full strength) 300 mg/ml concentration contrast medium, to the 18 gage introducer needle. Make a small incision with a #11 blade at the entry site.

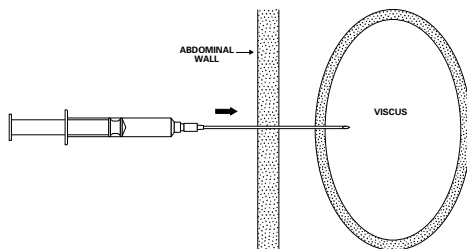


Figure 1

4. Advance the introducer needle through the anterior abdominal wall and then, under fluoroscopic guidance, rapidly thrust the needle another 2 to 3 cm into the air-filled hollow viscus.

NOTE: Air should be freely aspirated. Injection of contrast medium under fluoroscopy must be performed to ensure proper needle position. (Figure 1)

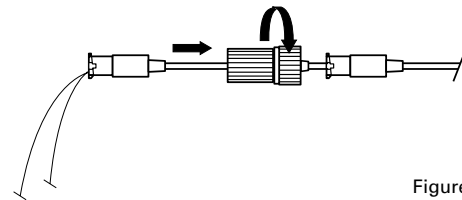


Figure 2

5. Remove the 10 cc syringe from the needle hub. Introduce the metal end of the loading cartridge containing the two suture anchors into the base of the 18 gage introducer needle and Luer lock into place.

NOTE: Make sure the cannula tip of the loading cartridge is seated within the hub of the introducer needle to prevent suture anchors from jamming. (Figure 2)

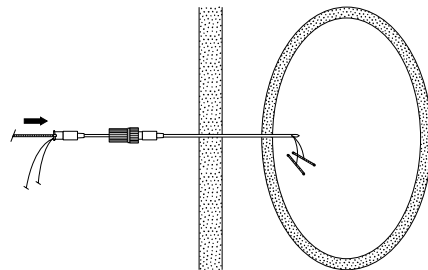


Figure 3

6. Advance the distal tip of the Amplatz Ultra Stiff Wire Guide, then push the two anchors out of the loading cartridge and through the 18 gage introducer needle into the hollow viscus cavity. (Figure 3)

Confirm the suture anchors are within the hollow viscus.

Continued