

Bard® CruraSoft™ Patch Technique Guide

Bard® CruraSoft™ Patch

Tension-free repair technique for the hiatal crura

PRODUCT OFFERING


Catalog No.	Description	Quantity	Size
0116001	Small Patch	1/cs	7cm x 6cm (2.8" x 2.4")
0116003	Large Patch	1/cs	11cm x 8cm (4.3" x 3.1")



Davol Inc.
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Specifically designed for use during laparoscopic fundoplications and paraesophageal hernia procedures.

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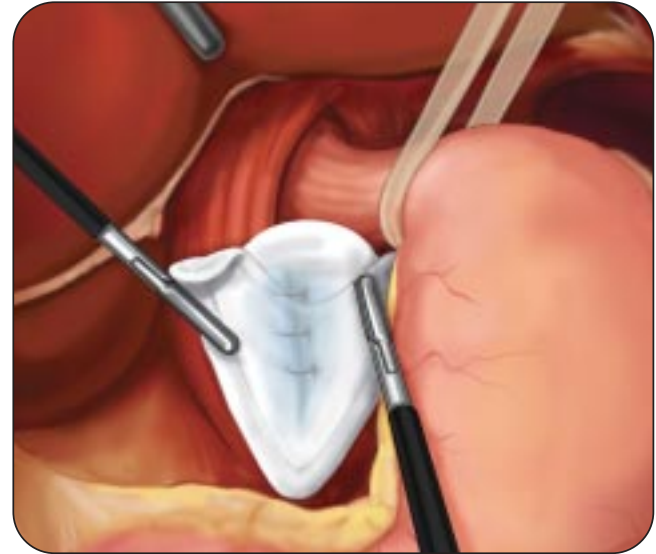
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Ref.# MMCSPTG



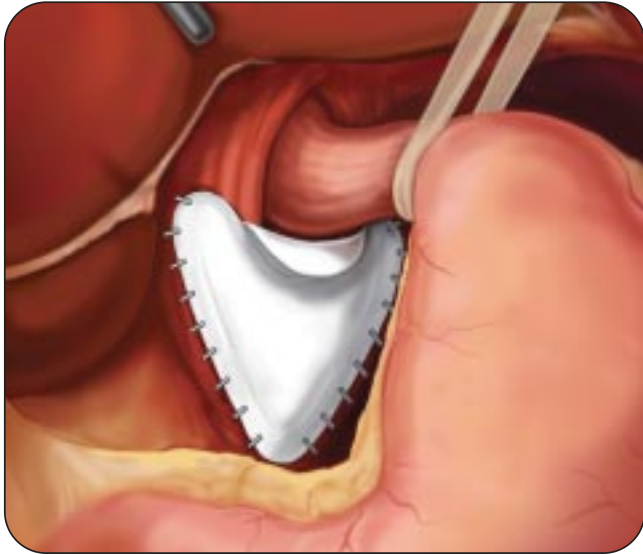
Benefits of the CruraSoft Patch:

- ePTFE minimizes tissue ingrowth and adhesions to the prosthesis.
- PTFE mesh encourages tissue ingrowth to repair the defect.
- Tension-free repair technique eliminates need to reapproximate crura.
- ePTFE flap creates a cradle for the esophagus to protect against adhesion to the prosthesis.
- Soft and flexible patch is designed to fit the anatomy.



7. Reinforcement/Buttress Surgical Technique.

For use of the patch as reinforcement of the conventional crural closure, the crus is closed with sutures after proper bougie sizing. The mesh is then placed in position with the mesh side against the crura and diaphragm. Ensure that the patch extends beyond the margins of the defect. Position the shelf and secure the patch as described in steps 4-6.

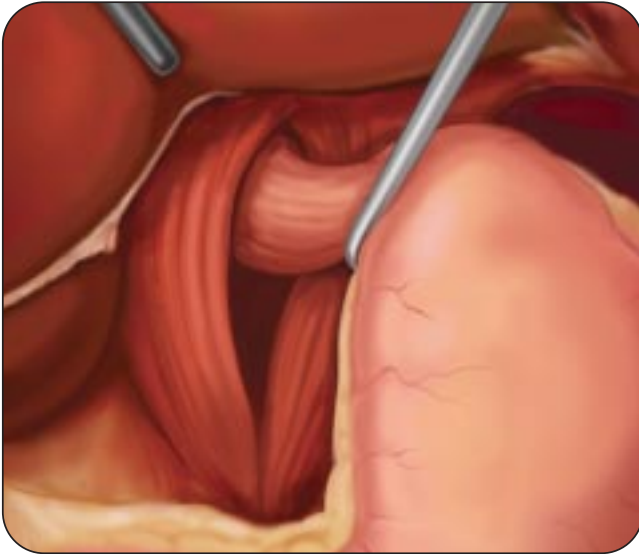


6b. The Bard CruraSoft Patch with fixation complete.



In response to the growing interest in the use of mesh for treatment of crural/hiatal defects, the CruraSoft™ Patch is the latest innovation in a broad line of market-leading Davol soft tissue repair products. The CruraSoft Patch is designed for use in a tension-free repair technique to repair esophageal hiatal defects during laparoscopic funduplications and para-esophageal hernia repairs. The patch can also be used to reinforce or buttress the hiatal hernia that has been closed primarily with sutures.

STEPS OF THE PROCEDURE



1. The esophagus and the stomach are mobilized, and the hiatus is dissected in the standard fashion.

Special thanks to:

Paul vonRyll Gryska, MD FACS • Department of Surgery
Newton-Wellesley Hospital • Newton, MA



- 6a. An appropriate sized bougie is placed in the esophagus per the standard fundoplication procedure. The bougie must properly size the hiatal defect prior to final fixation of the mesh. Once the defect is sized, then secure the right crus. When the patch is fixated, the procedure can continue as it would in the normal fashion.

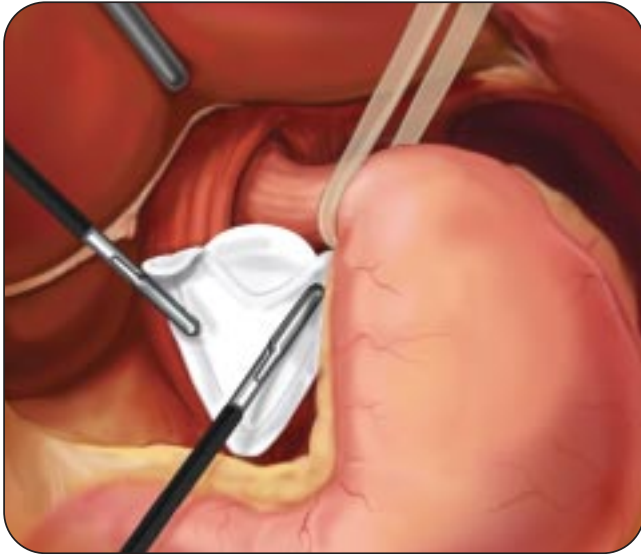
The technique presented herein is for informational purposes only. The decision of which technique to use in a surgical application lies with the surgeon based on patient profile and previous surgical experience. Please consult product labels for any indications, contraindications, warnings, precautions, and instructions for use.



- 5.** Starting at the left crus, the patch is secured in place using hernia staples and/or appropriate sutures. Staple placement is recommended at least every 1cm. Key fixation points include the crura and diaphragm. Special care should be taken to avoid stapling the very apex of the patch, the arcuate ligament, the vagus nerve, and nearby blood vessels.



- 2.** The Bard CruraSoft Patch is folded in half, mesh side out, grasped lengthwise, and inserted through the 10mm cannula.



3. Tension-Free Surgical Repair Technique.

If a tension-free surgical repair technique is preferred, the crura are not reapproximated under tension. The patch is positioned with the mesh side posterior (against the crura and diaphragm), with the lobes and the patch overlapping the left and right crus. Ensure that the patch extends beyond the margins of the defect. The ePTFE (smooth surface) should be positioned facing the abdominal side. The apex of the patch should lay over the crossing of the crural fibers.



4. The ePTFE flap on the superior edge of the patch is intended to provide additional protection for the esophagus and other structures. The flap should lay into the abdomen to provide a shelf or cradle for the esophagus and other structures.