

HEARTSTRING™ III Proximal Seal System

Information for Prescribers

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

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IMPORTANT: Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

1.0 DESCRIPTION

The Guidant HEARTSTRING™ III Proximal Seal System delivers a hemostatic seal device designed to enable the proximal anastomosis of an aortic graft without the need for an aortic clamp during coronary artery bypass graft (CABG) surgery.

The HEARTSTRING™ III Proximal Seal System is comprised of the Proximal Seal (Figure 1), Delivery Device (Figure 2), Loader (Figure 3) and Guidant Aortic Cutter (Figure 4). The Proximal Seal is a device that is delivered into the aorta via the punch hole site and provides a sealed region to facilitate the proximal anastomosis. The Delivery Device is a syringe-like tube with plunger that is used to deploy the Seal inside of the aorta. The Loader is a mechanism that rolls the Proximal Seal and loads the Seal into the Delivery Device. The Guidant Aortic Cutter is a single use (one aortotomy) device that consists of a Grip, a Cutter, Aortic Stops, a Cap, a Needle, a Safety Lock and an Actuation Button. It may be used to create the aortotomy for the anastomosis.

Figure 1. Proximal Seal

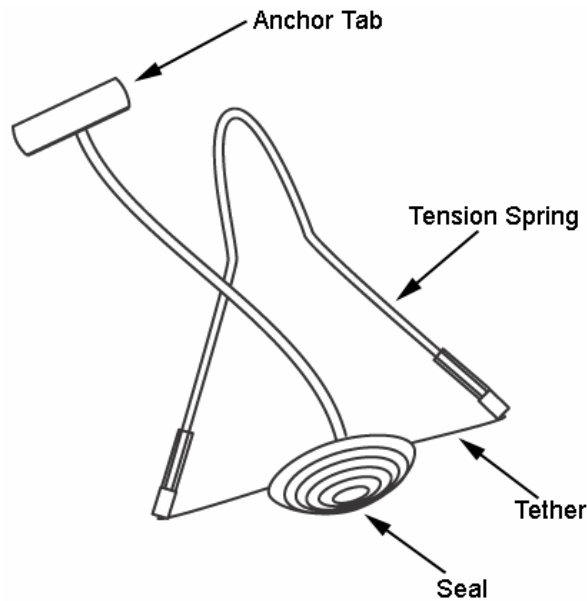


Figure 2. Delivery Device

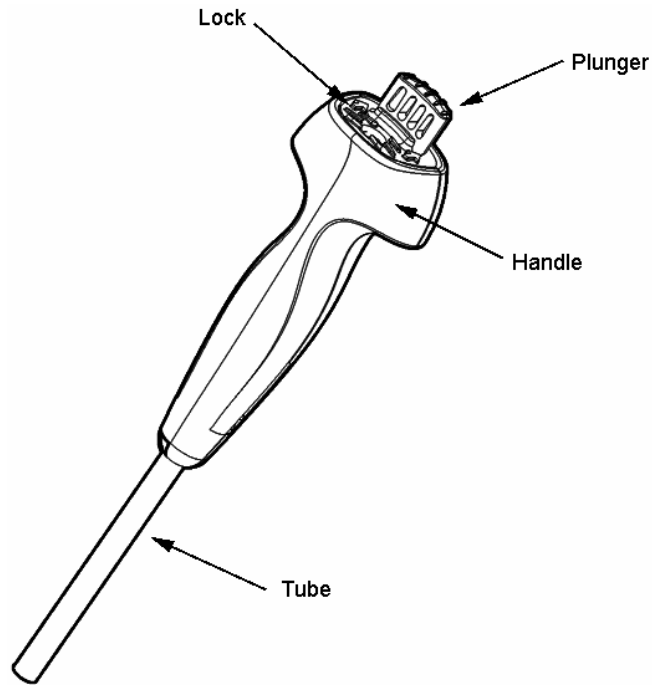
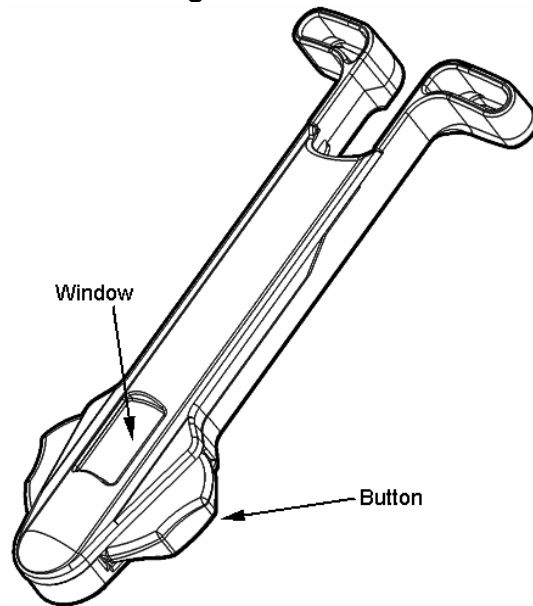
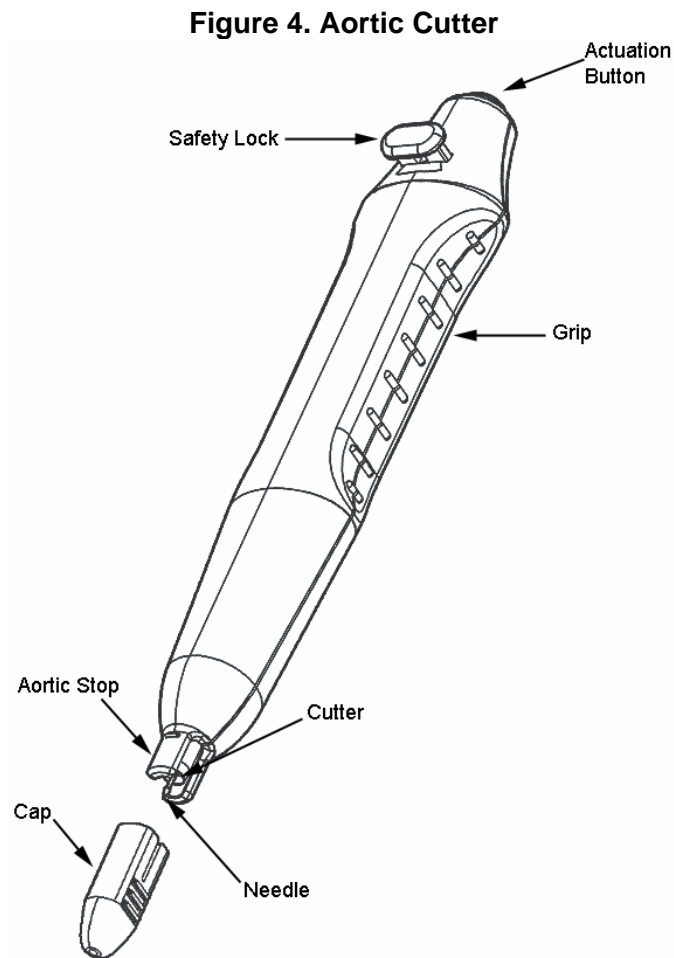


Figure 3. Loader





2.0 INDICATIONS

The HEARTSTRING™ III Proximal Seal System is intended for use by Cardiac Surgeons during CABG procedures to maintain hemostasis and to facilitate the completion of a proximal anastomosis without application of an aortic clamp.

3.0 CONTRAINDICATIONS

1. Do not use the HEARTSTRING™ III Proximal Seal System in the portion of the aorta where conventional surgical anastomosis would typically not be created due to the presence of palpable disease. Such determination may also be based upon echocardiograms.
2. Do not use the HEARTSTRING™ III Proximal Seal System on patients with aortas less than 2.5cm in diameter.

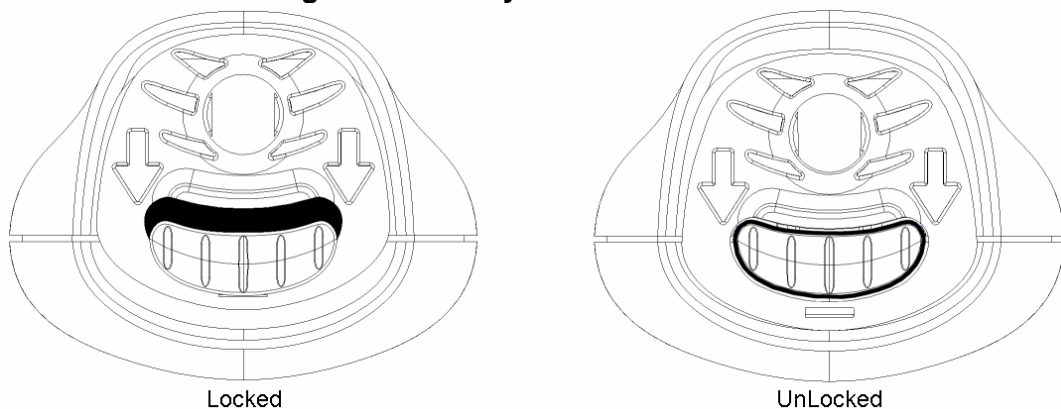
4.0 WARNINGS AND PRECAUTIONS

- Physicians should be properly trained prior to using the HEARTSTRING™ III Proximal Seal System.
- Physicians should not use the HEARTSTRING™ III Proximal Seal System on portions of the aorta where a partial occlusion clamp cannot be applied, to prevent patient compromise due to hemorrhage.
- The HEARTSTRING™ III Proximal Seal System should not be used in patients with thin-walled aortas due to the potential risk of the Tether (Figure 1), lacerating the side of the aortotomy.
- When performing multiple anastomosis, ensure that all anastomotic sites are at least 1.5cm apart to ensure hemostasis.
- Do not re-use or re-sterilize the HEARTSTRING™ III Proximal Seal System or any of its components.
- Do not use the HEARTSTRING™ III Proximal Seal System if the packaging is damaged or opened.
- Inspect the devices to ensure no damage has occurred during transit.
- The Guidant Aortic Cutter is a single use (one aortotomy) device. Any attempt to reuse the Guidant Aortic Cutter may result in the introduction of air emboli into the aorta.
- The Guidant Aortic Cutter is for use on unaltered tissue only. Use on altered tissue (e.g., cardioplegia hole, aortotomy incision) may cause the aortic plug to not be captured by the device and result in the introduction of emboli into the aorta.

5.0 INSTRUCTIONS FOR USE

1. Heparinize the patient per standard practice for CABG procedures.
2. Remove the device from sterile packaging and ensure Lock is locked (Figure 5).

Figure 5. Delivery Device Lock



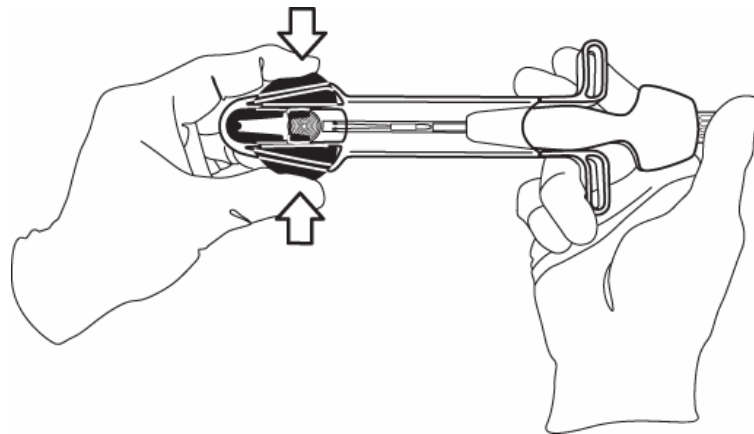
PRECAUTION: If Lock is unlocked, care should be taken to avoid accidentally depressing the Delivery Device Plunger during unpacking, Seal loading, and handling. Do not unlock the Lock on the Delivery Device handle until ready to deploy Seal into aorta. Do not use the HEARTSTRING™ III if the product is defective, the Seal is cracked or the Delivery Device is separated from the Loading Device.

3. Load the Seal into the Delivery Device tube:

PRECAUTION: Care should be taken not to actuate the buttons of the loading device unintentionally. Care should be taken during the loading of the Seal into the Delivery Device to prevent damage to the Seal and not to trigger the Delivery Device during loading.

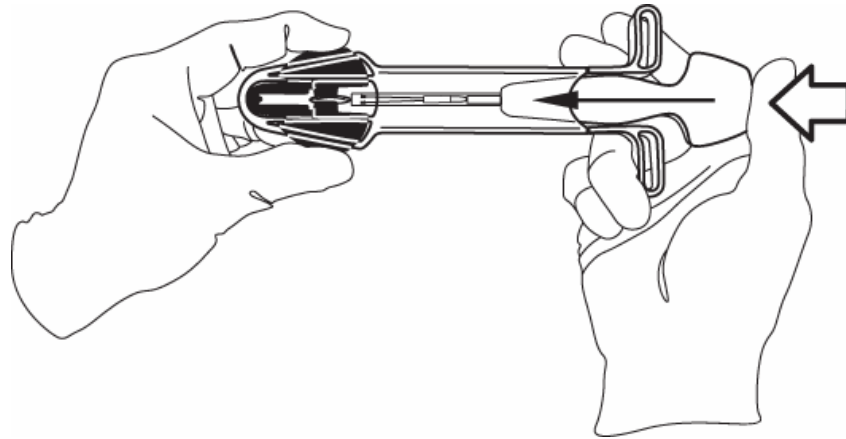
- 3.1 Support the Delivery Device and Loader. To roll the Proximal Seal, slowly squeeze and hold both Buttons of the Loading Device at the same time (Figure 6). Do not release the Buttons.

Figure 6. Actuation of Buttons, Loading proximal Seal



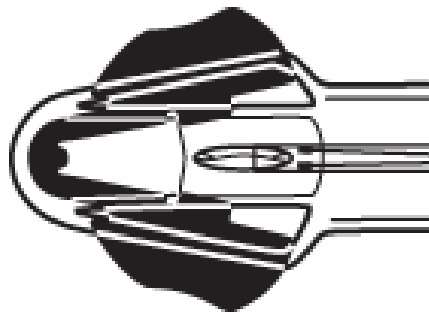
- 3.2 While holding the buttons in, push on the top of the handle, (green surface) of the Delivery Device (Figure 7). Slowly advance the Delivery Device until it stops.

Figure 7. Advancing Delivery Device



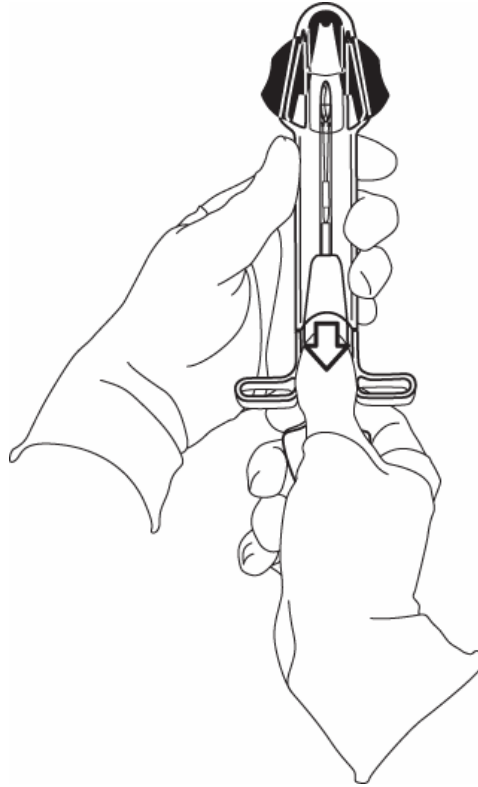
- 3.3 Release both buttons on the side of the Loader (Figure 8).

Figure 8. Completion of Seal loading



- 4. Remove the Delivery Device from the Loading Device:
 - 4.1 Hold the Delivery Device and the Loading Device as shown in (Figure 9).

Figure 9. Removal of Delivery Device



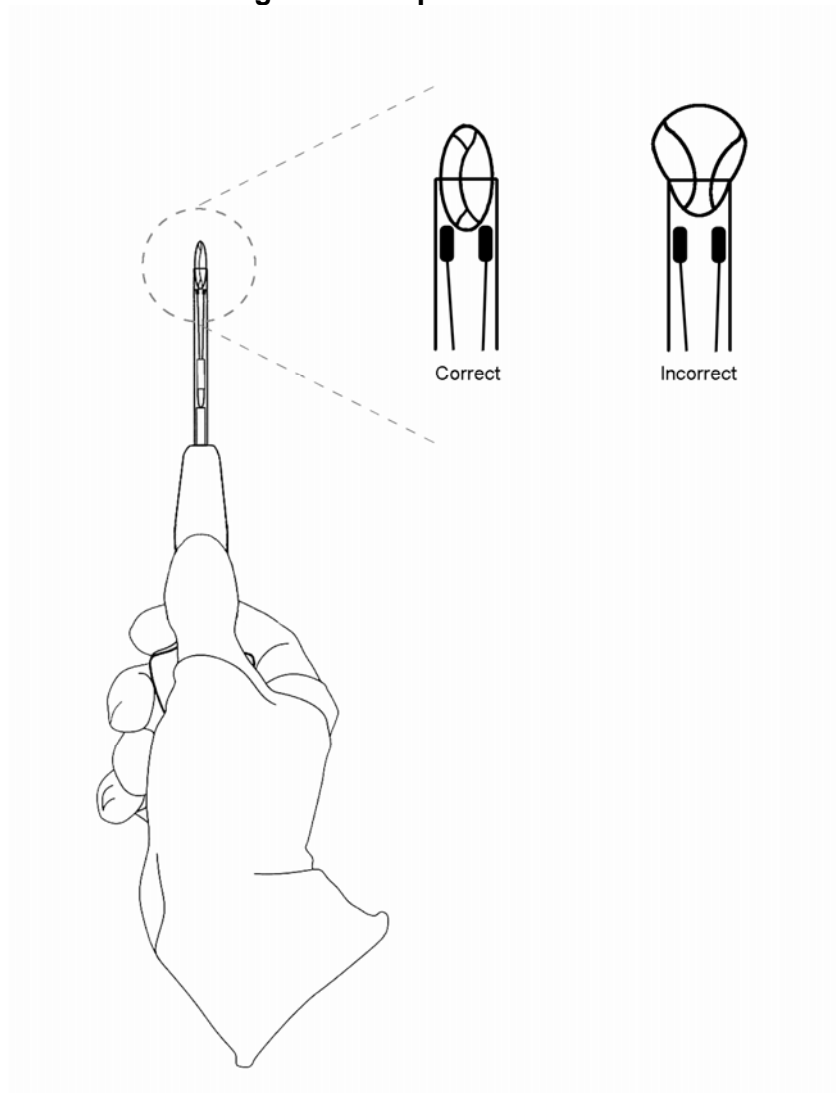
- 4.2 Remove the Delivery Device from the Loading Device. Do not press Buttons on Loader while removing the Delivery Device.
- 4.3 Inspect all sides of the Seal by rotating it 360 degrees after loading is complete. Ensure that there is no delamination ("crack") between Seal strands or at the end of the Seal.

NOTE : Do not use the Seal if a delamination occurs during loading.

- 4.4 Ensure that the portion of the Seal not loaded into the Tube does not flare wider than the diameter of the Delivery Device Tube (Figure 10).

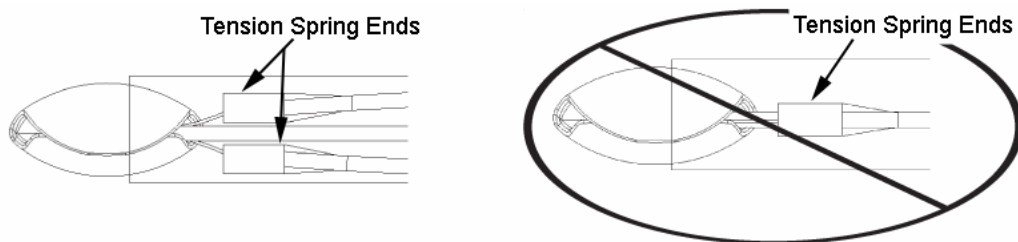
NOTE : Do not use the Seal if the portion of the Seal not loaded into Tube flares wider than the diameter of the Tube.

Figure 10. Inspection of Seal



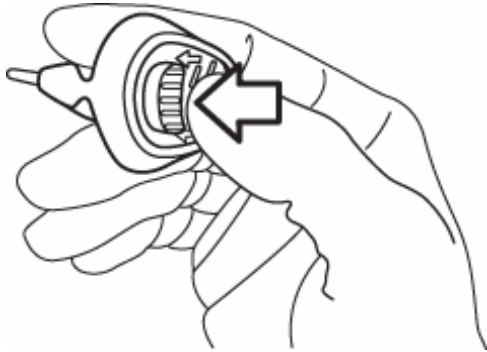
- 4.5 Ensure that the Tension Spring ends are aligned such that they will contact both sides of the Seal during Seal delivery (Figure 11.)

Figure 11. Tension Spring end alignment

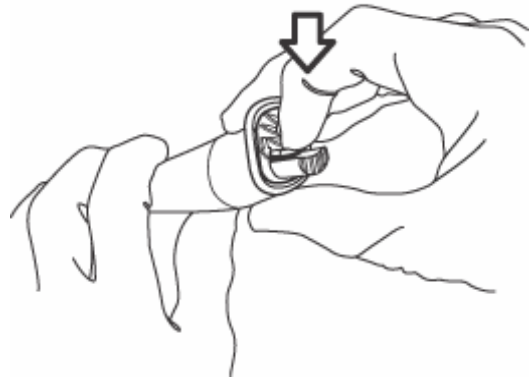


5. Unlock the lock by sliding it in the direction as indicated by the arrows (Figures 12 and 13.)

**Figure 12. Unlock the Lock
(One handed approach)**



**Figure 13. Unlock the Lock
(Two handed approach)**



6. Create a 3.8 - 4.5 mm aortotomy with a punch/aortic cutting device designed for use on unclamped aortas, per manufacturer's instructions. If using the Guidant Aortic Cutter to create the aortotomy, follow steps 6.1 to 6.6.

- 6.1 Clean the aortic surface by removing any loose tissue and ensuring the tissue is unaltered.

WARNING: Use on altered tissue (e.g., cardioplegia hole, aortotomy incision) may cause the aortic plug to not be captured by the device and result in the introduction of emboli into the aorta.

- 6.2 Carefully remove the protective cap covering the cutter and needle. Ready the cutter by fully depressing the Safety Lock (Figure 4), until it is flush with the device outer body.

PRECAUTION: Care should be taken not to actuate the Aortic Cutter accidentally. When the Safety Lock is depressed, the Aortic Cutter is ready to be actuated.

- 6.3 Hold the Aortic Cutter as shown in (Figure 14), with one hand supporting the body and the other hand ready to actuate the device in a syringe-like fashion.

Figure 14. Actuate Device



- 6.4 Choose the location of the anastomosis and place the Aortic Stops so that they are flush with the aortic surface. The needle does not need to fully penetrate the aortic wall.

WARNING: Ensure that the mean blood pressure is greater than 55mmHg to reduce the risk of back-walling with the Aortic Cutter.

- 6.5 Ensure that the Aortic Cutter is held perpendicularly to the surface of the aorta, and depress the Actuation Button to activate the Cutter.

PRECAUTION: Care should be taken not to exert excessive downward force while actuating the Aortic Cutter to reduce the risk of back-walling.

- 6.6 When the aortotomy is complete, remove the Cutter and Needle from the aorta and control the bleeding manually.

PRECAUTION: Care should be taken to avoid the sharp Needle and Cutter upon removal.

NOTE: The aortic plug may be viewed by using a standard surgical needle to slide the plug down the shaft of the needle.

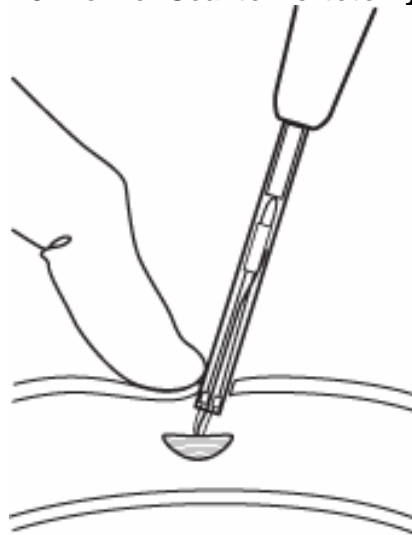
7. Deliver the HEARTSTRING™ III Proximal Seal into the anastomotic site:

- 7.1 Insert Delivery Device tip into the anastomotic site and actuate the Plunger to deploy the Seal (Figure 15). An audible click will confirm actuation.

NOTE: Blood within Delivery Device is an indication of proper insertion.

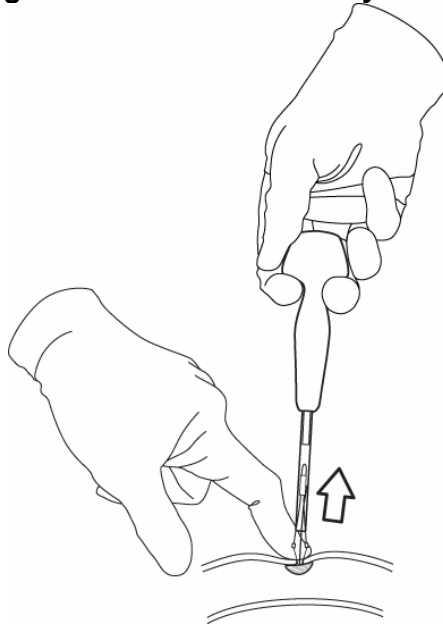
PRECAUTION: Care should be taken while inserting the Delivery Device to reduce the risk of back-walling.

Figure 15. Deliver Seal to Aortotomy



- 7.2 Place a single finger over the Seal to anchor in place while slowly pulling the Delivery Device back (Figure 16.)

Figure 16. Withdraw Delivery Device

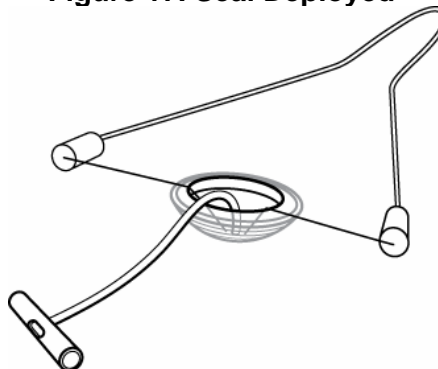


- 7.3 After the Delivery Device is removed, gently pull back the Proximal Seal Tension Spring until the Tension Spring opens (Figure 17). If hemostasis is not adequate, use a blower mister, fine tip suction or saline syringe to clear the field. If hemostasis is still not adequate, gently adjust the Tension Spring to ensure that it is fully deployed. If still not adequate, use finger for temporary hemostasis, remove Seal and replace.

PRECAUTION: To prevent the risk of dislodging emboli, do not manipulate the aorta to adjust the Seal.

- 7.4 The Anchor Tab will weigh down the Seal Stem adjacent to the Anchor Tab (farthest from the anastomosis), and provide a clear field for suturing. Verify that the aortotomy created by the punch or cutter is acceptable for anastomosis construction.

Figure 17. Seal Deployed

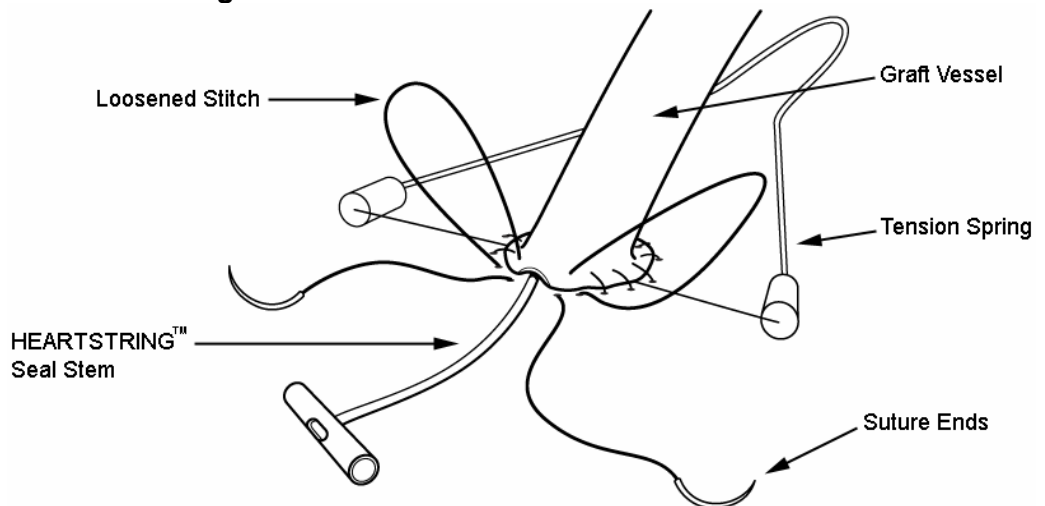


8. With the Proximal Seal deployed in position, perform the anastomosis:
 - 8.1 Suture using an inside-out suturing technique. Ensure that the Seal is maintained in a position between the first and last suture bites of the anastomosis.
 - 8.2 The horizontal distance between the Seal and the tail should be large enough to facilitate Seal removal. Fully complete the entire anastomosis, but do not tie down the suture.

WARNING: Care should be taken when suturing to avoid inadvertent stitching or dislodging of the Seal or wrapping the suture around the Seal Stem. If this occurs, back the needle up and confirm adequate hemostasis. If inadequate hemostasis, apply partial occlusion clamp, remove Seal and complete anastomosis under clamp.

9. The following technique should be used to remove the Proximal Seal after completion of anastomosis:
 - 9.1 Loosen the two stitches immediately adjacent to the Seal Stem (one stitch per side). The suture should be loosened between the graft and the aortic tissue, forming a loop of free suture between the graft and aorta approximately 1 cm in diameter, or approximately 3 cm in length (Figure 18).

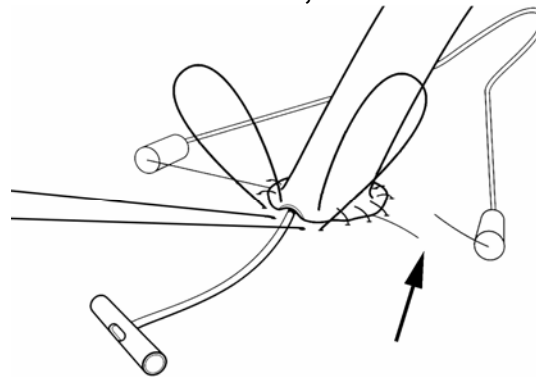
Figure 18. Location of Loosened Stitches



- 9.2 Have an assistant hold the untied suture ends during Seal removal.
- 9.3 While securing the Seal Stem, cut one end of the Tether and remove the Tension Spring (Figure 19).

WARNING: To prevent any risk of Seal embolization, do not release Seal Stem until the Seal is fully removed.

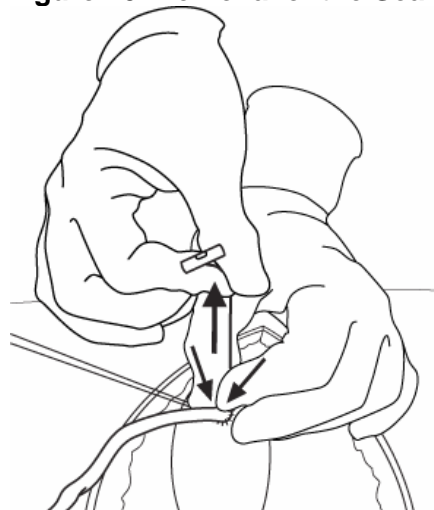
Figure 19. Secured Seal Stem, Cut end of Tether



- 9.4 To begin Seal removal, use thumb and forefinger to provide support for the suture line of the anastomosis and the surrounding tissue. Light downward pressure with the thumb and forefinger will facilitate the Seal removal.
- 9.5 Hold the Seal Stem right below the Anchor Tab and gently pull the Seal Stem to unravel and remove the Seal (Figure 20). Continuously monitor the resistance felt while removing the Seal.

WARNING: Do not pull the Anchor Tab to unravel the Proximal Seal.

Figure 20. Removal of the Seal



- 9.6 If an abrupt and **SUBSTANTIAL RESISTANCE** to unraveling is felt before the Seal is completely removed, immediately discontinue pulling the Seal Stem, and go to step 9.6.1.

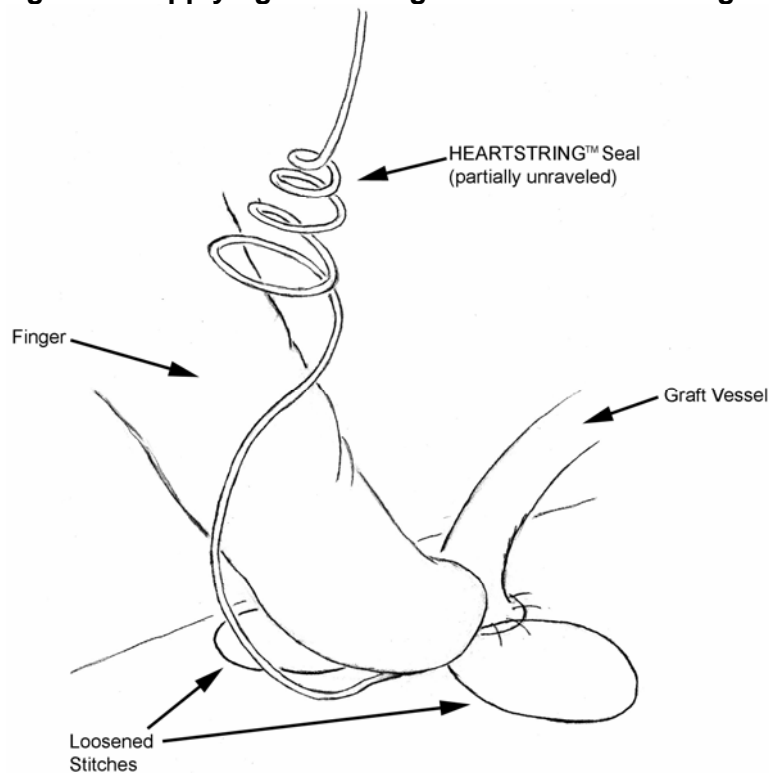
If **ADDITIONAL RESISTANCE IS NOT** felt during Seal removal, go to step 9.7 and complete Seal removal per IFU.

- 9.6.1 Gently place index finger of one hand over the aorta-graft junction, and apply light pressure to control bleeding.

- 9.6.2 Extract remainder of Seal through anastomosis by pulling the Seal Stem with other hand (as in Step 9.5.) Adjust pressure from index finger to minimize resistance to the Seal as it is removed from the temporary gap at the graft to aorta interface (Figure 21.)

WARNING: If Seal Stem continues to feel tight during Seal extraction, or atraumatic Seal extraction is unsuccessful, do not continue to pull on Seal Stem. Apply a partial occlusion clamp, remove the anastomosis followed by the Seal, and complete the anastomosis.

Figure 21. Applying Index Finger to Control Bleeding



- 9.7 Visually confirm the complete removal of the Seal by the presence of an angled cut at the end of the unraveled Seal.
 - 9.7.1 Carefully apply tension to the free ends of the suture to draw closed the loosened stitches and attain a hemostatic anastomosis. Complete the anastomosis per standard surgical procedure.
- 10. The Guidant Aortic Cutter is a single use (one aortotomy) device; however, if performing multiple anastomoses with an Aortic Cutter or Aortic Punch that is indicated to do so:
 - 10.1 Select an anastomosis site at least 1.5 cm apart from the previous anastomosis.
 - 10.2 Remove excised aortic tissue from punch.
 - 10.3 Repeat steps 2-8.

6.0 HOW SUPPLIED

The Guidant HEARTSTRING™ III Proximal Seal System is available in two configurations:

- 1. 5-Pack HEARTSTRING™ III Proximal Seal: One (1) 5-pack includes five (5) individual packages of one (1) Proximal Seal and one (1) Delivery Device and one (1) Loader Device.
- 2. HEARTSTRING™ III Proximal Seal System: One (1) Proximal Seal, one (1) Loader Device, one (1) Delivery Device, and one (1) Guidant Aortic Cutter.

The Guidant HEARTSTRING™ III Proximal Seal System is supplied STERILE and NON-PYROGENIC in an unopened and undamaged package. It has been sterilized using gamma irradiation and is for single use only. **DO NOT RESTERILIZE. DO NOT REUSE.**








CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician.

There are no latex components in the HEARTSTRING™ III Proximal Seal System.

7.0 WARRANTY

GUIDANT CORPORATION (GUIDANT) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond GUIDANT's control directly affect the instrument and the results obtained from its use. GUIDANT's obligation under this warranty is limited to the repair or replacement of this instrument and GUIDANT shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. GUIDANT neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **GUIDANT assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

8.0 GRAPHICAL SYMBOL DEFINITIONS

REF Model Number:	 Contents (Numeral represents quantity of units inside)
 Lot Number:	 Read instructions WWW.GUIDANT.COM/IFU U.S. Only
 Use By:	
 Sterilization by irradiation	 Federal Law (USA) restricts this device to sale by or on the order of a physician.
 Do Not Reuse	

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EL7000494 Rev. A