



Heartstring III Proximal Seal System technique

Reduce clamp-related complications

Do more. Clamp less.

Technique overview

The proximal anastomotic seal technology allows for clamp-less hemostasis during proximal anastomoses in CABG procedures. Minimizing the manipulation of the ascending aorta reduces the risk of neurologic complications.¹

Benefits

In patients with minimal aortic diseases the cerebral emboli number is significantly reduced when the heartstring device is used.¹

Optimal patency

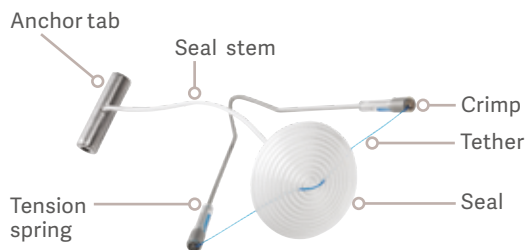
The device allows a hand-sewn angled take-off of venous or arterial anastomoses for optimal patency and procedural flexibility.

Easy to use

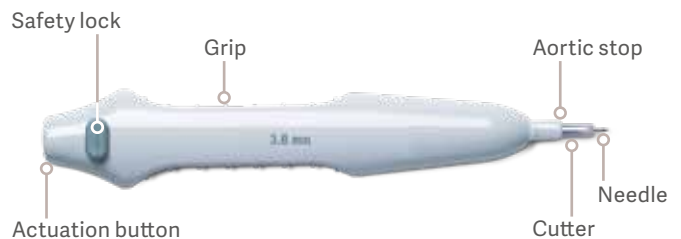
An innovative loading device makes seal placement fast and easy.

Heartstring III Proximal Seal System consists of 3 components:*

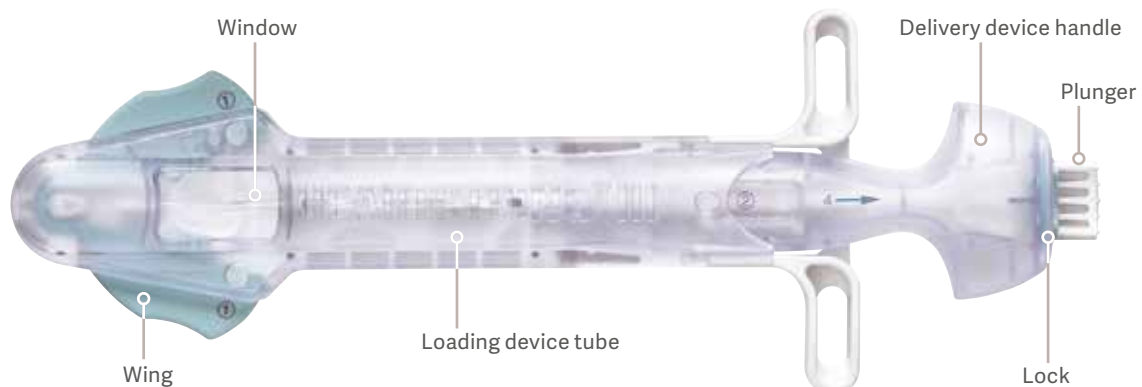
Seal



Aortic Cutter



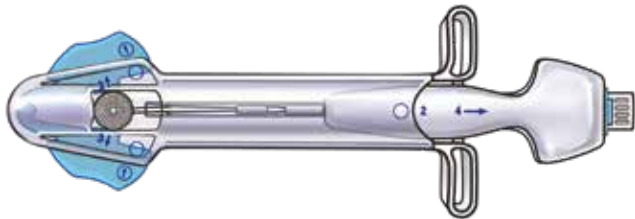
Seal Loader and Delivery Device



*Images of Heartstring III Proximal Seal System components are not to scale but only for illustrative purposes.

Loading the device

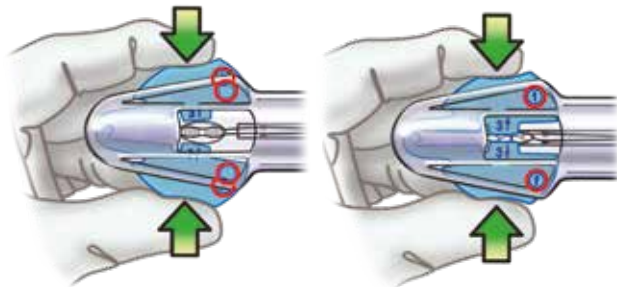
Easy setup



Remove the Getinge Heartstring III Proximal Seal System from the packaging and follow the “**SHARP**” four-step process for loading the Heartstring III Proximal Seal into the seal loader and delivery device.

S = Squeeze
H = Hold
A = Advance
R = Release
P = Pull

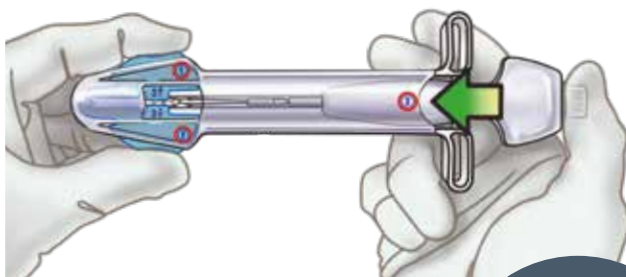
View the Getinge Heartstring III Proximal Seal through the window of the loading device while performing these steps.



Step 1

Using your fingertips, **(S) squeeze** and **(H) hold** the two blue wings until the [1] visual cue appears in the adjacent window. Visually confirm that the Getinge Heartstring III Proximal Seal is rolled.

Do not release the blue wings through until the end of Step 2.



Step 2

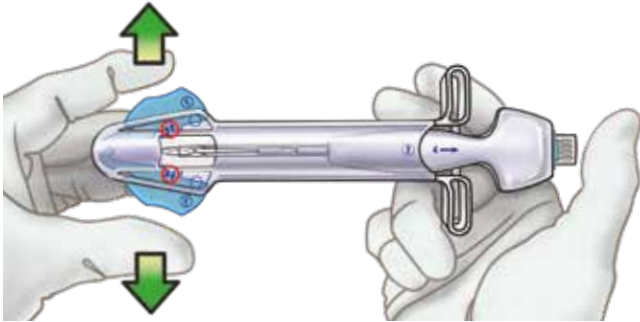
(A) Advance the delivery device onto the rolled Getinge Heartstring III Proximal Seal by pushing on the top, blue area of the delivery device until the [2] visual cue appears in the adjacent window.

Do not push on the white plunger during this step.



Loading the device

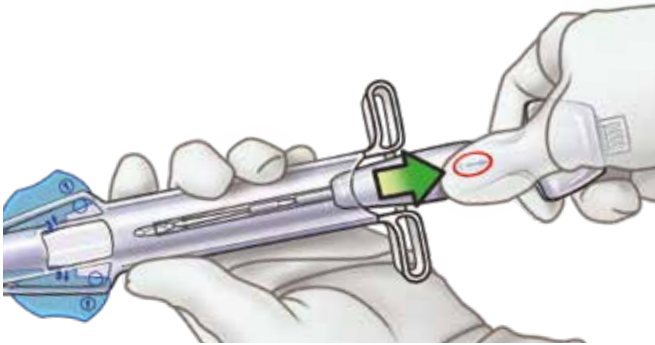
(continued)



Step 3

(R) Release the blue wings. You will see [3] arrows in the window. (See circled areas in diagram.)

Visually inspect the Getinge Heartstring III Proximal Seal to ensure it is correctly loaded in the delivery device tube.



Step 4

(P) Pull the delivery device from the loading device in the direction indicated by the [4] arrow.

Do not hold the loading device near the blue wings during this step.



Inspect the Getinge Heartstring III Proximal Seal for correct orientation. Confirm that there are no cracks.



Unlock the Getinge Heartstring III delivery device. The delivery device is now ready for use.

Procedural technique

Create the aortotomy

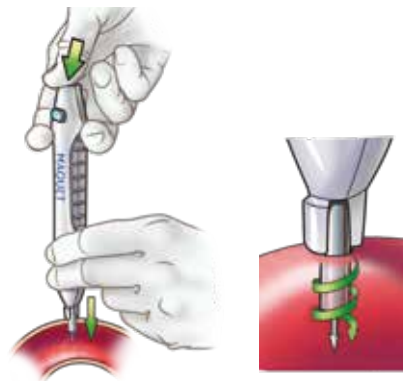
Use the aortic cutter only on a pressurized aorta that is at least 2.5 cm in diameter. The mean aortic pressure must be at least 55 mm/Hg. If desired, clean the adventitia from the area of the aorta to be used for the proximal anastomosis. (Please refer to the Instructions for Use.)

The aortic cutter is contraindicated for use on aortic tissue that has been altered.

- Remove the protective cap from the aortic cutter and release the safety lock.
- Hold the aortic cutter with two hands. Support the body of the aortic cutter as if deploying a syringe-like instrument.
- Place the aortic cutter onto the aorta. The aortic cutter stops should be flush and perpendicular with the surface of the aorta. The needle does not have to fully penetrate the aortic wall.



- Stabilize the aortic cutter and depress the dark gray actuation button at the top. An audible click will confirm deployment.



- Remove the aortic cutter and cover the aortotomy with your index finger.



Procedural technique

(continued)

Deploy the Heartstring III Seal

- Keeping your index finger in place, slide the delivery device under your index finger and into the aortotomy.



- Depress the white plunger to deploy the Getinge Heartstring III Seal into the aorta. A click will confirm delivery.



- Remove the delivery device while continuing to cover the aortotomy until the tension spring is fully open and the seal is in place.

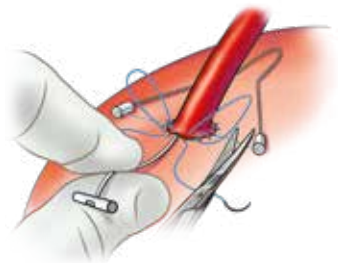
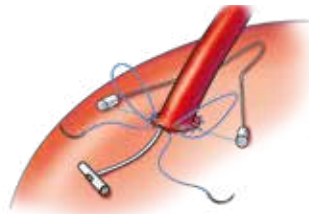
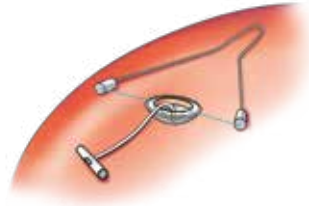


Procedural technique

(continued)

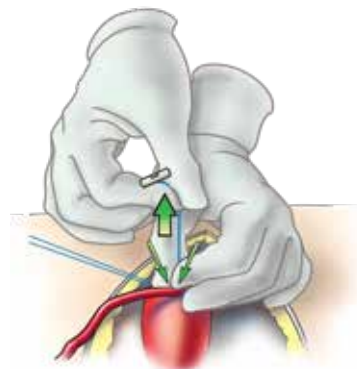
Construct the anastomosis

- Position the anchor tab to the side to weigh down the seal stem.
- Suture the anastomosis so that the seal stem is located between the first and last stitch. An RB-1 or RB-2 needle is recommended.
- An inside-out suturing technique on the aorta is recommended to minimize the risk of catching the edge of the Getinge Heartstring III Proximal Seal with the suture.
- Complete suturing of the anastomosis. Loosen the first and last stitches approximately 1 cm in diameter.
- While securing the seal stem, cut one end of the monofilament suture of the tension spring tether and remove the tension spring.



Remove the Getinge Heartstring III Seal

- Support the anastomosis with your thumb and index finger of one hand.
- Remove the seal by grasping the seal stem (not the anchor tab) with your other hand. Using steady tension, pull up on the seal stem*.
- Tie down your anastomosis.



* If you feel tension when removing the seal, stop pulling. Switch to a single finger technique, and cover the aortotomy with the index finger only. If resistance continues, place a side biting clamp on the aorta. Then take down the anastomosis and sew in the usual fashion, keeping the side biting clamp in place.

Ordering information

Description	Code
Heartstring III Proximal Seal System	
Seal, Delivery Device, Loader, and 3.8 mm Aortic Cutter	HSK-3038
Seal, Delivery Device, Loader, and 4.3 mm Aortic Cutter	HSK-3043
Heartstring III Proximal Seal	
Seal, Delivery Device, and Loader	HS-3045
Aortic Cutter	
Seal, Aortic Cutter, 3.8 mm	AC-3038
Seal, Aortic Cutter, 4.3 mm	AC-3043

References

1. El Zayat H, Puskus JD, Hwang S, et al. Avoiding the clamp during off-pump coronary artery bypass reduces cerebral embolic events: results of a prospective randomized trial. *Interactive CardioVascular and Throacic Surgery*. 2012; 14(1): 12-16.



Getinge is a registered trademark of Getinge AB, its subsidiaries, or affiliates in the United States or other countries •
⚠ CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician. Refer to Instructions for Use for current indications, warnings, contraindications, and precautions.

Sales Office · 45 Barbour Pond Drive · Wayne, NJ 07470 · USA · 888 627 8383

www.getinge.com

MCV00026077 REVC
EXP03/20