

HEARTSTRING Aortic Cutter

Information for Prescribers

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

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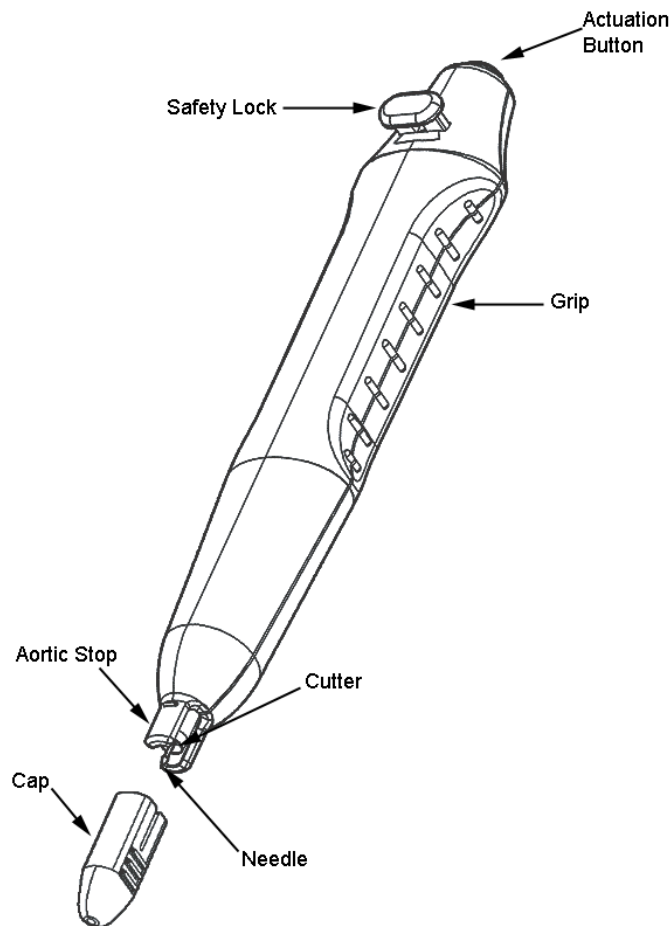
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IMPORTANT: Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

1.0 DESCRIPTION

The HEARTSTRING Aortic Cutter (Figure 1) is a single use (one aortotomy) device that creates an aortotomy for the construction of a proximal anastomosis without the use of clamps. The HEARTSTRING Aortic Cutter 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. HEARTSTRING Aortic Cutter



2.0 INDICATIONS

The HEARTSTRING Aortic Cutter is intended for use by Cardiac Surgeons during CABG procedures to facilitate a proximal anastomosis.

3.0 CONTRAINDICATIONS

1. Do not use the HEARTSTRING Aortic Cutter 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 Aortic Cutter 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 Aortic Cutter.
- Physicians should not use the HEARTSTRING Aortic Cutter on portions of the aorta where a partial occlusion clamp cannot be applied.
- 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 Aortic Cutter or any of its components.
- Do not use the HEARTSTRING Aortic Cutter if the packaging is damaged or opened.
- Inspect the devices to ensure no damage has occurred during transit.
- The Aortic Cutter is a single use (one aortotomy) device. Any attempt to reuse the Aortic Cutter may result in the introduction of air emboli into the aorta.
- The 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. Remove the device from sterile packaging.
2. To create a 3.8 - 4.5 mm aortotomy using the Aortic Cutter follow steps 2.1 – 2.6.

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

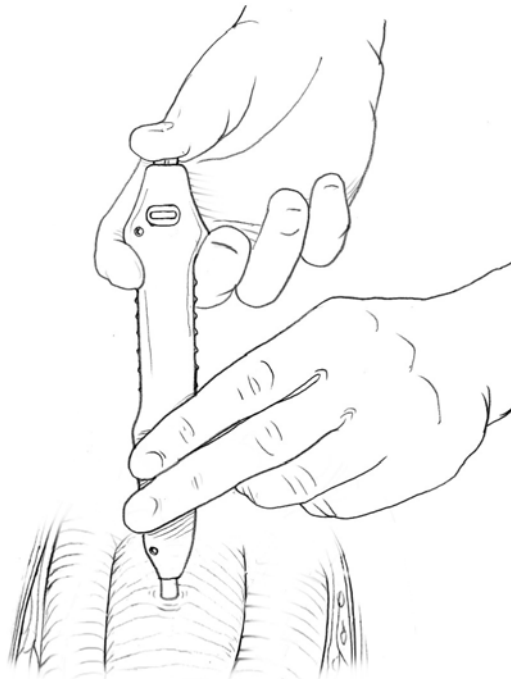
WARNING: Use on altered tissue (e.g., cardioplegia hole, aortotomy Incision) may cause the aortic plug to not be captured by the device and result in the introduction of emboli into the aorta.

- 2.2 Carefully remove the protective cap covering the cutter and needle. Ready the cutter by fully depressing the Safety Lock (Figure 1), 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.

- 2.3 Hold the Aortic Cutter as shown in (Figure 2), with one hand supporting the body and the other hand ready to actuate the device in a syringe-like fashion.

Figure 2. Actuate Device



- 2.4. 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.

- 2.5 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.

- 2.6 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.

3. The HEARTSTRING Aortic Cutter is a single use (one aortotomy) device; however, if performing multiple anastomoses, use multiple HEARTSTRING Aortic Cutters:

- 3.1 Select an anastomosis site at least 1.5 cm apart from the previous anastomosis.

- 3.2 Repeat steps 2.1-2.6.

6.0 HOW SUPPLIED

The HEARTSTRING Aortic Cutter is available in two configurations:

1. 5-Pack 3.8mm HEARTSTRING Aortic Cutter: One (1) 5-pack includes five (5) individual packages of Aortic Cutters.
2. 5 Pack 4.3mm HEARTSTRING Aortic Cutter: One (1) 5-pack includes five (5) individual packages of Aortic Cutters.

The HEARTSTRING Aortic Cutter 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.**












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There are no latex components in the HEARTSTRING Aortic Cutter.

7.0 WARRANTY

MAQUET Cardiovascular LLC (MAQUET) 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 MAQUET's control directly affect the instrument and the results obtained from its use. MAQUET's obligation under this warranty is limited to the repair or replacement of this instrument and MAQUET shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. MAQUET neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **MAQUET 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

 Catalogue Number :	 Sterilization by Irradiation
 Lot Number:	 Read Instructions WWW.MAQUET.COM/IFU U.S. Only
 Use By:	 Contents (Numeral represents quantity of units inside)
 Do Not Reuse	 Keep away from heat.
 Manufacturer:	 Keep dry.
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