

INSTRUCTIONS FOR USE

Control Number: 100826

Revision: D (DRAFT)



PAS-PORT®

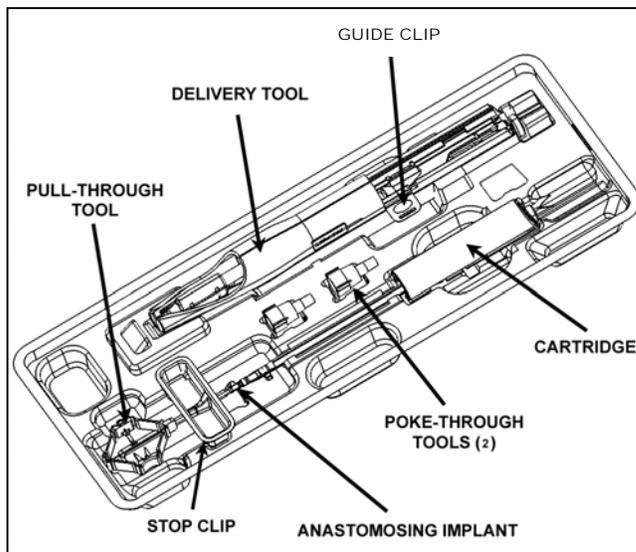
PROXIMAL ANASTOMOSIS SYSTEM
FG-000001

Caution: This device is restricted to sale, distribution, and use by or on the order of a physician.

System Description

The Cardica® PAS-Port® System delivers an Implant designed to create an anastomosis between a large target vessel (e.g. aorta) and small caliber conduit (e.g. saphenous vein). The Implant is a self-closing stainless steel clip that will create a complete end-to-side anastomosis that is 4.65 mm in internal diameter when deployed and which is functionally equivalent to a standard hand-sutured anastomosis. The PAS-Port® System is contained in a package that is designed to facilitate attachment of the conduit to the Implant, as well as to ensure that the conduit (after attachment to the system and before deployment) is kept moist and vital.

The PAS-Port® System is comprised of the following components (see Figure 1):



- Delivery Tool with Guide Clip
- Poke-Through Tool (2)
- Pull-Through Tool
- Cartridge with Anastomosing Implant
- Stop Clip

Intended Use

PAS-Port® System is designed to create an anastomosis between a large target vessel, such as aorta, and a conduit, such as a venous conduit.

Indications

PAS-Port® System is intended to create an everting anastomosis between the aorta and an autologous graft. Caution: This product has not been studied in arterial grafts.

- Figure 1 -

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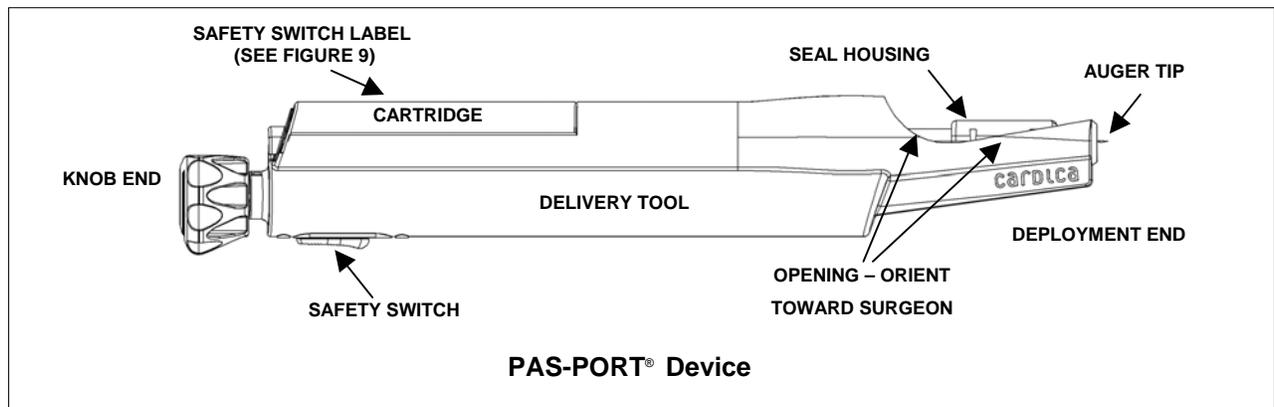
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Contraindications

1. Do not use this product on target vessels where conventional surgical anastomoses would typically not be created due to the presence of palpable disease. Such determination may also be based upon echocardiographic demonstration of either mural (e.g. calcification) and/or intimal (e.g. plaque, exudates) disease.
2. Do not use this product on target vessels less than or equal to 18 mm in outside diameter and with wall thicknesses that would not be acceptable for a hand-sewn anastomosis.
3. Do not use this product with conduit vessels that would not typically be used for bypass grafting procedures.
4. Do not use this product with conduit vessels that have an outside diameter of less than 4.0 mm or greater than 6.0 mm, or with double wall thicknesses greater than 1.4 mm.

Precautions

1. The PAS-Port® System is designed for a single surgical procedure only. **DO NOT REUSE.**
2. The sterile package of the PAS-Port® System should be inspected prior to use. If the sterility or integrity of the package is suspect or compromised, the product should not be used.
3. No component of the PAS-Port® System should be resterilized.
4. The components of the PAS-Port® System must remain in the package inner tray during conduit preparation and conduit attachment to the Implant. Do not remove the product from the inner tray until the Cartridge containing the conduit and Implant is ready for loading into the Delivery Tool, as described in the *Directions for Use* section.
5. Do not use the conduit if there are valves or side branches within 15 mm of the end that will be attached to the Implant.
6. Do not use clips to ligate side branches of the conduit.
7. If the conduit cannot easily be pulled through the Cartridge using gentle and constant force, it should not be used.
8. If eversion of the conduit over the Implant is only possible with difficulty due to its small size or lack of elasticity, the conduit should not be used.
9. Do not contact the sharp point (Auger Tip) at the deployment end of the Device.
10. The PAS-Port® System should only be used by physicians who have been adequately trained by Cardica, Inc., or representatives.
11. The possibility of graft kinking can be minimized by careful selection of the anastomotic site on the target vessel, careful determination of appropriate graft length, and placing individual stay stitches along the course of the graft (see Sections 1.4 and 2.1).



- Figure 2 -

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Warnings

1. The PAS-Port® System creates the hole in the target vessel and completes the anastomosis automatically. Do not create a hole in the target vessel prior to using this product.
2. Do not use blood or glucose containing solutions as a storage solution for the conduit vessel during preparation for Device deployment.
3. The mean arterial pressure must be at least 50 mmHg at the initiation of Device deployment.
4. Coronary Artery Bypass Surgery has inherent risks associated with the procedure, such as stenosis and occlusion of the graft, and these risks vary according to each patient's specific health conditions.
5. Failure to follow the directions can potentially result in damage to device components and/or injury to the patient.
6. Patients allergic to stainless steel may suffer an allergic reaction to this implant.

Directions for Use

1. Harvest the Conduit

- 1.1. Harvest the conduit using standard procedures. Thoroughly remove connective tissue. Ensure that side branches are tied with suture not larger than 4-0. Do not use ligation clips to tie the side branches of the segment being used as the conduit. Avoid excessive lengths of the side branches; the ends of the branches remaining in the patient may be clipped. Do not occlude (e.g. tie off, etc.) the distal end of the conduit prior to Device deployment. The distal end of the conduit is defined as the end that will be anastomosed to the coronary artery.
- 1.2. Inflate the conduit with non-cellular physiologic solution to check for leaks and to counter spasm per standard surgical routine.
- 1.3. Use the Cardica® Vein/Aorta Gauge (provided separately) to determine the adequacy of the conduit vessel. Do not use conduits that have an outer diameter of less than 4.0 mm or greater than 6.0 mm, or with double wall thickness greater than 1.4 mm.

NOTE: The Cardica® Vein/Aorta Gauge (VAG) is not intended for accurate measurement of vessel dimensions. All assessments are approximate. Ensure that there is approximately 15 mm at the end of the conduit that will be connected to the Implant that is free of valves and side branches. Cleanly cut the conduit at the end that will be connected to the Implant at approximately a 90° angle, making sure to keep track of the direction of flow through the conduit.

- 1.4. Determine an adequate length for the conduit. Appropriate conduit length can be determined by using a string or suture and marking the estimated required conduit length with clips, then sizing the inflated conduit to match the length marked on the string or suture. **Graft kinking can be minimized by determining the correct conduit length while the heart is contracting and fully engaged with blood.**
- 1.5. Store the conduit in a non-cellular physiologic solution until use.

2. Prepare the Target Vessel

- 2.1. Conduit placement recommendation: For conduits that target the left lateral wall of the heart, left posterior or left anterior sections of the myocardium, anastomoses should be placed on the lesser curvature or left lateral wall of the ascending target vessel or aortic arch. For conduits that target the right lateral or right posterior surface of the heart, anastomoses should be placed on the anterior surface of the ascending target vessel and can be routed to the left of or over the right atrial appendage. **Placement of the PAS-Port® Implant on the right lateral wall of the ascending target vessel should be avoided due to a higher risk of graft kinking or external compression.** Place individual stay stitches along the course of the graft as necessary to avoid kinking, which may occur following closure of the chest.
- 2.2. Use the Cardica® Vein/Aorta Gauge (provided separately) to determine the adequacy of the target vessel at the site of the planned proximal anastomosis. Do not use the PAS-Port® System on target vessels that have an outer diameter of less than or equal to 18 mm.
- 2.3. Palpate the target vessel to determine that there is an area at least 25 mm in diameter free of severe alterations and/or disease. The area where the surgeon is planning to place the proximal anastomosis should be of sufficient quality to be considered suitable for a hand-sewn anastomosis.
- 2.4. Denude the proposed anastomosis site only if there is excessively thick connective tissue.

3. Open the Package

- 3.1. Inspect the sealed package containing the PAS-Port® System for evidence of damage and inspect the label to verify that the product expiration date has not passed. If the product is expired, do not use.
- 3.2. Retain the Lot Number and Expiration Date of the PAS-Port System by peeling off the removable Lot Number and Expiration Date label and affixing it to the patient's record.

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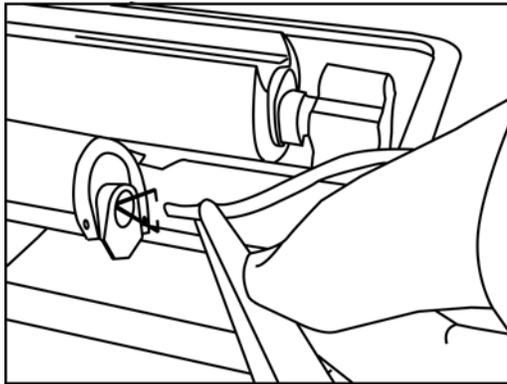
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- 3.3. Open the package and discard outer package material.
- 3.4. The inner tray and inner tray lid are sterile and should only be handled in a sterile fashion.
- 3.5. Remove and discard the inner tray lid. All components of the system should remain in their compartments in the inner tray.

4. Load the Conduit into the Cartridge

NOTE: Refer to the PAS-Port® Graphic Instructions for more illustrations.

- 4.1. To ensure smooth loading through the Cartridge, thoroughly wet the conduit and flush the Cartridge through the rear inlet with non-cellular physiologic solution (see graphic #1 on PAS-Port® Graphic Instructions).
- 4.2. Identify the wire hooks at the end of the Pull-Through Tool. Lay the conduit in the groove in the inner tray that aligns with the wire hooks. Place the end of the conduit that will be connected to the Implant



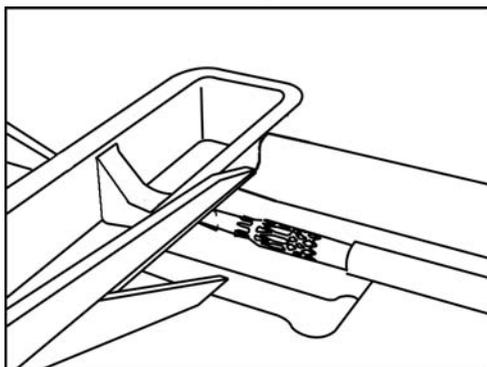
- Figure 3 -

between the wire hooks (see Figure 3 or graphic #2 on PAS-Port® Graphic Instructions). Squeeze the handle of the Pull-Through Tool until it is locked in position (see graphic #3 on PAS-Port® Graphic Instructions). Keep the handle of the Pull-Through Tool firmly seated and stationary in the tray during actuation to grip the conduit. Check to ensure that the wire hooks securely grip the conduit.

- 4.3. Pull the Pull-Through Tool with the attached conduit through the Cartridge. Ensure that the conduit is fed into the Cartridge so that side branches do not catch on the inlet. Continue to pull until the conduit exits the Implant end of the Cartridge. Approximately 8 mm of conduit should be

protruding beyond the Implant tip.

- 4.4. NOTE: If the Pull-Through Tool disengages from the conduit during loading, do the following:
 - 4.4.1. Pull the Pull-Through Tool out of the Cartridge.
 - 4.4.2. If the conduit can be grasped from the rear inlet end of the Cartridge, carefully pull the end of the conduit until it is completely removed from the Cartridge. Take care to not tear the conduit.
 - 4.4.2.1. Squeeze the handle of the Pull-Through Tool into the locked position so that the wire hooks are closed together. Carefully insert the Pull-Through Tool back into the Cartridge through the Implant end. Take great care not to damage the Implant tines during this process. Unlock the Pull-Through Tool handle, firmly seat the handle in the tray, and replace the Stop Clip. Return to Step 4.1.
 - 4.4.3. If the conduit cannot be removed using gentle and constant force, or if the conduit is not accessible from the rear inlet end, the Cartridge must be disassembled.
 - 4.4.3.1. The long tube supporting the Implant consists of top and bottom halves that separate lengthwise. They are attached at the end holding the Implant. Grasp the tube with one hand; hold the Cartridge in the other hand and pull until the tube separates from the Cartridge.
 - 4.4.3.2. Splay the tube's top and bottom halves by separating the features that locked the tube into the Cartridge. Remove the conduit.
 - 4.4.3.3. Dispose of the PAS-Port® System. Open a new PAS-Port® System to complete the procedure using the retrieved conduit.



- Figure 4 -

- 4.5. Note: If the conduit has inadvertently been pulled too far past the Implant, do not attempt to pull the conduit back into the Cartridge, as this may damage the Implant tines. Continue to pull the conduit through the Cartridge until it is removed. Release the conduit from the Pull-Through Tool and refer to Section 4.4.2.1 to proceed.
- 4.6. When the conduit has been successfully pulled through the Cartridge, cut off the end of the

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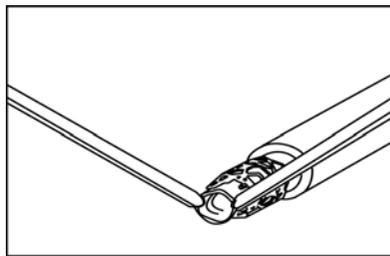
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conduit close to the penetration points of the wire hooks. This can be done without releasing the hooks. Take care that the conduit does not recoil into the Cartridge upon cutting. Ensure that any tissue damaged by the wire hooks is removed (see Figure 4 or graphic #4 on PAS-Port® Graphic Instructions). The optimal eversion length of the end of the conduit protruding beyond the Implant tip is between 3 mm to 6 mm.

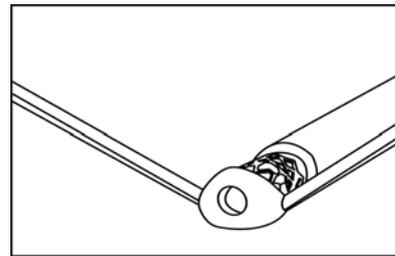
- 4.7 Set the Pull-Through Tool aside. Remove the Stop Clip from the package and set it aside (see graphic #5 on PAS-Port® Graphic Instructions).

5. Evert and Poke-Through the Conduit

- 5.1 Using two fine-tip forceps and holding the conduit at two points 180° apart, gently evert the conduit over the Implant, making sure all nine tines are covered (see Figure 5a and 5b or graphic #6 and #7 on PAS-Port® Graphic Instructions). In a successfully everted conduit, the intima shall be visible on the outer perimeter of the Implant. The conduit should not be everted less than 2 mm and not more than 5 mm over the Implant tines (see graphic #8 on PAS-Port® Graphic Instructions). **If the conduit cannot easily be everted it should not be used even if it is**



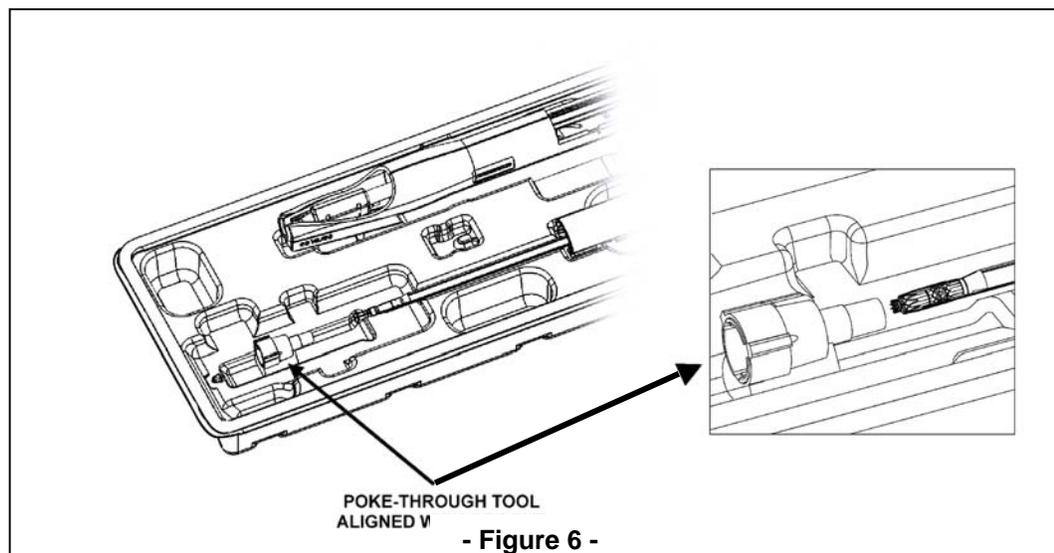
- Figure 5a -



- Figure 5b -

within the specifications for use with the PAS-Port® System.

- 5.2 In order to inspect the eversion, it may be necessary to remove the Cartridge from the inner tray by carefully unsnapping the Cartridge from its cradle. After inspecting the eversion, return the Cartridge to its cradle in the inner tray and be sure that the components snap into their correct positions.
- 5.3 Remove one of the Poke-Through Tools and place it in the groove in the inner tray that aligns with the Cartridge, with the small end of the Poke-Through Tool closest to the Implant (see Figure 6 or graphic #9 on PAS-Port® Graphic Instructions).



- Figure 6 -

- 5.4 While applying light downward pressure on the grey tube of the Cartridge in the inner tray with one hand, use the other hand to slide the Poke-Through Tool forward over the Implant until the Tool reaches a hard stop, then carefully pull it straight back and remove it (see Figure 7a, and 7b, and 7c or graphic #10 on PAS-Port® Graphic Instructions).

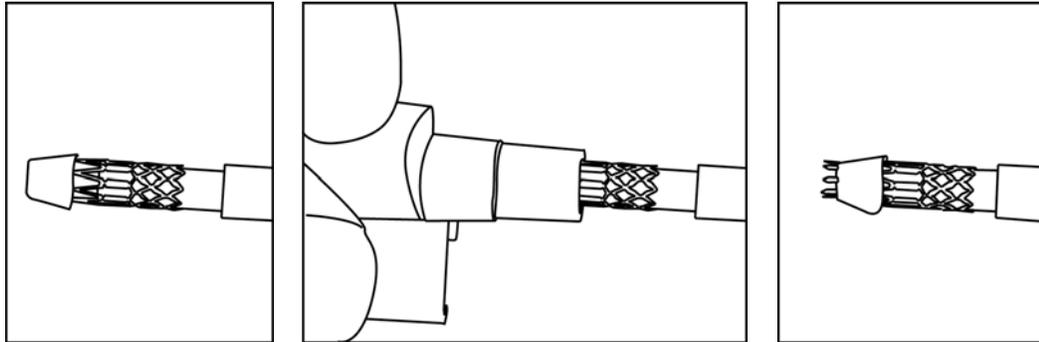
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5.5. Inspect the Implant and conduit and ensure the following (see Figure 7a, 7b, and 7c or graphic #11 on PAS-Port® Graphic Instructions):

5.5.1. All of the conduit layers have been pierced by all nine Implant tines. If not, repeat the poke-through process with the second Poke-Through Tool. Do not reuse a Poke-Through Tool.



BEFORE POKE-THROUGH

- Figure 7a -

DURING POKE-THROUGH

- Figure 7b -

AFTER POKE-THROUGH

- Figure 7c -

5.5.2. The conduit remains everted towards the base of the Implant. If the conduit has un-everted, use fine tip forceps to re-evert the conduit, ensuring that the Implant does not get damaged during this process.

5.5.3. Inspect the Implant to ensure that all nine tines of the Implant are symmetrical and are not bent. If a bent tine is evident, retrieve the conduit and discard the PAS-Port® System. Retrieve the conduit by loading the Cartridge into the Delivery Tool and firing the Device in air within the sterile surgical field. Using forceps, pull the conduit from the Device and place on a sterile surface. The conduit can then be cut away from the Implant. The conduit may also be removed by un-everting and pulling the conduit from the Cartridge. Remove any portion of the conduit that may have been damaged by the tines. Dispose of the PAS-Port® System.

5.5.4. Fill the reservoir surrounding the Cartridge with non-cellular physiologic solution to keep the conduit moist and vital until just before Delivery Tool loading (see graphic #12 on PAS-Port® Graphic Instructions).

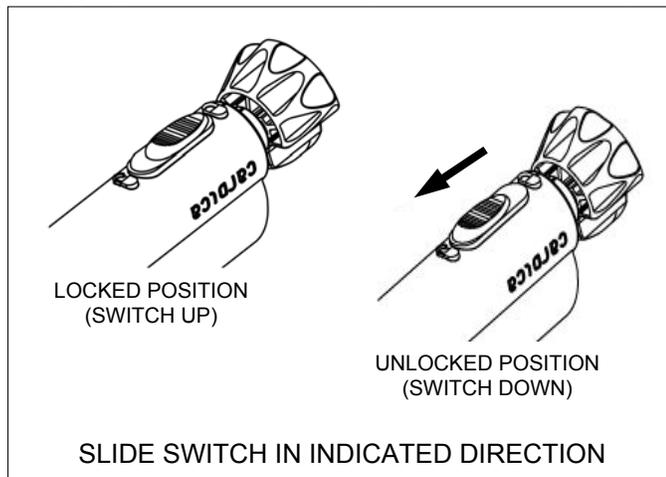
6. Load the Cartridge into the Delivery Tool

6.1. When the surgeon is prepared to perform the proximal anastomosis, remove the Cartridge from the inner tray.

6.2. Rest the Implant end of the Cartridge on the Guide Clip and slide the Cartridge forward until the Cartridge base is seated in the rails of the -Delivery Tool, see Figure 1. Great care should be taken to avoid damaging the Implant during loading.

6.3. Remove the Guide Clip by pulling the tab. (see graphic #13 on PAS-Port® Graphic Instructions).

6.4. Firmly grasp the case of the Delivery Tool with one hand and push the Cartridge forward with the other hand until it locks in place.



- Figure 8 -

locks in place. Complete insertion of the Cartridge can be verified by hearing an audible "click"; the Knob will also partially rotate. This step cannot be reversed. The PAS-Port® System is now ready for deployment.

7. Deploy the Implant

7.1. Prepare the target vessel at the site of the intended

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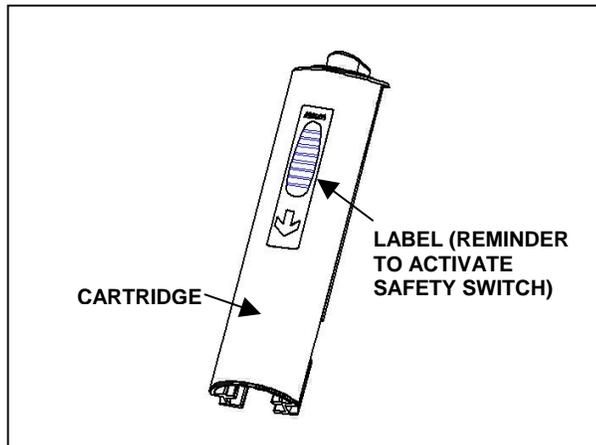
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anastomosis by briefly cauterizing the connective tissue to the adventitia in a circular area approximately equal to 4 mm in diameter.

- 7.2. The possibility of graft kinking can be minimized by careful selection of the anastomotic site on the target vessel (see Section 2.1).
- 7.3. Remove the Device from the inner tray and unlock the Safety Switch by sliding it to the unlocked position (see Figure 8). The Cartridge contains a label reminding the user to activate the Safety Switch. (see Figure 9).

NOTE: The Safety Switch cannot be moved to the unlocked position if the Cartridge is not properly loaded in the Delivery Tool. Once the Safety Switch has been moved to the unlocked position, Knob rotation will immediately result in firing of the cutter.

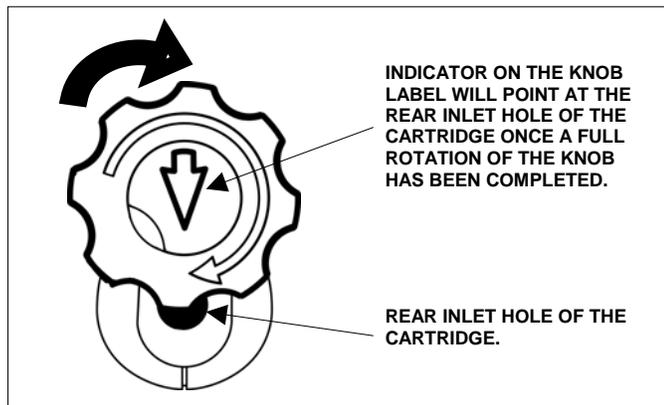


- Figure 9 -

- 7.4. Position the Device at a 90° angle to the surface of the target vessel at the prepared site for the anastomosis.
- 7.5. Pierce the target vessel with the Auger Tip, see Figure 2. If the Auger Tip does not easily penetrate the target vessel, a different anastomosis site should be chosen.
- 7.6. Ensure there is full contact between the Device and the surface of the target vessel without compressing or indenting the target vessel. Do not move the Device laterally after it has been placed against the target vessel. Do not hover above the target vessel.

7.7. To provide visibility of the deployment process, orient the Device such that the opening at the deployment end of the Device is facing the surgeon.

- 7.8. Ensure that the mean arterial pressure during deployment is at least 50 mmHg.
- 7.9. To complete the anastomosis, turn the Knob in a **clockwise** direction until a hard stop is felt. The label on the Knob includes an indicator that will point at the rear inlet hole of the Cartridge once a full rotation of the Knob has been completed (see Figure 10). The tip of the Device should stay in contact with the target vessel surface during the entire deployment process. The surgeon should ensure that the Device does not compress or indent the target vessel.



- Figure 10 -

- 7.10. After the aortotomy has been created and before the Implant is inserted into the target vessel, blood will flow freely through the Seal Housing into the surgical field. The Seal Housing is the clear plastic casing located within the opening at the Deployment End of the Device. Use a suction device to clear the surgical field as necessary. If blood does not enter the Seal Housing or enters the Seal Housing slowly, abort the deployment and use standard surgical

techniques to repair the target vessel if necessary.

- 7.11. After the Knob reaches the hard stop, slowly lift the Device away from the target vessel. Hold the conduit close to the Implant with forceps while the Device is being removed to avoid placing tension on the anastomosis. Take care not to manipulate the remaining tines when grasping the conduit as they could detach from the Device. If there is

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difficulty removing the Device because the conduit has become dried to the inside of the Device, wet the conduit and the Device by flushing non-cellular physiologic solution into the inlet hole at the Knob End of the Device.

- 7.12. Remove the Device from the surgical field. Check the Device to ensure all remaining 9 tines are present.
- 7.13. Place an appropriate clamp on the end of the graft per standard surgical routine.
- 7.14. Before closing the chest: inspect the anastomosis for leaks and to verify that the Implant appears properly deployed; inspect the amount of tension on the graft after completion of both the proximal and distal anastomosis with the heart completely engorged with blood and in its normal position; and place individual stay stitches along the course of the graft as necessary to avoid kinking.
 - 7.14.1. If individual tines of the implant's outer flange have deployed correctly, but are not in contact with the connective tissue of the target vessel, the surgeon should not attempt manual manipulation of the tines. A purse-string stitch can be placed around the Implant to further secure attachment to the target vessel wall.
 - 7.14.2. If the implant is not fully or correctly deployed the implant should be removed, see Section 8.2.

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8. Troubleshooting

- 8.1 Should anastomotic hemorrhage be observed following Implant deployment, the surgeon may attempt to obtain hemostasis by placing a purse-string stitch around the Implant.
- 8.2 If blood does not enter the seal housing during device deployment, hemostasis cannot be obtained, blood does not enter the graft after device deployment, or the implant did not deploy properly place a side-biting clamp around the Implant, if deemed appropriate, and remove the Implant by using a needle holder to crush the body of the Implant towards the center of the Implant. Repair the attempted anastomosis site. Do not use the aortotomy produced by the PAS-Port™ System for deployment of a new PAS-Port® System.

Packaging/Storage

The PAS-Port® System is provided sterile and is designed to remain sterile unless the primary packaging seal has been opened or damaged. Store in a dry, cool place.

Cardica® PAS-PORT®

Manufactured in the USA by:

Cardica, Inc.
900 Saginaw Drive
Redwood City, CA
94063

Authorized European Representative:

MDSS, GmbH
Burckhardstr. 1
30163 Hannover
Germany



Symbols used:



CAUTION STATEMENT:
See instructions for use



EXPIRATION DATE:
Use By YYYY/MM



DO NOT REUSE:
Single-use device



STERILE STATEMENT AND
STERILIZATION METHOD:
Sterilized by irradiation



REFERENCE:
Model Number



LOT NUMBER:
Manufacturing Lot Number

Universal



+M296FG0000011R

Product Number BAR CODE: Includes manufacturer and product number, in HIBC format.

Translations:

Go to www.cardica.com/PAS-port/ifu

Username: cardica

Password: pasport

The Cardica website can be properly viewed with the following browsers: Netscape™ and Internet Explorer™ Version 5 or higher. The Instructions for Use are available as PDF files that can be viewed with Adobe Acrobat Reader™. Adobe Acrobat Reader™ can be downloaded free of charge from the Adobe Inc. website (www.adobe.com). Instructions for use must be available during surgery.

<i>Deutsch</i>	Die Anleitung muss während der Operation verfügbar sein.
<i>French</i>	Le mode d'emploi doit être disponible pendant la chirurgie.
<i>Italian</i>	Le istruzioni per l'uso devono essere disponibili durante l'intervento chirurgico
<i>Spanish</i>	Las instrucciones de uso deben tenerse a mano durante las intervenciones quirúrgicas.
<i>Swedish</i>	Brugsanvisning måste finnas tillgänglig under kirurgi.
<i>Dutch</i>	De gebruiksaanwijzing moet tijdens de operatie voorhanden zijn.
<i>Greek</i>	Οι οδηγίες χρήσης θα πρέπει να είναι διαθέσιμες κατά τη διάρκεια της επέμβασης.
<i>Portuguese</i>	As instruções de utilização têm de estar disponíveis durante a cirurgia.
<i>Danish</i>	Brugsanvisningen skal være disponibel under operation.