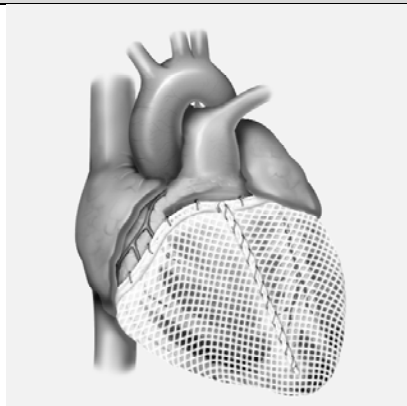


CorCap™ Cardiac Support Device

Instructions for Use

DESCRIPTION



The CorCap™ Cardiac Support Device (CSD) is a proprietary polyester mesh wrap implanted around the heart to provide support and reduce ventricular wall stress.

INTENDED USE

The CorCap CSD provides beneficial changes in cardiac structure associated with a reverse remodeling effect as defined by a reduction in left ventricular (LV) size, a reduction in LVEF, and a change to a more elliptical shape. The CorCap CSD also provides a decrease in the need for additional major cardiac procedures associated with the progression of heart failure and an overall improvement in quality of life.

INDICATIONS

The CorCap CSD is indicated for use in adult patients who have been diagnosed with dilated cardiomyopathy and are symptomatic despite treatment with optimal heart failure medical management. Patients appropriate for this procedure have a dilated heart ($LVEDD \geq 60\text{mm}$ or $LVEDDI \geq 30\text{mm/m}^2$) and an $LVEF \leq 35\%$ ($LVEF \leq 45\%$ if planned mitral valve repair replacement).

CONTRAINDICATIONS

Patients with any condition considered to be a contraindication for cardiac surgery should not undergo surgery for implant of the CorCap CSD.

WARNINGS

1. Do not perform procedure in patients with an active infection.
2. Do not perform procedure in patients with primary restrictive disease.
3. Patients who are not good candidates for cardiac surgery (i.e., patients diagnosed with end-stage NYHA functional class IV or patients dependent upon intravenous inotropes, intra aortic balloon pump, and/or left ventricular assist device) may not be suitable candidates for CorCap CSD therapy.
4. Placement of device over pre-existing coronary artery bypass grafts has not been evaluated and may compromise graft patency.
5. In patients with previous CorCap CSD implant, location of appropriate anastomotic sites for coronary artery bypass surgery may be extremely difficult.
6. Patients undergoing cardiac surgery may be at a greater risk for development of fibrosis and adhesions. This could potentially increase the surgical time required for subsequent cardiac surgeries.

PRECAUTIONS

1. Patients with hypertrophic obstructive cardiomyopathy or primary diastolic dysfunction may not benefit from the CorCap CSD implant.
2. Procedure may not be possible in patients with profound cardiomegaly (>14.6 cm external cardiac diameter), which exceeds the largest CorCap CSD size available.
3. As with any cardiac surgery, use of an adhesion barrier may be considered, particularly in patients with an increased potential for requiring future operations.
4. Procedure requires ability to obtain complete circumferential access to the heart, which may be compromised in patients with pre-existing pericardial or epicardial adhesions.
5. Alteration to the device or implant procedure beyond these instructions may result in unknown device performance.
6. Direct application of antibiotics to the CorCap CSD should be avoided.
7. Patient risks or discomforts expected include standard risks of a patient undergoing cardiothoracic surgery. These may include: bleeding; development of cardiac pulmonary embolism, infarct, or peripheral embolism; hemodynamic compromise potentially leading to cardiogenic shock and/or neurological deficit; infection; pneumonia; pulmonary, renal, or hepatic compromise potentially leading to failure; death; other surgical trauma; reoperation; and/or allergic response to anesthesia, medications or device material.
8. Use of an IABP is recommended in patients where manipulation of the heart could cause hemodynamic instability.
9. If hemodynamic instability cannot be managed by pharmacological means, CPB is recommended.

IMPLANT PROCEDURE

1. **Expose the Heart**

The CorCap CSD can be implanted using standard surgical approaches. After gaining access, open the pericardium to expose the heart. It may be helpful to use the pericardium as a cradle to position the heart for better access.

2. **Obtain Heart Size Baseline Measurements for Device Fitting**

- a. Obtain baseline intra-operative Left ventricular end-diastolic dimension (LVEDD) measurements using TEE. While use of TEE is strongly recommended, heart size may be determined by measuring the circumference of the heart at its largest diameter (during end-diastole).
- b. Measure the circumference of the heart at its largest diameter during end diastole. This measurement is typically near the AV groove.
- c. Measure the length of the heart from apex to base during end diastole.
- d. The CorCap™ Cord Sizer may be used for the circumferential and apex-to-base measurements.

Note:

- Intraoperative conditions, including use of blood products, fluids and medications, may influence the size of the heart and therefore should be taken into account when obtaining baseline measurements.
- Ensure that sizing tool is placed at true apex to obtain accurate measurements.

3. **Select the Correct CorCap CSD Size**

Compare the circumference and length measurements obtained in Step 2 to the CorCap Size Selection Guide (Table 1) and select the device size indicated.

Table 1. CorCap CSD Sizing Chart

		Circumference (cm)																														
		31.0	31.5	32.0	32.5	33.0	33.5	34.0	34.5	35.0	35.5	36.0	36.5	37.0	37.5	38.0	38.5	39.0	39.5	40.0	40.5	41.0	41.5	42.0	42.5	43.0	43.5	44.0	44.5	45.0	45.5	46.0
Length (cm)	10.5																															
	11.0	11.5 x 32																														
	11.5																															
	12.0				12.0 x 37																											
	12.5																															
	13.0																															
	13.5									13.5 x 39																						
	14.0																															
	14.5																															
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	15.5																															
	16.0																															
	16.5																															
	17.0																			17.0 x 44												
	17.5																															
	18.0																															
	18.5																															
	19.0																										19.0 x 46					
	19.5																															
20																																
20.5																															No Size Available	

CAUTION: Selection of a device that is smaller than indicated in the sizing chart may lead to inappropriately reduction in cardiac size, or necessitate intra-operative removal and replacement with an appropriate sized device.

4. **Concomitant Cardiopulmonary Bypass or Cardiac Surgery**
If cardiopulmonary bypass will be used or concomitant MVR surgery performed, review the “Special Conditions” section for related modifications to the implant procedure.
5. **Open CorCap CSD Package**
Check integrity of CorCap CSD package. Do not use if damage to package or seals is noted. Open the outer package and deliver the sterile inner package to the sterile field. Open the inner package and place CorCap CSD in sterile saline until ready for implant.
6. **Inspect and Prepare the CorCap CSD**
 - a. Inspect CorCap CSD for any irregularities. Do not use if device is torn, frayed or missing threads.
 - b. Remove the device tag, located on the outside of the CorCap CSD.
7. **Secure Hem of CorCap CSD to Heart**
 - a. Position the CorCap CSD around the ventricles with the smooth side of hem and seam against the heart.
 - b. Align device such that hem is positioned near level of the AV groove and seam is positioned on the anterior surface of the heart. Device length may extend beyond apex; this will be adjusted when new anterior seam is created (Steps 9-10). Do not shorten device by trimming hem.
 - c. Starting at the most posterior location, secure the hem to the circumference of the heart near the AV groove using interrupted attachments every 2-4 cm.
 - d. Work from side to side placing attachments around the circumference, moving towards the mid-anterior of the heart. The fabric should not wrinkle or pucker between attachment points.
 - e. To facilitate seam fitting later in the procedure, fabric located within 5cm of the seam should *not* be attached to the heart at this time.

WARNING: When securing device, ensure that attachments do not cause injury to coronary arteries.

WARNING: Manipulation of the heart may precipitate arrhythmias and/or hemodynamic compromise, particularly during placement of posterior attachments.
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CAUTION: Use of an IABP is recommended in patients where manipulation of the heart could cause hemodynamic instability. If hemodynamic instability cannot be managed by pharmacological means, CPB is recommended.

Note: Taper point needles and 4.0 or stronger non-bioabsorbable suture material are recommended for suturing; taper cut or other cutting needles may sever CorCap CSD fabric fibers.

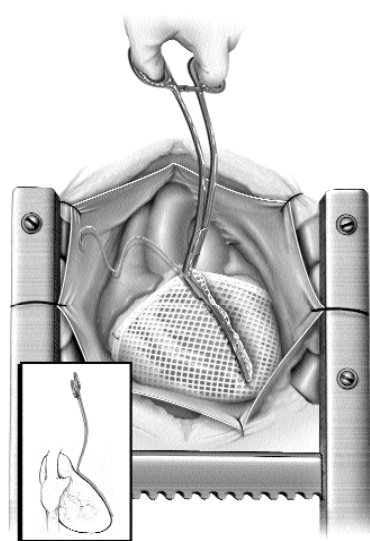


Figure 1: Approximate Anterior Seam

8. **Approximate Anterior Seam of CorCap CSD**
 - a. Using CorCap™ fitting clamp, gather excess CorCap CSD fabric toward the anterior seam. (See **Figure 1**.)
 - b. If device length extends beyond the apex, collect excess fabric into clamp.
 - c. Check that the tension on the device is evenly distributed over the entire circumference of the CorCap CSD.
 - d. The CorCap CSD should maintain complete contact with the ventricular walls throughout the cardiac cycle, with no gaps and no evidence of hemodynamic compromise.
 - e. Measure LVEDD with TEE to anticipate final fit. Adjust the amount of gathered fabric within the clamp to ensure the appropriate degree of LVEDD reduction.

WARNING: Reduction in LVEDD should not exceed 10% as compared to baseline. Intraoperative conditions, including use of blood products, fluids and medications, may influence the size of the heart and therefore should be taken into account when approximating the CorCap CSD.

CAUTION: Do not decrease the apex to base dimension of the heart while approximating the anterior seam.

Note:

- The clamp should not be allowed to rest on the heart, as this could lead to errors in dimensional measurements.
- Use the CorCap fitting clamp for this procedure. Surgical clamps not specifically designed for this purpose could tear or snag the CorCap CSD fabric.

9. **Create New Anterior Seam**

With the CorCap fitting clamp in place, place a running mattress suture under the jaws of the CorCap fitting clamp, starting at the apex and continuing to the hem, to create a new anterior seam.

Note:

- Taper point needles and 4.0 or stronger non-bioabsorbable suture material are recommended for suturing; taper cut or other cutting needles may sever CorCap CSD fabric fibers.

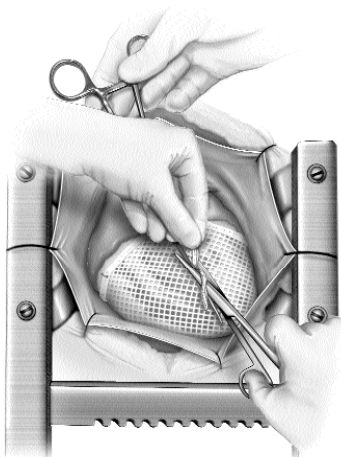


Figure 2: Trim Fabric

10. **Trim Fabric**

Keeping the CorCap fitting clamp in place, trim fabric above the clamp jaws. (See **Figure 2.**)

11. **Complete Final Anterior Attachment**

Secure the device hem at the mid-anterior of the heart. near the AV groove using interrupted attachments every 2-4 cm.

WARNING: When securing device, ensure that attachments do not cause injury to coronary arteries.

12. **Reinforce New Anterior Seam**

- a. Remove the CorCap fitting clamp. There should be approximately 3-5mm of remaining above the running
- b. Reinforce the new anterior placing a running interrupted the apex to the hem. (See Stitch should provide and leave no gaps in seam, maintaining even tension on
- c. Continuously evaluate final #13) during placement of anterior seam. Adjust suture accordingly.

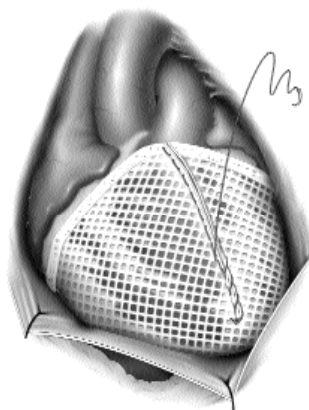


Figure 3: Reinforce New Anterior Seam

fabric suture. seam by suture from **Figure 3.)** redundancy while the device. fit (see step this new placement

13. **Evaluate Final Fit of the**

- a. Evaluate fit using the Tension Test (“tent test”).
 - Using a blunt surgical instrument, gently lift fabric approximately 1-2 cm off the heart.
 - Release the “tent” – it should re-conform to the surface of the heart within 1-2 cardiac cycles.
 - Repeat this test in several locations away from the hem and seams of the CorCap CSD.
- b. The CorCap CSD should cover both ventricles with no gaps between the device and the heart throughout the entire cardiac cycle.

CorCap CSD

Fabric

14. **Measure Final Fit of the CorCap CSD**

- a. Measure LVEDD with TEE at the same location used to obtain the baseline circumference measurement in Step 2. While use of TEE is strongly recommended, heart size may be determined by measuring the circumference of the heart at its largest diameter (during end-diastole).

WARNING: Reduction should not exceed 10% as compared to baseline LVEDD. Intraoperative conditions, including use of blood products, fluids and medications, may influence the size of the heart and therefore should be taken into account when fitting the CorCap CSD.

- b. If reduction in LVEDD of greater than 10% is noted, remove sutures from the anterior seam and adjust fit. If suture removal damages the CorCap CSD or if there is not enough fabric to recreate a 3-5 mm seam, remove device and repeat procedure with a new device.

15. **Perform Final Inspection**

- a. Remove any excess particulate matter that is found in-situ.
- b. Ensure that any fabric or seam damage is repaired
- c. Visually inspect the device and device hem to ensure that the device fits uniformly over all surfaces of the ventricles.

SPECIAL CONSIDERATIONS

1. Cardiopulmonary Bypass

If cardiopulmonary bypass is used, the following considerations are advised:

- a. Baseline heart size measurements (Step 2) and size selection (Step 3) should be made before placing the patient on bypass. If this is not possible, heart should be filled to an approximation of baseline.
- b. Fitting of the device (Steps 8-12) should not be performed until patient is off bypass and has a full, stable beating heart.

2. Mitral Valve Repair/Replacement (MVR)

If concomitant mitral valve repair or replacement is indicated, the following considerations are advised:

- c. Baseline heart size measurements (Step 2) and size selection (Step 3) should be made before placing the patient on bypass. If this is not possible, heart should be filled to an approximation of baseline.
- a. To minimize need for cardiac manipulation following placement of mitral valve prosthesis, position CorCap CSD and place posterior attachments prior to valve replacement or repair.
- b. Fitting of the device (Steps 8-12) should not be performed until patient is off bypass and has a full, stable beating heart post-MVR.

DEVICE NOTES

- The CorCap CSD is provided sterile and is for single use only.
- The CorCap CSD may not be resterilized.
- The CorCap CSD is latex free.
- The CorCap CSD is MRI compatible.
- The CorCap CSD is nuclear scan-compatible.
- The CorCap CSD does not complicate future cardiac catheterization.

WARRANTY

Acorn Cardiovascular, Inc.™, has taken reasonable care in the design and manufacture of this product. Other than this representation, there are NO EXPRESS OR IMPLIED WARRANTIES INCLUDING, WITHOUT LIMITATION, and WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Acorn Cardiovascular, Inc., shall not be liable for any incidental or consequential damages other than as expressly provided by specific law. No person has the authority to make any representation or warranty other than as set forth in this paragraph.

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CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

