## The SVR System

| Product Code | Description |
|---|---|
| SVC-0080S | SVR System with 80cc Mannequin - without Patch |
| SVC-0085S | SVR System with 85cc Mannequin - without Patch |
| SVC-0090S | SVR System with 90cc Mannequin - without Patch |
| SVC-0100S | SVR System with 100cc Mannequin - without Patch |
| SVC-0110S | SVR System with 110cc Mannequin - without Patch |
| SVC-0120S | SVR System with 120cc Mannequin - without Patch |
| SVC-0130S | SVR System with 130cc Mannequin - without Patch |
| SVC-0140S | SVR System with 140cc Mannequin - without Patch |
| SVC-0150S | SVR System with 150cc Mannequin - without Patch |

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## The SVR System

**Product Description:**
The SVR System* consists of a *Mannequin* Endoventricular Shaper, Patch Sizer, Syringes and Marking Pen. Physicians may also use a Hemashield Patch as part of procedure (not included).

- The *Mannequin* is shaped to fit inside the left ventricle. It is available in multiple sizes to hold the appropriate volumes of fluid to accommodate different sized ventricles.
- The Patch Sizer is a transparent flexible film with a stem and a separate handle that inserts into the stem.
- The syringes are sized to the specific volume of the *Mannequin* selected.
- The blue surgical marking pen is used to mark on the Patch Sizer.

**Sterile, Nonpyrogenic, Disposable, Single use only**

**Indication for Use:**
The SVR System is used inter-operatively in a Surgical Ventricular Restoration procedure on certain heart failure patients to assist the surgeon in restoring the left ventricle to its appropriate size and shape. The SVR System provides the surgeon with the tools to consistently achieve the proper size and elliptically shaped ventricle in proper orientation for each individual patient.

**Contraindications:**
This device is not intended for use except as indicated above.

**Warnings:**

- **DO NOT REUSE OR RESTERILIZE.** Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Proper surgical procedures and techniques are the responsibility of the medical professional. The surgical team must evaluate the appropriateness of the procedure based on their experience. The procedure detailed below is for information purposes only.[1] The outcome is dependent on many variables, including patient anatomy, pathology, surgical technique and anesthesia management.
- Although product has been carefully designed, manufactured and inspected or tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the product labeling and in this document provide more detailed information and should be read by the user prior to use of product.
- Do not over-inflate the device.
- Do not attempt to insert or remove the device while the device is fully inflated.
- Do not insert device into the mitral valve.
- If a Hemashield Patch is used, refer to the manufacturer's Directions for Use for proper surgical technique.

**Precautions:**

- Store at room temperature 15° - 25° C (59° -77° F). Protect from extreme heat or humidity.
- Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.
- The Directions for Use are furnished for information purposes only.
- Product is Ethylene Oxide sterilized.
- Sterile unless package is opened or damaged.
- Ensure that the appropriately sized Mannequin is selected.[2]
- If using a patch, cutting the patch to proper size is essential. Use the sizer to gauge the size and shape of the grafting area prior to cutting the patch. Use the sizer holder to position the sizer.

**Adverse Effects:**
None Known.

**Directions for Use:**

1. Carefully read instructions prior to use.
2. Inspect package and product for damage and expiration date prior to opening the package
3. If undamaged and unexpired, use aseptic technique to remove the tray from the pouch and remove the components from the tray.
4. If not already cannulated, cannulate to place the patient on total bypass and arrest the heart.
5. Identify the center of the scar on the epicardial surface. Incise the center of the scar lateral to the LAD and extend through the scarred area.
6. Secure the four corners of the opening with suture.
7. Palpate the inside of the ventricle circumferentially to determine the extent of the thinned (scarred) area (or transition zone) and extend the incision as necessary. Inspect the ventricle and remove any thrombus.
8. Identify the transition zone between viable and non-viable myocardium.
9. Fill the included syringes with normal saline.
10. Fully inflate the *Mannequin* with normal saline and remove all air through the inflation/deflation port.



11. Gently squeeze the *Mannequin* and check for leaks. Do not use if leaking.
12. Withdraw 80% of the saline from the *Mannequin* into a syringe.
13. Insert the partially filled *Mannequin* approximately 3 cm into the ventricle then fully inflate to the stated volume. Seat the base of the *Mannequin* against the mitral valve. **Ensure the *Mannequin* does not slip into the mitral valve**. Once positioned, the tip of the *Mannequin* identifies the new apex.
14. If a gap exists between the transition zone and new apex, remove the *Mannequin* and reinforce the scarred area by plicating the inferior wall. This technique defines the longitudinal diameter from the mitral valve to the new apex.
15. Using 2.0 Prolene suture, start the Fontan purse string at the new apex. Continue the purse string stitch along the transition zone using the Mannequin as a guide. Continue clockwise until the suture is back at the apex. If akinetic tissue will not be excluded by the Fontan stitch due to the size of the scar, follow the outline of the shaping device with the suture.
16. Snare the purse string suture and inspect with a finger to ensure that the ventricle is pulled tightly around the shape of the *Mannequin* and to respect the longitudinal diameter of the new ventricle.
17. If the opening of the ventricle is less than 3 cm, it may be closed without a Hemashield Patch.

    **If using the Hemashield Patch:**
18. Place the handle of the patch sizer into the stem of the sizer until secured.
19. Hold the sizer over the opening of the ventricle. With the marking pen provided, mark the sizer to estimate the size of the ventricle's opening. **Note:** Do not mark tissue with marking pen.
20. Away from the surgical field, trim the sizer to be 0.5 cm larger in the shape and size of the ventricle's opening to help ensure hemostasis.
21. Place the sizer on the Patch and trim the Patch to the appropriate shape and size using the sizer as a guide.
22. Begin to suture the patch into the opening starting at the basal portion and continuing down the septal side of the Patch towards the apex. Repeat the suturing down the other side of the Patch starting again at the basal portion.
23. After approximately 75% of the patch has been sutured into the ventricle, withdraw the saline from the *Mannequin* and remove it from the ventricle.
24. Complete suturing the Patch into the ventricle.
25. Suture the excluded tissue over the patch using the "vest over pants" technique. Optional: Apply a felt strip on either side of the closed incision to prevent suture from rupturing.
26. Complete the procedure. When finished, discard the *Mannequin* and all components according to approved hospital procedures.

* Patents: US6681773, US6994093.

[1] L. Menicanti, M. DiDonato, Seminars in Thoracic and Cardiovascular Surgery, Vol 13, No 4, 2001 pp. 496-503

[2] "Endoventricular Patch Reconstruction…" Vincent Dor et. al. Journal of Cardiac Surgery 1999, 14:46-52.

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