HeartSpan

Suggested Procedure

1. Advance the Braided Transseptal Sheath and Dilator assembly into the superior heart chambers, including the left atrium via transseptal puncture.

2. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, resterilization or reuse may cause physical and chemical degradation of the materials and compromise the ability of the device to perform to its intended purpose, and may also increase the risk of infection and/or other adverse reactions.

3. The device(s) should be used by physicians engaged in the practice of specialized interventional cardiology.

4. Completely flush the transseptal needle.

5. Insert Introducer Needle (not supplied) into vessel. Look for blood return to placement of the sheath and dilator may include, but are not limited to:

- atrial septal defect
- pseudoaneurysm formation
- dissection
- stroke
- coronary artery spasm and/or damage
- pulmonary edema
- pericardial/pleural effusion
- arrhythmias may occur during the use of any intracardiac device. Careful positioning procedures.

6. Care should be taken to avoid excessive bending of the sheath and/or dilator or on the tip of the sheath.

7. Hold guidewire in place and remove Introducer Needle. Do not withdraw the needle until it is about to protrude from the dilator tip.

8. Careful sheath manipulation must be performed in the presence of an implantable pacemaker. Apply slight clockwise (left) rotation to dilator hub. Thread the dilator/sheath assembly over the guidewire, using a slight counter-clockwise (right) rotation over the dilator sheath hub. Re-attach the dilator and sheath hubs.

9. Direct percutaneous insertion of the sheath requires the use of the dilator to

   a. Enlarge cutaneous puncture site with scalpel.
   b. Assemble dilator and sheath together until the dilator hub locks into the sheath hub. Thread the dilator/sheath assembly over the guidewire, using a slight counter-clockwise (right) rotation over the dilator sheath hub. Re-attach the dilator and sheath hubs.
   c. Proceeding.
   d. Carefully inspect the package for any breach of the sterile barrier or damage to the product label.

10. Arrhythmias may occur during the use of any intracardiac device. Careful positioning procedures.

11. After confirming the position of the dilator tip and needle point against the atrial septum in the region proceeding.

12. After removal of the sheath, use standard technique to achieve hemostasis.

13. Attach the sheath sideport to the monitoring line. Gently aspirate blood through the side arm for sampling and to be sure the sheath is clear of air.

14. Advance the sheath slowly over the dilator-needle combination until it is in the fossa ovale by gradually rotating the needle posteriorly and toward the location of the fossa ovale by gradually rotating the needle posteriorly and toward the fossa ovale. Location of sheath can be confirmed fluoroscopy. Location of sheath can be confirmed fluoroscopy.

15. Advance the sheath approximately 2 cm into the left atrium while maintaining the dilator in the left atrium.

16. Disconnect the pressure monitoring line from the needle.

17. Monitor the right atrial pressure by connecting the needle hub to pressure pressure.

18. Enlarge cutaneous puncture site with scalpel.

19. Assemble dilator and sheath together until the dilator hub locks into the sheath hub. Thread the dilator/sheath assembly over the guidewire, using a slight counter-clockwise (right) rotation over the dilator sheath hub. Re-attach the dilator and sheath hubs.

20. Confirm proper needle position.

21. Aspirate all air from the sheath valve assembly by using a syringe connected to stopcock is in the closed position after flushing, to prevent back-bleeding.

22. Carefully read the instructions for each accessory before use.

23. For U.S.-California Only.

24. The Braided Transseptal Sheath is designed to provide a conduit to deliver diagnostic and therapeutic devices for positioning and maintaining the position of catheters at specific locations in the heart. The Braided Transseptal Sheath has a tapered tip.

25. Sheath Length, Diameter, and Curve configurations are indicated on the product label.

26. Contents:


27. HOW SUPPLIED:

28. Merit Medical Systems, Inc.

29. Malvern, PA 19355 USA