Suggested Procedure

**USE STERILE TECHNIQUE**

**PROCEDURAL CONSIDERATIONS**

**Inspect all components before use.**

**Monitor vital signs throughout the procedure.**

**Infusion through the sideport should only be done after all air is removed from the catheter.**

**Contents are supplied STERILE using an ethylene oxide (EO) process. Do not use if the package is damaged!**

**The steerable introducer contains a hemostasis valve to minimize blood loss during procedures.**

**Not made with natural rubber latex.**

**The HeartSpan Steerable Sheath Introducer set consists of a dilator, guide wire, and catheter.**

**For U.S.-California Only.**

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

**Merit Medical Systems, Inc. relies on the physician to determine, assess, and communicate to each patient all directions. Failure to do so may result in patient complications.**

**Ref 403194001 ID092315**

**There is a risk of air embolization when withdrawing objects from the sheath.**

**If pericardial or aortic entry occurs, do not advance the dilator over the sheath.**

**Left atrial access can be confirmed with contrast injections.**

**When using this device, fluoroscopy should be used to confirm positioning throughout the procedures.**

**The sheath, dilator, and guide wire are designed for single use only. Reuse may expose the device to communicable disease and/or injury. Sheath Introducer and/or dilator. When advancing the sheath and/or dilator across a cardiac device of any kind, to minimize the potential to displace or dislodge lead transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. reprocessing or resterilization may also create a risk of contamination of the device sterile barrier is damaged.**

**Do not use any unit if this device is supplied sterile and intended for one-time use only. Do not use any unit if the package is damaged!**

**Maximum in vivo time: 7 hours**

**Fluoroscopic monitoring of the location of the distal tip of the sheath using the radiopaque marker, especially when used in a transseptal approach, is recommended.**

**Patients who do not tolerate anticoagulation therapy.**

**Presence of atrial thrombus.**

**The following conditions require that special care be taken when using this product:**

- intimal tear
- interatrial septum dissection
- death
- air embolism

**During insertion, always use the stylette to facilitate HeartSpan needle passage.**

**Flush the HeartSpan needle with clean heparinized saline, ensuring that no air enters.**

**Aspirate and flush the dilator with clean heparinized saline, ensuring that no air enters.**

**After the HeartSpan needle curve is advanced beyond the hemostasis valve portion of the sheath, reconnect the sheath and dilator by retracting the sheath back over the dilator hub and the HeartSpan needle hub.**

**If the patient does not tolerate the guide wire, insert a J-tipped guide wire and withdraw the needle.**

**OPTIONAL:**

- Introduce a “J” tip guide wire into the superior vena cava.
- Withdraw the HeartSpan needle assembly until the tip of the stylette is just within the foot end of the patient.
- Prepare the HeartSpan transseptal needle.
- Connect a pressure monitoring line to the HeartSpan needle stopcock.
- After confirming that the tip of the HeartSpan needle is within the dilator, drag the dilator over the sheath and needle assembly. Observe the dilator tip for medial (or rightward) movement during the drag, indicating that the tip has engaged the fossa ovalis. It is critical to maintain the previous orientation of the HeartSpan needle hub. **OPTIONAL:**

- Confirm that the needle tip is inside the dilator by fluoroscopy and previous injection of contrast within the left atrium. **OPTIONAL:**

- Aspirate and flush the dilator with clean heparinized saline, ensuring that no air enters. **OPTIONAL:**

- Flush the HeartSpan needle with clean heparinized saline, taking care to prevent air bubbles. **OPTIONAL:**

- If pericardial or aortic entry occurs, do not advance the dilator over the sheath. **OPTIONAL:**

- Left atrial access can be confirmed with contrast injections. **OPTIONAL:**

- The sheath, dilator, and guide wire are designed for single use only. Reuse may expose the device to communicable disease and/or injury. Sheath Introducer and/or dilator. When advancing the sheath and/or dilator across a cardiac device of any kind, to minimize the potential to displace or dislodge lead transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. reprocessing or resterilization may also create a risk of contamination of the device sterile barrier is damaged.**

**Do not use any unit if this device is supplied sterile and intended for one-time use only. Do not use any unit if the package is damaged!**

**Maximum in vivo time: 7 hours**

**Fluoroscopic monitoring of the location of the distal tip of the sheath using the radiopaque marker, especially when used in a transseptal approach, is recommended.**

**Patients who do not tolerate anticoagulation therapy.**

**Presence of atrial thrombus.**

**The following conditions require that special care be taken when using this product:**

- intimal tear
- interatrial septum dissection
- death
- air embolism