HeartSpan®
STEERABLE SHEATH INTRODUCER

INSTRUCTIONS FOR USE

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications. Merit Medical Systems, Inc. relies on the physician to determine, assess, and communicate to each patient all foreseeable risks of the procedure.

For U.S.-California Only.
Proposition 65, a State of California voter initiative requires the following notice:
WARNING: This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

CAUTION:
- Federal (USA) law restricts this device to sale by or on the order of a physician. This device should be used only by physicians thoroughly trained in percutaneous procedures.
- Do not alter this device in anyway.
- This device is supplied sterile and intended for one-time use only. Do not use any unit if its package is opened or damaged. Do not re-sterilize and/or reuse.

HOW SUPPLIED:
Sterile: Sterilized with ethylene oxide gas.
Non-pyrogenic.
Not made with natural rubber latex.

Contents:
One (1) Radiopaque Steerable Sheath
One (1) Radiopaque Dilator
One (1) Guide wire

DESCRIPTION
The HeartSpan Steerable Sheath Introducer set consists of a dilator, guide wire, and steerable sheath, which are designed for catheter introduction into the cardiac anatomy. The steerable introducer contains a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The introducer handle includes a rotating knob to enable clockwise and counterclockwise tip deflection ≥180°. The steerable introducer also includes distal holes to facilitate aspiration and minimize cavitation, a radiopaque tip marker to improve fluoroscopic visualization, an atraumatic soft tip, and a lubricious coating on the inner and outer surfaces. The dilator is designed to conform to the inner diameter of the sheath, and has a tapered tip.

INDICATIONS
The HeartSpan Steerable Sheath Introducer is indicated for introduction of various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS
- Previous intra-atrial septal patch.
- Known or suspected atrial myxoma.
- Myocardial Infarctions within the last two weeks.
- Unstable angina.
- Recent Cerebral Vascular Accident (CVA).
- Patients who do not tolerate anticoagulation therapy.
- Patients with an active infection.
- Presence of atrial thrombus.

WARNINGS
- Contents are supplied STERILE using an ethylene oxide (EO) process. Do not use if the sterile barrier is damaged.
- For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, 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, reprocessing 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.
- The device should be used by physicians engaged in the practice of specialized invasive cardiology techniques. Use of the device should be restricted to those physicians specifically trained in the approach to be used.
- When the sheath is left in the vessel, a continuous heparinized infusion under pressure through the sheath sideport is strongly recommended.
- Infusion through the sideport should only be done after all air is removed from the unit.
- Do not use a power injector through the sideport extension or 3-way stopcock.
- Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve components, resulting in blood flow through the valve, as well as cause a vacuum which may allow air to enter the sheath.
- Aspiration of the sideport is recommended when withdrawing the catheter, probe, or dilator, to remove any fibrin deposition which may have accumulated in or on the tip of the sheath.
- Careful sheath manipulation must be performed in the presence of an implantable cardiac device of any kind, to minimize the potential to displace or dislodge lead placement.
- Direct percutaneous insertion of the sheath requires the use of the dilator to minimize the potential risk of vessel injury due to a flared tip.
- 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.
- Maintain continuous hemodynamic monitoring throughout the procedure.
- Prior to removing the steerable introducer, reinsert the guide wire through the introducer. Re-introduce the dilator over the guide wire, straighten the steerable introducer, then remove the dilator, guide wire, and introducer as a unit.
- Maximum in vivo time: 7 hours

PRECAUTIONS
- Aspiration and flushing of the sheath, dilator, and catheter should be performed frequently to help minimize the potential for air embolism or thrombus formation.
- Indwelling sheaths should be internally supported by a catheter, electrode, or dilator.
- Never advance, torque, or withdraw the guide wire, dilator, or sheath when resistance is met. Determine the cause by fluoroscopy and take remedial action.
- Use only the sideport for injection or aspiration of the sheath and sideport assembly. Assure that the stopcock is in the closed position after flushing, to prevent back-bleeding. Aspirate slowly.
- The following conditions require that special care be taken when using this product involving the transseptal approach.
  - » enlarged aortic root
  - »marked right atrial enlargement
  - »small left atrium
  - »marked distortion of the thoracic configuration (e.g. kyphosis or scoliosis)
- Care should be taken to avoid excessive bending of the sheath and/or dilator before and during use.
- Fluoroscopic procedures involve exposure to ionizing radiation by the patient and staff. Precautions to minimize exposure should be taken and protective equipment should be used.
- Fluoroscopic guidance should be used when advancing the HeartSpan Steerable Sheath Introducer and/or dilator. When advancing the sheath and/or dilator across a valve, a guide wire or pigtail should be used.
- The sheath, dilator, and guide wire are designed for single use only. Reuse may expose the patient to communicable disease and/or injury.
- Arrhythmias may occur during the use of any intracardiac device. Careful monitoring and availability of emergency equipment are mandatory.
- When using the HeartSpan Steerable Sheath Introducer in the presence of radio frequency ablation, care must be taken to assure all ablating elements are outside the sheath.
- The French sizes specified on the product labeling represent the inside and outside diameters of the introducer sheath.
- Do not attempt to insert a catheter having a distal tip or body size larger than the inside diameter indicated on the product labeling.
- The HeartSpan Steerable Sheath Introducer is designed to interlock only with the accompanying dilator. Misuse may result in serious complications.
- Do not attempt to use a guide wire larger than the maximum diameter specified on the package label.
- Before inserting the device into the patient, assemble the steerable Introducer and dilator.
- Do not remove the dilator or catheter rapidly. Damage to the sheath valve could occur.
- Do not deflect the device beyond 180° prior to Insertion of an 8 mm tip electrode catheter.
- STORE IN A COOL, DARK, DRY PLACE.

POTENTIAL COMPLICATIONS
Potential complications that may occur during the use of this device include, but are not limited to:
- air embolism
- arterial thromboembolism
- cardiac tamponade
- death
- infection
- interatrial septum dissection
- intimal tear
- hematoma
- perforation
- peri-interventional stroke
- pseudoaneurysm
- thrombus formation

Please consult the respective manufacturer's labeling for adverse events associated with the use of cardiovascular catheters.

HOW SUPPLIED
The HeartSpan device kit is supplied sterile within a chevron pouch. The package contents are listed above.

PROCEDURAL CONSIDERATIONS
Carefully read the instructions before use of this device to help reduce the potential risks associated with the transseptal technique, such as air emboli or perforation of the aorta or left atrium. Only those physicians who are trained in transseptal procedures should use this device. Fluoroscopy should be used to confirm positioning throughout the procedure. Transseptal procedures should be performed only in appropriately equipped and staffed facilities. Lab capabilities should include, but are not limited to:
- »intracardiac pressure monitoring capabilities
- »systemic pressure monitoring
- »contrast media injection, and management of untoward reactions to contrast media
- »pericardiocentesis
- »surgical backup
- »anticoagulation therapy and monitoring

- Monitor vital signs throughout the procedure.
- Inspect all components before use.
- Use only a HeartSpan transseptal needle with a mating stylette.
- Prior to inserting the device into the patient, assemble the sheath and dilator, insert the HeartSpan needle into the dilator, and check for excessive resistance as the tip of the HeartSpan needle advances through the sheath/dilator assembly.
- During insertion, use caution to avoid excessive bends in the device, which could inhibit advancement of the needle and result in inadvertent needle puncture of the dilator/sheath assembly.
- During insertion, always use the stylette to facilitate HeartSpan needle passage through the dilator / sheath assembly. (Failure to use the stylette could inhibit needle advancement, and could result in inadvertent puncture of the dilator/sheath assembly or skiving of material from the inner surface of the dilator).
- Remove components and make catheter exchanges slowly to minimize the potential for creating a vacuum in the sheath.
- After the sheath is inserted into the vasculature and the dilator is removed, aspirate prior to flushing or infusion until steady blood return is achieved.
- All fluid infusion should be through the sideport.
- Because thrombus could accumulate in or on the sheath tip during the procedure, aspirate when moving the dilator or catheter.
- To minimize embolic risk, either provide a continuous infusion of heparinized solution or periodically aspirate and flush through the sideport while the sheath is positioned in the vasculature.
- If resistance is met when advancing or withdrawing the guide wire or introducer, determine the cause and perform a corrective action before continuing with the procedure.
- Indwelling intracardiac introducer sheaths should always be supported with a catheter, dilator, or electrode.
- Do not manipulate the sheath within the heart without a device extending from its distal tip.

USE STERILE TECHNIQUE
Suggested Procedure
NOTE: Typical variations may occur within these steps, depending on available capabilities and operator preference. See OPTIONAL steps below.

1. COMPONENT PREPARATION AND ASSEMBLY
Preparation requires the following Items:
- »One HeartSpan sheath and dilator.
- »One HeartSpan transseptal needle, with a mating stylette.
- »One guide wire with "J" tip.
- »Syringes for aspiration and flushing.
- »Sterile heparinized saline.
- »**OPTIONAL:** One 3-way rotating stopcock

- Flush the dilator and sheath with sterile heparinized saline.
- Position the handle of the sheath stopcock so that it is in the OFF position. (The OFF marking should point toward the sideport tube.)
- Fully insert the dilator into the sheath.
- Prepare the HeartSpan transseptal needle.
- Remove the stylette from the HeartSpan needle and flush the needle with sterile heparinized saline.
- Re-insert the stylette into the HeartSpan needle and lock it onto the hub.
- Insert the HeartSpan needle and stylette into the sheath/dilator.
  Note: due to the internal stop feature of the dilator, there will be a gap between the dilator hub and the HeartSpan needle hub.
- Withdraw the HeartSpan needle assembly until the tip of the stylette is just within the tip of the dilator.
- Measure the distance between the HeartSpan needle hub and the dilator hub. Record this measurement for use during the procedure.

CAUTION: It is critical to maintain this distance between the HeartSpan needle hub and the dilator hub during the procedure, to ensure that the tip of the HeartSpan needle assembly does not protrude from the dilator tip until it is deployed for transseptal crossing.
OPTIONAL: A secondary measurement can be performed to establish the distance between the HeartSpan needle hub and the dilator hub when the HeartSpan needle tip is just inside the tip of the dilator (without the stylette inserted).
- Remove the HeartSpan needle from the dilator.
- Remove the stylette from the HeartSpan needle and flush the HeartSpan needle again. Reinsert and lock the stylette onto the HeartSpan needle hub. Flush the dilator again.
- This completes component preparation and assembly.

2. ADVANCEMENT OF SHEATH/DILATOR ASSEMBLY INTO SUPERIOR VENA CAVA
- Obtain femoral venous access (right femoral preferred).
- **OPTIONAL:** A larger bore introducer sheath may be left in place to maintain access for exchanges and hemostasis. If used, choose a sheath 2½ French sizes larger than the HeartSpan introducer.
- Introduce a "J" tip guide wire into the superior vena cava.

NOTE: 0.038" is the maximum guide wire diameter that can be used with the HeartSpan dilator.
- Insert the sheath and dilator assembly over the guide wire and advance the assembly into the superior vena cava (SVC). Once the dilator tip is in the SVC, make sure the tip is pointed medially.

3. POSITIONING OF THE NEEDLE/STYLETTE ASSEMBLY INSIDE THE SHEATH/ DILATOR ASSEMBLY
- Remove the guide wire from the dilator.
- Aspirate and flush the dilator with clean heparinized saline, ensuring that no air enters the bloodstream.
- Partially withdraw the dilator from the sheath by a distance sufficient to accommodate the HeartSpan needle curve. This will facilitate passage of the HeartSpan needle curve through the dilator and sheath hubs.
- Confirm that the stylette is locked onto the hub of the HeartSpan needle. Then insert the HeartSpan needle into the dilator, allowing the needle to rotate freely as it advances.
- 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, while maintaining the position in the SVC. (DO NOT advance the dilator into the sheath.)
- Advance the HeartSpan needle and stylette until the distance between the dilator and HeartSpan needle hubs is the same as the distance previously measured during COMPONENT PREPARATION AND ASSEMBLY.
- Remove the stylette and set it aside. (Do not discard it.)
- **OPTIONAL:** The HeartSpan needle may be advanced slightly. Do not exceed the secondary measurement of the distance between the HeartSpan needle and dilator hubs. (See "COMPONENT PREPARATION AND ASSEMBLY" section above.)
- Attach a syringe to the HeartSpan needle hub and aspirate until blood return is observed. Discard the syringe.

NOTE: The use of a slip-tip (non·Luer) syringe may prevent air aspiration.
- Flush the HeartSpan needle with clean heparinized saline, ensuring that no air enters the bloodstream. Close the needle stopcock.
- **OPTIONAL:** Attach a syringe with radiopaque contrast media to the HeartSpan needle stopcock. After aspirating the needle until blood return is observed, load the HeartSpan needle with the contrast media under fluoroscopic guidance.
- **OPTIONAL:** Connect a pressure monitoring line to the HeartSpan needle stopcock.
- **OPTIONAL:** Use a standard 3-stopcock manifold setup to connect contrast, pressure, and flushing lines.

4. FOSSA OVALIS ENGAGEMENT
- Visualize and identify anatomic landmarks. Set the fluoroscopy unit to an appropriate angle, parallel to the plane of the mitral valve and orthogonal to the plane of the septum. This will typically be LAO, approximately 30° to 40°.
- **OPTIONAL:** Placement of catheters in the coronary sinus (CS) and His positions can assist in identification of anatomic landmarks. In the appropriate LAO view, the CS catheter can be seen in profile. In the appropriate RAO view, the His catheter will appear in profile. The fossa ovalis is located at or slightly below the His catheter, and superior and posterior to the coronary sinus ostium.
- **OPTIONAL:** Placement of a pigtail catheter in the non-coronary cusp of the aortic root can facilitate the identification of anatomic landmarks.
- **OPTIONAL:** Observe the pressure waveform being recorded through the HeartSpan transseptal needle. Adjust the HeartSpan needle hub so that the needle is perpendicular to the fossa ovalis (typically between 3:00 and 5:00, as viewed from the foot end of the patient).
- Confirm that the needle tip is inside the dilator by fluoroscopy and previous measurement of the distance between the HeartSpan needle and dilator hubs.
- After confirming that the tip of the HeartSpan needle is within the dilator, drag the assembly slowly while preventing any relative movement of the assembly components. It is critical to maintain the previous orientation of the HeartSpan needle hub.
- Observe the dilator tip for medial (or rightward) movement during the drag, indicating that the tip has engaged the fossa ovalis.
- **OPTIONAL:** If pressure is being monitored, note that the pressure through the HeartSpan needle will not be accurate at this point, since the tip is contacting the fossa ovalis.

5. FOSSA OVALIS PUNCTURING WITH THE TRANSSEPTAL NEEDLE
CAUTION: Confirm the correct location of the needle on the fossa ovalis before advancing the needle.
- Once the correct location is confirmed, advance the HeartSpan needle across the interatrial septum.
- **OPTIONAL:** If pressure is being monitored, entry into the left atrium is confirmed when the pressure tracing shows a left atrial pressure waveform.
- **OPTIONAL:** Left atrial access can be confirmed with contrast injections.
- If there is any resistance to needle advancement, re-evaluate the anatomic landmarks.

CAUTION: If pericardial or aortic entry occurs, do not advance the dilator over the HeartSpan needle. If the needle has penetrated the pericardium or aorta, it must be withdrawn. Monitor vital signs closely.

6. ADVANCEMENT OF THE SHEATH/DILATOR ASSEMBLY
- While maintaining a fixed needle position, advance the sheath/dilator assembly over the HeartSpan needle.

7. ADVANCEMENT OF THE SHEATH OVER THE DILATOR AND NEEDLE INTO THE LEFT ATRIUM
- Withdraw the HeartSpan needle until its tip is just inside the dilator tip. Maintain the position of the needle and dilator across the septum.
- With the dilator in a fixed location, advance the sheath over the dilator.

8. WITHDRAWAL OF THE HEARTSPAN TRANSSEPTAL NEEDLE AND DILATOR.
CAUTION: There is a risk of air embolization when withdrawing objects from the sheath. Take precautions to prevent air infiltration.
- Disconnect any attachments to the HeartSpan needle hub.
- Withdraw the HeartSpan needle from the dilator. Immediately attach a syringe to the dilator and aspirate. Continue aspirating blood while holding the sheath in position and withdrawing the dilator. Confirm the presence of arterial blood.
- Once the dilator is removed, aspirate blood through the sideport of the sheath, and then flush it with heparinized saline, taking care to prevent air bubbles.
- The sheath is now in position within the left atrium.

NOTE: The symbols section below contains the symbols included on product labels. The product is labeled as required.

ENGLISH

Symbol	Meaning
STERILE EO	
	Contents are non-pyrogenic
STERILIZE	Do Not Resterilize
	Single use only. Do not reuse!
	Manufactured by
	Manufacturing Date
LOT	Lot Number
	Use Before
#	Contents
	Do not use if package is damaged!
REF	Catalog No./Model No.
	Caution: Consult accompanying documents
EC REP	Authorized European Representative
	Inner Diameter
	Outer Diameter
	Store in a cool, dark, and dry place.

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