# SafeSept®
Transseptal Guidewire

STERILE EO

15° C – 30° C

**Rx ONLY** CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.


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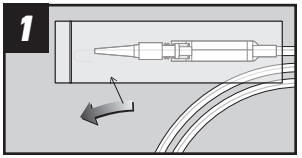
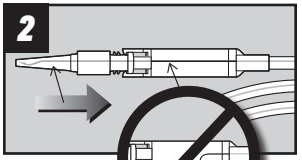
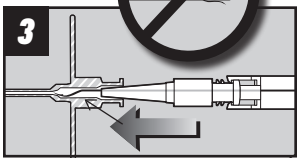
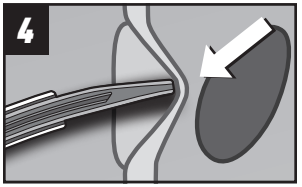
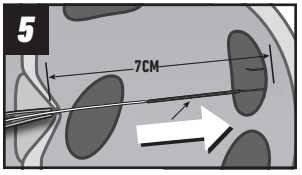
Pressure® Products
ACCESSING THE HEART OF INNOVATION

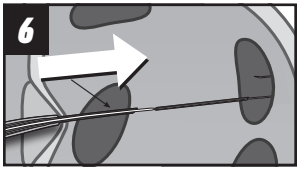


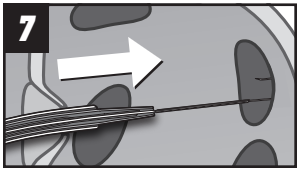




## en-Instructions for Use

The SafeSept® Transseptal Guidewire is a nitinol guidewire designed to cross the interatrial septum when supported by a transseptal introducer and be atraumatic when advanced unsupported into the left atrium. A radiopaque coil is positioned on the distal end of the device to provide visual guidance during the procedure. Black markers are positioned on the proximal end of the device to provide approximate Transseptal Guidewire tip location relative to the needle tip during the procedure.

### INTENDED USE

The SafeSept® Transseptal Guidewire is used in conjunction with a transseptal needle to create the primary puncture in the interatrial septum and to guide the needle, dilator, and introducer through the septum from the right side of the heart to the left side.

### INDICATIONS FOR USE

Indicated for use in procedures where access to the left atrium via the transseptal technique is desired. The SafeSept® Transseptal Guidewire is intended for single use only.

### CONTRAINDICATIONS

The use of the SafeSept® Transseptal Guidewire is contraindicated in patients with the following conditions:

- Distorted anatomy due to congenital heart disease or other causes
- Significant chest or spine deformity
- The inability to lie flat
- Ongoing anticoagulation
- Left atrial thrombus or tumor
- Dilated aortic root
- Previous patch repair of the interatrial septum

### WARNINGS AND PRECAUTIONS

- Single-Use Only: Do not re-use this device. After use thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from re-use of this device.
- Ensure compatibility with transseptal needle inner diameter prior to use
- Store in a cool, dark, and dry place
- Prolonged exposure to temperatures above 30 °C (86 °F) may damage the product
- Do not use if package is open or damaged in any way
- Do not use if tip protector not in place

### ADVERSE EVENTS

In addition to all of the complications associated with any transseptal cardiac catheterization, the following can occur during the use of the SafeSept® Transseptal Guidewire:

- Puncture of the atrial free wall
- Puncture of the aorta
- Puncture of the inferior vena cava
- Puncture of the coronary sinus
- Tamponade
- Hemothorax
- Arterial embolism from thrombus at the puncture site
- Pulmonary embolism
- Stroke
- Death
- Atrial arrhythmias
- Residual atrial septal defects

### INSTRUCTIONS FOR USE

*Follow standard transseptal technique:*

1. Per standard technique, aspirate and flush the transseptal system (including the needle, dilator, and sheath) before and after it is inserted into the right atrium.
2. Remove the protective tip cover and back the SafeSept® Transseptal Guidewire slowly into the guidewire tip straightener. Do not pull the Transseptal Guidewire completely out of the tip straightener.
3. Fully insert the tip straightener into the hub of the transseptal needle.
4. Advance the SafeSept® Transseptal Guidewire until the tip enters the curved portion of the transseptal needle (Black markers are provided as a guide for common commercially available needle systems. The Transseptal Guidewire can generally be advanced to the first marker when using a transseptal needle. Do not advance the guidewire beyond the tip of the needle).
5. Tent the fossa ovalis with the transseptal dilator. The transseptal needle tip position should be less than .5cm back from the tip of the dilator.
6. Under visual guidance, while tenting and maintaining constant force on the septum with the dilator, slowly advance the SafeSept® Transseptal Guidewire through the transseptal needle, dilator, and across the interatrial septum, into the left atrium. Continue to advance into one of the pulmonary veins (The radio-opaque coil on the guidewire should be seen to be within the left atrium and subsequently the pulmonary vein). **At no time should the guide wire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action. Confirm proper location of the SafeSept® Transseptal Guidewire prior to proceeding.**
7. The Transseptal Guidewire should be advanced approximately 7cm into the left atrium so that the entire radiopaque coil is across the septum and visible to ensure that the transseptal needle tip does not engage the radiopaque coil during advancement.
8. Slowly advance the transseptal needle through the dilator and over the SafeSept® Transseptal Guidewire across the septum. **Do not hold or pin the Transseptal Guidewire when advancing the transseptal needle.** If desired, measure pressures and/or inject contrast through the needle before advancing the dilator and introducer sheath. Once the needle tip position is confirmed in the left atrium, advance the dilator and introducer sheath over the Transseptal Guidewire into the left atrium.
9. Slowly remove the SafeSept® Transseptal Guidewire, needle, and dilator as a unit, leaving the introducer sheath in place. **Do not remove the Transseptal Guidewire first, leaving the transseptal needle point exposed inside the left atrium. At no time should the introducer, needle, or guide wire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action.**
10. After use, the Transseptal Guidewire may be a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

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|---|---|
| REF | Model Number |
| LOT | Lot Number |
| | Use Before |
| | Quantity |
| | Size |
| | Length |
| | Manufacturing Date |
| Rx ONLY | CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician. |
| | Consult technical manual! |
| | Do not use if packaging is damaged! |
| | Keep away from sunlight |
| | Keep dry |
| 15° C – 30° C | Temperature limitation |
| STERILE EO | Sterilized with ethylene oxide |
| | Single use only. Do not reuse! |
| | Do not resterilize! |
| | Manufacturer |
| | Distributor |