SafeSept RF™ Transseptal Guidewire

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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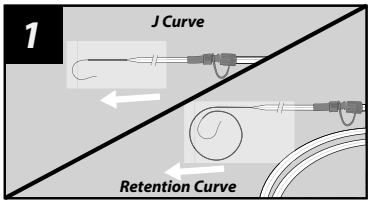
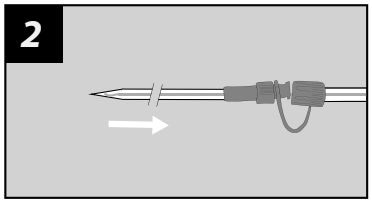
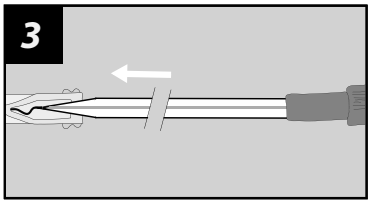
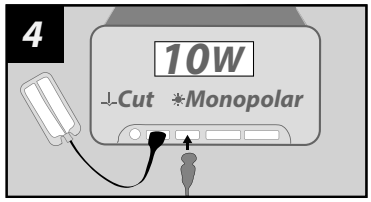
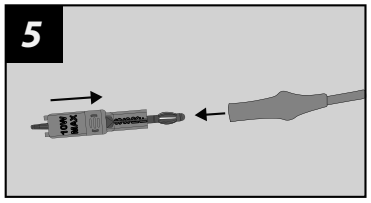
SafeSept RF is a trademark of Pressure Products Medical Supplies, Inc. Patents 10,716,920; 9,821,145; 8,500,697; EP3804800; EP2668972; EP2647405; EP2259832. Other U.S. and worldwide patents pending. Protected by Patent Insurance.

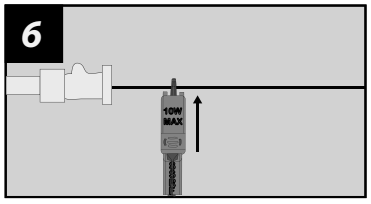


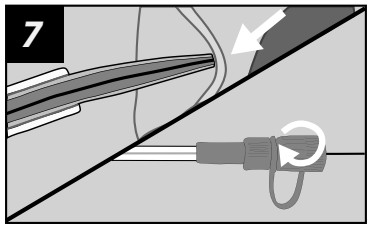


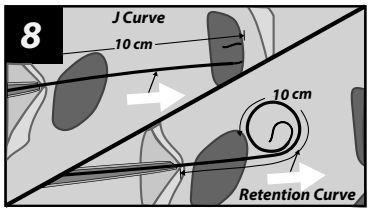












en-Instructions for Use

The SafeSept RF 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. Dark markers are positioned on the proximal end of the device to provide approximate Transseptal Guidewire tip location relative to the dilator tip during the procedure.

Intended Use

The SafeSept RF Transseptal Guidewire is used in conjunction with a transseptal introducer to create the primary puncture in the interatrial septum and to guide the 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 RF Transseptal Guidewire is intended for single use only.

Contraindications

The use of the 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

Electromagnetic Compatibility

- The SafeSept RF Transseptal Guidewire complies with IEC 60601-1-2 emissions limits and immunity requirements.

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 the re-use of this device.
- RF puncture should only be performed by physicians trained in radio frequency cutting or puncture in a fully equipped catheterization laboratory.
- During operation of the electrosurgical unit (ESU), conducted and radiated electrical fields may interfere with other electrical devices or equipment and care should be taken to limit any electromagnetic interference. Ensure that connector and electrode cables are positioned in such a way to avoid contact with the patient or other leads. In order to avoid burns or interference with other equipment, electrodes should be placed as far away from the access site as possible. Incorporating high frequency current limiting devices is also recommended.
- Refer to the ESU Manufacturer's Instructions for Use for proper setup (including application of a compatible grounding pad electrode if applicable), operation, electromagnetic disturbances, and safety precautions prior to use.
- Refer to ESU Manufacturer's Guidance and Declaration for compliance levels regarding electromagnetic emissions, electromagnetic immunity, and recommended separation distances between portable and mobile RF communications equipment.
- Do not attempt to mechanically puncture with the Transseptal Guidewire without the use of RF energy.
- Do not attempt to deliver RF energy unless the Transseptal Guidewire tip is engaged with the target tissue.
- During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.
- To prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application.
- Do not apply more than 10 Watts of power to cross.
- Do not apply power for a duration longer than three seconds to cross.
- Do not attempt to insert and use the proximal end of the Transseptal Guidewire as the active tip.
- Store in a cool, dark, and dry place.
- Prolonged exposure to temperatures above 50C (122F) may damage the product.
- Do not use if the package is open or damaged in any way.
- Do not use if the tip protector is 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 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
- Tissue burns

EQUIPMENT NEEDED (Monopolar Setup)

- Monopolar Electrosurgical Unit (ESU) (also known as electrosurgical generator, or radiofrequency (RF) generator) with digitally selectable power settings in Watts
- Monopolar 4mm cable compatible with ESU
- Grounding pad electrode and cable compatible with ESU

Instructions for Use

Follow the standard transseptal technique:

1. Per standard technique, aspirate and flush the transseptal system (including the transseptal cannula (if used), dilator, and sheath) before and after it is inserted into the right atrium.

2. Refer to the manufacturer's Instructions for Use for application site and placement of the grounding pad electrode and connection of the monopolar cables.

3. Set the Electrosurgical Unit (ESU) power to 10 Watts or less and configure the ESU to "Monopolar" and "Cutting or Cut or Pure" mode as applicable. **Do not use more than 10 Watts power or a power duration longer than three seconds as excess power and/or duration may cause injury to the patient or user.**

4. If using a footswitch to activate, attach the male end of the monopolar 4mm cable to the ESU, and attach the adapter clip (provided) to the 4mm cable by sliding the 4mm male connector fully into the 4mm female cable end.

5. Remove the protective tip cover and back the SafeSept RF Transseptal Guidewire slowly into the guidewire tip straightener. Do not pull the Transseptal Guidewire completely out of the tip straightener.

6. Fully insert the tip straightener into the hub of the vascular access needle (i.e. 19G UTW) (when using the Transseptal Guidewire as an introducer guidewire), transseptal cannula, or dilator. When using the SafeSept RF Transseptal Guidewire as an introducer guidewire, advance the wire into the superior vena cava and follow the transseptal introducer instructions for use.

7. When ready to perform the transseptal crossing, advance the SafeSept RF Transseptal Guidewire until the tip enters the curved portion of the transseptal dilator (dark markers are provided as a guide for common commercially available transseptal introducer systems. Do not advance the Guidewire beyond the tip of the dilator).

8. If using a footswitch to actuate the ESU, attach the adapter clip directly onto the Transseptal Guidewire or the transseptal cannula (if used) by gently squeezing the clip open, inserting over the silver outer surface, and allowing the clip to close firmly over the wire or cannula. If using an electrosurgical pencil, position the pencil so that it is able to engage the Guidewire or cannula silver outer surface.

9. Tent the fossa ovalis with the transseptal dilator. A shorter dilator length may be needed to access the fossa ovalis. This may be accomplished by retracting the dilator into the introducer sheath.

10. Advance the Guidewire so that the tip engages the fossa ovalis but remains within the dilator.

11. Position the tip straightener approximately 10cm from the proximal end of the introducer (use the dark markers as a guide) and lock the tip straightener onto the Guidewire by engaging and rotating the Luer cap clockwise.

12. Under visual guidance, while tenting and maintaining constant force on the septum with the dilator and Guidewire (by holding the tip straightener), apply energy via the ESU and slowly advance the SafeSept RF Transseptal Guidewire across the interatrial septum, into the left atrium. **Do not apply power for a duration longer than three seconds to cross. Once the Guidewire has crossed the interatrial septum, stop applying energy to the Guidewire, and use visual guidance to confirm proper location. At no time should the Guidewire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action. Confirm proper location of the SafeSept RF Transseptal Guidewire prior to proceeding.**

13. The Transseptal Guidewire should be advanced approximately 10cm into the left atrium so that the entire radiopaque coil is across the septum and visible to ensure that the full body diameter portion of the Transseptal Guidewire has crossed the septum. **Advancement of the full body diameter portion into the left atrium should be observed tactilely or visually as the septum is dilated up to the full body diameter.**

14. Slowly advance the transseptal dilator and introducer sheath over the SafeSept RF Transseptal Guidewire across the septum. **Do not hold or pin the Transseptal Guidewire when advancing the dilator. If the introducer dilator tip resists advancement through the septum with typical applied force, apply an oscillating rotation to the dilator while advancing. This will facilitate the dilator tip advancing through the septum (when a steerable introducer sheath is being used, relaxing the sheath curve shape to a straight position will facilitate the rotation and tracking over the Guidewire).** If desired, measure pressures and/or inject contrast through the dilator before completely advancing the dilator and introducer sheath (the SafeSept RF Transseptal Guidewire must be partially retracted into the dilator in order to measure pressure through the dilator). Once the dilator tip position is confirmed in the left atrium, advance the dilator and introducer sheath over the SafeSept RF Transseptal Guidewire into the left atrium. **If the introducer sheath tip resists advancement through the septum with typical applied force, apply an oscillating rotation to the introducer sheath while advancing. This will facilitate the sheath tip advancing through the septum (when a steerable introducer sheath is being used, relaxing the sheath curve shape to a straight position will facilitate the rotation and tracking over the Guidewire).**

15. Slowly remove the SafeSept RF Transseptal Guidewire, and dilator as a unit, leaving the introducer sheath in place. **At no time should the introducer, dilator, or Guidewire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action.**

16. After use, the SafeSept RF 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.

REF	Catalog Number
LOT	Lot Number
	Use-by Date
QTY	Quantity
	Inner Diameter
	Outer Diameter
	Curve
	Length
	Date of Manufacture
Rx ONLY	CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
	Consult Instructions for Use
	Do not use if packaging is damaged
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using ethylene oxide
MD	Medical device
UDI	Unique device identifier
	Single sterile barrier system
	Do not re-use
	Do not resterilize
	Manufacturer
	Distributor