EastEndMedical

SafeCross

Transseptal RF Puncture and Steerable Balloon Introducer System with Short Access Dilator

Instructions for Use

REF	3005	Small
	3006	Medium
	3007	Large

WARNING

Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.

Manufactured by:
East End Medical I, LLC
10320 USA Today Way
Miramar, FL 33025
Tel: +1(954)507-7887
www.safecrossdevice.com

International Symbols Glossary

	Sterilized using Ethylene Oxide		Keep dry
	Do not re-use		Keep away from sunlight
	Do not re-sterilize		Protect from heat and radioactive sources
	Read all instructions before use.		Do not use if package is damaged
	Use by date indicated in label		Caution
	Manufacturer		Non-pyrogenic
	Batch code		Not made with natural rubber latex
	Catalogue number		Prescription only
	Temperature Limit. Indicates the temperature limits to which the medical device can be safely exposed.		

A. Device Description

The SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System with Short Access Dilator, Figure 1, is used to access the heart left atrium through a puncture of the atrial septum. The system comes as a kit consisting of the following three elements: A) Steerable Introducer Sheath (SIS), B) RF Puncture Dilator (PD) and C) Short Access Dilator (AD).

A) Steerable Introducer Sheath (SIS)

B) RF Puncture Dilator (PD)

C) Short Access Dilator (AD)

Figure 1. SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System with Short Access Dilator:
A) Steerable Introducer Sheath (SIS), B) RF Puncture Dilator (PD), C) Short Access Dilator (AD)

Steerable Introducer Sheath

The Steerable Introducer Sheath features a compliant, specially shaped, atraumatic overhanging radiopaque and echogenic Positioning Balloon on its distal end intended to facilitate the accurate positioning and stability of the Steerable Introducer Sheath/RF Puncture Dilator assembly on the fossa ovalis prior and during transseptal puncturing. With an ergonomic single hand control knob, the user is able to bi-directionally deflect the distal segment of the sheath in a range of 0° to 180° to facilitate maneuverability. Three different Steerable Introducer Sheath deflectable distal segment lengths (small, medium, large) are offered to accommodate patient size and anatomy.

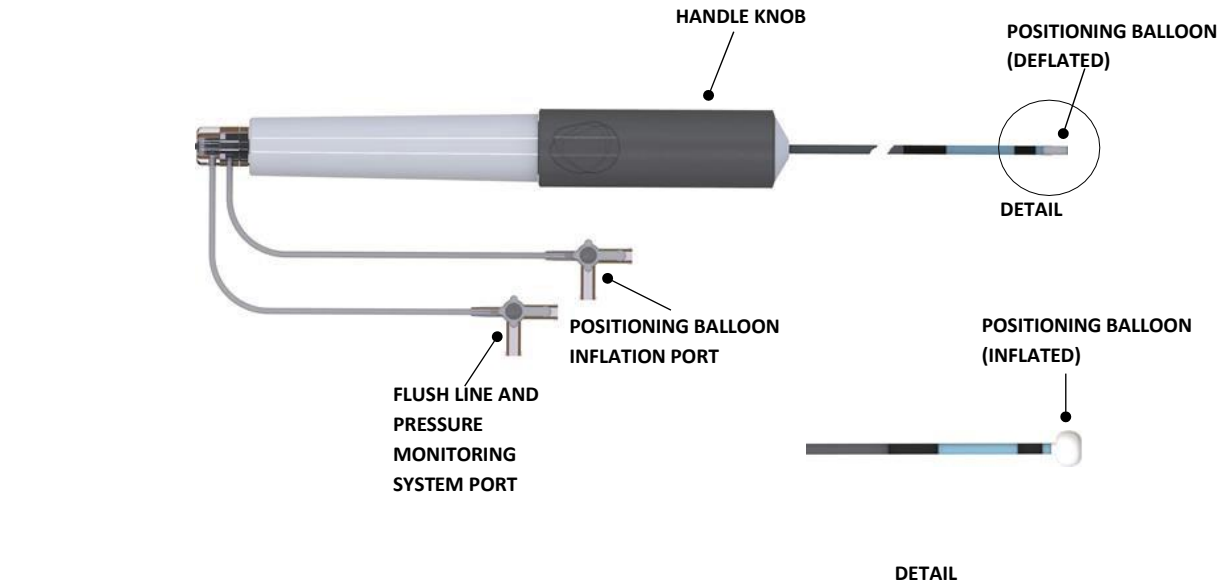

Figure 2. Steerable Introducer Sheath (shown with Positioning Balloon inflated and deflated).

RF Puncture Dilator

The RF Puncture Dilator is compatible with the commercially available electrosurgical generators listed in Section D. The connector on the proximal end of the RF Puncture Dilator is compatible with the Bovie (Apyx Medical) 4mm D-Shaped Disposable Monopolar Active Cable (Ref. No. BOV-A1210D) OR a 2.4mm tipped monopolar electrosurgical pen/pencil, which is used to connect to the monopolar port of the electrosurgical generator unit. The RF Puncture Dilator is advanced over a 0.035" guidewire (not included in the kit) through the Steerable Introducer Sheath lumen and delivers RF energy through its RF Tip (indicated in the detail of Figure 3) to create the puncture in the septum. The RF Tip is shaped in a semi-circular configuration, also shown in the detail of Figure 3. Its proximal luer connector serves as the 0.035" guidewire port and pressure monitoring system connection.

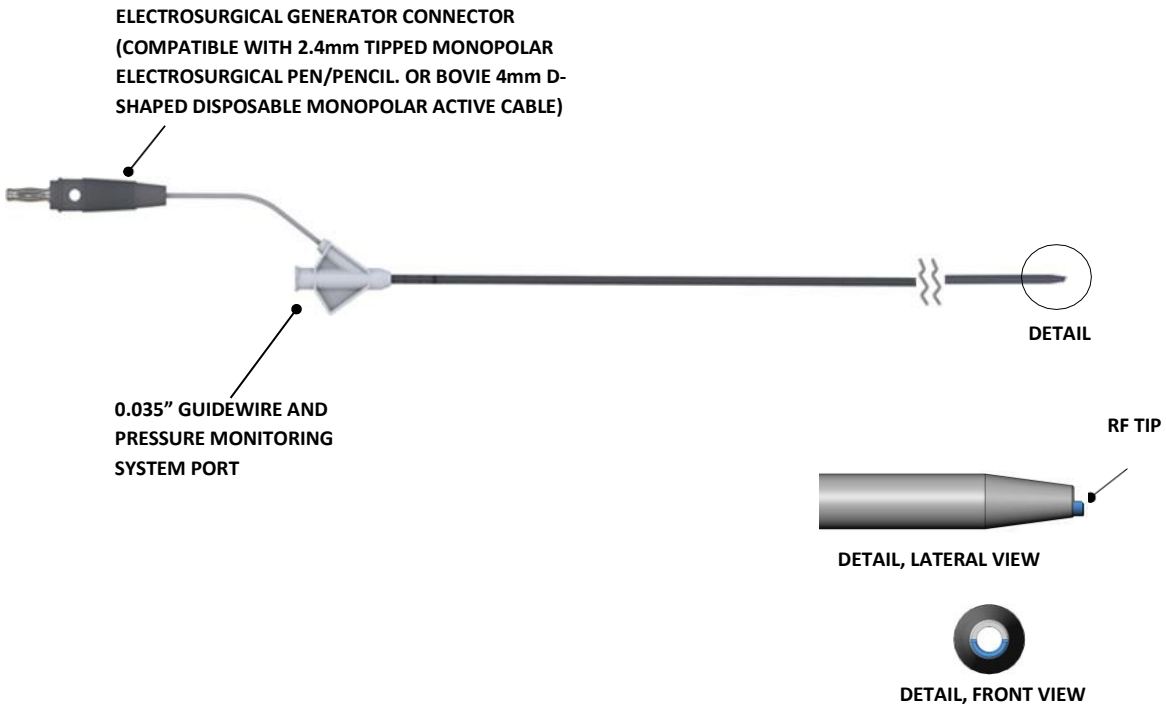

Figure 3. RF Puncture Dilator

Short Access Dilator

The Short Access Dilator is compatible with 0.035" standard guidewires and is used for dilating the access site prior to introduction of the Steerable Introducer Sheath and RF Puncture Dilator into the patient's venous vasculature.

Figure 4. Short Access Dilator

B. Intended Use / Indications for Use

The SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System with Short Access Dilator is used for introducing various cardiovascular catheters into the heart, including the left side of the heart. The system enables left heart access through a puncture of the atrial septum during a transseptal catheterization procedure. In addition, the device can be used for monitoring intracardiac pressures, sampling blood, and infusing solutions.

C. Contraindications

The SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System with Short Access Dilator is contraindicated for patients with:

- Previous intra-atrial patch
- Known or suspected atrial myxoma
- Unstable angina
- Myocardial infarctions within the last two weeks
- Recent cerebrovascular accident
- Anticoagulation therapy intolerance
- Ongoing infection
- Presence of atrial thrombus
- Conditions that do not require cutting or coagulation of tissue

D. Precautions and Warnings

- The SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System with Short Access Dilator must only be used by physicians trained in cardiac transseptal procedures and in the East End Medical I SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System.
- Read the Instruction for Use carefully before using this device to reduce risks and complications associated with transseptal puncture procedures such as air emboli and/or perforations.
- This product is supplied STERILE using an ethylene oxide (EO) process. Carefully inspect the device packaging prior to use. Do not use if package appears open or damaged.
- Carefully inspect all system components prior to use. Do not use if any component appears damaged or if any of the components are missing.

- Use the device only prior to the “Use By” date listed on the package label.
- Store in a dry, cool place.
- Do not alter any of the system components in any way.
- This product is designed and intended for single use. Do not re-use.
- Do not re-sterilize.
- Re-using or re-sterilizing may be detrimental to the structural integrity and proper function of the product, resulting in patient injury or death. Reusing the product may also result in product contamination which may lead to infection and/or the transmission of infectious disease(s), resulting in patient injury, illness, or death.
- Dispose of the product and package according to hospital and/or local government policies.
- The French size indicated in the label reflects the inner diameter of the Steerable Introducer Sheath.
- Do not attempt to introduce a catheter with a distal tip or body size larger than the inner diameters indicated on the label.
- The Steerable Introducer Sheath is designed to interlock only with the RF Puncture Dilator. Attempted use of components other than those from the SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System may result in serious complications.
- Use only the guidewire size indicated in these instructions.
- If resistance is encountered when advancing or withdrawing any system component inside the vasculature, determine the cause before proceeding. Advancing or withdrawing when resistance is felt may result in vessel trauma or device damage.
- All fluids to be infused must be used according to the manufacturer’s instructions for use.
- Only use the Flush Line port of the Steerable Introducer Sheath for the infusion of fluids.
- Maintain continuous hemodynamic monitoring during the procedure.
- Advance system components only after acceptable hemodynamic parameters have been confirmed.
- Aspirate and flush the Steerable Introducer Sheath continuously with saline to reduce the risk of thrombus formation.
- Withdraw components slowly to minimize the vacuum produced during withdrawal.
- Do not remove the RF Puncture Dilator or any other catheter from the Steerable Introducer Sheath rapidly, as it may result in damage to the hemostasis valve.
- Advance the RF Puncture Dilator into the steerable introducer sheath in small increments to prevent damage to the puncture dilator.
- Aspirate slowly to minimize the vacuum produced due to aspiration.
- Aspirate all air prior to fluid infusion using only the Flush Line Port of the Steerable Introducer Sheath.
- Inject or flush with saline only from the Flush Line Port of the Steerable Introducer Sheath.
- Flush and prime the entire Steerable Introducer Sheath, Short Access Dilator and RF Puncture Dilator with heparinized saline prior to placement to avoid accidental introduction of air into the system.
- Conduct continuous heparinized saline infusion while the system is inside the patient.
- There is a potential risk for thrombus formation in the absence of anticoagulation. Appropriate anticoagulation therapy should be administered, which reduces the thrombosis risk of the device.
- To prevent dislodgement of potential thrombus produced due to fibrin accumulation on the Steerable Introducer Sheath, aspirate through the Flush Line port when removing the Short Access Dilator, RF Puncture Dilator, or any other catheter from the Steerable Introducer Sheath.
- Indwelling introducers should always have the lumen supported with a catheter device.
- Certain patient conditions must be considered when using this product. These conditions include, but are not limited to, an enlarged aortic root, small left atrium, right atrial enlargement, thorax distortion (i.e. kyphosis or scoliosis), congenital heart malformations.

- The Transseptal RF Puncture and Steerable Balloon Introducer System are designed to be used under standard fluoroscopic observation and standard echocardiographic guidance.
- Keep the distal segment of the Steerable Introducer Sheath in its straight configuration and do not deflect during advancement and withdrawal. Failure to do so may result in vessel damage.

RF Puncture

- The SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System is intended to be used only with the electrosurgical generators listed below in the monopolar modality and only with the settings specified below.

Electrosurgical Generator	Mode	CUT Power	COAG Power
Bovie (Apyx Medical) OR/PRO 300	Cut II	50 W	0 W or minimum setting allowed
CONMED System 5000	Pure Cut, Gen Prog L	50 W	
ERBE VIO 300D	Auto Cut, Effect 1	50 W	
Ethicon / Megadyne Mega Power	Pure Cut	50 W	
Medtronic / Covidien / Valleylab Force FX / FX -C	Low Cut	50 W	

- RF puncture must only be performed by physicians trained in transseptal puncture techniques using radiofrequency in a catheterization lab environment.
- The electrosurgical generator is capable of delivering substantial electrical power which may result in patient injury or death. Read and follow the instructions for use of the electrosurgical generator.
- The patient must not be in contact with ground metal surfaces during the transseptal puncture procedure.
- Use only dispersive electrodes that meet IEC 60601-2-2 requirements.
- Completely remove the guidewire from the system and place it where it cannot come into contact with the patient and the RF circuit.
- Read and follow the instructions for use of the Patient Return Electrode pad.
- Use only Patient Return Electrode pads complying or exceeding IEC 60601-2-2 electrosurgical electrode requirements.
- Refer to the electrosurgical generator instructions for use for any error message appearing during the RF transseptal puncture procedure.
- Ensure that flammable material is not present in proximity during RF application.

E. Potential Complications

- Intimal damage
- Atrial, ventricular, or vascular perforation
- Vessel spasm
- Hemorrhage
- Allergic reactions
- Infection
- Thrombosis
- Ischemia
- Pain and tenderness
- Hematoma at the site of entry
- Air embolism
- Atrial Fibrillation

F. Preparations for Use

1. Prepare the following additional items according to their manufacturer's instructions for use:
   - Guidewire, 0.035", 260 cm long recommended.
   - 1cc syringe for Steerable Introducer Sheath Positioning Balloon inflation
   - Syringes for aspiration and flushing
   - One three-way stopcock
   - One Y-connector Rotating Hemostasis Valve (RHV)
   - One of the following electrosurgical generators:
     Bovie (Apyx Medical) OR/PRO 300
     CONMED System 5000
     ERBE VIO 300D
     Ethicon / Megadyne Mega Power
     Medtronic/Covidien/Valleylab Force FX / FX –C

WARNING: use only the electrosurgical generators listed above. The use of any other electrosurgical generator not listed in these Instructions for Use may result in serious harm to the patient or death.

- Bovie 4mm D-Shaped Disposable Monopolar Active Cable (Ref. No. BOV-A1210D) or equivalent Fig 1. OR Monopolar electrosurgical pen/pencil with removable 2.4mm diameter electrode Fig 2.
- Patient return electrode (DIP Grounding Pad, IEC 60601-2-2 - compliant)

2. Remove the Transseptal RF Puncture and Steerable Balloon Introducer System kit components from the packaging using standard sterile technique.
3. Inspect the Steerable Introducer Sheath, Short Access Dilator, and RF Puncture Dilator in their entirety after removal from the package.
   WARNING: Do not use the product if any of its components show any sign of damage. If damage is detected, replace with an undamaged product.
   NOTE: The distal segment of the Steerable Introducer Sheath has been color coded to indicate the length listed in the product label:

Green	Small
Orange	Medium
Blue	Large

4. Verify proper deflection of the Steerable Introducer Sheath distal segment turning the handle knob.
5. Set the Steerable Introducer Sheath distal segment back to its straight configuration.
6. Attach a Y-connector Rotating Hemostasis Valve (RHV) to the RF Puncture Dilator Luer connector. An additional 3-way stopcock may need to be connected to the Y-connector RHV if cardiac monitoring using the RF Puncture Dilator is planned.
7. Flush all SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System components (Steerable Introducer Sheath, Short Access Dilator and RF Puncture Dilator) with sterile heparinized saline.
   WARNING: Do not flush balloon inflation line of the Steerable Introducer Sheath.
8. Insert fully the RF Puncture Dilator into the Steerable Introducer Sheath up to the 2nd Mark (10mm).
9. Connect a Patient Return Electrode pad to the patient and to the electrosurgical generator; connect foot pedal switch to the electrosurgical generator and a monopolar electrosurgical pen/pencil with removable 2.4mm electrode OR Bovie 4mm D-Shaped Disposable Monopolar Active Cable to the corresponding monopolar port of the electrosurgical generator OR per electrosurgical pen/pencil manufacturer instructions, and remove the electrode, if present.

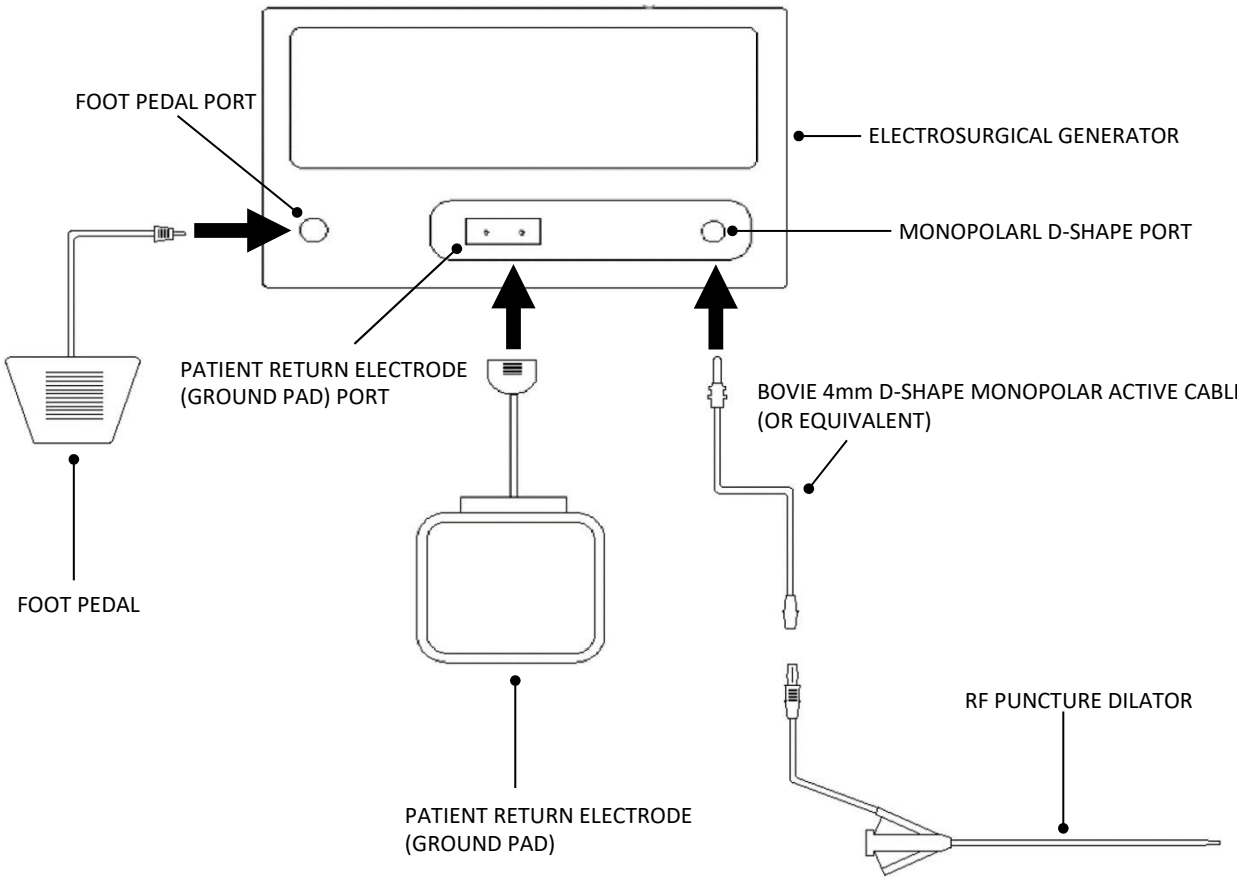

Figure 1 Bovie 4mm Banana Plug

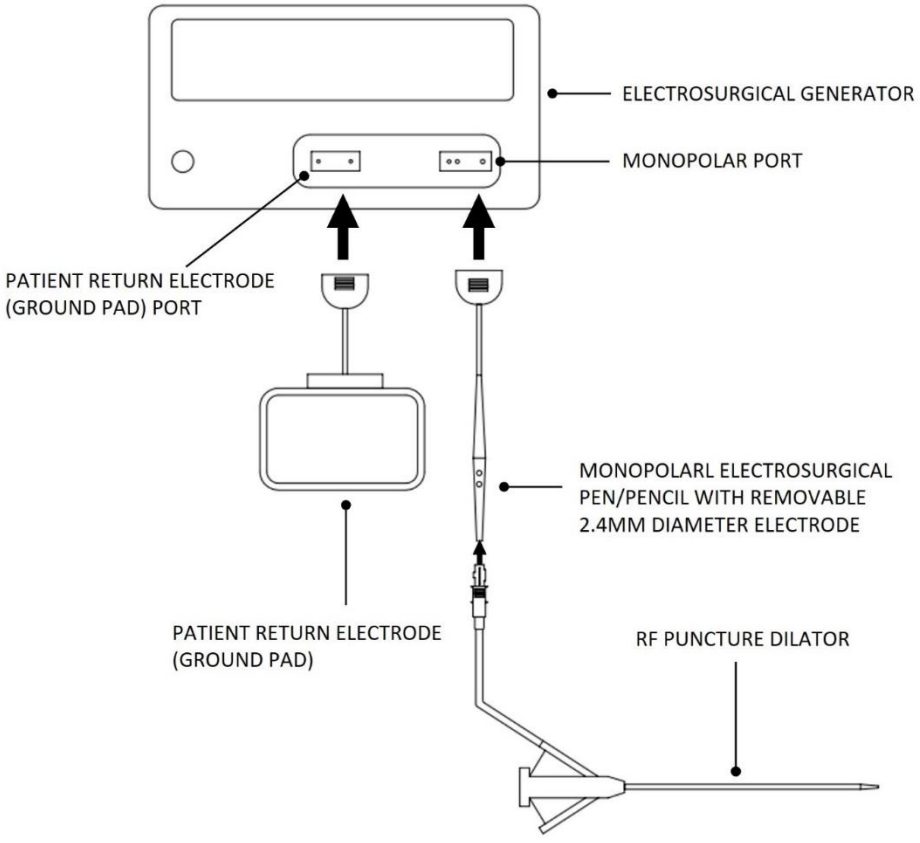

Figure 2 Monopolar Electrosurgical Pen/Pencil

10. Set the electrosurgical generator according to the settings indicated below:

Electrosurgical Generator	Mode	CUT Power	COAG Power
Bovie (Apyx Medical) OR/PRO 300	Cut II	50 W	0 W or minimum setting allowed
CONMED System 5000	Pure Cut, Gen Prog L	50 W	
ERBE VIO 300D	Auto Cut, Effect 1	50 W	
Ethicon / Megadyne Mega Power	Pure Cut	50 W	
Medtronic / Covidien / Valleylab Force FX / FX -C	Low Cut	50 W	

G. Instructions for Use

1. Establish femoral venous access per standard technique and insert 0.035" guidewire and Short Access Dilator into the vasculature until its tip reaches the inferior vena cava (IVC).

WARNING: For the following steps, stop if resistance is found when advancing the SafeCross™ system inside the vasculature. Determine the cause of resistance before proceeding. Do not use excessive force to advance or withdraw any system component.

2. If using a cardiac pressure monitoring system with the Steerable Introducer Sheath, connect it to the Steerable Introducer Sheath flush line port.
3. Using standard technique, the short access dilator is used to dilate the access site and removed after flushing with heparinized saline. The Steerable Introducer Sheath and the RF Puncture Dilator Assembly is advanced over the guidewire to the inferior vena cava (IVC).
4. The RF Puncture Dilator is withdrawn into the Steerable Introducer Sheath ensuring it does not protrude from the Steerable Introducer Sheath.
5. If using a cardiac pressure monitoring with the RF Puncture Dilator, connect it to the RF Puncture Dilator Luer connector.
6. Inflate the Steerable Introducer Sheath Positioning Balloon injecting up to 2cc of 20% contrast – 80% saline solution through the Positioning Balloon Inflation Port.
7. Advance the Steerable Introducer Sheath and RF Puncture Dilator assembly to the right atrium per standard technique.
8. Completely remove the 0.035" guidewire from the system and set aside where it cannot come in contact with the patient and the RF circuit. The guidewire may be reinserted as needed and after conducting the transseptal puncture.
9. Aspirate blood through the RF Puncture Dilator flush port and flush with heparinized saline immediately after.
10. Connect the RF Puncture Dilator's 2.4mm / 4mm plug to the port on monopolar electrosurgical pen/pencil or Bovie 4mm D-Shaped Disposable Monopolar Active Cable.
11. Verify that the electrosurgical generator is set according to the settings listed below:

Electrosurgical Generator	Mode	CUT Power	COAG Power
Bovie (Apyx Medical) OR/PRO 300	Cut II	50 W	0 W or minimum setting allowed
CONMED System 5000	Pure Cut, Gen Prog L	50 W	
ERBE VIO 300D	Auto Cut, Effect 1	50 W	
Ethicon / Megadyne Mega Power	Pure Cut	50 W	
Medtronic / Covidien / Valleylab Force FX / FX -C	Low Cut	50 W	

NOTE: If available, adjunctive echocardiography is recommended for the following steps.

WARNING: Verify that guidewire has been completely removed from the system and that it is not making contact with the patient or any component of the RF circuit.

WARNING: Verify that the electrosurgical generator COAG power setting is set to zero or to the minimum setting allowed by the unit.

12. Under fluoroscopic visualization, turn the Steerable Introducer Sheath handle knob to deflect the Positioning Balloon to position it at the desired location of the fossa ovalis.

13. Tent the fossa ovalis with the Steerable Introducer Sheath Positioning Balloon.
14. Advance the RF Puncture Dilator onto the fossa ovalis so that appropriate tenting is achieved.
15. Activate the electrosurgical generator to deliver RF power to produce septum puncture.
    WARNING: Limit RF power delivery to 2 seconds at a time.
16. RF power application can be repeated in short durations as indicated above.
    WARNING: Use alternate method if septal puncture is not achieved after five RF power applications
17. Disconnect the RF Puncture Dilator from the Bovie or electrosurgical pen/pencil. Store the electrosurgical pen/pencil per manufacturer's instructions when not in use.
18. Re-insert the 0.035" guidewire and advance it into the left atrium.
19. Deflate the Steerable Introducer Sheath Positioning Balloon.
20. Advance the Steerable Introducer Sheath and RF Puncture Dilator assembly through the septum until reach the left atrium.
21. Withdraw the RF Puncture Dilator over the 0.035" per standard technique. Immediately after the RF Puncture Dilator has been removed, aspirate blood through the Steerable Sheath Introducer flush port and immediately after flush with heparinized saline, ensuring that no air is introduced.
    NOTE: If desired, the complete Steerable Introducer Sheath and RF Puncture Dilator assembly can be withdrawn together, leaving the guidewire in place if desired.
22. Prior removal of the Steerable Introducer Sheath, straighten its distal segment with the handle knob and remove per standard technique.

H. Handling, Storage and Operation Environment

Storage and Transportation Temperature	-30°C (-22°F) to 60°C (140°F)
Operation Temperature	10°C (50°F) to 40°C (104°F)
Storage, Transportation and Operation Relative Humidity	15% to 90%
Storage, Transportation and Operation Atmospheric Pressure	80 kPa (11.6 psi) to 109 KPa (15.8 psi)

I. Standards Compliance

The system composed of the SafeCross™ Transseptal RF Puncture and Steerable Balloon Introducer System and the listed electrosurgical generators comply with IEC 60601-1 and IEC 60601-2-2 for safety and IEC 60601-1-2 for EMC compliance.

Bovie (Apyx Medical) OR/PRO 300
CONMED System 5000
ERBE VIO 300D
Ethicon / Megadyne Mega Power
Medtronic / Covidien / Valleylab Force FX / FX -C