Boston Scientific
Advancing science for life™

Achieve Left Heart Access with **Globally Dedicated RF Transseptal Technologies**

Contents

Back to Contents

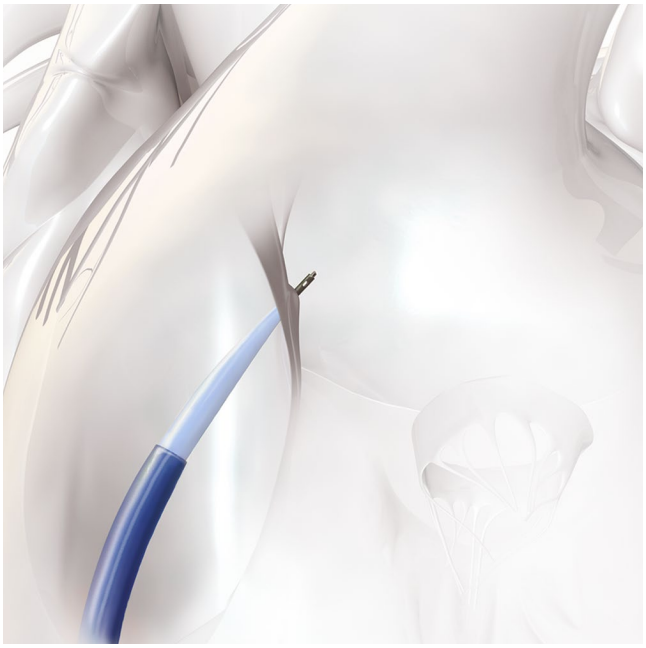
Background

Over **10 years of globally recognized clinical studies** demonstrate Boston Scientific RF transseptal technologies are the preferred choice for reliable, consistent, controlled, and precise crossing of the septum.

Boston Scientific RF transseptal technologies built for left-heart access include:

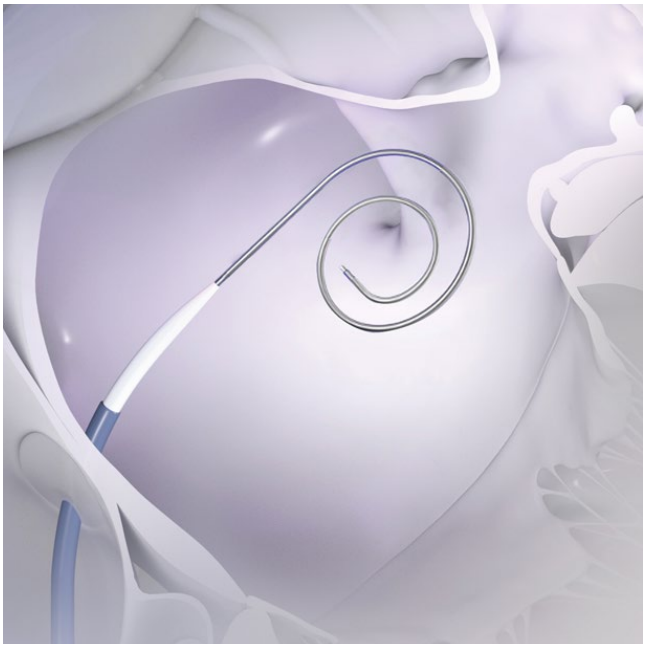
NRG™

RF Needle-Based Platform*



VersaCross™

RF Wire-Based Platform†



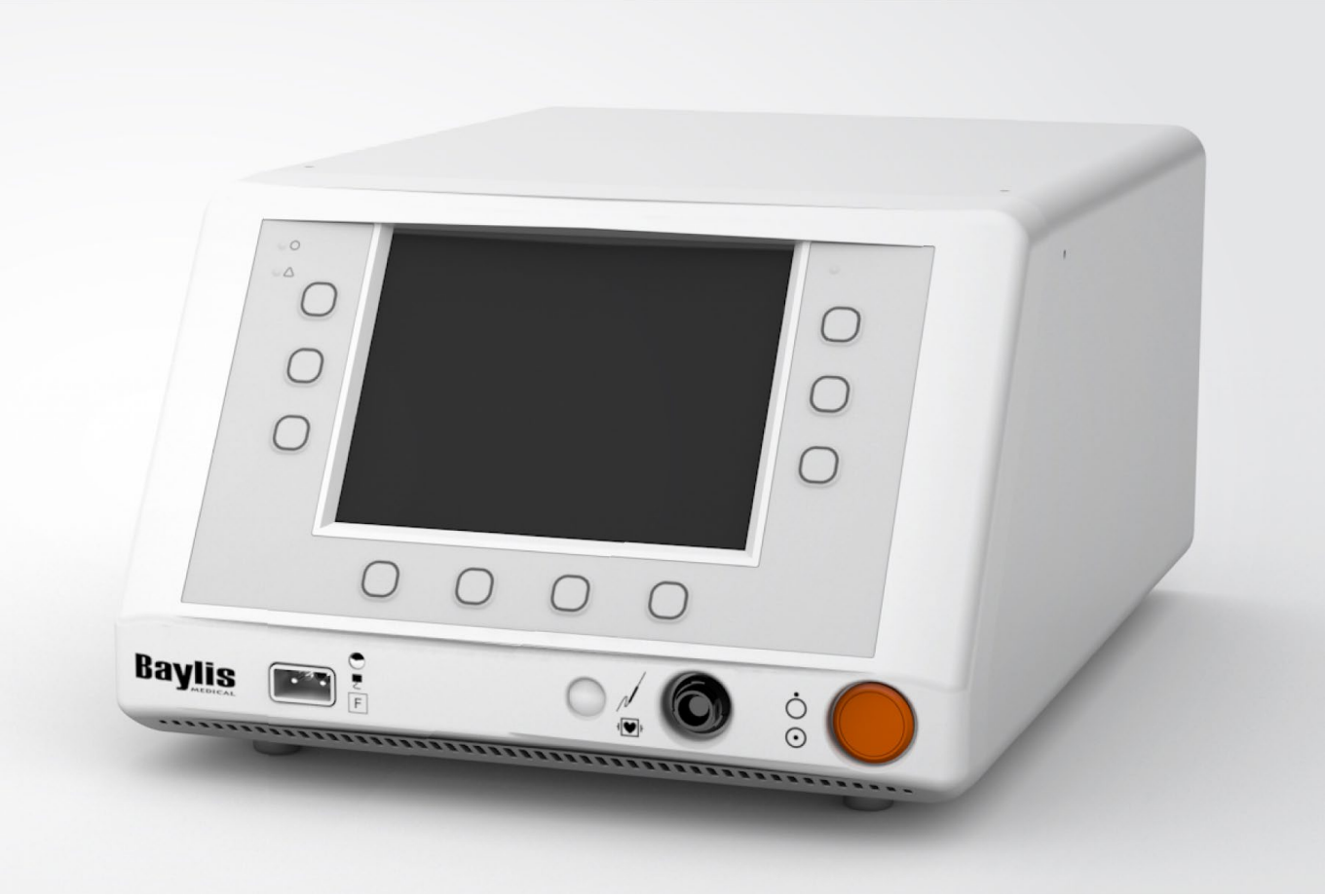
*Includes **NRG**™ Transseptal Needle
†Includes **VersaCross**™ RF Wire

Reliable Transseptal

The **NRG**™ Transseptal Needle has been associated with an improved rate of successful transseptal puncture.[1,2]

The **RFP-100A RF Puncture Generator*** is purpose-built to:

- Optimize RF delivery for perforation of the atrial septum.[3] RF settings that are not optimized for tissue perforation cause more extensive areas of tissue desiccation and preservation of collagenous structures, which leads to coagulative necrosis.[4]
- Protect against contact with metal.[5] The **RFP-100A generator*** is designed to detect changes in impedance and auto-terminate with metal contact, such as with nitinol septal occluders.



*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A.
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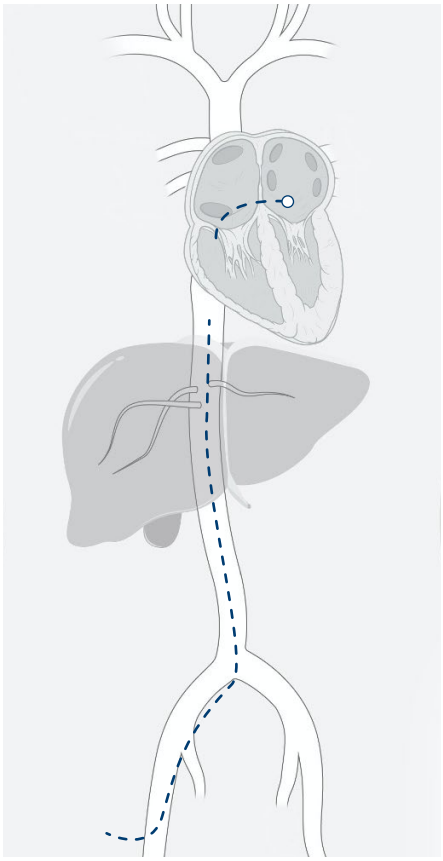
Adaptable: Transseptal Puncture from Any Approach

The **RFP-100A RF Puncture Generator*** optimizes the power delivered on all Boston Scientific RF transseptal solutions to enable facile transseptal puncture from any approach:

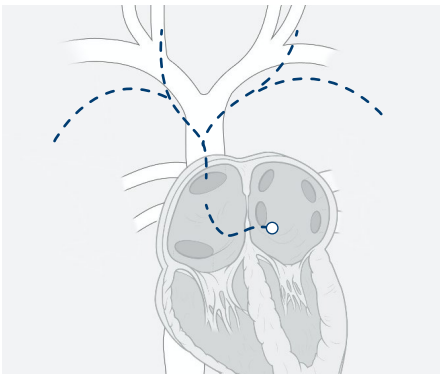
Femoral vein access

- Right femoral venous access is typically used to introduce the **NRG**™ Transseptal Needle[7] or **VersaCross**™ RF Transseptal Solution[14] to perform transseptal puncture.



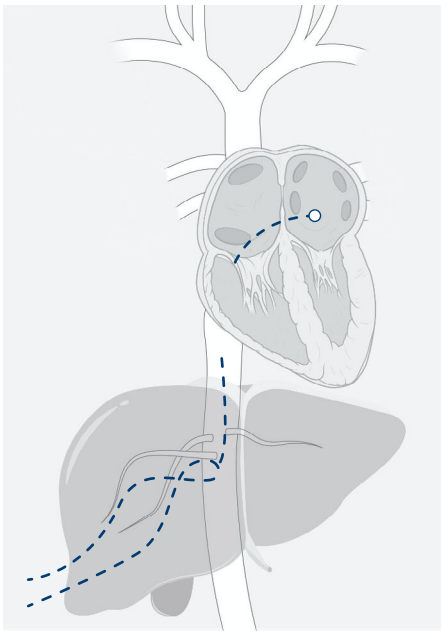
Subclavian or jugular vein access

- In patients with absent or interrupted inferior vena cava (IVC), the internal jugular vein, subclavian vein, or axillary veins can be used to access the right atrium and perform transseptal puncture.
- The **SupraCross**™ RF Solution uses a specialized RF wire and steerable sheath to enable angle correction from the subclavian or jugular vein approach to optimize positioning on the fossa ovalis and tenting of the interatrial septum.[42]
- Use of the **SupraCross**™ RF Solution has been demonstrated in both RF ablations[42-44], and transcatheter mitral valve repair[40] (i.e. MitraClip™ procedure, Abbott).



Hepatic vein access

- An alternative approach in the absence of IVC access is using the hepatic vein, which offers operators an inferior access route that is similar to femoral vein access.
- Transhepatic access has been used to access the right atrium and perform transseptal puncture using the **SupraCross**™ RF Solution in both RF ablation[45,46], and left atrial appendage occlusion procedures[46].



*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A.
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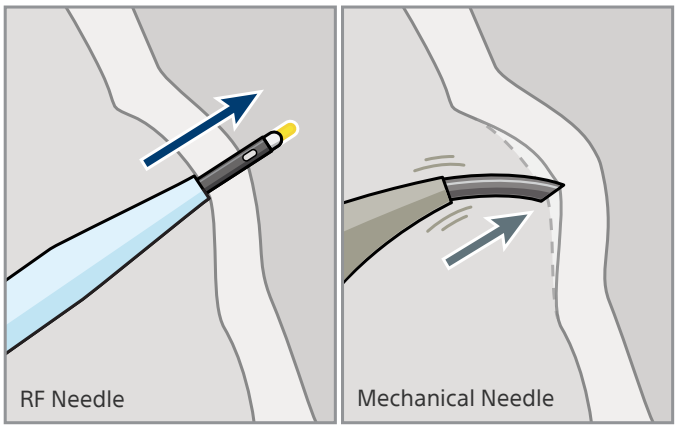
Back to Contents

Improved Crossing for Any Anatomy

Boston Scientific RF transseptal technologies reduce the need for forward force and tissue tenting during atrial septal puncture[1,6-10], and have been associated with lower rates of pericardial effusion and cardiac tamponade[2,6].

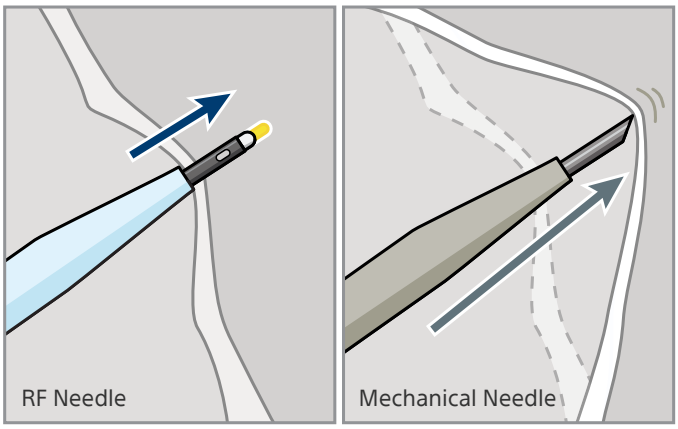
- The round atraumatic tip of Boston Scientific RF transseptal technologies reduces the incidence of plastic particle skiving (0%) when compared to the conventional mechanical needle (33.3% or more)*.[7,11]
- Boston Scientific RF transseptal technologies have been associated with reduced incidence of cardiac tamponade (0% vs 0.92%, respectively)[9], and pericardial effusion (0% vs 3.06%, respectively)[6] when compared to a mechanical needle group.
- The **NRG™** Transseptal Needle has been associated with 40% lower incidence of silent acute cerebral embolism compared to a mechanical needle.[12]

Fibrotic (thickened) septum



Cross **fibrotic septum** while reducing mechanical force.[4,9]

Aneurysmal (elastic) septum



Cross thin **aneurysmal septum** while reducing excessive tenting.[8]

*Based on ex vivo findings.

Back to Contents

Characterized Tissue Healing

Boston Scientific RF transseptal technologies are optimized for improved puncture of the atrial septum **without coagulative necrosis or prolonged healing.**[3]

- No coagulative necrosis: A study by Veldtman et al. showed a similar pattern of injury when using Boston Scientific RF transseptal technology as mechanical needle puncture. Minimal mural thrombus and thermal injury were restricted to the myocardium adjacent to the puncture lumen immediately post-puncture, and fell short of coagulative necrosis characteristic of ablative RF energy.[3]
- Well-developed healing: The extent of acute injury using Boston Scientific RF transseptal technology was similar to that seen with conventional mechanical needle puncture. Minimal inflammation and homogenous fibrosis were observed at one month post-puncture.[3]

There was a low rate of persistent atrial septal defects (8.4%) in patients at 15.5 months following the use of the **NRG™** Transseptal Needle[16], similar to mechanical needle puncture[50].* All patients were asymptomatic, and persistence was correlated with atrial septal angle.[16]

*Results from different clinical investigations are not directly comparable.
Information provided for educational purposes only.

Back to Contents

Time Savings

Boston Scientific RF transseptal technologies have been associated with time savings[2,8,13], and improved success rate for transseptal puncture[2,8].

- **NRG™ Transseptal Needle:** Significantly lower total instrumentation time was reported from procedure start to transseptal puncture (27.1±10.9 min) compared to the conventional mechanical needle system (36.4±17.7 min).[9]
- **VersaCross™ RF Transseptal Solution:** Significantly faster time was reported from femoral access to transseptal puncture (4.1±2.5 min) compared to the conventional mechanical needle system (8.4±4.0 min), leading to two times faster therapy delivery sheath access.[13*]

*Based on initial retrospective comparative study which found that **VersaCross™** RF Transseptal Solution delivered LAAC sheath in a mean time of 6.7 mins as compared to 13.4 mins (p=0.002) using BRK™ needle and SL1 sheath. Inohara et al. J Interv Card Electrophys. 2021 DOI: 10.1007/s10840-020-00931-7

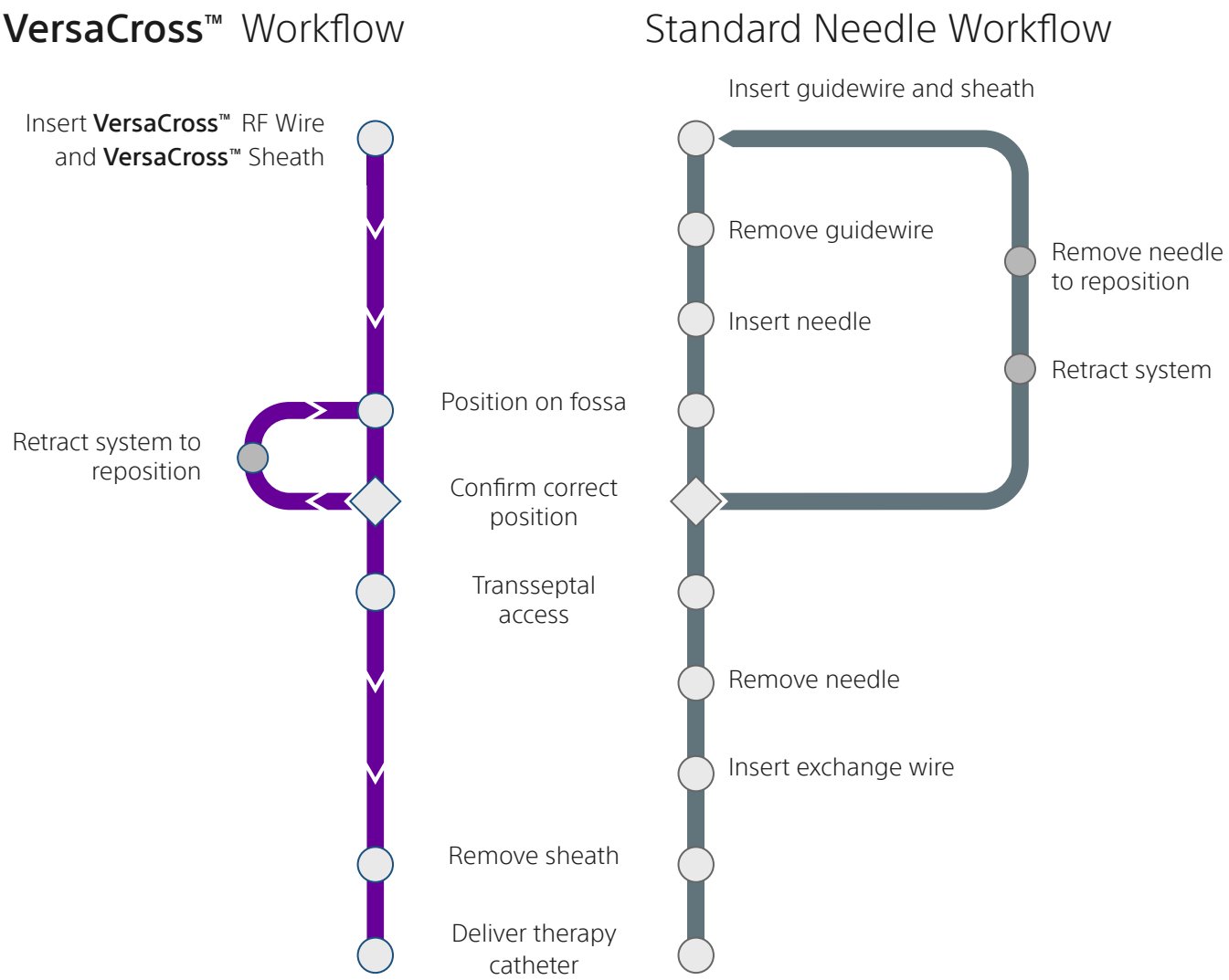
Back to Contents

Reduced Exchanges

Catheter manipulation[17,18], device exchange[19,20], and procedure time[21] have been associated with incidence of embolism due to air bubbles, and/or dislodgment of cardiac thrombus.

Catheter ablation procedures have been associated with silent cerebral embolism[22], which may cause long-term cognitive dysfunction[23,24].

The **VersaCross™** RF Transseptal Solution reduces the number of device exchanges through exchangeless vascular cannulation, transseptal puncture, and catheter delivery into the left atrium.[13,14]

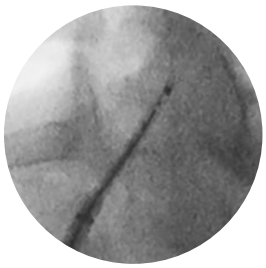


Back to Contents

Enhanced Visualization

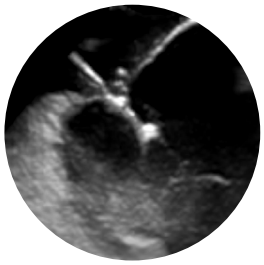
The **NRG**™ Transseptal Needle and **VersaCross**™ RF Transseptal Solution are engineered with **OMNIviz**™ Technology to enable visualization of the RF tip on fluoroscopy, ultrasound, and electrical anatomical mapping.

OMNIviz™ Technology



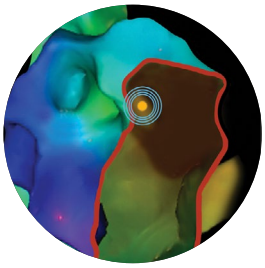
Radiopaque

Visualize your entire solution on fluoroscopy



Echogenic

Reliably locate your devices on ultrasound to reduce reliance on fluoroscopy



Mapping

Track and mark RF tip position on your mapping system

Back to Contents

Fluoroscopy Reduction

Catheter ablation procedures expose patients to approximately 15 mSv of radiation (the equivalent of 750 chest X-rays) per procedure, and staff to 5 mSv (the equivalent of 250 chest X-rays) per year[25].

- Radiation exposure presents a risk of **acute skin injuries**[26] and **fatal malignancies** to patients.[25]
- Electrophysiology staff have an elevated risk of **brain tumor** and **cancers**.[27,28]
- Staff have a risk of **orthopedic injuries** from prolonged use of heavy protective lead apparel.[29]

Electroanatomic mapping (EAM) and intracardiac echocardiography (ICE) have been used to reduce radiation exposure during catheter ablation procedures; however, transseptal puncture remains one of the critical steps that requires fluoroscopy due to inadequate visualization of the transseptal needle.[30]

Studies show that transseptal puncture can be performed safely using the **NRG™** Transseptal Needle or **VersaCross™** RF Transseptal Solution by visualizing the unique RF tip under 3-dimensional EAM, ICE, and/or transesophageal electrocardiography (TEE).[31-33]

Successful use of Boston Scientific RF transseptal technologies in non-fluoroscopic procedures have been well studied in:

- Double transseptal punctures for RF ablation[34]
- Single transseptal puncture for cryoballoon ablation[35,36]
- Complex anatomies[31,33]
- Without echocardiography[31]

Fluoroscopy Reduction (continued)

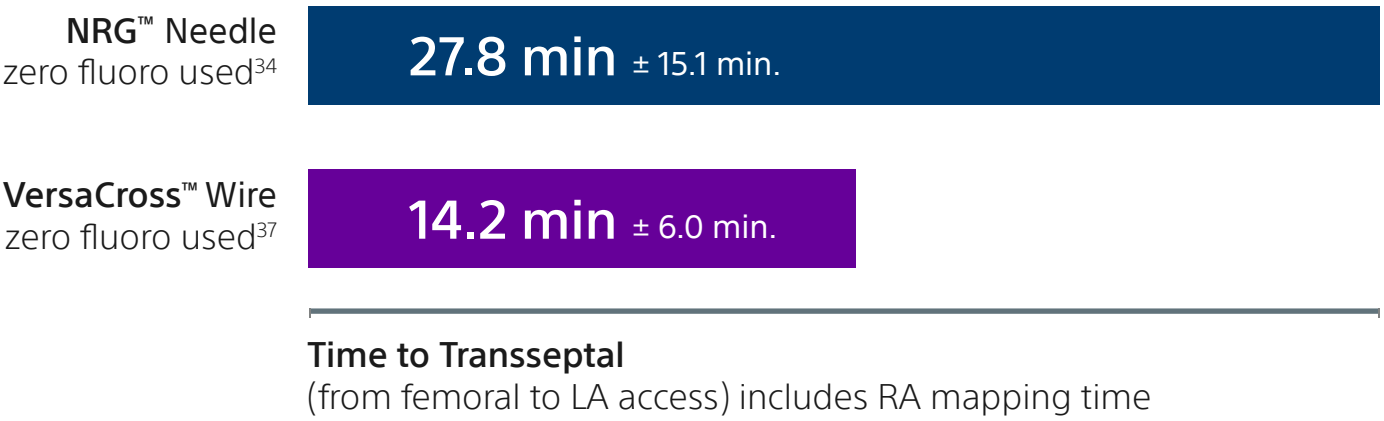
Zero Fluoro. Zero Compromise.™

Transseptal efficiency was maintained in fluoroless procedures, demonstrated by short left heart access times using:

- **NRG™ Transseptal Needle:** 27.8±15.1 min.[34]
- **VersaCross™ RF Transseptal Solution:** 14.2±6.0 min.[37]

No procedure-related complications were reported during fluoroless transseptal puncture.[34,37]

Maintain efficient transseptal access **without fluoroscopy***

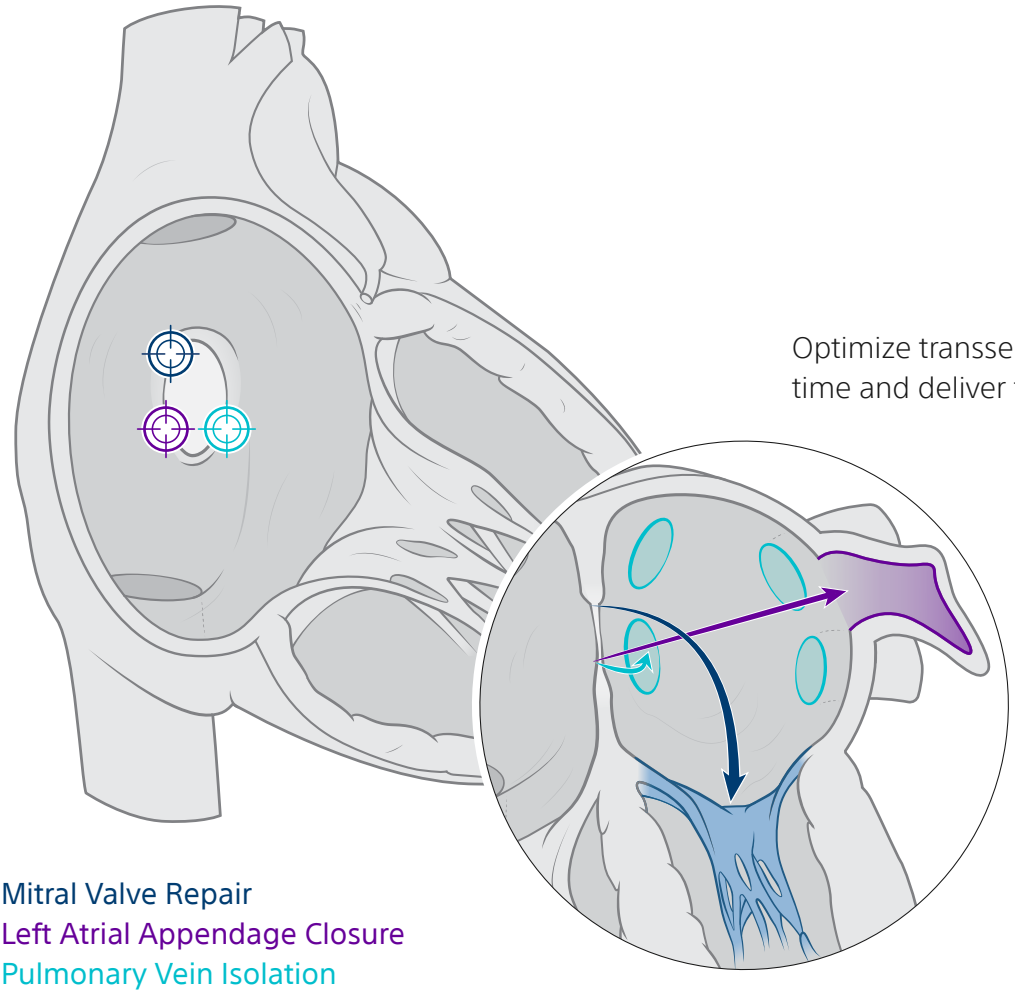


*Based on transseptal times from femoral to LA access from two non-comparative fluoroless case series[34,37] compared to using conventional fluoroscopy-guided procedures[2].

Targeted Precision

Precise crossing is necessary to avoid unintended perforation of nearby structures. Targeted transseptal puncture (TSP) at the intended location on the interatrial septum is necessary to ensure optimal trajectory for therapy sheaths in transcatheter structural heart procedures:

- Off-target TSP can add complexity and time to a procedure.[38]
- The **NRG**™ Transseptal Needle was used to provide controlled site-specific crossing of the interatrial septum without complications.[39]
- Boston Scientific RF transseptal technology enables site-specificity even in the presence of atrial septal occluders.[40]



Optimize transseptal location to save time and deliver therapy on target.[47,48]

Mitral Valve Repair
Left Atrial Appendage Closure
Pulmonary Vein Isolation

Back to Contents

Conclusion

Boston Scientific RF transseptal technology enables access to the left atrium in a reliable and consistent manner. This is supported by published clinical evidence showing that transseptal puncture using Boston Scientific RF technology provides:

1. Reliable Transseptal
2. Adaptable Transseptal from Any Approach
3. Improved Crossing for Any Anatomy
4. Characterized Tissue Healing
5. Time Savings
6. Reduced Exchanges
7. Enhanced Visualization
8. Fluoroscopy Reduction
9. Targeted Precision

Back to Contents

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Brief Summary

VersaCross™ RF Wire

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Rx only. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

CONTRAINDICATIONS: The VersaCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device.

WARNINGS: • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures. • The VersaCross RF Wire and Connector Cable are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The VersaCross RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse either devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The VersaCross RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Do not use the VersaCross RF Wire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury. • The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included VersaCross RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The VersaCross RF Wire must be used with 0.035" compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the VersaCross RF Wire or accessory devices and may cause patient injury. • The VersaCross RF Wire has only been validated for transseptal puncture use through VersaCross dilators which have been demonstrated to provide the required support for optimal function. • The active tip and distal curve of the VersaCross RF Wire are fragile. Be careful not to damage the tip or the distal curve while handling the VersaCross RF Wire. If the tip or the distal curve becomes damaged at any time during its use, discard the VersaCross RF Wire immediately. Do not attempt to straighten the active tip if bent. Damage to device can lead to patient injury. • The VersaCross RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the VersaCross RF Wire. • Do not attempt to insert or retract the VersaCross RF wire through a metal cannula or a percutaneous needle, which may damage the device and may cause patient injury.

PRECAUTIONS: • Do not attempt to use the VersaCross RF Wire and the Connector Cable before thoroughly reading the accompanying Instructions for Use. • RF puncture procedures should be performed only by physicians thoroughly trained in the techniques of RF-powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use. Do not use the devices if the packaging has been damaged or compromised. • Visually inspect the VersaCross RF Wire and Connector Cable prior to use to ensure there are no cracks or damage to the insulating material. Do not use the wire or the cable if there is any damage. • Do not use the VersaCross RF Wire and/or Connector Cable after the use-by date indicated on the label. • The VersaCross RF Wire and Connector Cable are intended for use with only those devices listed in Section VIII, Equipment Required. • Read and follow the manufacturer's Instructions For Use for the DIP electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the DIP electrode on the thigh could be associated with higher impedance. • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Baylis RF Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Baylis RF Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications. • Do not attempt to insert and use the proximal end of the VersaCross RF Wire as the active tip. • Do not bend the VersaCross RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/ or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the VersaCross RF Wire and Connector Cable. • Careful manipulation of the VersaCross RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device. • VersaCross RF Wire and ancillary sheath and/or dilator assembly advancement should be done under imaging guidance. The use of visible markers on the wire body are only an approximate guide for positioning the wire tip with the distal end of the dilator. • Do not attempt to deliver RF energy until the active tip of the VersaCross RF Wire is confirmed to be in good contact with the target tissue. • Avoid RF energy delivery of the VersaCross RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture. • It is recommended not to exceed five (5) RF power applications per VersaCross RF Wire. • Never disconnect the Connector Cable from the Baylis RF Generator while RF power is being delivered. • Never disconnect the Connector Cable from the Baylis RF Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable. • Do not twist the Connector Cable while inserting or removing it from the Isolated Patient Connector on the Baylis RF Generator. Twisting the cable may result in damage to the pin connectors. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCross RF Wire and/or DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the active tip of the VersaCross RF Wire against the atrial septum. Only increase the power if low power output persists. • If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device.

POTENTIAL ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Arteriovenous fistula • Pericardial/pleural effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/Entanglement • Foreign body/wire fracture

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NRG™ Transseptal Needle

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. • Do not alter this device in any way. • The NRG Transseptal Needle is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The NRG Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • For RFP-100: Do not attempt to puncture with an initial power setting of greater than 10 Watts. The initial attempt should be made with a setting of 10 Watts. In subsequent punctures, the power setting can be increased, if necessary. • The pressure transducer system used with the NRG Transseptal Needle must comply with the electrical safety requirements of IEC 60601. Failure to use compliant pressure transducers may result in patient or operator injury.

PRECAUTIONS: • Do not attempt to use the NRG Transseptal Needle or ancillary equipment before thoroughly reading the accompanying Instructions for Use. • Radiofrequency puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised. • Visually inspect the needle prior to use. Do not use the needle if there is any damage or visibly exposed metal on the shaft where it connects to the handle. • Do not use the NRG Transseptal Needle after the "Use By" date indicated on the label. • The NRG Transseptal Needle is intended for use with only those devices listed in section VII "Equipment Required" • Read and follow the manufacturer's instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • Do not attempt to puncture until firm position of the active tip has been achieved against the atrial septum. • It is not recommended to exceed five (5) radiofrequency power applications per NRG Transseptal Needle. • Do not bend the NRG Transseptal Needle. Excessive bending or kinking of the needle shaft may damage the integrity of the needle and may cause patient injury. Care must be taken when handling the needle. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the needle and DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the tip of the needle against the atrial septum. Only increase the power if low power output persists. • Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the Baylis Medical Radiofrequency Puncture System. • Ensure the distal tip is protruding the dilator/sheath assembly when visualizing on electroanatomic mapping systems. Visualization of the distal tip of the NRG Transseptal Needle may be lost when retracted within the dilator/sheath assembly.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

97185932 (Rev. A.1)

Brief Summary

SupraCross™ RF Wire

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Rx only. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: . The SupraCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

CONTRAINDICATIONS: The SupraCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device. **In the EU:** The SupraCross™ RF Wire is not intended for use with neonatal patients that are less than one month of age.

WARNINGS: • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures. • The SupraCross™ RF Wire and Connector Cable are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The SupraCross™ RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse either devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The SupraCross™ RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Do not use the SupraCross™ RF Wire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury. • The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included SupraCross™ RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The SupraCross™ RF Wire must be used with 0.035" compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the SupraCross™ RF Wire or accessory devices and may cause patient injury. • The SupraCross™ RF Wire has only been validated for transseptal puncture use through SupraCross™ dilators which have been demonstrated to provide the required support for optimal function. • The active tip and distal curve of the SupraCross™ RF Wire are fragile. Be careful not to damage the tip or the distal curve while handling the SupraCross™ RF Wire. If the tip or the distal curve becomes damaged at any time during its use, discard the SupraCross™ RF Wire immediately. Do not attempt to straighten the active tip if bent. Damage to device can lead to patient injury. • The SupraCross™ RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the SupraCross™ RF Wire. • Do not attempt to insert or retract the SupraCross™ RF wire through a metal cannula or a percutaneous needle, which may damage the device and may cause patient injury.

PRECAUTIONS: • Do not attempt to use the SupraCross™ RF Wire and the Connector Cable before thoroughly reading the accompanying Instructions for Use. • RF puncture procedures should be performed only by physicians thoroughly trained in the techniques of RF-powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use. Do not use the devices if the packaging has been damaged or compromised. • Visually inspect the SupraCross™ RF Wire and Connector Cable prior to use to ensure there are no cracks or damage to the insulating material. Do not use the wire or the cable if there is any damage. • Do not use the SupraCross™ RF Wire and/or Connector Cable after the use-by date indicated on the label. • The SupraCross™ RF Wire and Connector Cable are intended for use with only those devices listed in Section VIII, Equipment Required. • Read and follow the manufacturer's Instructions For Use for the DIP electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the DIP electrode on the thigh could be associated with higher impedance. • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Baylis RF Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Baylis RF Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications. • Do not attempt to insert and use the proximal end of the SupraCross™ RF Wire as the active tip. • Do not bend the SupraCross™ RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/ or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the SupraCross™ RF Wire and Connector Cable. • Careful manipulation of the SupraCross™ RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the SupraCross™ RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device. • SupraCross™ RF Wire and ancillary sheath and/or dilator assembly advancement should be done under imaging guidance. The use of visible markers on the wire body are only an approximate guide for positioning the wire tip with the distal end of the dilator. • Do not attempt to deliver RF energy until the active tip of the SupraCross™ RF Wire is confirmed to be in good contact with the target tissue. • Avoid RF energy delivery of the SupraCross™ RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture. • It is recommended not to exceed five (5) RF power applications per SupraCross™ RF Wire. • Never disconnect the Connector Cable from the Baylis RF Generator while RF power is being delivered. • Never disconnect the Connector Cable from the Baylis RF Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable. • Do not twist the Connector Cable while inserting or removing it from the Isolated Patient Connector on the Baylis RF Generator. Twisting the cable may result in damage to the pin connectors. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the SupraCross™ RF Wire and/or DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the active tip of the SupraCross™ RF Wire against the atrial septum. Only increase the power if low power output persists. • If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device.

POTENTIAL ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Arteriovenous fistula • Pericardial/pleural effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/Entanglement • Foreign body/wire fracture

97186433 (Rev. B.6)

SupraCross™ Steerable Sheath

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: . The SupraCross™ Steerable Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The SupraCross Steerable Sheath kitis intended for single patient use only. Do not attempt to sterilize and reuse the SupraCross Steerable Guiding Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Care should be taken when inserting or removing the dilator and catheters from the sheath. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Damage to guidewire may result if withdrawn through a metal needle cannula. • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel. • To minimize vacuum effects during withdrawal, remove components/aspirate slowly. Refrain from aspiration if a wire is directly through the valve. • Avoid contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. • Prior to steerable sheath's delivery and removal, ensure distal section is as straight as possible. • Do not kink, stretch or severely bend steerable sheath. • Do not use surgical instruments to handle sheath. • The sheath device shaft in its entirety is coated with a hydrophobic lubricious coating for smoother device manipulation. The following warning must be considered: • Excessive wiping and/or wiping with a dry gauze may damage the coating. • The guidewire is coated with a lubricious coating. The following warnings must be considered: - Use with incompatible introducers or dilators may affect the device performance and integrity, including coating integrity. - Excessive manual bending and/or shaping of the device may affect the coating integrity. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.

PRECAUTIONS: • Do not attempt to use the SupraCross Steerable Sheath kit before thoroughly reading the accompanying Instructions for Use. • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The SupraCross Steerable Sheath kit is supplied STERILE using an ethylene oxide process. • The sterile packaging and all components should be visually inspected prior to use. Do not use if the device, packaging or sterile barrier have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • Only physicians or personnel trained in aseptic techniques should perform aseptic presentation. • Do not use device after its "Use By" date. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • The SupraCross Steerable Sheath kit is not compatible with transseptal needles such as the "NRG™ Transseptal Needle". • Do not reshape the distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury. • Only use compatible tip straighteners with the guidewire. • Do not attempt to insert the proximal end of the guidewire as the distal end. • Confirm ancillary devices are compatible with the dilator and guidewire diameters before use. • Individual patient anatomy and physician technique may require procedural variations. • Do not attempt to use the guidewire with electrocautery tools. • Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution, or saline.

ADVERSE EVENTS: Adverse events that may occur while using the SupraCross™ Steerable Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Stroke • Valve damage • Myocardial infarction • Pacemaker/ defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion

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Brief Summary

Baylis Medical Company Radiofrequency Puncture Generator **RFP-100A**

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The Baylis Medical Company Radiofrequency Puncture Generator & Footswitch (optional accessory) is to be used with separately approved radiofrequency devices in general surgical procedures to cut soft tissues.

CONTRAINDICATIONS: The BMC Radiofrequency Puncture Generator is not recommended for uses other than the indicated use.

WARNINGS: • DO NOT attempt to operate the Generator before thoroughly reading this User's Manual. It is vital that the operating instructions for the equipment be read, understood, and followed properly. For future reference, retain this User's Manual in a convenient, readily accessible place. • The Generator is intended for use with separately cleared BMC RF Devices, BMC connector cables, and the accessory footswitch only. For respective devices/accessories, refer to individual IFUs for more information. • To avoid risk of electric shock, Generator must only be connected to supply mains with protective earth. • Do not remove the cover of the Generator. Removal of the cover may result in injury and/or damage to the Generator. • When the Generator is activated, conducted and radiated electrical fields may interfere with other medical and electrical equipment. Care should be taken to limit the effects that electromagnetic interference (EMI) produced by the Generator has on other equipment. • Laboratory staff and patients can undergo significant x-ray exposure during RF Puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • Do not attempt to perform an RF puncture with an initial cut setting other than that recommended by the BMC RF Device Instructions for Use. The cut setting (and therefore output power) should be as low as possible (as recommended for BMC RF device) to avoid any unintended result. • Failure of the Generator could result in an unintended increase of output power. • Place monitoring electrodes as far away from the surgical site as possible, to avoid burns or interference with other equipment. The use of needle monitoring electrodes (or other small area electrodes) during RF output is not recommended. In all cases, incorporating high frequency current limiting devices are recommended. • Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze. • During RF output, implanted devices such as pacemakers may be affected. Qualified advice should be obtained as necessary, to minimize the risk from injury due to implanted device malfunction. • Unless a compatible monitoring return electrode that meets or exceeds IEC 60601-2-2 is used with the contact quality monitor, loss of safe contact between the return electrode and patient will not result in an auditory alarm. • The Generator should not be operated if the display area (LCD screen) is cracked or broken. • Devices should be checked for exposed metal between shaft and handle, as well as check for any connection issues prior to use. • Devices should not be used in the presence of flammable materials, chemicals, and substances (anesthetics, oxygen, etc.). • No modification of Generator is allowed. Modification may result in patient or operator harm. • Flammable solutions may pool under the patients or in body depressions such as the umbilicus, and in body cavities such as the vagina. • Generator failure can lead to neuromuscular stimulation. • When using RF On/Off switch, the Generator can deliver RF energy without continuous depression of RF On/Off switch for the specified treatment time. Failure to specify correct treatment time could result in an unintended RF delivery.

PRECAUTIONS: • The Generator is intended for use with separately cleared BMC RF Devices, BMC connector cables and an optional accessory footswitch only. Ensure that the rated accessory voltage is equal to or greater than the Generator's maximum output voltage. • Ensure that the Generator connector cables and dispersive electrode cables are positioned in such a way that contact with the patient or other leads is avoided. • Ensure the application and connections of dispersive electrode before selecting a higher output setting on generator. • Temporarily unused Devices should be disconnected from the Generator, from the Connector Cable or they should be stored in a location that is isolated from the patient. • It is recommended not to exceed the specified number of RF energy applications per BMC RF Device, as indicated within the BMC RF Device's specific instructions for use. • Only physicians thoroughly trained in RF Puncture techniques, in a fully equipped catheterization laboratory, should perform RF Puncture procedures. • Read and follow the manufacturer's instructions for use of the return (dispersive) electrode. Only use dispersive electrodes that meet or exceed IEC 60601-2-2 requirements. The entire area of the dispersive electrode should be reliably attached to the patient's body and as close to the operating field as possible. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the BMC RF Device and dispersive electrode, particularly when operating the BMC RF Device. • During RF energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces or metal surfaces which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose. • Apparent failure of the equipment to function properly at normal settings may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. • Regularly inspect and test re-usable connector cables and accessory footswitch. • Perform regular inspections of all system components, including separately cleared BMC RF Devices and BMC Connector Cables, for damage to insulations. • Associated equipment and BMC RF Devices should be selected with a rated accessory voltage equal to or greater than the maximum output voltage of the mode it is to be used for. • Baylis Medical Company relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of the Generator. • The mains power cord of the Generator must be connected to a properly grounded receptacle to avoid the risk of electric shock. Extension cords, portable multiple socket outlets and/or adapter plugs must not be used. The mains power cord assembly should be periodically checked for damaged insulation or connectors. • Although the BMC RF Device and BMC Connector Cables are sterilized, the Generator is not. The Generator must not enter the surgical sterile field. • Fluids pooled in the body depressions and cavities should be mopped up before RF energy is delivered. • There is a danger of ignition of endogenous gases (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced) during normal use of Generator. • The use of a smoke-plume extractor is recommended for the operator during RF procedures.

ADVERSE EVENTS: Adverse events that may occur while using the Generator include: • Atrial Fibrillation and/or Atrial Flutter • Myocardial Infarction • Sustained Arrhythmias leading to Ventricular Tachycardia • Neuromuscular stimulation • Electric shock • Thermal damage to tissue • Thromboembolic Episodes • Sepsis and Infection • Unintended Perforation

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