

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



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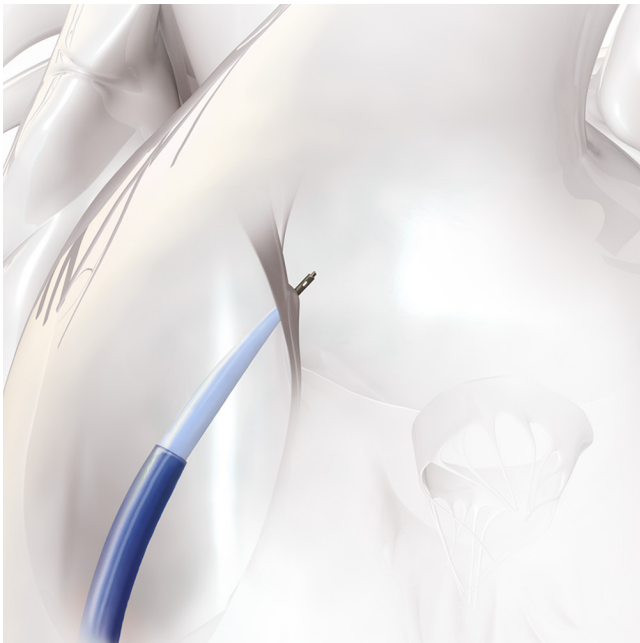
## Background

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:

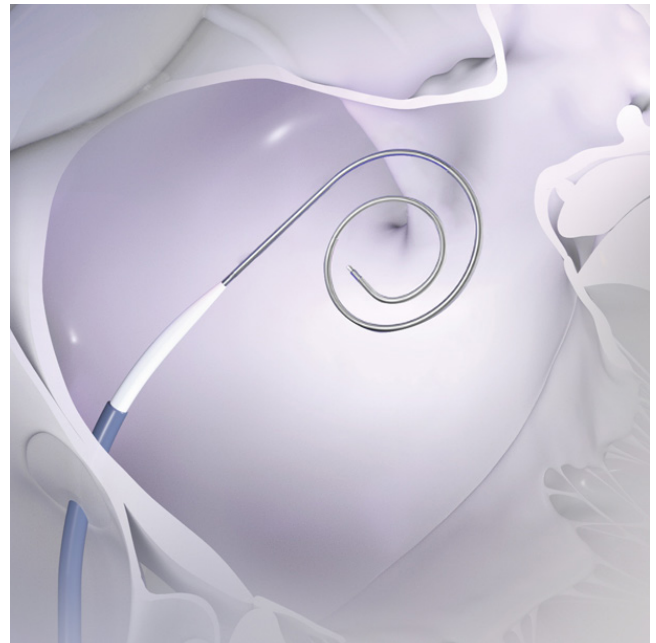
### **NRG™**

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.<sup>1,2</sup>

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

- Optimize RF delivery for perforation of the atrial septum.<sup>3</sup> 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.<sup>4</sup>
- Protect against contact with metal.<sup>5</sup> The **RFP-100A generator\*** is designed to detect changes in impedance and auto-terminate with metal contact, such as with nitinol septal occluders.



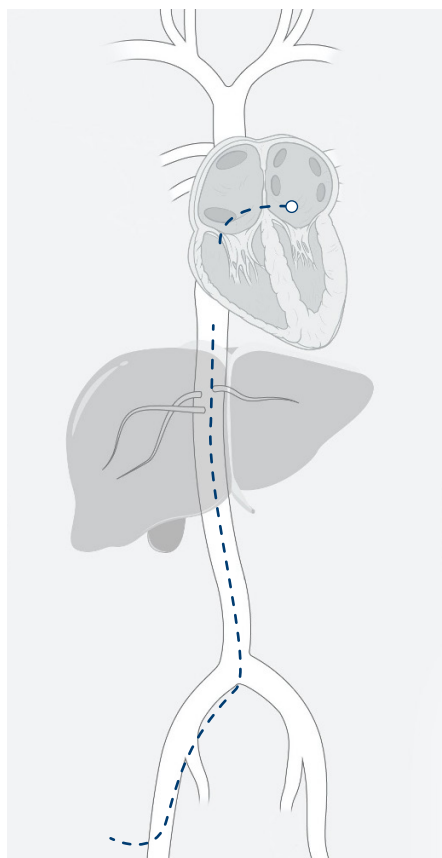
\*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A.  
Baylis Medical Company is a wholly-owned subsidiary of Boston Scientific Corporation.

## 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:

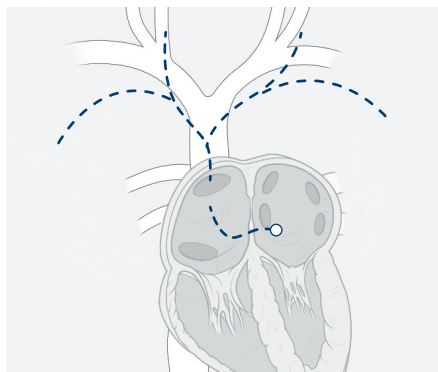
### Femoral vein access

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



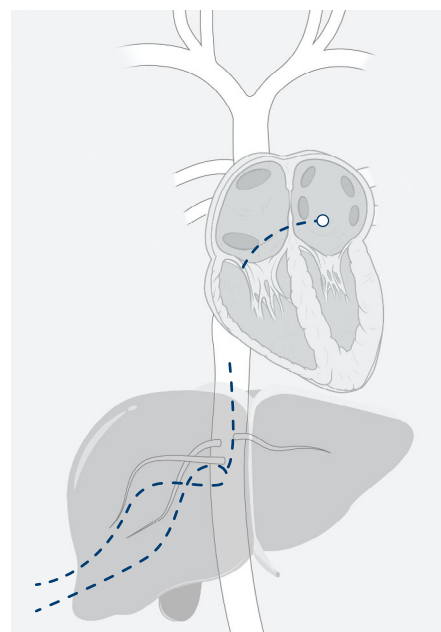
### Subclavian or jugular vein access

- 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.<sup>42</sup>
- Use of the **SupraCross™** RF Solution has been demonstrated in both RF ablations<sup>42-44</sup>, and transcatheter mitral valve repair<sup>40</sup> (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<sup>45,46</sup>, and left atrial appendage occlusion procedures<sup>46</sup>.



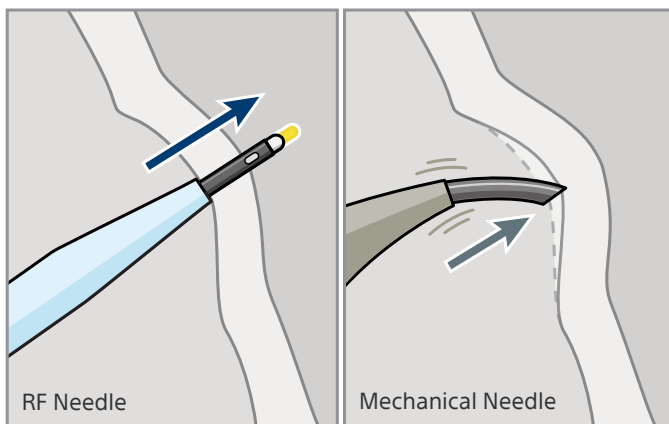
\*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A.  
Baylis Medical Company is a wholly-owned subsidiary of Boston Scientific Corporation.

## Improved Crossing for Any Anatomy

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

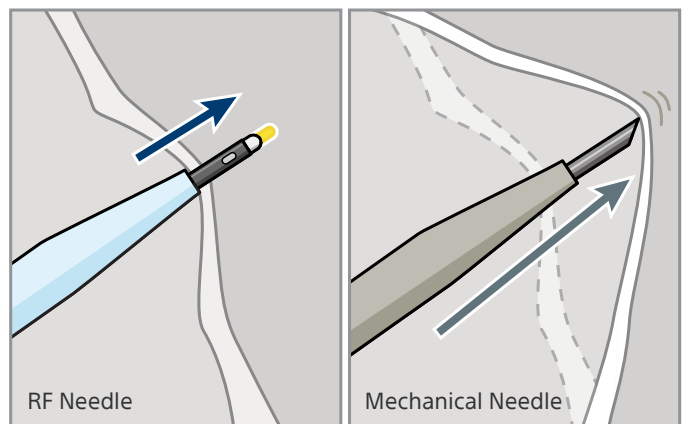
- The round atraumatic tip of Boston Scientific RF transeptal technologies reduces the incidence of plastic particle skiving (0%) when compared to the conventional mechanical needle (33.3% or more)<sup>7,11</sup>
- Boston Scientific RF transeptal technologies have been associated with reduced incidence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

### Fibrotic (thickened) septum



Cross **fibrotic septum** while reducing mechanical force.<sup>49</sup>

### Aneurysmal (elastic) septum



Cross thin **aneurysmal septum** while reducing excessive tenting.<sup>8</sup>

\*Based on ex vivo findings.

## Characterized Tissue Healing

Boston Scientific RF transseptal technologies are optimized for improved puncture of the atrial septum **without coagulative necrosis or prolonged healing.**<sup>3</sup>

- **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.<sup>3</sup>
- **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.<sup>3</sup>

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<sup>16</sup>, similar to mechanical needle puncture<sup>50</sup>.<sup>\*</sup> All patients were asymptomatic, and persistence was correlated with atrial septal angle.<sup>16</sup>

<sup>\*</sup>Results from different clinical investigations are not directly comparable.  
Information provided for educational purposes only.

## Time Savings

Boston Scientific RF transeptal technologies have been associated with time savings<sup>2,8,13</sup>, and improved success rate for transeptal puncture<sup>2,8</sup>.

- **NRG™ Transeptal Needle:** Significantly lower total instrumentation time was reported from procedure start to transeptal puncture (27.1±10.9 min) compared to the conventional mechanical needle system (36.4±17.7 min).<sup>9</sup>
- **VersaCross™ RF Transeptal Solution:** Significantly faster time was reported from femoral access to transeptal 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.<sup>13\*</sup>

\*Based on initial retrospective comparative study which found that **VersaCross™** RF Transeptal 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



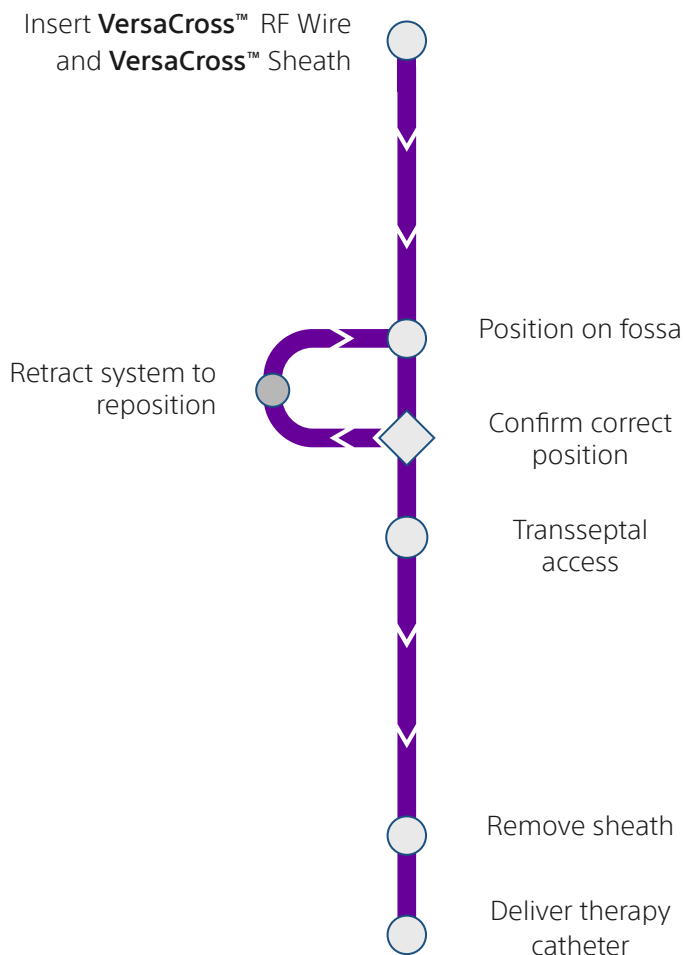
## Reduced Exchanges

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

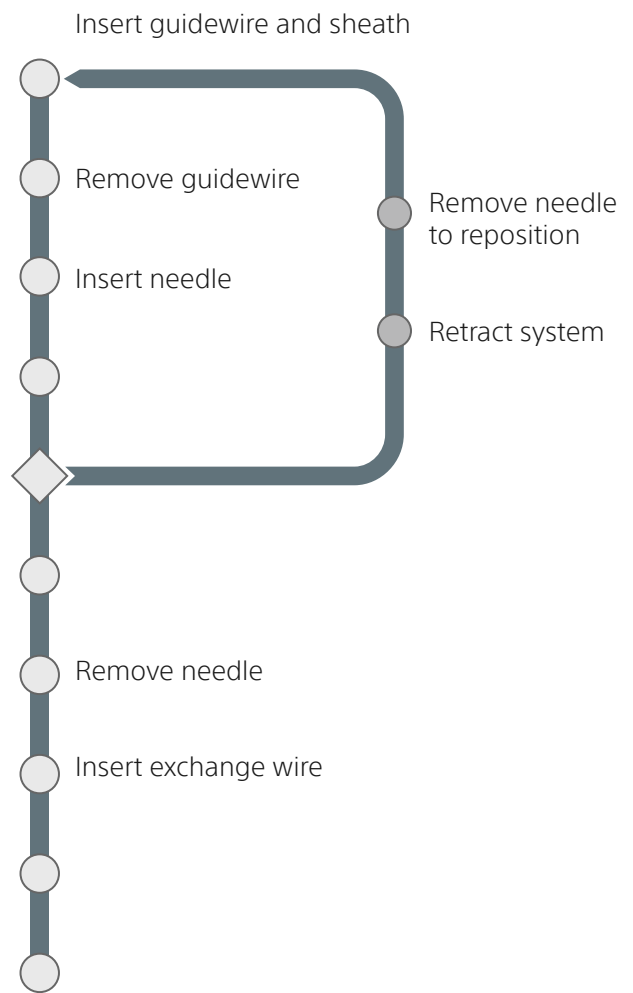
Catheter ablation procedures have been associated with silent cerebral embolism<sup>22</sup>, which may cause long-term cognitive dysfunction<sup>23,24</sup>.

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

### VersaCross™ Workflow



### Standard Needle Workflow



## 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



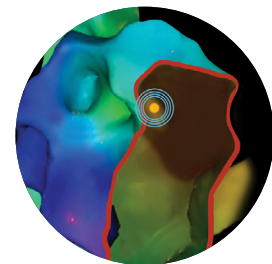
Radiopaque

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

## 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<sup>25</sup>.

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

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.<sup>30</sup>

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).<sup>31-33</sup>

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

- Double transseptal punctures for RF ablation<sup>34</sup>
- Single transseptal puncture for cryoballoon ablation<sup>35,36</sup>
- Complex anatomies<sup>31,33</sup>
- Without echocardiography<sup>31</sup>

## 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.<sup>34</sup>
- **VersaCross™ RF Transseptal Solution:** 14.2±6.0 min.<sup>37</sup>

No procedure-related complications were reported during fluoroless transseptal puncture.<sup>34,37</sup>

### Maintain efficient transseptal access **without fluoroscopy\***

**NRG™ Needle**  
zero fluoro used<sup>34</sup>

**27.8 min** ± 15.1 min.

**VersaCross™ Wire**  
zero fluoro used<sup>37</sup>

**14.2 min** ± 6.0 min.

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#### **Time to Transseptal**

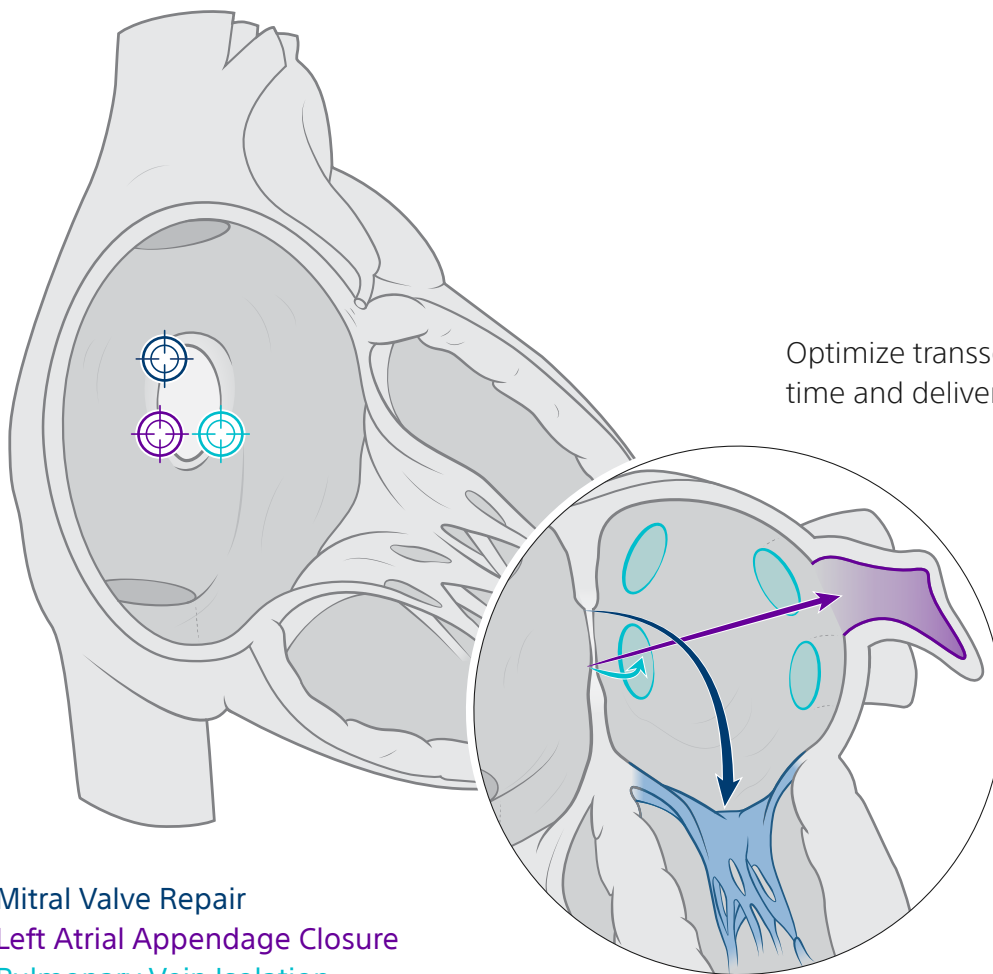
(from femoral to LA access) includes RA mapping time

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

## 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.<sup>38</sup>
- The **NRG™** Transseptal Needle was used to provide controlled site-specific crossing of the interatrial septum without complications.<sup>39</sup>
- Boston Scientific RF transseptal technology enables site-specificity even in the presence of atrial septal occluders.<sup>40</sup>



## Conclusion

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

1. Reliable Transeptal
2. Adaptable Transeptal 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

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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 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 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:** • 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 transeptal 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 transeptal puncture use through VersaCross™ dilators which have been demonstrated to provide the required support for optimal function. • 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.

**PRECAUTIONS:** • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • 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. • 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. • 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.

**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 effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/ entanglement • Foreign body/wire fracture

EP-1504711-AA

## 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:** • 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.

**PRECAUTIONS:** • 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. • 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. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

**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

EP-1506305-AA

## SupraCross™ RF Wire

**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™ 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 RF Generator or any other device.

**WARNINGS:** • 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 transeptal 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 transeptal puncture use through SupraCross™ dilators which have been demonstrated to provide the required support for optimal function. • 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.

**PRECAUTIONS:** • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • 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. • 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. • 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.

**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 effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/entanglement • Foreign body/wire fracture

EP-1515002-AA



# Brief Summary

## 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 kit is 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. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • 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:** • 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. • 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.

**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

EP-1515304-AA

## 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.

**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.

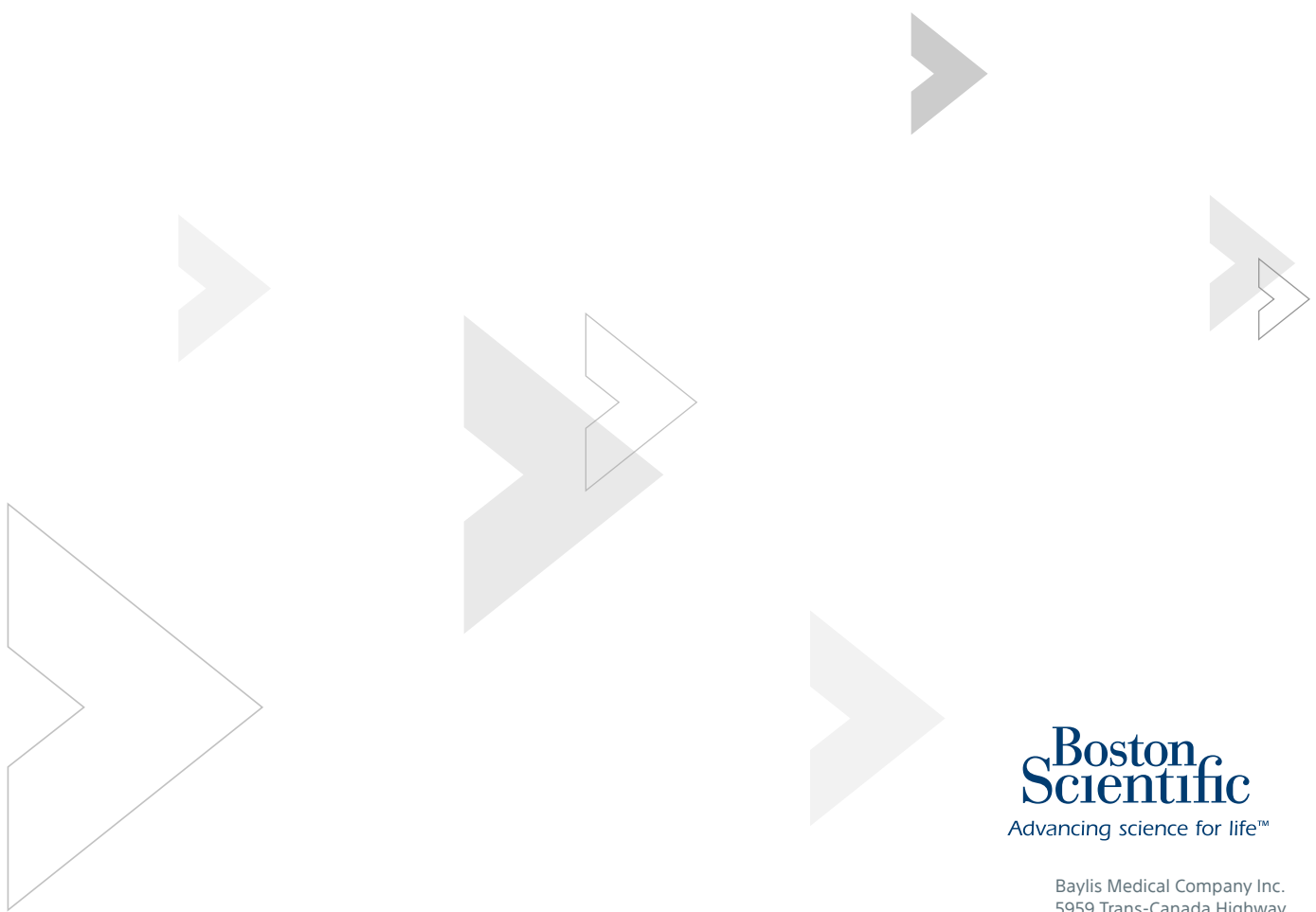
**CONTRAINDICATIONS:** The BMC Radiofrequency Puncture Generator is not recommended for uses other than the indicated use.

**WARNINGS:** • 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. • 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. • 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. • 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. • 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. • Read and follow the manufacturer's instructions for use of the return (dispersive) electrode. Only use dispersive electrodes that meet or exceed IEC 60601-2-2:2017 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. • 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. • 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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Scientific**  
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Baylis Medical Company Inc.  
5959 Trans-Canada Highway  
Montreal, QC Canada H4T 1A1  
[www.baylismedical.com](http://www.baylismedical.com)  
[info@baylismedical.com](mailto:info@baylismedical.com)

General Inquiries  
(514) 488-9801

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