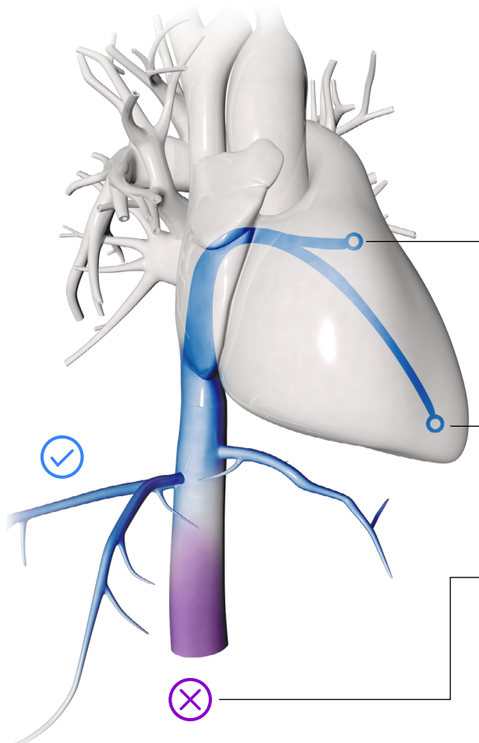
Boston Scientific
Advancing science for life™

SupraCross™

RF Solutions

LEFT ATRIAL ACCESS FROM ANY APPROACH™

Transhepatic Solution



Successful transseptal access has been achieved by transhepatic approach[1,2]. Optimized transseptal approach may be required in:

Mitral Valve Repair

Successful transcatheter mitral valve repair has been performed through transseptal access via hepatic venous approach, which provides a direct trajectory to the mitral annulus[3].

Ventricular Tachycardia (VT) Ablation

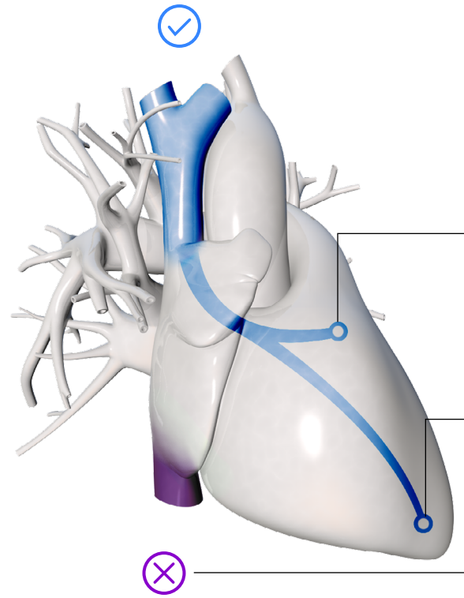
Successful ablation for atrioventricular nodal reentry tachycardia has been performed in the left ventricle via hepatic venous approach[4].

Impaired Inferior Vena Cava (IVC)

- Pulmonary Vein Isolation (PVI)
- Left Atrial Appendage Occlusion (LAAO)

Successful transcatheter therapies such as PVI (cryoablation[5] and RF ablation[1]) and LAAO[2] have been performed through transseptal access via hepatic venous approach in patients with impaired IVC[2].

Jugular/Subclavian Solution



Successful jugular / subclavian venous access cases[6,9,11,15,16] completed globally using the **SupraCross™** RF Solution. Optimized transseptal approach may be required in:

Mitral Valve Repair

Successful transcatheter mitral valve repair has been performed through transseptal access via jugular venous approach[6], which provides a direct trajectory to the mitral annulus.

Ventricular Tachycardia (VT) Ablation

Successful ablation for VT has been performed in the left ventricle via jugular venous approach[7].

Impaired Inferior Vena Cava (IVC)

- Pulmonary Vein Isolation (PVI)
- Left Atrial Appendage Occlusion (LAAO)

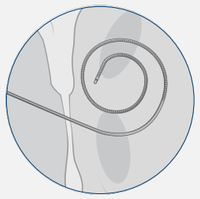
Successful transcatheter therapies such as PVI (cryoablation[8] and RF ablation[9,10,11]) and LAAO[12] have been performed through transseptal access via jugular venous approach in patients with impaired IVC.

SupraCross™ RF Solutions Include RF Wire and Sheath:

A **3-in-1** RF Wire

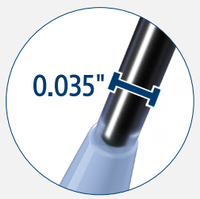
RF Puncture Technology

Reliably cross normal, fibrotic, and aneurysmal septa[9,10,13,14] using a short, focused RF energy pulse.*



Instantly Secure Access

Flexible spiral tip helps to maintain left atrial access[9].



Sturdy Exchange Rail

0.035" rail to facilitate sheath exchange with ease[10].

*Studies used **NRG™** Transseptal Needle, which employs the same RF puncture technology as the **SupraCross™** RF Wire.

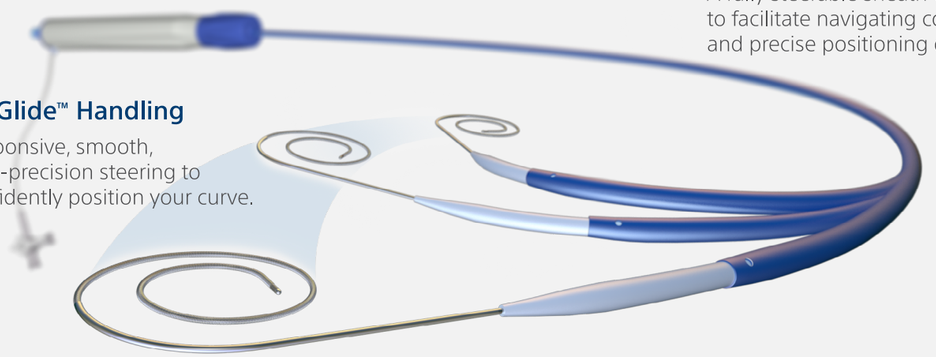
B **Precision** Steerable Sheath

Flexible Dilator

A fully steerable sheath with flexible dilator to facilitate navigating complex anatomy and precise positioning on the fossa[10].

TruGlide™ Handling

Responsive, smooth, high-precision steering to confidently position your curve.



SupraCross™ RF Solutions

SPECIFICATIONS

SupraCross™ Steerable Sheath

French Size	8.5F
Sheath Usable Length	45 cm
Sheath Overall Length	65 cm
Dilator Usable Length	67 cm
Compatible Guidewire	0.035"
Distal Curve	Bidirectional (90° CCW, 180°CW)
Distal Curve Diameter	S (17 mm), M (22 mm), L (50 mm)

*Compatible with 12.5F introducers

SupraCross™ RF Wire

Wire Length	180 cm
Diameter	0.035"
Radiopaque Marker	Platinum Tungsten Coil
Distal Coil Diameter	2.4 cm

*Compatible with 0.035" dilators

ORDERING INFORMATION

Product Number	Sheath	Wire
SCAK0001	**SupraCross**™ Sheath (S)	**SupraCross**™ RF Wire
SCAK0002	**SupraCross**™ Sheath (M)	**SupraCross**™ RF Wire
SCAK0003	**SupraCross**™ Sheath (L)	**SupraCross**™ RF Wire

Product Number	Sheath
SSS0004	**SupraCross**™ Sheath (S)
SSS0005	**SupraCross**™ Sheath (M)
SSS0006	**SupraCross**™ Sheath (L)

All **SupraCross**™ Solutions also include:
0.035" mechanical guidewire, Single-use connector cable, compatible with RFP-100A Generators*

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 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 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

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. Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

[1]Suryanarayana et al. Heart Rhythm Case Rep. 2020; 6(7).
[2]Morcos et al. Reports. 2018; 1(15).
[3]Brito et al. JACC: Cardiovasc Interv. 2018; 11(14).
[4]Nguyen et al. Europace. 2013; 15(4).
[5]Orme et al. Heart Rhythm Case Rep. 2018; 4(8).
[6]Yap et al. Cath Cardiovasc Interv. 2020.
[7]Han et al. J Cardiovasc Electrophysiol. 2013; 24(5).
[8]Baszko et al. EP Europace. 2015; 17(7).
[9]Liang et al, JACC: Clin Electrophysiol. 2020; 6(3).
[10]Santangeli et al, J Cardiovasc Electrophysiol. 2020; 31(1).
[11]Hernandez-Ojeda et al, Heart Rhythm Case Reports. 2020; 6(4).
[12]Aizer et al. Circ: Arrhythm Electrophysiol. 2015; 8(4).
[13]Sharma et al. Catheter Cardiovasc Interv. 2017; 89(6).
[14]Smelley et al. J Cardiovasc Electrophysiol. 2010; 21(4).
[15]Fam et al. EuroIntervention. 2017.
[16]Hanley et al. J Cardiovasc Electrophysiol. 2020.

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EP-1574908-AA