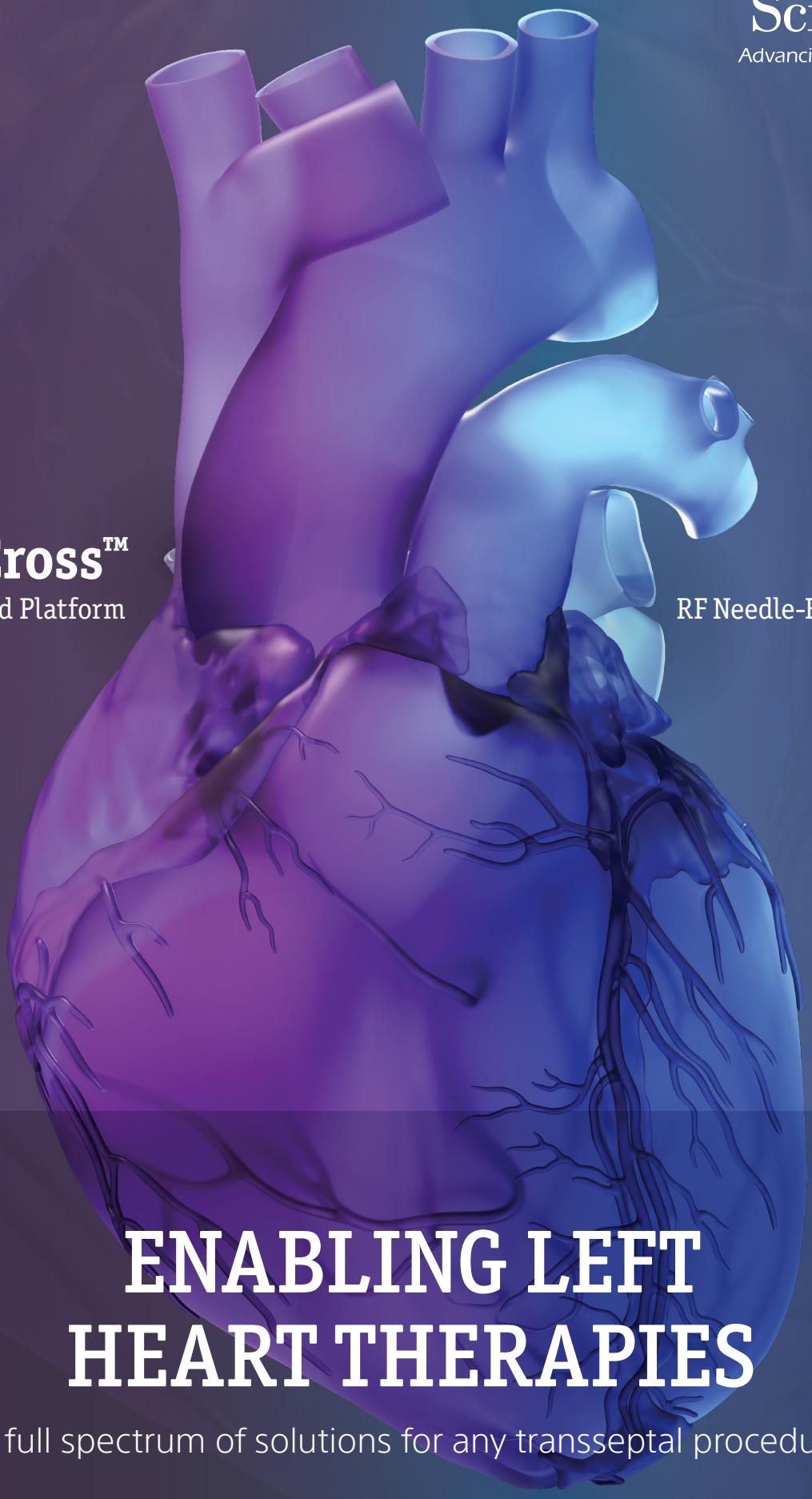
Boston Scientific
Advancing science for life™

VersaCross™
RF Wire-Based Platform

NRG™
RF Needle-Based Platform



ENABLING LEFT HEART THERAPIES

A full spectrum of solutions for any transseptal procedure

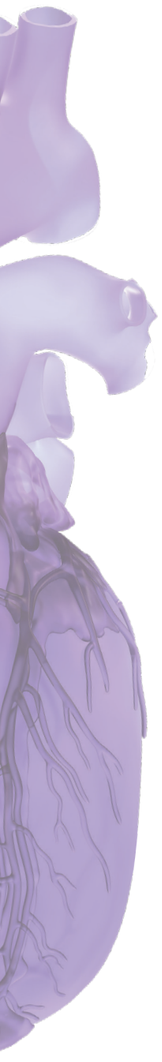
VersaCross™
RF Wire-Based Platform

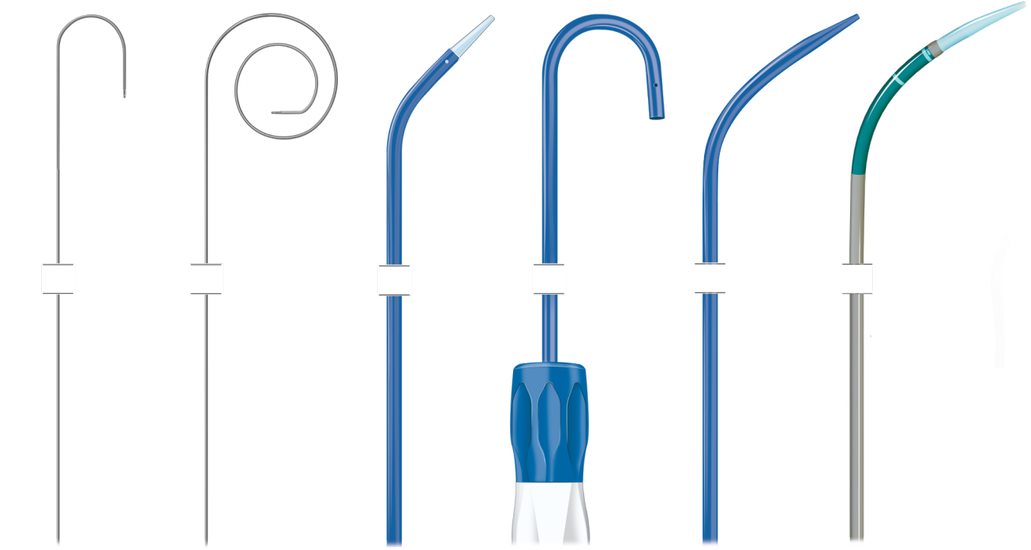
NRG™
RF Needle-Based Platform

PROVEN RF TRANSSEPTAL FOR ALL NEEDS

Transseptal Reimagined

The only exchangeless* solution
for access-to-delivery of left heart therapy devices





VersaCross™
RF Wire
(J-Tip)

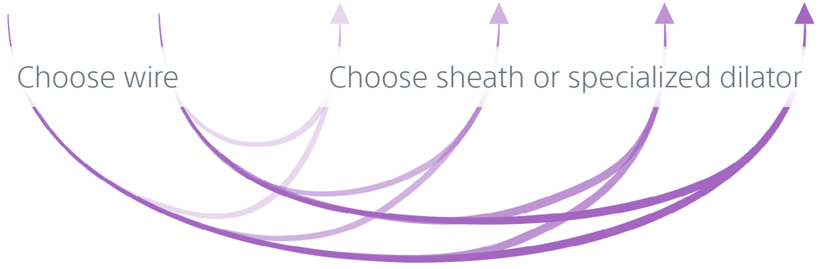
VersaCross™
RF Wire
(Pigtail)

VersaCross™
Transseptal
Sheath

VersaCross™
Steerable
Sheath

VersaCross™
Large Access
Transseptal Dilator

VersaCross Connect™†
Transseptal Dilator



PERSONALIZE YOUR SOLUTION

The Standard in Transseptal Access

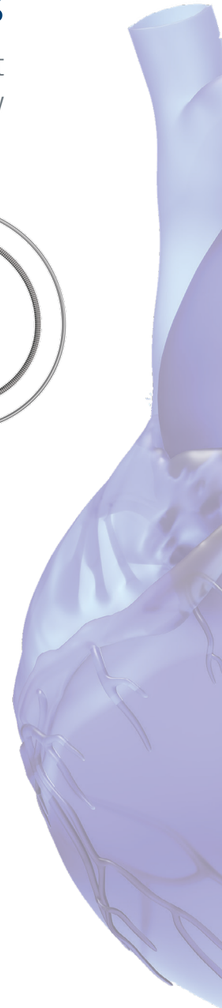
Interchangeable solutions that
easily integrate with your current workflow

NRG™
Transseptal
Needle

TorFlex™
Transseptal
Guiding Sheath

SureFlex™
Steerable
Guiding Sheath

ProTrack™
Pigtail Wire



INTERCHANGEABLE DEVICES

* VersaCross™ RF Wire can be used, without exchanges, as a guidewire, as a transseptal puncture device or as an exchange rail for delivering therapy sheaths.

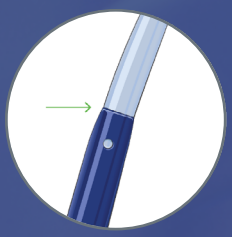
† The VersaCross Connect™ Transseptal Dilator is for use with a 12F ID WATCHMAN™ Access Sheath that is 75 cm in length, specifically: WATCHMAN™ Access System [Models: M635TU40060, M635TU10060, M635TU20060]; WATCHMAN™ TruSeal™ Access System [Models: M635TU70010, M635TU70040, M635TU70020]; WATCHMAN FXD Curve™ Access System [Models: M635TU80010, M635TU80020]. WATCHMAN™ Access Sheaths and devices sold separately.

TRANSSEPTAL SOLUTIONS FEATURE:

Benchmark Technology:

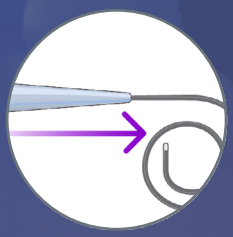
Proven RF Puncture Technology

Precise RF puncture technology to optimize transseptal location for any anatomy



Smooth Transition

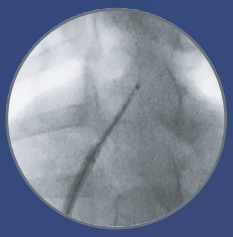
Facilitate advancement across septum with a sleek dilator-to-sheath profile



Secure effortless delivery

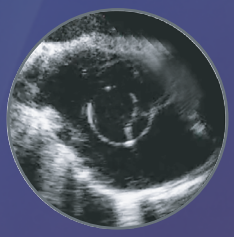
Instantly gain and maintain access without exchanges

OMNIviz™ Technology:



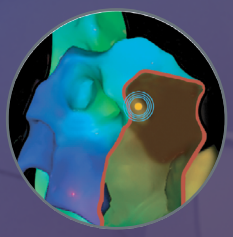
Radiopaque

Visualize your tip on fluoroscopy



Echogenic

Reliably locate your active tip on ultrasound for precise puncture



Mapping

Track and mark RF tip position on your mapping system

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.

NDICATIONS 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 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 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

Boston Scientific

Advancing science for life™

Baylis Medical Company Inc.
5959 Trans-Canada Highway
Montreal, QC Canada H4T 1A1

www.baylismedical.com
info@baylismedical.com

General Inquiries
(514) 488-9801

EP-1536604-AB