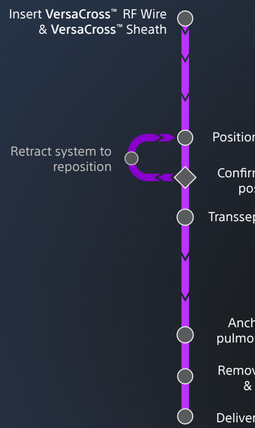
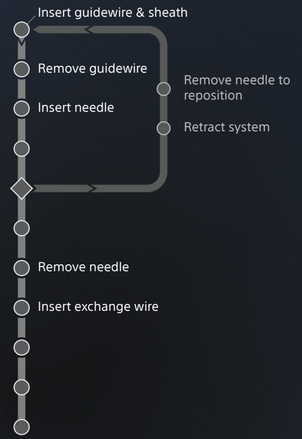
the FAST TRACK to your ablation delivery in a single solution

VersaCross™ Workflow



Mechanical Needle Workflow



Eliminate exchanges

Access with precision

Secure effortless delivery

VersaCross™ RF Transseptal Solution

Full platform of tools to personalize your solution

Personalize your solution

1 Choose your **VersaCross™** RF Wire

VersaCross™ RF Wire

RF Wire length: 180 cm, 230 cm
Wire diameter: 0.035"
Curve diameter: 9 mm (J-tip), 24 mm (Pigtail)

2 Choose your **VersaCross™** Sheath to complete your solution available in Dilator curves D1 or D0 with **TRUform™** Shapeable Technology

A **VersaCross™** Transseptal Sheath

French size compatibility: 8.5F (2.84 mm)
Sheath usable length: 63 cm, 81 cm
Dilator usable length: 67 cm, 85 cm

B **VersaCross™** Steerable Sheath

Sheath curves: S (17 mm), M (22 mm), L (50 mm)
Bidirectional angles: 90 CCW, 180 CW

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-1004 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

Brief Summary | **VersaCross™** Transseptal Dilator

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™ Transseptal Dilator 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 VersaCross™ Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to follow this instruction may result in patient complications • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel.

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.

ADVERSE EVENTS: Adverse events that may occur while using the VersaCross™ 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 • Thromboembolic events • Stroke • Valve damage • Myocardial infarction • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion
EP-1506213-AA

Brief Summary | **VersaCross™** 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 VersaCross™ 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 use of echocardiography is recommended. • The VersaCross™ Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel. • 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 VersaCross™ Steerable Sheath kit is not compatible with transseptal needles such as the "NRG™ Transseptal Needle".

ADVERSE EVENTS: Adverse events that may occur while using the VersaCross™ 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 • Emboli events • Stroke • Valve damage • Myocardial infarction • Pericardial/pleural effusion • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pacemaker/defibrillator lead displacement
EP-1506705-AA

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Advancing science for life™

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EP-1559409-AA

Boston Scientific
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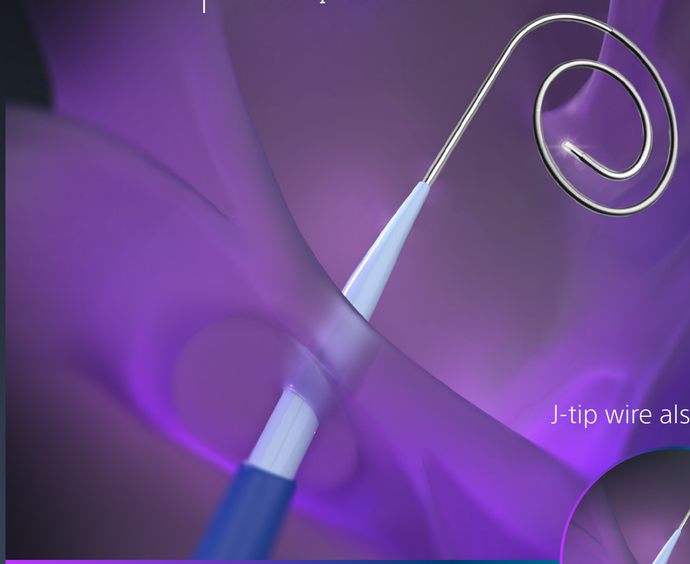
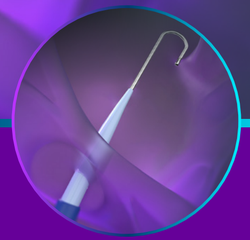
VersaCross™
RF Transseptal Solution



J-tip wire also available



SINGLE, EXCHANGELESS SOLUTION

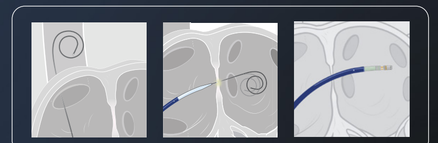
Deliver left heart ablation devices with ease

VERSATILITY

the only EXCHANGELESS* solution for access-to-delivery of left heart ablation devices

ELIMINATE EXCHANGES

Left heart access using a SINGLE SOLUTION from start to finish



Drop down to optimize transseptal location WITHOUT THE HASSLE of exchanging a needle

*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.

INSTANTLY SECURE ACCESS

RF Puncture Technology allows crossing even in challenging anatomy. Instantly probe and anchor into pulmonary vein without exchanges.

TRUform™
SHAPEABLE TECHNOLOGY

Shapeable dilator with true-to-form curve retention

DELIVER CONSISTENT CONTACT FORCE†

Retain your curve and support consistent contact force† with the **VersaCross™** Steerable Sheath. Consistent contact force of ablation catheters provides better therapeutic results.[1]

TruGlide™
RESPONSIVE HANDLING

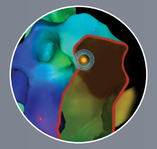
Responsive, smooth, high-precision steering to confidently position your curve

†Assessed by repeated bidirectional curving up to 100 cycles while tracing the curve radius at each step (p<0.001) and by full bidirectional articulation to maximal extension up to 10 times to achieve mechanical fatigue (p=0.007). Comparisons done using 5 SureFlex™ and 3 competitor sheaths, with needle and dilator inside sheath. Based on bench testing conducted using SureFlex™ Steerable Guiding Sheath, which has identical steering mechanisms to VersaCross™ Steerable Sheath. Bench testing or pre-clinical study results may not necessarily be indicative of clinical performance. The testing was performed by or on behalf of Boston Scientific. Data on file.

[1]Piorkowski C, et al. Circ Arrhythm Electrophysiol. doi: 10.1161/CIRCEP.110.957761

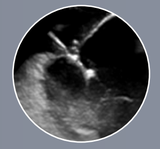
Know where you are at all times with

OMNIviz™ Technology



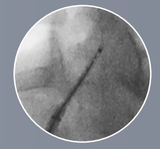
MAPPING

Track and mark RF tip position on your mapping system



ECHOGENIC

Reliably locate your devices on ultrasound to reduce reliance on fluoroscopy



RADIOPAQUE

Visualize your entire solution on fluoroscopy

POSITIONAL MARKERS

Visibly confirm position of RF tip within dilator

VersaCross™
RF Transseptal Solution