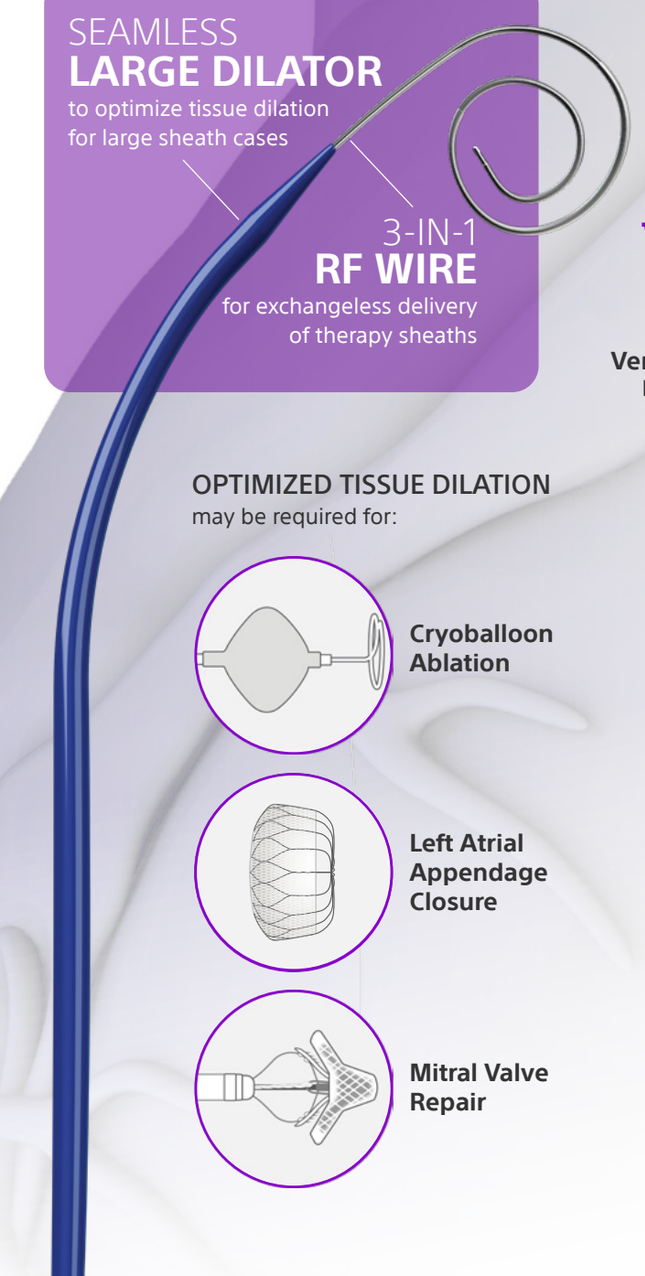
VersaCross™
Large Access Solution

FAST TRACK DELIVERY
of large therapy sheaths
with a single solution

SEAMLESS
LARGE DILATOR
to optimize tissue dilation
for large sheath cases

3-IN-1
RF WIRE
for exchangeless delivery
of therapy sheaths



VersaCross™
Large Access Solution

Mechanical
needle

VersaCross™
RF Wire &
Dilator

1. **INSERT**
2. **POSITION** on fossa
3. **CONFIRM** position
4. **TRANSSEPTAL** access
5. **RETRACT** dilator/sheath
6. **DELIVER** therapy device

1. Guidewire & sheath
2. **RETRACT** guidewire
3. **INSERT** needle
4.
5.
6.
7. **RETRACT** needle
8.
9.
10.

OPTIMIZED TISSUE DILATION
may be required for:

Cryoballoon Ablation

Left Atrial Appendage Closure

Mitral Valve Repair

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 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™** Large Access Transseptal Dialtor

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™ Large Access Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.

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™ Large Access Transseptal Dilator and accompanying guidewire are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Large Access Transseptal Dilator or accompanying guidewire. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may results in patient complications. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury.

PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Dilator and guidewire advancement should be performed under imaging guidance, such as fluoroscopy or echocardiography. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The VersaCross™ Large Access Transseptal Dilator is compatible with introducer sheaths 12.5Fr or larger. • The VersaCross™ Large Access Transseptal Dilator is compatible with .035" transseptal devices and guidewires • The VersaCross™ Large Access Transseptal Dilator is NOT compatible with transseptal needles such as the "NRG™ Transseptal Needle". • Do not reshape 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 VersaCross™ Large Access Transseptal Dilator and accompanying guidewire include: • Infection • Air embolus • Local nerve damage • Vessel trauma • Vessel spasm • Pseudoaneurysm • AV fistula formation • Atrial septal defect • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Valve damage • Pericardial/pleural effusion
EP-1506604-AA

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EP-1548906-AA

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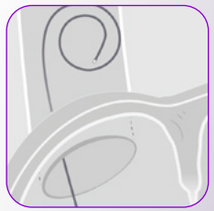
VersaCross™
Large Access Solution

ACCESS DILATE & DELIVER
large therapy sheaths with a single, exchangeless* solution

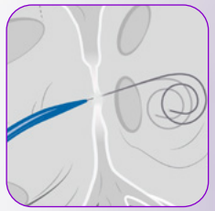
*VersaCross™ RF Wire can be used, without exchanges, as a guidewire, as a transseptal puncture device or as an exchange rail for delivering therapy sheaths.

ACCESS
with precision

EXCHANGELESS **3-in-1** RF Wire



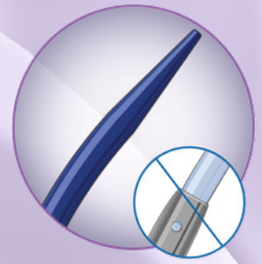
1 Start at the SVC



2 RF transseptal puncture

3 Supportive exchange rail

DILATE
to optimize delivery of large therapy sheaths



SINGLE
SEAMLESS
dilator for controlled crossing into the left atrium

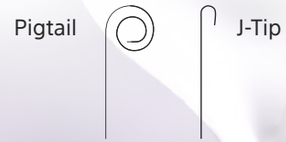
12.5F
DILATION
at the femoral vein and septum to deliver large sheaths with ease

DELIVER
large therapy sheaths effortlessly

INSTANTLY DEPLOY
0.035" WIRE
to deliver therapy sheaths with confidence

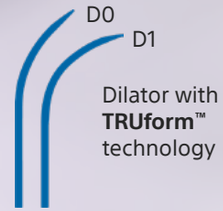
Personalize your solution

1. Choose your **VersaCross**™ RF Wire



Length: 180 cm, 230 cm
Diameter: 0.035"

2. Choose your **VersaCross**™ Large Access Transseptal Dilator



Dilator with **TRUform**™ technology

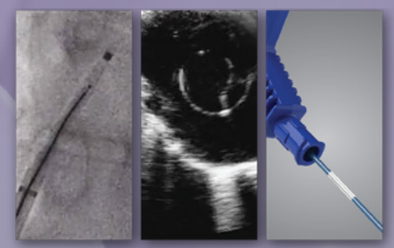
Inner Diameter: 0.035"
Outer Diameter: 12.5F
Useable Length: 67 cm, 85 cm

The **VersaCross**™ Large Access Solution comes with a single-use connector cable and mechanical guidewire

DELIVER THERAPY ON TARGET

Precision RF Puncture Technology

TRUform™ Shapeable Technology



OMNIviz™ Technology

Reliably locate your solution on fluoroscopy, ultrasound and visibly with positional markers