FAST TRACK

to your therapy delivery
in a **SINGLE SOLUTION**

VersaCross Connect™
Access Solution†

Needle-based workflow

VersaCross™ RF Wire, VersaCross Connect™ Dilator, POLARSHEATH™ Steerable Sheath†	1	**INSERT**	1 Guidewire and sheath
	2	**RETRACT** guidewire	2
	3	**INSERT** needle	3
	4	**POSITION** on fossa	4
	5	**CONFIRM** position	5
	6	**TRANSSEPTAL** access	6
	7	**RETRACT** needle	7
	8	**INSERT** exchange wire	8
	9	**RETRACT** dilator/sheath	9
	10	**INSERT** therapy sheath/dilator	10
	11	**RETRACT** dilator	11
	12	**DELIVER** therapy*	12

VersaCross Connect™

Access Solution for **POLARSHEATH™**

DESIGNED for use with the
POLARSHEATH™
Steerable Sheath‡

3-IN-1
RF WIRE
for ZERO EXCHANGE delivery

Smooth transition between VersaCross Connect™ Dilator and POLARSHEATH™ Sheath‡

Snap-lock designed for POLARSHEATH™ Sheath‡

†POLARSHEATH™ Steerable Sheaths as shown in this brochure is sold separately.

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

VersaCross Connect™ 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 Connect Transseptal Dilator is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture. United States: The VersaCross Connect 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 Connect Transseptal Dilator is intended for single patient use only. Failure to do so may result in patient complications. • Do not attempt to sterilize and reuse the VersaCross Connect Transseptal Dilator. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • The VersaCross Connect Transseptal Dilator is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Care should be taken when inserting or removing the dilator from access sheaths or introducer sheaths. • Manual shaping of the distal curve shall be done with smooth motions along the curve. Do not use excessive force and/or pressure when reshaping. • Care should be taken when inserting or removing compatible guidewires from the dilator lumen. • Direct percutaneous insertion of the dilator without a sheath is not recommended. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. **PRECAUTIONS** • Do not attempt to use the VersaCross Connect Transseptal Dilator before thoroughly reading the accompanying Instructions for Use. • The sterile barrier system and dilator should be visually inspected prior to use. Do not use if the sterile barrier integrity or device have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • The VersaCross Connect Transseptal Dilator is compatible with introducer sheaths 12.5F or larger. • The VersaCross Connect Transseptal Dilator is for use with the 12F ID POLARSHEATH™ Steerable Sheath, which is 68 cm in length. • The VersaCross Connect Transseptal Dilator is compatible with 0.035" transseptal devices and guidewires or smaller. • The VersaCross Connect Transseptal Dilator is NOT compatible with transseptal needles such as the "NRG™ Transseptal Needle". **ADVERSE EVENTS** Adverse events that may occur while using the VersaCross Connect Transseptal Dilator include: • Infection • Local nerve damage • Vessel spasm • AV fistula formation • Arrhythmias • Hematoma • Catheter entrapment • Valve damage • Air embolus • Vessel trauma • Pseudoaneurysm • Atrial septal defect • Perforation and/or tamponade • Hemorrhage • Embolic events • Pericardial/pleural effusion

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*The therapy referred to here may be one of several left heart procedures that require transseptal access. Additional procedural steps and/or devices may be required to deliver the therapy. Before use, consult Instructions for Use for any devices accordingly.

†POLARSHEATH™ Steerable Sheaths as shown in this brochure is sold separately.

‡The VersaCross Connect Transseptal Dilator is for use with a 12F (4.04 mm) ID POLARSHEATH™ Steerable Sheath that is 68 cm in length, specifically, model: M004CRBS3150 (US) and M004CRBS3050 (Canada).

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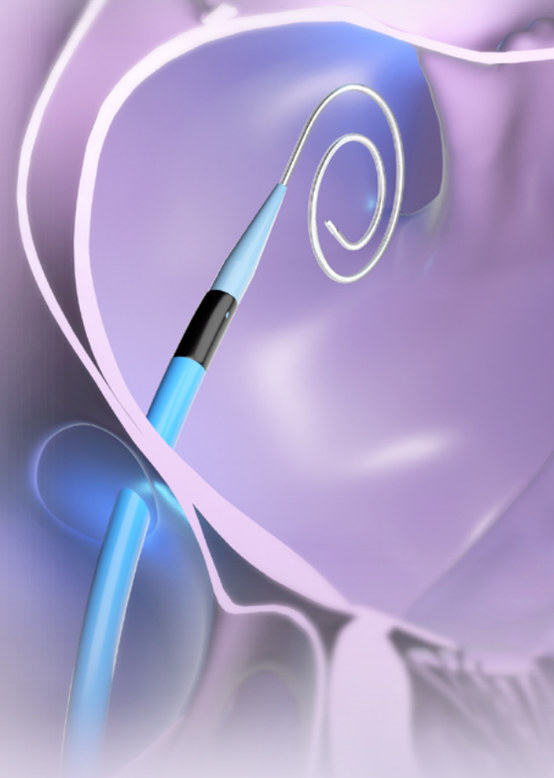
VersaCross Connect™

Access Solution for **POLARSHEATH™**



Greater Confidence
in Left Heart Access

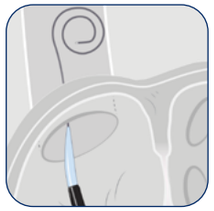
ZERO EXCHANGE

POLARSHEATH™ Steerable Sheath delivery.
For use with the POLARx™ Cryoablation System.

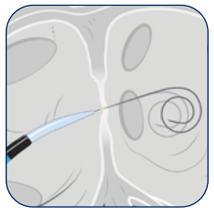
SIMPLE, SEAMLESS, SMOOTH ZERO EXCHANGE

POLARSHEATH™ Steerable Sheath Delivery‡

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



1 Start
easily track up the SVC



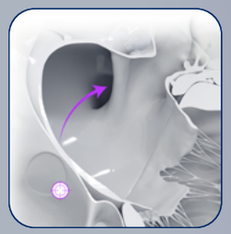
2 Access
with purpose-built RF

3 Deliver
with confidence

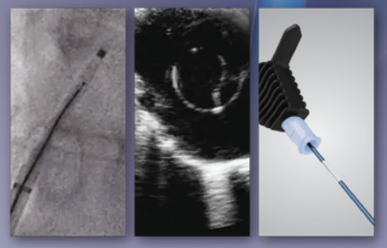
INSTANTLY DEPLOY
0.035" WIRE
To deliver **POLARSHEATH™**‡
Steerable Sheath
with confidence

DELIVER THERAPY ON TARGET

TRUform™
Shapeable Technology



Precise RF
Puncture Technology



OMNIviz™ Technology

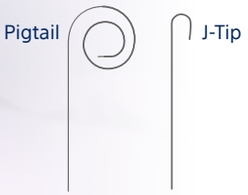
Reliably locate the **VersaCross Connect™** solution on fluoroscopy and ultrasound. Positional markers indicate position of RF tip within dilator. Connect to DuoMode™ Cable to track and mark RF tip on mapping systems.

VersaCross Connect™

Access Solution for **POLARSHEATH™**

Personalize your solution

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



Length: 180 cm
Diameter: 0.035"

2. Connect with **VersaCross Connect™** Transseptal Dilator

Dilator with **TRUform™** technology

Inner diameter: 0.035"
Outer diameter: 12F (4.04 mm)
Useable length: 84 cm

Ordering information

Part. No.	Wire	Wire length	Dilator curve	Dilator length
VXAK0031	Pigtail	180 cm	D1	84 cm
VXAK0035	J-Tip	180 cm	D1	84 cm