

Instructions for Use

VersaCross Connect™ Transseptal Dilator

English.....1



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English

Carefully read all instructions prior to use. Observe all warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Baylis Medical Company relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of the procedure. CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Notice (EU): Any serious incident as defined in the EU Medical Device Regulation (2017/745) that has occurred in relation to the VersaCross Connect Transseptal Dilator should be reported to Baylis Medical Company Inc. and the competent authority of the EU Member State in which the physician and/or patient is established.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) is to be added to the European database on medical devices (Eudamed, <https://ec.europa.eu/tools/eudamed>) once it is available.

DEVICE DESCRIPTION

The VersaCross Connect™ Transseptal Dilator consists of two components: a 12F dilator (4.2mm maximum OD) and a 0.035" J-tipped Mechanical Guidewire.

The VersaCross Connect Transseptal Dilator is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The dilator provides torque control and is flexible. The dilator features a tapered tip and a shaft that can be reshaped manually. The echogenic shaft and tip and radiopaque tip maximize visualization of the dilator during manipulation.

The J-tipped Mechanical Guidewire, hereafter referred to as the "guidewire", is comprised of a stainless-steel core with a flexible, spiral shaped PTFE coated steel coil along the full length of this device. The guidewire is in its entirety coated with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for these coatings.

The VersaCross Connect Transseptal Dilator is for use with a 12F ID WATCHMAN™ Access Sheath that is 75cm in length, specifically:

- WATCHMAN™ Access System
Models: M635TS40060, M635TS10060, M635TS20060
- WATCHMAN TruSeal™ Access System
Models: M635TS70010, M635TS70040, M635TS70020
- WATCHMAN FXD Curve™ Access System
Models: M635TS80010, M635TS80020

Carefully read the applicable WATCHMAN™ Access Sheath instructions prior to use. Observe all warnings and precautions noted in these instructions. Failure to do so may result in patient complications.

INTENDED USE

The VersaCross Connect Transseptal Dilator is indicated for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture. The VersaCross Connect Transseptal Dilator is intended for use in percutaneous transseptal procedures in patients requiring delivery of cardiovascular catheters to the heart, including the left side via transseptal puncture. The device is intended for use in adults (not pediatric) patients, with the exclusion of pregnant and/or nursing patients. The VersaCross Connect Transseptal Dilator is a single-use device. Only physicians trained in the techniques of the approach to be used should perform the interventional procedures.

INDICATIONS FOR USE

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.

Rest of world: 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.

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 and accompanying guidewire are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Connect 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 result in patient complications.
- The VersaCross Connect Transseptal Dilator and accompanying guidewire are 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.

- The Mechanical Guidewire is coated with a lubricious coating. The following warnings must be considered:
 - Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity.
 - Excessive manual bending and/or shaping of the device may affect the coating integrity.
 - 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.

- Dilator can be inserted fully into the compatible access sheath and a manual curve may be added to the dilator and sheath set prior to insertion into the body.
- Thread the dilator and compatible access sheath over the guidewire, allowing the device to twist freely while under imaging guidance such as fluoroscopy or echocardiography up to the SVC. If resistance is encountered, DO NOT use excessive force to advance or withdraw the dilator over the guidewire. Determine the cause of resistance before proceeding.
- Use standard technique to position the sheath/dilator/guidewire assembly into the desired heart chamber.
- If transseptal puncture is required, refer to the Instructions for Use of the transseptal puncture device.
- Ensure the dilator is clear of air. To aspirate blood, use the dilator hub.
- Monitor the location of the radiopaque tip frequently under imaging guidance, such as fluoroscopy or echocardiography.
- Deliver a continuous heparinized solution infusion or aspirate periodically. This may help reduce the risk of thromboembolic complications due to thrombus formation, as there may be a possibility of thrombus development at the distal dilator tip or inside the dilator lumen. Also aspirate when removing the transseptal device or dilator.
- After removal of the dilator, use standard technique to achieve hemostasis.

PRECAUTIONS

- Do not attempt to use the VersaCross Connect Transseptal Dilator or accompanying guidewire before thoroughly reading the accompanying Instructions for Use.
- The sterile barrier system, dilator, and guidewire should be visually inspected prior to use. Do not use if the sterile barrier integrity or devices 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 specified models of 12F ID WATCHMAN™ Access Sheath that are 75cm 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".
- 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.
- Only use compatible tip straighteners with the guidewire.

CLEANING AND STERILIZATION INSTRUCTIONS

Do not clean or re-sterilize the VersaCross Connect Transseptal Dilator or the accompanying guidewire. The VersaCross Connect Transseptal Dilator and the accompanying guidewire are intended for single use only.

DISPOSAL OF WASTE

Treat the used device(s) as biohazardous waste and dispose of in compliance with standard hospital procedures.

CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION

If you have any problems with or questions about Baylis Medical Equipment contact our technical support personnel.

CONTRAINDICATIONS

There are no known contraindications for this device.

SPECIAL STORAGE AND/OR HANDLING INSTRUCTIONS

Keep away from sunlight.

ADVERSE EVENTS

Adverse events that may occur while using the VersaCross Connect Transseptal Dilator and accompanying guidewire include:

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|----------------------|------------------------------|
| 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 |

PRODUCT COMPATIBILITY

The following devices are compatible with the VersaCross Connect Transseptal Dilator

- Male luer lock syringes
- Introducer sheaths 12.5F or larger
- 12F ID WATCHMAN™ Access Sheath that is 75cm in length
- 0.035" or smaller Transseptal Puncture Devices and Guidewires (Such as VersaCross RF wire)

PREPARATION FOR USE

Prior to use of the VersaCross Connect Transseptal Dilator and accompanying guidewire, the individual components should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment. Do not reuse the device.

SUGGESTED DIRECTIONS FOR USE

- Carefully read all instructions prior to use. Failure to do so may result in complications.
- Carefully read the applicable WATCHMAN™ Access Sheath instructions prior to use. Failure to do so may result in complications.
- Use of VersaCross Connect is expected to reduce the number of exchanges in the procedure resulting in a more efficient transseptal puncture. This should be taken into account when estimating the timing for heparin administration to ensure appropriate ACT levels after transseptal puncture.
- Thoroughly flush the dilator and guidewire with heparinized saline solution prior to use.
- Gain access to the right femoral vein using standard methods.
- Note that a compatible access introducer sheath may be used at the venous cutaneous puncture site if desired. Refer to the compatible introducer sheath's Instructions for Use for details and directions.
- Introduce the guidewire through the vasculature access point and advance to required depth. If resistance is encountered, DO NOT use excessive force to advance or withdraw the guidewire. Determine the cause of resistance before proceeding.

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NOTES:

1. In order to return products, you must have a return authorization number before shipping the products back to Baylis Medical Company. Product Return Instructions will be provided to you at this time.
2. Ensure that any product being returned to Baylis Medical has been cleaned, decontaminated and/or sterilized as indicated in the Product Return Instruction before returning it for warranted service. Baylis Medical will not accept any piece of used equipment that has not been properly cleaned or decontaminated as per the Product Return Instructions.

LABELING AND SYMBOLS

	Manufacturer		EU Authorized Representative
	Sterile using ethylene oxide		Single Use – Do not reuse
	Use By		Batch Code
	Caution		Do not use if package is damaged and consult instructions for use
	Consult Instructions for Use		Keep Away from Sunlight
	Catalogue number		Do Not Re-sterilize
	Non-Pyrogenic		Date of Manufacture
	Single Sterile Barrier System		Medical Device
	Contains hazardous substances: Cobalt (Co)		EU Importer

	The VersaCross Connect Transseptal Dilator is for use with the WATCHMAN™ Access Sheath		The VersaCross Connect Transseptal Dilator has an outer diameter of 12F (4.2mm)
Max Guidewire O.D.		Maximum guidewire outside diameter that can be used with this device	
Standard Curve D0		Standard Curve (D0)	
Large Curve D1		Large Curve (D1)	
For use with: WATCHMAN™ Access Sheath WATCHMAN™ Tri-Set™ Access Sheath WATCHMAN FXD Curve™ Access Sheath		For use with respective sheath(s)	

LIMITED WARRANTIES

Baylis Medical Company Inc. (BMC) warrants its Disposable and Accessory products against defects in materials and workmanship. BMC warrants that sterile products will remain sterile for a period of time as shown on the label as long as the original package remains intact. Under this Limited Warranty, if any covered product is proved to be defective in materials or workmanship, BMC will replace or repair, in its absolute and sole discretion, any such product, less any charges to BMC for transportation and labor costs incidental to inspection, removal or restocking of product. The length of the warranty is: (i) for the Disposable products, the shelf life of the product, and (ii) for the Accessory products, 90 days from shipment date. This limited warranty applies only to new original factory delivered products that have been used for their normal and intended uses. BMC's Limited Warranty shall not apply to BMC products which have been resterilized, repaired, altered, or modified in any way and shall not apply to BMC products which have been improperly stored or improperly cleaned, installed, operated or maintained contrary to BMC's instructions.

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No agent, employee or representative of Baylis Medical has the authority to bind the Company to any other warranty, affirmation or representation concerning the product.

This warranty is valid only to the original purchaser of Baylis Medical products directly from a Baylis Medical authorized agent. The original purchaser cannot transfer the warranty.

Use of any BMC product shall be deemed acceptance of the terms and conditions herein.

The warranty periods for Baylis Medical products are as follows:

Disposable Products	The shelf life of the product
Accessory Products	90 days from the shipment date