Instructions for Use

VersaCross Connect™ Transseptal Dilator

Baylis Medical Company Inc.
5959 Trans-Canada Highway
Montreal, Quebec, Canada, H4T 1A1
Tel: (514) 488-9801/ (800) 850-9801
Fax: (514) 488-7209
www.baylismedical.com

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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

DEVICE DESCRIPTION
The VersaCross Connect™ Transseptal Dilator consists of two components: a dilator and a 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: M635TU40060, M635TU10060, M635TU20060
- WATCHMAN™ TruSeal™ Access System
  Models: M635TU70010, M635TU70040, M635TU70020
- WATCHMAN FXD Curve™ Access System
  - Models: M635TU80010, M635TU80020

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.

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 results 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.

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 com patible 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.

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:

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

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.
- 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 within the superior vena cava (SVC). If resistance is encountered, DO NOT use excessive force to advance or withdraw the guidewire. Determine the cause of resistance before proceeding.
- 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.
- 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.

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.

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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 warrantied 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	Rx ONLY	*Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.*
STERILE EO	*Sterile using ethylene oxide*		*Single Use – Do not reuse*
	Use By	LOT	*Batch Code*
	Caution		*Do Not Use if Packaging is Damaged*
	Consult Instructions for Use		*Keep Away from Sunlight*
REF	*Model number*		*Do Not Re-sterilize*
	Non-Pyrogenic	Max Guidewire O.D.	*Maximum guidewire outside diameter that can be used with this device*

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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