Baylis MEDICAL

www.baylismedical.com

Instructions for Use

VersaCross® Transseptal Sheath

English……1

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

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.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the procedure.

I. DEVICE DESCRIPTION

The VersaCross® Transseptal Sheath kit consists of three components: a sheath, a dilator, and a J-tipped guidewire.

The VersaCross® Transseptal Sheath kit is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The sheath device shaft in its entirety is coated with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for this coating. The dilator provides support for the sheath, features a tapered tip and a shaft that can be reshaped manually. Radiopaque tips maximize visualization of the sheath and dilator during manipulation.

II. INDICATIONS FOR USE

The VersaCross® Transseptal Sheath kit 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.

III. 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® Transseptal Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross® Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- The VersaCross® Transseptal Sheath kit is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged.
- The sheath's shaft is coated with a lubricious coating. The following warnings must be considered:
  - Use of the sheath with introducer sheaths smaller than the size listed in the section below may result in a tight fit that affects device performance, including coating integrity.
  - Excessive wiping and/or wiping of the sheath with a dry gauze may damage the coating.
  - Manual shaping of the sheath distal curve shall be done with smooth motions along the curve without applying excessive pressure. Excessive manual bending and/or shaping of the sheath shaft may affect the coating integrity.
- Care should be taken to ensure that all air is removed from the sheath before infusing through the side port.
- Care should be taken when removing the dilator and catheters from the sheath.
- Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury.
- Damage to guidewire may result if withdrawn through a metal needle cannula.
- Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

IV. PRECAUTIONS

- Do not attempt to use the VersaCross® Transseptal Sheath kit before thoroughly reading the accompanying Instructions for Use.
- 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.
- The sterile packaging and sheath should be visually inspected prior to use. Do not use the device if it has been compromised or damaged.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- Note product "Use By" date.
- The VersaCross® Transseptal Sheath is compatible with introducer sheaths 11Fr or larger.
- The VersaCross® Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires .035" or smaller.
- The VersaCross® Transseptal Sheath kit is NOT compatible with transseptal needles such as the "NRG® Transseptal Needle".

V. ADVERSE EVENTS

Adverse events that may occur while using the VersaCross® Transseptal Sheath kit include:

Infection	Air embolus
Local nerve damage	Hemorrhage
Embolic events	Vessel spasm
AV fistula formation	Atrial septal defect
Pseudoaneurysm	Perforation and/or tamponade
Arrhythmias	Pericardial/pleural effusion
Hematoma	Vessel trauma
Valve damage	Catheter entrapment

VI. INSPECTION PRIOR TO USE

Prior to use of the VersaCross® Transseptal Sheath kit, 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.

VII. EQUIPMENT REQUIRED

Intracardiac puncture procedures should be performed in a sterile environment in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, echocardiographic imaging, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

VIII. SUGGESTED DIRECTIONS FOR USE

- Carefully read all instructions prior to use. Failure to do so may result in complications.
- Thoroughly flush the sheath, guidewire and dilator with heparinized saline solution prior to use.
- Perform a standard vein puncture of the right femoral vein using an access needle (not supplied).
- Introduce the guidewire 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.
- Leaving the guidewire in place, withdraw the needle. Enlarge the cutaneous puncture site as necessary.
- 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.
- Assemble the dilator and sheath until the dilator hub locks into the sheath hub. The sideport of the sheath and curve indicator of the dilator should be in the same orientation.
- The distal curvature of the dilator may be adjusted manually if desired. Do not use excessive force when reshaping.
- Thread the dilator/sheath assembly over the guidewire using a slight twisting motion into the superior vena cava (SVC) under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the dilator/sheath assembly over the guidewire. Determine the cause of resistance before proceeding.
- Use standard technique to position the sheath/dilator assembly into the desired heart chamber.
- If transseptal puncture is required, refer to the Instructions for Use of the transseptal puncture device. Echocardiographic guidance is also recommended.
- Ensure the sheath is clear of air. To aspirate blood, use the sheath side port.
- Monitor the location of the radiopaque tip of the sheath and dilator frequently under fluoroscopy. Echocardiographic guidance is also recommended.
- 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 sheath tip or inside the sheath lumen. Also aspirate when removing the transseptal device or dilator.
- After removal of the sheath, use standard technique to achieve hemostasis.

IX. CLEANING AND STERILIZATION INSTRUCTIONS

Do not clean or re-sterilize the VersaCross® Transseptal Sheath kit. The VersaCross® Transseptal Sheath kit is intended for single use only.

X. DISPOSAL OF WASTE

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

XI. CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION

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

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

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.

XII. 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	Lot number
	Caution		Do not use if packaging is damaged
	Consult Instructions for Use		Keep away from sunlight
REF	Model number		Keep dry
	Non-pyrogenic		Do not resterilize

XIII. LIMITED WARRANTY – Disposables and Accessories

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.

DISCLAIMER AND LIMITATION OF LIABILITY

THE LIMITED WARRANTY ABOVE IS THE SOLE WARRANTY PROVIDED BY SELLER. SELLER DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

THE REMEDY SET FORTH HEREIN SHALL BE THE EXCLUSIVE REMEDY FOR ANY WARRANTY CLAIM, AND ADDITIONAL DAMAGES, INCLUDING CONSEQUENTIAL DAMAGES OR DAMAGES FOR BUSINESS INTERRUPTION OR LOSS OF PROFIT, REVENUE, MATERIALS, ANTICIPATED SAVINGS, DATA, CONTRACT, GOODWILL OR THE LIKE (WHETHER DIRECT OR INDIRECT IN NATURE) OR FOR ANY OTHER FORM OF INCIDENTAL, OR INDIRECT DAMAGES OF ANY KIND, SHALL NOT BE AVAILABLE. SELLER'S MAXIMUM CUMULATIVE LIABILITY RELATIVE TO ALL OTHER CLAIMS AND LIABILITIES, INCLUDING OBLIGATIONS UNDER ANY INDEMNITY, WHETHER OR NOT INSURED, WILL NOT EXCEED THE COST OF THE PRODUCT(S) GIVING RISE TO THE CLAIM OR LIABILITY. SELLER DISCLAIMS ALL LIABILITY RELATIVE TO GRATUITOUS INFORMATION OR ASSISTANCE PROVIDED BY, BUT NOT REQUIRED OF SELLER HEREUNDER. ANY ACTION AGAINST SELLER MUST BE BROUGHT WITHIN EIGHTEEN (18) MONTHS AFTER THE CAUSE OF ACTION ACCRUES. THESE DISCLAIMERS AND LIMITATIONS OF LIABILITY WILL APPLY REGARDLESS OF ANY OTHER CONTRARY PROVISION HEREOF AND REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, AND FURTHER WILL EXTEND TO THE BENEFIT OF SELLER'S VENDORS, APPOINTED DISTRIBUTORS AND OTHER AUTHORIZED RESELLERS AS THIRD-PARTY BENEFICIARIES. EACH PROVISION HEREOF WHICH PROVIDES FOR A LIMITATION OF LIABILITY, DISCLAIMER OF WARRANTY OR CONDITION OR EXCLUSION OF DAMAGES IS SEVERABLE AND INDEPENDENT OF ANY OTHER PROVISION AND IS TO BE ENFORCED AS SUCH.

IN ANY CLAIM OR LAWSUIT FOR DAMAGES ARISING FROM ALLEGED BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, PRODUCT LIABILITY OR ANY OTHER LEGAL OR EQUITABLE THEORY, THE BUYER SPECIFICALLY AGREES THAT BMC SHALL NOT BE LIABLE FOR DAMAGES OR FOR LOSS OF PROFITS, WHETHER FROM BUYER OR BUYER'S CUSTOMERS. BMC'S LIABILITY SHALL BE LIMITED TO THE PURCHASE COST TO BUYER OF THE SPECIFIED GOODS SOLD BY BMC TO BUYER WHICH GIVE RISE TO THE CLAIM FOR LIABILITY.

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