Instructions for Use

VersaCross™ Transseptal Sheath

English...1

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VIII. 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.

IX. 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 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.
• Enlarge the 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) 498-9801 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 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.

XII. LABELING AND SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>Product</td>
<td>Manufacturer Rx ONLY</td>
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<tr>
<td>Rx ONLY</td>
<td>Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.</td>
</tr>
<tr>
<td>Single use - Do not reuse</td>
<td>Use by</td>
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<tr>
<td>Do not use if packaging is damaged</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>Do not re-sterilize</td>
<td>Model number</td>
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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, at 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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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 ACCRUED.

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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:

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<thead>
<tr>
<th>Category</th>
<th>Warranty Period</th>
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<tbody>
<tr>
<td>Disposable Products</td>
<td>The shelf life of the product</td>
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<tr>
<td>Accessory Products</td>
<td>90 days from the shipment date</td>
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