Baylis MEDICAL

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Instructions for Use

ExpanSure® Large Access Transseptal Dilator

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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.

The ExpanSure® Large Access Transseptal Dilator consists of two components: a dilator and a J-tipped guidewire.

The ExpanSure® Large Access Transseptal Dilator is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The dilator provides superior torque control and is flexible. The radiopaque and echogenic tip maximizes visualization of the dilator during manipulation.
The dilator has a tapered tip.
The device shaft in its entirety is coated with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for this coating.

INDICATIONS FOR USE

Canada: The ExpanSure® Large Access 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 ExpanSure® Large Access 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 ExpanSure® Large Access Transseptal Dilator's shaft is coated with a lubricious coating. The following warnings must be considered:
  - Use with sheaths smaller than the size(s) listed in the section below may result in a tight fit that affects device performance, including coating integrity.
  - Excessive wiping and/or wiping with a dry gauze may damage the coating.
  - Manual shaping of the distal curve shall be done with smooth motions along the curve without applying excessive pressure. Excessive manual bending and/or shaping of the shaft may affect the coating integrity.
- The ExpanSure® Large Access Transseptal Dilator and accompanying guidewire is intended for single patient use only. Do not attempt to sterilize and reuse the ExpanSure® Large Access Transseptal Dilator or the 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 ExpanSure® Large Access 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.
- Damage to the guidewire may result if withdrawn through a metal needle cannula.
- Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator and guidewire advancement should be done under imaging guidance such as fluoroscopy or echocardiography.

PRECAUTIONS

- Careful manipulation must be performed to avoid cardiac damage, or tamponade. Dilator and guidewire advancement should be done under imaging guidance such as fluoroscopy or echocardiography. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.
- The sterile packaging, dilator, and guidewire should be visually inspected prior to use. Do not use the device if it has been compromised or damaged.
- Do not attempt to use the ExpanSure® Large Access Transseptal Dilator or the accompanying guidewire before thoroughly reading the accompanying Instructions for Use.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- Note product "Use By" date.
- The "ExpanSure® Large Access Transseptal Dilator" is compatible with the "NRG® Transseptal Needle".
- The "ExpanSure® Large Access Transseptal Dilator" is compatible with 12.5F introducer sheaths.
- The "ExpanSure® Large Access Transseptal Dilator" is compatible with .032" and .035" transseptal devices.
- The "ExpanSure® Large Access Transseptal Dilator" is compatible with .032" and .035" guidewires.

ADVERSE EVENTS

Adverse events that may occur while using the ExpanSure® Large Access Dilator 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 ExpanSure® Large Access Transseptal Dilator, the dilator and guidewire 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.

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.

SUGGESTED DIRECTIONS FOR USE

- Carefully read all instructions prior to use. Failure to do so may result in complications.
- Thoroughly flush the 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 the 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 access 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.
- Thread the dilator over the guidewire using a slight twisting motion into the superior vena cava (SVC) under imaging guidance such as fluoroscopy or echocardiography. 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 dilator 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 perforating device or dilator.
- After removal of the dilator, use standard technique to achieve hemostasis.

CLEANING AND STERILIZATION INSTRUCTIONS

Do not clean or re-sterilize the ExpanSure® Large Access Transseptal Dilator or the accompanying guidewire. The ExpanSure® Large Access Transseptal Dilator and 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.

ABELING 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*		*Do not reuse*
	Use-by date	LOT	*Batch Code*
	Non-Pyrogenic		*Do Not Re-Sterilize*
	Caution		*Do Not Use if Packaging is Damaged*
	Consult Instructions for Use		*Keep Away from Sunlight*
REF	*Model number*		
Max Guidewire O.D.	Maximum guidewire outside diameter that can be used with this device		

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