## Instructions for Use

### EPstar Fixed Electrophysiology Catheter with Lumen

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Baylis Medical Company Inc.  
5959 Trans-Canada Highway  
Montreal, Quebec, Canada, H4T 1A1  
Tel: (514) 488-9801 / (800) 650-8801  
Fax: (514) 488-7209  
www.baylismedical.com

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### WARNINGS

- Use in cardiac electrophysiological examinations.
- The EPstar Fixed Electrophysiology Catheter with Lumen is recommended only for use in cardiac electrophysiological examinations.
- Adequate filtering must be used to allow continuous monitoring of the electrocardiogram (ECG) signals during the procedure.
- Excessive bending or kinking of the catheter shaft may damage the integrity of the catheter and may cause patient injury including the detachment or fall of the catheter tip. Care must be taken when handling the catheter.
- Do not wipe the product with organic solvents such as alcohol as this may damage the catheter and electrical apparatus to be used on the patient in addition to the EPstar Fixed Electrophysiology Catheter with Lumen.
- Adequate catheter manipulation must be performed to avoid cardiac damage, or tamponade. Catheter advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the catheter.
- Do not bend the EPstar Fixed Electrophysiology Catheter with Lumen excessively.
- Do not use the EPstar Fixed Electrophysiology Catheter with Lumen after the “Use By” date indicated on the label.
- Do not use the EPstar Fixed Electrophysiology Catheter with Lumen if there is any damage.
- Do not use the EPstar Fixed Electrophysiology Catheter with Lumen in combination with a heart stimulator or external cardioverter defibrillator (ICD), pay attention to respective lead electrodes.
- When the product is inserted in a patient with pacemaker implant or implantable cardioverter defibrillator (ICD), pay attention to respective lead electrodes.
- Pay full attention to potential for suppression of pacing or malfunction of an ICD due to stimulation by electrophysiology studies of the heart; deal with the matter by changing the settings.
- It has been reported that polycarbonate, which is the raw material of the center port, may be damaged by contact with fat emulsion and drugs containing fat emulsion, oil ingredients such as castor oil, or drugs containing solubilizing agent such as surfactant or alcohol when these drugs are administered as well as by contact with disinfectant containing alcohol.
- Do NOT allow the metal parts of the connector, including the connecting pins and the junction of the connector parts, to contact any fluid including blood.
- In the case that this product is used in combination with a heart stimulator or external pacemaker, pay careful attention to the location so that the electrodes of this product do not contact other leads.
- Store under stable conditions, avoiding vibration and shock (including during transportation).
- Avoid storing in locations where chemical agents are stored or locations where any gas may be.
- Avoid exposure to direct sunlight.
- Do not bend or twist the catheter excessively.
- Do NOT handle device through the cable, as the device may act as a suspending mass.
- Use only for cardiac electrophysiological examinations.
- The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised.
- Do not use the EPstar Fixed Electrophysiology Catheter with Lumen if there is any damage.

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### CONTRAINDICATIONS

- Patients with excessive prolongation of coagulation time contraindicated for antiplatelet therapy and anticoagulation therapy [the antiplatelet therapy and anticoagulation therapy may be required when the product is used].
- Patients with a serious allergy to drugs necessary for the procedure such as a contrast medium.
- Patients with severe circulation instability or shock.
- Patients with severe allergy to lead electrodes.
- Patients with severe allergy to drugs necessary for the procedure.
- Patients with excessive prolongation of coagulation time contraindicated for anticoagulation therapy.
- Patients with excessive tightness of the vessel.
- Patients with excessive tortuosity of the vessel.
- Patients with excessive wall thickness of the vessel.
- Patients with excessive tightness of the vessel.

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### PRECAUTIONS

- Do not attempt to use the EPstar Fixed Electrophysiology Catheter with Lumen or ancillary equipment before thoroughly reading the accompanying Instructions for Use.
- Do not use the EPstar Fixed Electrophysiology Catheter with Lumen if there is any damage.
- Do not use the EPstar Fixed Electrophysiology Catheter with Lumen in combination with a heart stimulator or external cardioverter defibrillator (ICD), pay attention to respective lead electrodes.
- When the product is inserted in a patient with pacemaker implant or implantable cardioverter defibrillator (ICD), pay attention to respective lead electrodes.
- Pay full attention to potential for suppression of pacing or malfunction of an ICD due to stimulation by electrophysiology studies of the heart; deal with the matter by changing the settings.
- It has been reported that polycarbonate, which is the raw material of the center port, may be damaged by contact with fat emulsion and drugs containing fat emulsion, oil ingredients such as castor oil, or drugs containing solubilizing agent such as surfactant or alcohol when these drugs are administered as well as by contact with disinfectant containing alcohol.
- Do NOT allow the metal parts of the connector, including the connecting pins and the junction of the connector parts, to contact any fluid including blood.
- In the case that this product is used in combination with a heart stimulator or external pacemaker, pay careful attention to the location so that the electrodes of this product do not contact other leads.
- Store under stable conditions, avoiding vibration and shock (including during transportation).
- Avoid storing in locations where chemical agents are stored or locations where any gas may be.
- Avoid exposure to direct sunlight.
- Do not bend or twist the catheter excessively.
- Do NOT handle device through the cable, as the device may act as a suspending mass.
- Use only with legally marketed diagnostic EP equipment.
- Baylis Medical Company Inc. relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of an electrophysiology procedure.

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### ADVERSE EVENTS

Adverse events that may occur while using the EPstar Fixed Electrophysiology Catheter with Lumen includes:

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Air embolism  Difficulty in catheter retraction
Death  Ventricular fibrillation/tachycardia
Septic infections  Vascular tear, perforation or dissection
Cardiac tamponade  Arrhythmia with hemodynamic collapse
Pseudoneuromy  Bradycardia such as atrioventricular block
Hemorrhagic complication  Skin disorder by defibrillation
Thromboembolism  Myocardial infarction/ angina attack
Pneumothorax  Puncture-site complication
Excessive bleeding  Bradycardia including atrioventricular block
Malfunction of implantable pacemaker/ ICD  Distal embolization (air, tissue, thrombus) in the lung
Hypertension/hypotension  Subcutaneous hematoma formation
Laceration, perforation and dissociation of blood vessel  Cerebral infarction/cerebrovascular disorder
Ecchymoma formation  Cardiac valve damage such as valve insufficiency or valvular incompetence
Difficulty in retracting other concurrently-used medical device from product

EQUIPMENT REQUIRED
Electrophysiological diagnostic procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

INSPECTION PRIOR TO USE
Prior to use of the EPstar Fixed Electrophysiology Catheter with Lumen all the packages and the contents should be checked to confirm that there is neither damage in the contents nor breakage in the sterilized package. DO NOT use the product if the package is compromised and return to the manufacturer/distributor. The EPstar Fixed Electrophysiology Catheter with Lumen is sterilized and can be used promptly as it is. The EPstar Fixed Electrophysiology Catheter with Lumen is intended for a single use; use only once and DO NOT re-use. DO NOT resterilize or reuse.

DIRECTIONS FOR USE
• All instructions and equipment required should be carefully read, understood, and followed. Failure to do so may result in complications.
• The EPstar Fixed Electrophysiology Catheter with Lumen is supplied sterile. Use aseptic technique when opening the package and handling the catheter in the sterile field.
• Before insertion of the catheter, connect the electrocardiography system to the patient to monitor arrhythmia.
• Place the catheter in a sterile area, confirm that there is no breakage, and wipe the shaft with gauze soaked with heparinized saline.
• Insert the introducer sheath (not included in this product) percutaneously into the internal/external jugular vein, subclavian vein, or other vein or artery by the Seldinger technique.
• Insert the catheter into the introducer sheath under fluoroscopic guidance.
  • Caution: The EPstar Fixed Electrophysiology Catheter with Lumen can be used with any sheath larger than 6Fr.
  • Caution: Perform operations in a blood vessel with care under fluoroscopic guidance and, if resistance is encountered, do not force to advance or retract the catheter. If the procedure becomes difficult, pull out the system [the vessel or cardiac cavity may be injured and an event requiring open-heart surgery may occur].
  • Caution: If unintended bend is observed in the tip, pull out the catheter and check for any damage.
  • Caution: Replace the catheter immediately if the catheter is kinked during the procedure and/or during catheter manipulation.
  • Caution: If the EPstar Fixed Electrophysiology Catheter with Lumen is inserted through a guiding catheter, etc., do not advance the guiding catheter when the EPstar Fixed Electrophysiology Catheter with Lumen’s tip is protruding from the product.
• The following method may be used for the EPstar Fixed Electrophysiology Catheter with Lumen:
  • Inject the contrast medium into the lumen, and take an X-ray image. Advance the electrode catheter based on the X-ray image.
  • Insert the 0.035 inch guidewire (not included in this product) into the lumen and, after advancing the guidewire to the target region, advance the electrode catheter along the guidewire.
  • After advancing the EPstar Fixed Electrophysiology Catheter with Lumen, a compatible catheter (e.g. BMC EPstar Fixed Electrophysiology Catheter) can be inserted into the lumen and advanced to the target region.
  • Before using the EPstar Fixed Electrophysiology Catheter with Lumen, flush the lumen with heparinized saline from the center port. DO NOT use a high-pressure injection device for flushing.
  • Caution: If catheter is caught in a blood vessel, practice periodic aspiration and flushing or continuous injection of heparinized saline from the center port to maintain the opening of the lumen of the EPstar Fixed Electrophysiology Catheter with Lumen.
  • Connect the catheter to the EPstar Electrophysiology Cable (DEX-10) and connect the cable to electrophysiology recording system to perform the electrophysiology studies by general procedures.
  • Caution: Connect the catheter connector and cable connector appropriately by lining up the arrows of the connectors [inappropriate connection may damage the product].
  • After completion of the procedure, retract the catheter under fluoroscopic guidance.

CLEANING AND STERILIZATION INSTRUCTIONS
The EPstar Fixed Electrophysiology Catheter with Lumen is intended for single use only. Do not clean or re-sterilize the EPstar Fixed Electrophysiology Catheter with Lumen.

TROUBLESHOOTING
The following table is provided to assist the user in diagnosing potential problems.

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<th>PROBLEM</th>
<th>COMMENTS</th>
<th>TROUBLESHOOTING</th>
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<tbody>
<tr>
<td>Catheter breaks or kinks.</td>
<td>Breaks and kinks in the catheter are a potential cause of patient injury.</td>
<td>Discard immediately</td>
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</tbody>
</table>

CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION
If you have any problems with or questions about Baylis Medical Equipment, contact our technical support personnel.

NOTES:
1. In order to return products, you must have a return authorization number before shipping the products back to Baylis Medical Company Inc.
2. Baylis Medical will not accept any piece of used equipment without a sterilization certificate. Ensure that any product being returned to Baylis Medical has been cleaned, decontaminated and sterilized as indicated in the user instructions before returning it for warranted service.

LABELING AND SYMBOLS

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, 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 DAMAGE, OF ANY KIND, SHALL NOT BE AVAILABLE. SELLER’S MAXIMUM CUMULATIVE 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 CONSEQUENT DAMAGES OR DAMAGES FOR BUSINESS INTERRUPTION 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

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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:

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<th>Product Type</th>
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<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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