

Instructions for Use

EPstar™ Fixed Electrophysiology Catheter with Lumen

ENGLISH 1



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Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

I. DEVICE DESCRIPTION

The EPstar™ Fixed Electrophysiology Catheter with Lumen is placed in the heart percutaneously for the purpose of cardiac electrophysiological studies of the heart, such as the coronary sinus and the atrioventricular valve annulus. The EPstar™ Fixed Electrophysiology Catheter with Lumen is connected via the Baylis Medical Company Inc. (BMC) EPstar™ Electrophysiology Cable (DEX-10) to diagnostic electrophysiology equipment (diagnostic EP equipment), such as an electrocardiography system and/or cardiac stimulator. The dimensions for the EPstar™ Fixed Electrophysiology Catheter with Lumen can be found on the device label.

II. INDICATIONS FOR USE

The EPstar™ Fixed Electrophysiology Catheter with Lumen can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

III. CONTRAINDICATIONS

The EPstar™ Fixed Electrophysiology Catheter with Lumen is recommended only for use in cardiac electrophysiological examinations.

IV. WARNINGS

- DO NOT use if the physician has not undergone adequate training for cardiac electrophysiological examination techniques.
- Do not alter this device in any way.
- The EPstar™ Fixed Electrophysiology Catheter with Lumen is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged.
- The EPstar™ Fixed Electrophysiology Catheter with Lumen is intended for single patient use only. Do not attempt to sterilize and reuse the catheter. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications.
- The EPstar™ Fixed Electrophysiology Catheter with Lumen must be used with the EPstar™ Electrophysiology Cable (DEX-10). Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.
- Avoid excessive force as it can cause breaks or leakage at the tip of the catheter.
- Laboratory staff and patients can undergo significant x-ray exposure 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.

- Be sure to read the package insert of the medical device that will be used concurrently.
- DO NOT force to push or pull this product in vessels if you feel resistance during insertion of this product [because there is a risk of damaging the blood vessel or heart chamber, and a situation requiring thoracotomy may occur].
- DO NOT reuse
- DO NOT resterilize
- DO NOT use the product in the coronary arteries [it may induce myocardial infarction, arterial perforation, or cardiac tamponade, which may result in death]
- DO NOT use the product in the following patients:
 - Patients with excessive peripheral vascular diseases that prevent insertion of a sheath in an appropriate size [the vessel may be pierced]
 - 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
 - Pregnant or possibly pregnant patients
 - Patients with bacteremia or sepsis
 - Patients with hypercoagulation or hypocoagulation causing coagulation disorder
 - Patients not eligible for thoracotomy procedures
 - Patients with tricuspid replacement if the product needs to pass a cardiac valve
 - Patients with severe circulation instability or shock
 - Patients with intracardiac mural thrombus, myocardial and unstable angina

V. PRECAUTIONS

- Do not attempt to use the EPstar™ Fixed Electrophysiology Catheter with Lumen or ancillary equipment before thoroughly reading the accompanying Instructions for Use.
- 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.
- Visually inspect the EPstar™ Fixed Electrophysiology Catheter with Lumen prior to 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 after the "Use By" date indicated on the label.
- Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the EPstar™ Fixed Electrophysiology Catheter with Lumen.
- Adequate filtering must be used to allow continuous monitoring of the electrocardiogram (ECG) signals during the procedure.
- Careful 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. 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.
- Connect with other concurrently-used medical devices properly and perform maintenance and inspection appropriately to prevent microshocks.
- Do not wipe the product with organic solvents such as alcohol as this may damage the product.
- 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 a 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 high humidity, direct sunlight, and water.
- Store at temperatures between 10 °C to 32 °C and less than 90% humidity.
- 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.

VI. ADVERSE EVENTS

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

Air embolism	Difficulty in catheter retraction
Death	Ventricular fibrillation/tachycardia
Sepsis, infections	Vascular tear, perforation or dissection
Cardiac tamponade	Arrhythmia with hemodynamic collapse
Pseudoaneurysm	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 lumen
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	

VII. 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.

VIII. 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 reuse. DO NOT resterilize or reuse.

IX. DIRECTIONS FOR USE

- All instructions for 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.
 - Caution: 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.

X. 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.

XI. TROUBLESHOOTING

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

PROBLEM	COMMENTS	TROUBLESHOOTING
Catheter breaks or kinks.	Breaks and kinks in the catheter are a potential cause of patient injury.	Discard immediately















XII. CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION

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

NOTES:

- In order to return products, you must have a return authorization number before shipping the products back to Baylis Medical Company Inc.
- 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.

XIII. LABELING AND SYMBOLS

	Manufacturer		Do not re-use
Rx ONLY	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.		Do not resterilize
	Non-pyrogenic		Keep away from sunlight
	Keep dry		Do not use if package is damaged
	Refer to instruction manual/booklet		Sterilized using ethylene oxide
	Catalogue number		Caution
	Use-by date		Protect from heat and radioactive sources
	Batch Code		

XIV. 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.

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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