

Instructions for Use

EPstar Fixed Electrophysiology Catheter

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.

DEVICE DESCRIPTION

The EPstar Fixed Electrophysiology Catheter is placed in the heart percutaneously for the purpose of temporary cardiac pacing and electrophysiological studies of the heart, such as the coronary sinus and the atrioventricular valve annulus. The EPstar Fixed Electrophysiology Catheter 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 can be found on the device label.

INDICATIONS FOR USE

The EPstar Fixed Electrophysiology Catheter is intended for electrogram recording and pacing during diagnostic electrophysiology studies.

CONTRAINDICATIONS

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

WARNINGS

- DO NOT use if the physician has not undergone adequate training for cardiac electrophysiological examination techniques and temporary pacing techniques.
- Do not alter this device in any way.
- The EPstar Fixed Electrophysiology Catheter is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged.
- The EPstar Fixed Electrophysiology Catheter 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 transmission of infectious disease(s) from one patient to another. Reuse may result in patient complications.
- The EPstar Fixed Electrophysiology Catheter must be used with the BMC 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 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 use 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.

PRECAUTIONS

- Do not attempt to use the EPstar Fixed Electrophysiology Catheter or ancillary equipment before thoroughly reading the accompanying Instructions for Use.
- Use only for cardiac electrophysiological examinations and temporary pacing purposes.
- 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 prior to use. Do not use the EPstar Fixed Electrophysiology Catheter if there is any damage.
- Do not use the EPstar Fixed Electrophysiology Catheter 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.
- 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 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 the 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.
- 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.

ADVERSE EVENTS

Adverse events that may occur while using the EPstar Fixed Electrophysiology Catheter include:

Air embolism	Difficulty in catheter retraction
Death	Cardiac tamponade
Sepsis, infections	Vascular tear, perforation or dissection
Arrhythmia with hemodynamic collapse	Ventricular fibrillation/tachycardia
Myocardial infarction/angina attack	Cerebral infarction/cerebrovascular disorder

Thromboembolism	Hemorrhagic complication
Pneumothorax	Pseudoaneurysm
Pacing failure	Puncture-site complication
Skin disorder by defibrillation	Distal embolization (air, tissue, thrombus) in the lung
Malfunction of implantable pacemaker/ICD	Cardiac valve damage such as valve insufficiency or valvular incompetence
Hypertension/hypotension	Subcutaneous hematoma formation
Ecchymoma formation	Bradycardia including atrioventricular block
Laceration, perforation and dissociation of blood vessel	Difficulty in retracting other concurrently-used medical device from product
Excessive bleeding	

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, 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 is sterilized and can be used promptly as it is. The EPstar Fixed Electrophysiology Catheter is intended for a single use; use only once and DO NOT reuse. DO NOT resterilize or reuse.

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 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 femoral vein or other vein or artery by the Seldinger technique.
- Insert the catheter into the introducer sheath under fluoroscopic guidance.
 - Caution: If an inserter for prevention of damage to the catheter tip is attached, straighten the catheter tip using the inserter before inserting the catheter into the introducer sheath. After insertion, return the inserter to the catheter handle side.
 - 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: Exercise caution when cannulating smaller vessels. Anatomic variability may limit the device's ability to access vessel branches.
- Caution: Replace the catheter immediately if the catheter is kinked during the procedure and/or during catheter manipulation.
- Caution: Catheter is capable of being inserted into the BMC EPstar Fixed Electrophysiology Catheter with Lumen. Recommended guiding catheters for IVC approach: AL1, AL1.5, AL2 (Y connectors are necessary when using guiding catheters) or equivalent.
- Connect the catheter to the EPstar Electrophysiology Cable (DEX-10) and connect the cable to the electrophysiology recording system to perform the electrophysiology studies or temporary cardiac pacing 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 is intended for single use only. Do not clean or re-sterilize the EPstar Fixed Electrophysiology Catheter.

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

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

	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
	Refer to instruction manual/booklet		Do not use if package is damaged
REF	Catalogue number	STERILEEO	Sterilized using ethylene oxide
	Use-by date		Caution
LOT	Batch Code		

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