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 ventricular fibrillation/tachycardia
  - Patients with atrial flutter/atrial fibrillation
  - Patients with ventricular fibrillation/tachycardia
  - Patients with severe heart failure or cardiogenic 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. Air embolism
- 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:

<table>
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<tr>
<td>Air embolism</td>
<td>Difficulty in catheter retraction</td>
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<tr>
<td>Death</td>
<td>Cardiac tamponade</td>
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<td>Sepsis, infections</td>
<td>Vascular tear, perforation or dissection</td>
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<td>Arrhythmia with hemodynamic collapse</td>
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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.
TROUBLESHOOTING

recorder, emergency equipment and instrumentation for gaining vascular access. Electrophysiological diagnostic procedures should be performed in a specialized

INSPECTION PRIOR TO USE

• Baylis Medical will not accept any piece of used equipment without a

1. In order to return products you must have a return authorization number before

DIRECTIONS FOR USE

2. Baylis Medical will not reuse. DO NOT resterilize or reuse.

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

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.

1. Baylis Medical will not accept any piece of used equipment without a

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.

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 ADDITICAUTOGRAPHIC NEGLIGENCE, PRODUCT 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:

| Disposable Products | The shelf life of the product |
| Accessory Products | 90 days from the shipment date |

REFERENCES

• Baylis Medical will not reuse. DO NOT resterilize or reuse.

• Baylis Medical will not accept any piece of used equipment without a

PRODUCTS

| Manufacturer | Do not re-use |
| Non-pyrogenic | Keep away from sunlight |
| Reuse | Do not repurpose |
| Catalogue number | Sterilized by ethylene oxide |
| Use-by date | Caution |

CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION

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

NOTES:

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