

Instructions for Use

EPstar™ Electrophysiology Cable



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- The EPstar™ Electrophysiology Cable must only be used with a BMC EPstar™ Fixed Electrophysiology Catheter (DCF) or EPstar™ Fixed Electrophysiology Catheter with Lumen (DLF). Attempts to use it with other diagnostic catheters and devices can result in complications.
- Laboratory staff and patients can undergo significant X-ray exposure during diagnostic catheterization 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.
- Avoid exposing the connectors of the EPstar™ Electrophysiology Cable to any fluids during a procedure. Exposure to fluids may result in shorting of electrical signals.
- Diagnostic electrophysiology equipment is susceptible to electromagnetic interference. Do not operate near equipment that generate strong electromagnetic fields.
- Do not alter this device in any way.

V. PRECAUTIONS

- Do not attempt to use the EPstar™ Electrophysiology Cable or ancillary equipment before thoroughly reading the accompanying Instructions for Use.
- Use only for cardiac electrophysiological examinations.
- Catheterization procedures should be performed only by trained physicians in a fully equipped catheterization laboratory.
- 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 cable to ensure there is no damage to the insulating material. Do not use the cable if there is any damage.
- Never disconnect the EPstar™ Electrophysiology Cable from the catheter by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable.
- Do not twist the EPstar™ Electrophysiology Cable while inserting it to or disconnecting it from the catheter connector. Twisting the cable may result in damage to the pin connectors.
- Do not bend the cable excessively. Excessive bending or kinking of the cable may damage the integrity of the cable and may lead to patient injury. Care must be taken when handling the cable.
- Adequate filtering must be used to allow continuous monitoring of the electrocardiogram (ECG) signals during the procedure.
- Store under stable conditions, avoiding vibration and shock (including during transportation).
- Avoid exposure to direct sunlight and water
- Store at temperatures between 10 °C to 32 °C and less than 90% humidity.
- 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 associated with the use of this device are similar to those indicated for the DCF and DLF.

VII. PRODUCT SPECIFICATIONS

| | |
|---------------------------------|-------------------------------------|
| Model Number | DEX-10 |
| Overall Useable Length | 7.5 feet (2.3m) |
| Catheter Connector | 10-pin (Plug) |
| Diagnostic Equipment Connectors | Single-pin (Plug, DIN 42802-2) x 10 |

VIII. INSPECTION PRIOR TO USE

Perform the following checks before the patient is presented for the procedure. These tests will allow you to verify that the equipment you will use is in proper working order. Do these tests in a sterile environment. Do not use defective equipment.

| KEY ITEMS | QUESTION? | WARNINGS AND EXPLANATIONS |
|---------------------|---|---|
| Sterility | <i>Is the connector cable sterile?</i> | The EPstar™ Electrophysiology Cable is supplied sterile for its initial use. Inspect the packaging to ensure the package has not been damaged and sterility has not been compromised. Prior to each subsequent use it must be cleaned and sterilized. |
| Visual Check | <i>Have you done a visual check on the entire system?</i> | Ensure connectors and the cable have no visible damage, such as discoloration, cracks, label fading, cable splice, or kinks. Do not use damaged equipment. |

IX. EQUIPMENT REQUIRED

Diagnostic electrophysiology 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.

X. DIRECTIONS FOR USE

All instructions for equipment required should be carefully read, understood, and followed. Failure to do so may result in complications.

Ensure that the EPstar™ catheter is properly positioned in the patient and the diagnostic EP equipment is set up before connecting the Diagnostic Electrophysiology Cable.

1. Connect the 10-pin catheter connector of the cable to the connector of the EPstar™ catheter. The catheter connector is circular and keyed for proper alignment. Line up the arrow markings on the connector with the catheter receptacle and gently push in until the connector are mated. Any attempt to connect the cable otherwise will damage the pins on the connector. Use of excessive force may result in damage to the connector pins.

English

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 (U.S.A.) law restricts this device to sale by or on the order of a physician.

I. DEVICE DESCRIPTION

The EPstar™ Electrophysiology Cable connects the Baylis Medical Company Inc. (BMC) EPstar™ Fixed Electrophysiology Catheter (DCF) or EPstar™ Fixed Electrophysiology Catheter with Lumen (DLF) to diagnostic electrophysiology equipment (diagnostic EP equipment), such as an electrocardiography system and/or cardiac stimulator. This cable conducts intracardiac potentials between the DCF / DLF and a catheter input module of the diagnostic EP equipment.

Detailed information concerning the DCF or DLF is contained in a separate manual that accompanies the DCF or DLF Instructions for Use.

The dimensions for the EPstar™ Electrophysiology Cable can be found on the device label and in section VII "PRODUCT SPECIFICATIONS". The EPstar™ Electrophysiology Cable has a single 10-pin connector on one end that mates with the DCF or DLF, and ten single-pin connectors on the other end that mate with the catheter input module of diagnostic EP equipment.

II. INDICATIONS FOR USE

The EPstar™ Electrophysiology Cable used with the EPstar™ Fixed Electrophysiology Catheter is intended for electrogram recording and pacing during diagnostic electrophysiology studies.

The EPstar™ Electrophysiology Cable used with 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™ Electrophysiology Cable is not recommended for use with any other electrophysiology catheter.

IV. WARNINGS

- The EPstar™ Electrophysiology Cable is a reusable device. Only use the validated cleaning and sterilization methods as described in section XI "CLEANING AND STERILIZATION INSTRUCTIONS" to clean and sterilize the Cable. No other cleaning and sterilization methods have been tested. Failure to properly clean and sterilize the device can cause patient injury and/or the transmission of infectious disease(s) from one patient to another.
- The EPstar™ Electrophysiology Cable can be re-sterilized up to 5 times. Do not use if the cable has been re-sterilized more than 5 times.

- Connect the single-pin connectors at the diagnostic EP equipment end of the cable to the catheter input module of the diagnostic EP equipment. Observe the marking on each single-pin connector as they correspond to the electrode position of the catheter ("D" is associated with the most Distal electrode, where the numbers 2 to 10 indicate the relative position of the electrode from the tip of the catheter).
Note: The DCF only has 8 electrodes, hence the single-pin connectors "9" and "10" are not used.
- To disconnect the cable from the catheter: while securely holding the catheter, grasp the catheter connector of the cable and gently pull straight out of the receptacle. The connector housing will slide back and disengage the locking mechanism.
- To disconnect the cable from the catheter input module: firmly grasp one of the diagnostic EP equipment connectors and pull it straight out of the socket. Repeat for remaining connectors.

XI. CLEANING AND STERILIZATION INSTRUCTIONS

DANGER

The EPstar™ Electrophysiology Cable is supplied sterile, however it must be cleaned and re-sterilized before each subsequent use as described in this Instructions for Use document. Failure to properly clean and re-sterilize the device can cause patient injury and/or the transmission of infectious diseases from one patient to another.

IMPORTANT

The manufacturer recommends the user follow a quality control program for each sterilization cycle that ensures proper recording of:

- Type of sterilizer and cycle used
- Lot control number
- Load contents
- Exposure time and temperature, if not provided by a recording chart
- Operator's name
- Results of sterilization process monitoring (i.e. chemical, mechanical, biological)

The EPstar™ Electrophysiology Cable is rated for up to 5 re-sterilization cycles.

Cleaning and Decontamination

- Ensure that blood and other contaminants do not dry on the cable.
- Visually inspect the cable for defect. Do not use cable if damaged.
- Rinse the cable with de-ionized water until colourless run-off water occurs.
- Once the water runs clear, soak the cable (except for the connectors at the ends of the cable) in de-ionized water at 22°C-48°C for 1 minute.
Note: Do not let the connectors soak.
- Remove the cable from the water and scrub it with a soft bristle brush until it is visually clean. Wipe the connectors with lint-free cloths soaked with de-ionized water as necessary until they are visually clean.
- Using tap water, prepare an enzymatic cleaning solution (such as Terg-A-Zyme®) according to the manufacturer's instructions, dilution recommendations, and temperatures (manufacturer's recommendation for Terg-A-Zyme is 10 g/L in warm water <55°C).
- Soak the cable (except for the connectors) in the enzymatic cleaning solution for 20 minutes. Ensure all surfaces are in contact with the cleaning solution.
- Scrub the cable with a soft bristle brush.
- Remove the cable from the enzymatic cleaning solution and rinse with de-ionized water until all traces of detergent residue are removed.
- Visually inspect the parts for debris. If any is present repeat the cleaning process. Do not proceed with reprocessing of a soiled instrument.
- Dry the cable with clean, dry, lint free towels. Instruments should be completely dry before packaging for sterilization.

Sterilization

- Place cables into surgical sterilization pouches.
- Inspect the pouch to ensure no rips, punctures, or seal failures are present prior to loading into the sterilizer.
- Load the pouches into the sterilizer by following the manufacturer's recommended loading procedures and load configurations.
- Follow the sterilizer manufacturer's recommended procedures to program the sterilizer with the following sterilization cycle parameters:

| Cycle | Temperature | Exposure Time | Minimum Dry Time |
|------------|---------------|---------------|------------------|
| Pre-vacuum | 270°F (132°C) | 4 minutes | 30 minutes |

- Minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.
- Chamber size and chamber load differences may exist between industrial and health care facility sterilizer models. The sterilization parameters specified above can be achieved in both health care facility and larger, industrial sterilizer models. Because of the many variables involved in sterilization, each health care facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.
- Steam for sterilization should be generated from water treated to remove total dissolved solids and non-condensable gases, filtered to remove contaminants and water droplets, and supplied via piping without dead legs or other stagnant zones where contamination may collect.

NOTE:

Only the above cleaning and sterilization methods have been validated for the EPstar™ Electrophysiology Cable. No other cleaning and sterilization methods have been tested. Failure to follow these instructions can cause patient injury and/or the transmission of infectious disease(s) from one patient to another.

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 per user instructions before returning it for warranted service.

XIII. TROUBLESHOOTING

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

| PROBLEM | COMMENTS | TROUBLESHOOTING |
|--|---|--|
| Electrocardiography signals are not being displayed | The diagnostic EP equipment must be set up to match configuration in which the cable connectors are plugged into the catheter input module. | Check that the cable connectors are plugged into the catheter input module sockets that correspond to the settings of the diagnostic EP equipment. |
| Connector Cable does not fit into the connector of the EPstar™ catheter. | The connectors are designed to connect in a specific way for safety reasons. If the connector "keys" are not aligned, the connectors won't fit together | Check that the connector keys are lined up in the proper orientation. Ensure that the connectors are clean and unobstructed. |

XIV. LABELING AND SYMBOLS

| | | | |
|---|-------------------------------------|---|--|
|  | Manufacturer |  | Use By |
|  | Refer to instruction manual/booklet |  | Caution |
|  | Model number |  | Lot Number |
|  | Sterilized using ethylene oxide |  | Keep Away From Sunlight |
|  | Do Not Use if Packaging is Damaged |  | Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. |
|  | Keep dry | | |

XV. 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 re-sterilized, 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

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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 |