The Electrophysiology Cable (DEX-10) can be re-sterilized up to 5 times. Do not use if the cable has been re-sterilized more than 5 times.

The Electrophysiology Cable (DEX-10) 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 Electrophysiology Cable (DEX-10) 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 Electrophysiology Cable (DEX-10) 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 Electrophysiology Cable (DEX-10) 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 Electrophysiology Cable (DEX-10) 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.

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

There are no adverse events associated with the use of this device. Adverse events associated with the use of this device as part of a larger system are indicated for the EPstar Fixed Electrophysiology Catheter (DCF) and EPstar Fixed Electrophysiology Catheter with Lumen (DLF).

VII. PRODUCT SPECIFICATIONS

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Overall Useable Length</th>
<th>Catheter Connector</th>
<th>Diagnostic Equipment Connectors</th>
<th>Compatible Catheter Modes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEX-10</td>
<td>7.5 feet (2.3m)</td>
<td>10-pin (Plug)</td>
<td>Single-pin (Plug, DIN 42802-2) x 10</td>
<td>DCF-2-8-55-130</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DLF-6-10-28-65</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DLF-6-10-55-65</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>KEY ITEMS</th>
<th>QUESTION?</th>
<th>Warnings and Explanations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterility</td>
<td>Is the connector cable sterile?</td>
<td>The Electrophysiology Cable (DEX-10) is supplied sterile for its initial use. Inspect the packaging to ensure the package has not been damaged and sterile has not been compromised. Prior to each subsequent use it must be cleaned and sterilized. Do not use if cable is not sterile.</td>
</tr>
<tr>
<td>Visual Check</td>
<td>Have you done a visual check on the entire system?</td>
<td>Ensure connectors and the cable have no visible damage, such as discoloration, cracks, labeling, cable splice, or kinks. Do not use damaged equipment.</td>
</tr>
</tbody>
</table>

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.
XI. CLEANING AND STERILIZATION INSTRUCTIONS

DANGER

The Electrophysiology Cable (DEX-10) 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 Electrophysiology Cable (DEX-10) is rated for up to 5 re-sterilization cycles.

Cleaning and Decontamination

1. Ensure that blood and other contaminants do not dry on the cable.
2. Visually inspect the cable for defects. Do not use cable if damaged.
3. Rinse the cable with de-ionized water until colourless run-off water occurs.
4. 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.
5. 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.
6. 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).
7. 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.
8. Scrub the cable with a soft bristle brush.
9. Remove the cable from the enzymatic cleaning solution and rinse with de-ionized water until all traces of detergent residue are removed.
10. Visually inspect the parts for debris. If any is present repeat the cleaning process. Do not proceed with reprocessing of a soiled instrument.
11. Dry the cable with clean, dry, lint free towels. Instruments should be completely dry before packaging for sterilization.

Sterilization

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

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>270°F (132°C)</td>
<td>4 minutes</td>
<td>10 minutes</td>
</tr>
</tbody>
</table>

- Minimum dry times were validated by autoclaves 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 contaminates 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 Electrophysiology Cable (DEX-10). 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:

16. In order to return products you must have a return authorization number before shipping the products back to Baylis Medical Company Inc.
17. Baylis Medical will accept any piece of unused 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.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Comments</th>
<th>Troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrophysiology signals are not being displayed</td>
<td>The diagnostic EP equipment must be set up to match configuration in which the cable connectors are plugged into the catheter input module.</td>
<td>Check that the cable connectors are plugged into the catheter input module sockets that correspond to the settings of the diagnostic EP equipment.</td>
</tr>
<tr>
<td>Connector Cable does not fit into the connector of the EPstar catheter.</td>
<td>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.</td>
<td>Check that the connector “keys” are lined up in the proper orientation. Ensure that the connectors are clean and unobstructed.</td>
</tr>
</tbody>
</table>

There are two models of Electrophysiology Cables with different pin connector configurations.

Ensure that the correct cable is chosen for the EPstar catheter (refer to Product Specification table).

XIV. LABELING AND SYMBOLS

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Use By</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer to instruction manual/booklet</td>
<td>Caution</td>
</tr>
<tr>
<td>Model number</td>
<td>Lot Number</td>
</tr>
<tr>
<td>Sterilized using ethylene oxide</td>
<td>Keep Away From Sunlight</td>
</tr>
<tr>
<td>Do Not Use if Packaging is Damaged</td>
<td>Rx ONLY</td>
</tr>
</tbody>
</table>

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

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 resold, altered, 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 REMEDIES 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, DATA, CONTRACT, GOODWILL OR THE LIKE (WHETHER DIRECT OR INDIRECT IN NATURE) OR FOR ANY OTHER FORM OF INCIDENTAL, INDIRECT DAMAGES OF ANY KIND, SHALL NOT BE AVAILABLE. SELLER’S SOLE LIABILITY RELATIVE TO ALL OTHER CLAIMS AND LIABILITIES, INCLUDING OBLIGATIONS UNDER ANY INDENDUNT, WHETHER OR NOT INSURED, WILL NOT EXCEED THE COST OF THE PRODUCT(S) GIVING RISE TO THE CLAIM OR LIABILITY RELATIVE TO GRATUITOUS INFORMATION OR ASSISTANCE PROVIDED BY, BUT NOT REQUIRED TO SELLE 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 HEREIN AND THE LIMITED WARRANTY ABOVE.
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 CONDITION OR EXCLUSION OF DAMAGES 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 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:

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Warranty Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposable Products</td>
<td>The shelf life of the product</td>
</tr>
<tr>
<td>Accessory Products</td>
<td>90 days from the shipment date</td>
</tr>
</tbody>
</table>