

Instructions for Use

Electrophysiology Cable (DEX-14)



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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 Electrophysiology Cable (DEX-14) connects the Baylis Medical Company Inc. EPstarFixed 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 DLF and a catheter input module of the diagnostic EP equipment.

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

The dimensions for the Electrophysiology Cable (DEX-14) can be found on the device label and in section **Error! Reference source not found. "Error! Reference source not found."**. The Electrophysiology Cable (DEX-14) has a single 14-pin connector on one end that mates with the DLF, and fourteen single-pin connectors on the other end that mate with the catheter input module of diagnostic EP equipment.

II. INDICATIONS FOR USE

The Electrophysiology Cable (DEX-14) 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 Electrophysiology Cable (DEX-14) is not recommended for use with any other electrophysiology catheter.

IV. WARNINGS

- The Electrophysiology Cable (DEX-14) is a single-use device. Do not attempt to re-use or re-sterilize the device. Re-sterilization of the cable may compromise the device performance.
- The Electrophysiology Cable (DEX-14) must only be used with a BMC 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-14) 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-14) 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-14) 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-14) 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 with Lumen (DLF).

VII. PRODUCT SPECIFICATIONS

Model Number	DEX-14
Overall Useable Length	7.5 feet (2.3m)
Catheter Connector	14-pin (Plug)
Diagnostic Equipment Connectors	Single-pin (Plug, DIN 42802-2) x 14
Compatible Catheter Models	DLF-6-10-55-95R

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	Is the connector cable sterile?	The Electrophysiology Cable (DEX-14) is supplied sterile for its initial use. Inspect the packaging to ensure the package has not been damaged and sterility has not been compromised. Do not use if cable is not sterile.
Visual Check	Have you done a visual check on the entire system?	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 Electrophysiology Cable (DEX-14).

- Connect the 14-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.
- 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 remaining numbers indicate the relative position of the electrode from the tip of the catheter).

Note: Some pins may be unused for certain catheter/cable combinations.

- 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

The Electrophysiology Cable (DEX-14) is a single-use device supplied sterile and should not be re-sterilized or reused. The Electrophysiology Cable (DEX-14) can be considered sterile only if the package is not opened or damaged prior to use.

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.
	There are two models of Electrophysiology Cables with different connector pin configurations.	Ensure that the correct cable is chosen for the EPstar catheter (refer to Product Specification table).

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.
	Do not re-use		Do not re-sterilize

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.

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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