Reprocessed by

stryker

Instructions for use

Reprocessed Single Use Ablation Catheter Connection Cables

Reprocessed device for single use

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

Explanation of symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician.
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Clause 5.2.3	2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1 Clause 5.1.4	2607	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.1.7	2498	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Clause 5.2.6	2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1 Clause 5.2.8	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Clause 5.3.2	0624	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	ISO 15223-1 Clause 5.3.4	0626	Keep dry	Indicates a medical device that needs to be protected from moisture.

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Ablation Catheter Cable Description

The reprocessed ablation catheter connection cable has multi-pin connectors that connect the appropriate generator to the appropriate catheter. The ablation connection cable supports catheter positioning and navigation in ablation-enabled applications.

Intended use/Indications for use

The reprocessed ablation catheter connection cable is intended to be used with a compatible ablation catheter during an electrophysiology procedure for cardiac tissue ablation.

Users should consult the Instructions for Use for the specific compatible ablation catheter prior to use to ensure proper integration and application.

The reprocessed ablation catheter connection cable is supplied sterile and for single use only.

Contraindications for use

It is important to review the Contraindications section of the associated compatible catheter Instructions for Use prior to use.

Warnings

- The use of this device requires a thorough understanding of the techniques and principles of angiography, electrophysiology and transvenous intracardiac electrophysiology studies and temporary pacing and cardiac ablation.
- Prior to use, refer to the applicable catheter and equipment instructions for use. Observe all indications, contraindications, warnings and precautions described in these directions. Failure to do so may result in patient complications.
- Do not connect the ablation catheter cable to devices or power sources other than the appropriate ablation catheter(s) and equipment. Connecting the ablation catheter cable to an inappropriate electrical connection such as a wall socket may result in serious injury to patient and operator or damage to equipment.
- Employ proper electromechanical device guidelines and hospital standards in cases where conventional line powered equipment is used near the patient. Extraneous electrical currents may reach the ablation equipment, catheter and heart and could result in lethal arrhythmias.
- To prevent injury to patient or operator, use extreme caution if employing components with unprotected male pin connectors during device set-up.
- Verify that all amplifiers, pacing equipment and ECG equipment is isolated or patient injury or death may occur.
- Ensure the reusable sensor enabled connection cable is at room temperature before use to ensure accurate temperature measurement.
- Connected equipment must be patient isolated and current leakage must not exceed 10 microamps.
- Do not use if packaging is damaged. Do not use if labeling is incomplete or illegible.
- The cable should be visually inspected for any damage prior to use. If damage is present, discard the cable. Do not attempt to repair any damages.

Precautions

- It is important to carefully the Precautions sections in the associated compatible catheter Instructions for Use prior to use.
- Carefully check the condition of all packaging upon receipt of the cable. The cable is provided sterile. Sterility may be compromised if packaging is damaged. (e.g. cut, torn, punctured, or ripped).
- Carefully inspect the cable prior to use. Inspect for physical damage, including electrical insulation, cuts, kinks, nicks, crushed, elongated sections, or bent pins. Do not use damaged equipment.
- Do not immerse cable connectors in liquids. Ensure the cable remains dry throughout the procedure.
- Do not expose cables to strong or organic solvents.

- Use of additional electrical equipment could cause noise induction into the cable.
- Follow standard grounding precautions for electrosurgical instruments.
- Prior to use, verify compatibility of ablation catheter cable model with ablation catheter model in use.
- Improper handling may result in patient or operator injury.
- Do not alter this device.
- Observe polarity.
- Store this device in a cool, dark, dry area.
- To minimize the risk of damage, do not sharply bend or kink the cable. Do not use excessive force when connecting or disconnecting the cable connections.
- If the cable becomes electrically discontinuous or a break occurs in the cable wire, arcing may occur in the patient-return or active circuit and may burn the patient or create a fire.
- Personnel handling the connector cable should wear gloves.
- The connector cable has been evaluated at a maximum voltage of 240 volts.
- Refer to the appropriate radiofrequency (RF) or pulsed field ablation (PFA) generator manual for operating instructions.

Note for FARASTAR™ Catheter Connection Cables: Use only with the FARASTAR generator. Consult the FARASTAR Generator User Manual for more information.

Adverse reactions

It is important to review the Adverse Events section in the associated compatible catheter Instructions for Use and Generator User Manual prior to use.

Directions for use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
3. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the device if the sterility has been compromised. If the package is damaged or if it was opened and the instrument not used, return the device and the package to Stryker Sustainability Solutions.
4. Remove the device from the package and place it in a sterile work area using aseptic technique.
5. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Do not attempt to repair any damage. Return the device and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for the procedure.
6. In the sterile field, connect either end of the cable to a compatible catheter.
7. In the non-sterile field, connect the cable to the appropriate Generator.
8. Prior to using the cable, ensure that all cable connectors are securely attached.

Note for FARASTAR™ Catheter Connection Cables: To disconnect, rotate the latch ring toward the arrow symbol and pull gently.

Compatibility

- Use the appropriate ablation catheter cable for the ablation catheter being utilized. Refer to the catheter and equipment instructions for use for additional information on compatibility.

Storage and handling

- Store at -29°C to 60°C in a cool, dry, dark place.

Warranty

Reprocessed products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

Products for which Stryker is the original manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General warranty terms applicable to all products

To the fullest extent permitted by law, the express warranty set forth herein is the only warranty applicable to the products and is expressly in lieu of any other warranty by Stryker, expressed or implied, including, but not limited to, any implied warranty or merchantability or fitness for a particular purpose. In no event will Stryker's liability arising in connection with the sale of the product (whether under the theories of breach of contract, tort, misrepresentation, fraud, warranty, negligence, strict liability or any other theory of law) exceed the purchase price, current market value or residual value of the products, whichever is less. Stryker shall not be liable for indirect, special, incidental, punitive, or consequential damages resulting from any breach of warranty or under any other legal theory.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

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