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Sustainability Solutions

Instructions for Use
Reusable Connector Cable

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

- STERILE

Explanation of Symbols



Sterilized by Ethylene Oxide Gas

ROnly

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



Date of Processing



Use by Date

REF

Product Code



Do Not Use if Packaging is Damaged



See Instructions for Use



Keep Away From Sunlight

Reusable Connector Cable Description

The Reusable RFP-100A connector cable connects the Baylis Medical Company RFP-100A Radiofrequency Puncture Generator (RFP-100A Generator) to Baylis Medical approved radiofrequency puncture devices. This Cable enables radiofrequency (RF) power to be delivered from the Generator to the puncture device.

Detailed information concerning the RFP-100A Generator is contained in a separate manual that accompanies the Generator (RFP-100A Generator Instructions for Use). In addition, detailed information concerning the RF puncture devices is contained in separate manuals that accompany these devices.

The dimensions for the Reusable RFP-100A connector cable can be found on the device label and in the "Product Specifications" section. The Reusable RFP-100A connector cable has a four-pin connector on one end that mates with the RFP-100A Generator and a connector at the other end, which mates with the puncture device.

Indications for Use

The intended use of the Reusable RFP-100A connector cable is to connect the RFP-100A Generator to Baylis Medical approved puncture devices (RF puncture devices).

Contraindications for Use

The Reusable RFP-100A connector cable is not recommended for use with any other RF generator or any other device.

Warnings

- The Reusable RFP-100A connector cable is a reusable device. Only use the validated cleaning and sterilization methods as described in the "Cleaning and Sterilization Instructions" section to clean and sterilize the Connector 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 communication of infectious disease(s) from one patient to another.
- The Reusable RFP-100A connector cable must only be used with the RFP-100A Generator and RF puncture devices. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator.
- Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture 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.

Precautions

- Do not attempt to use the Reusable RFP-100A connector cable or ancillary equipment before thoroughly reading the accompanying Instructions for Use.
- Puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture 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 cracking or damage to the insulating material. Do not use the cable if there is any damage.
- The Reusable RFP-100A connector cable is intended for use with RF puncture devices only.
- Never disconnect the Reusable RFP-100A connector cable from the RFP-100A Generator while the Generator is delivering RF power.
- Never disconnect the Reusable RFP-100A connector cable from the RFP-100A Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable.
- Do not twist the Reusable RFP-100A connector cable while inserting or removing it from the Isolated Patient Connector on the Generator. Twisting the cable may result in damage to the pin connectors.
- Do not bend the cable. Excessive bending or kinking of the cable may damage the integrity of the cable and may cause patient injury. Care must be taken when handling the cable.
- Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Generator.
- Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.
- During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.
- In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application.

Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the Baylis Medical Radiofrequency Puncture System.

Adverse Events

Adverse events associated with the use of this device are similar to those indicated for the Baylis Medical Radiofrequency Puncture System.

Product Specifications

| | |
|------------------------------|--|
| Model Number | RFX-BAY-TS |
| Strain Relief Color | Black at device end, blue at generator end |
| Overall Usable Length | 10 feet (3m) |
| Generator Connector | 4-pin (plug) |
| Device Connector | 4-pin (receptacle) |

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 Reusable RFP-100A connector 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 | 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. |

Equipment Required

Puncture procedures should be performed in a specialized clinical setting which may be equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

Directions for Use

Once the RF puncture device is properly positioned at the puncture site, and the Generator is properly set up (following the instructions in the RFP-100A Generator Instructions for Use), the Reusable RFP-100A connector cable can be used to connect the catheter or wire to the Generator.

1. Connect the generator connector end of the cable to the isolated patient connector port on the RFP-100A Generator as per the Generator Instructions for Use. The generator connector end of the cable can be identified by the blue strain relief (the device connector end has a black strain relief). The Reusable RFP-100A connector cable uses a circular connector, keyed for proper alignment. Gently line up the connector pins with the socket and push in until the connector fits firmly into the socket. Any attempt to connect the cable otherwise will damage the pins on the connector.
2. Do not use excessive force in connecting the cable to the generator. Use of excessive force may result in damage to the connector pins.
3. Connect the device connector end of the cable to the RF Puncture Device. The Reusable RFP-100A connector cable uses a circular connector, keyed for proper alignment. Gently line up the connector pins with the RF Puncture Device connector and push in until the connector fits firmly into the plug.
4. To disconnect the puncture device from the Connector Cable: Firmly grasp the catheter connector (receptacle) end of the cable in one hand and gently pull it straight out of the device connector.
5. To disconnect the cable from the generator, grasp the connector firmly and gently pull it straight out of the socket.

Cleaning and Sterilization Instructions

The Reusable RFP-100A Connector Cable is supplied sterile, however it must be cleaned and sterilized before each subsequent use as described in this Instructions for Use document. Failure to properly clean and sterilize the device can cause patient injury and/or the communication of infectious diseases from one patient to another.

1. Product must be thoroughly cleaned and sterilized using a validated method after each use.
2. Devices to be cleaned using Stryker’s cleaning method should be placed in the appropriate collection container system and staged for pickup.

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.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE 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.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

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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