Instructions for Use
Reprocessed (Reusable) Connector Cable

Reprocessed Device for Single Use

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

DEVICE DESCRIPTION

The Reprocessed (Reusable) connector cable connects the Baylis Medical Company Radiofrequency 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).

The Reusable RFP-100A connector cable has a four-pin connector on one end that mated with the RFP-100A Generator and a connector at the other end, which mates with the puncture device.

Cable Specifications

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

Note: Puncture devices are not provided by Innovative Health.

INDICATIONS FOR USE

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

The cable may be re-used subject to the cleaning and sterilization services provided by Innovative Health.

CONTRAINDICATIONS FOR USE

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

WARNINGS

- Patient or operator injury can result from improper handling or storage of the cable.
- Failure to isolate unused connector pins may result in accidental current pathways to the heart.
- Misconnection of the pins to the sockets could lead to malfunction of the catheter.
- No modification of the device or equipment is allowed.
- The Reusable 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.

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- 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 connector cable or ancillary equipment before thoroughly reading the Instructions for Use.
- Puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture in a fully equipped catherization laboratory.
- The Reusable connector cable is intended for use with RF puncture devices only.
- Never disconnect the Reusable connector cable from the RFP-100A Generator while the Generator is delivering RF power.
- Never disconnect the Reusable 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 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 risk of ignition make sure that flammable material is not present in the room during RF power application.
- Do not immerse the cable connectors in fluids.
- Personnel handling the cable should wear gloves.
- Standard grounding procedures should be followed if electrosurgical instruments are used.
- Do not expose cable to organic solvents.
- Inspect the sterile packaging and cable for damage or defects (i.e. bent pins, cuts, kinks, nicks, crushed, cracking or elongated sections) prior to use. Do not use the cable if the cable is damaged or the packaging has been compromised.

ADVERSE REACTIONS

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

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Before beginning the procedure, verify compatibility of all devices and accessories.
- 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.
- Inspect the cable and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the cable is damaged or the packaging is compromised, do not use the cable. Do not attempt to repair any damage. Return the cable and packaging to Innovative Health.
- Do not attempt to resterilize.
- Once the RF puncture device is properly positioned at the puncture site, and the Generator is properly set up

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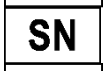
(following the instructions in the RFP-100A Generator Instructions for Use), the Reusable connector cable can be used to connect the catheter or wire to the Generator.

- 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 connector cable uses a circular connector, keyed for proper alignment. Gently line up the connector pins with the socket and push in until connector fits firmly into the socket. Any attempt to connect the cable otherwise will damage the pins on the connector.
- Do not use excessive force in connecting the cable to the generator. Use of excessive force may result in damage to the connector pins.
- Connect the device connector end of the cable to the RF puncture Device. The Reusable connector cable uses a circular connector, keyed for proper alignment. Gently push in until the connector fits firmly into the plug.
- 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.
- To disconnect the cable from the generator, grasp the connector firmly and gently pull it straight out of the socket.

EXPLANATION OF SYMBOLS

	Federal Law in the USA restricts this device to sale by or on the order of a physician
	Sterilized by Ethylene Oxide Gas
	Item Number
	Serial Number
	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

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

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

The third-party trademarks used herein are for device identification and are trademarks of their respective owners.

Please refer to www.innovative-health.com for product warranty.