

**Instructions for Use**  
**DuoMode™ Cable**



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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 reusable DuoMode Cable is an extension cable that is used with Baylis Medical approved radiofrequency puncture devices, the Baylis Medical Company Radiofrequency Puncture Generator (RFP-100 Generator for RFX-BAY-DUO-100) and to diagnostic equipment.

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

The DuoMode Cable has a four-pin connector on a cable that mates with the RFP Generator and a puncture device connector port that accepts other Baylis RFP connector cables that facilitates connection to the puncture device. The DuoMode connector cable also has a Diagnostic Equipment Connector that consists of a protected 2mm pin.

**II. INDICATIONS FOR USE**

The DuoMode Cable is intended to serve as an extension cable that is used with the Baylis Medical radiofrequency puncture devices, the Baylis Medical Company Radiofrequency Puncture Generator and diagnostic equipment.

**III. CONTRAINDICATIONS**

The DuoMode Cable is not recommended for use with any other RF generator.

**IV. WARNINGS**

- The DuoMode Cable is a reusable device. Failure to properly clean the device can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- The DuoMode Cable must only be used with Baylis RF Puncture Generators 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.

**V. PRECAUTIONS**

- Do not attempt to use the DuoMode 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 RF powered puncture in a fully equipped catheterization laboratory.

- 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 DuoMode Cable is intended for use with RF puncture devices only.
- Never disconnect the DuoMode Cable from the RF Puncture Generator while the Generator is delivering RF power.
- Never disconnect the DuoMode Cable from the Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable.
- Do not twist the DuoMode 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 RF 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.

**VI. ADVERSE EVENTS**

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

**VII. PRODUCT SPECIFICATIONS**

|                                   |                                 |
|-----------------------------------|---------------------------------|
| Model Number                      | RFX-BAY-DUO-100                 |
| Generator Connector               | 4-pin (Plug)                    |
| Generator Connector Cable Colour  | Black                           |
| Diagnostic Equipment Cable Colour | Red                             |
| Diagnostic Equipment Connector    | Protected 2mm Pin (DIN 42802-2) |
| Puncture Device Connector Port    | 4-pin (receptacle)              |

**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.

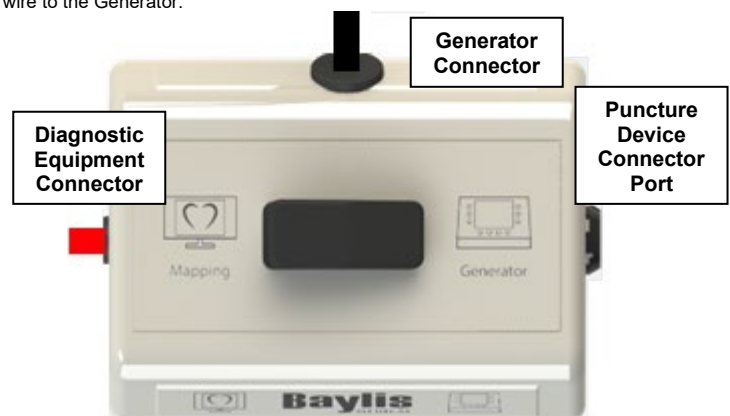
| KEY ITEMS    | QUESTION?  | WARNINGS AND EXPLANATIONS  |
|--------------|--|--|
| Visual Check | Have you done a visual check on the entire system? | Ensure connectors and the cable have no visible damage, such as discoloration, cracks, label fading, cable splice, or kinks. Do not use damaged equipment. |

**IX. EQUIPMENT REQUIRED**

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.

**X. 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 Generator Instructions for Use), the DuoMode Cable can be used to connect the catheter or wire to the Generator.



**Connecting the DuoMode cable**

1. Connect the Generator connector end (black cable) of the DuoMode Cable to the isolated patient connector port on the RF Puncture Generator as per the Generator Instructions for Use. The DuoMode Cable Generator Connector 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. For the RFX-BAY-DUO-100 only: Secure the screw-on locking ring mechanism of the Generator Connector.
  2. Connect the Diagnostic Equipment Connector (red cable) to the input of the diagnostic equipment.
  3. Connect the Generator connector end of the RFP Connector cable (used to connect the puncture device) to the Puncture Device Connector Port on the DuoMode cable. Follow the RFP Connector Cable Instructions for Use.
- Note: The generator connector of the RFP Connector cable can plug directly into the isolated patient connector on the Generator, if the DuoMode Cable is not used.
4. Do not use excessive force in connecting any of the cables. Use of excessive force may result in damage to the connector pins.
  5. Connect the device connector end of the RFP Connector cable to the RF Puncture Device, according to the RFP Connector cable Instructions for Use.

**Switching the DuoMode Cable**

6. To connect the puncture device to the Diagnostic Equipment, press the rocker switch down towards the Mapping symbol.
7. To connect the puncture device to the RF Puncture Generator, press the rocker switch down towards the Generator symbol.  
Do not activate RF delivery on the generator while the switch is set to the Mapping setting.  
Do not change the rocker switch position while RF is being delivered.

**Disconnecting the DuoMode Cable**

8. To disconnect the puncture device from the RFP Connector Cable, follow the RFP Connector Cable Instructions for Use.
9. To disconnect the RFP Connector Cable from the DuoMode cable, follow the RFP Connector Cable Instructions for Use.
10. To disconnect the Generator Connector – For the RFX-BAY-DUO-100 only: rotate the locking rings of the Generator Connector counter clockwise to unlock.
11. To disconnect the Generator Connector, grasp the Generator Connector firmly and gently pull it straight out of the socket.
12. To disconnect the Diagnostic Equipment, grasp the Diagnostic Equipment Connector firmly and gently pull it straight out of the socket.

**XI. CLEANING AND STERILIZATION INSTRUCTIONS**

The DuoMode cable is a non-body contact device and therefore is NOT sterile and CANNOT be sterilized. If cleaning is necessary, the surface of the DuoMode cable can be cleaned with a damp low lint cloth with non-abrasive detergent dissolved in water. Dry the surface after wiping down. Do not spray or pour liquids directly on the DuoMode Cable.

**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:**

1. In order to return products you must have a return authorization number before shipping the products back to Baylis Medical Company.
2. 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   |
|--|--|---|
| <b>Generator Alert Messages</b>  | In order to successfully puncture tissue using radiofrequency energy, the entire system must be connected and all devices must be in good working order. | Ensure that all connections are made:<br>- puncture device to connector cable<br>- connector cable to DuoMode cable<br>- DuoMode cable to generator<br>- generator to power outlet<br>- generator to grounding pad<br>Visually inspect the catheter/wire or cable for damage. Immediately discard any damaged equipment. If the problem persists discontinue use.<br>For error/alert messages encountered while attempting puncture, refer to the operator's manual that accompanies the Generator. If errors persist, attach a new connector cable. If this solves the problem, discard the damaged connector cable. |
| <b>DuoMode Cable does not fit into the Isolated Patient Connector on the front panel</b> | The connectors are designed to connect in a specific way for safety reasons. If the connector "keys" are out of line, the connectors won't fit together  | Check that the connector keys are lined up in the proper orientation.<br>Ensure that the connectors are clean and unobstructed.   |

|                                  |   |                |  |
|----------------------------------|---|----------------|--|
| of the generator                 |   |                |  |
| <b>XIV. LABELING AND SYMBOLS</b> |   |                |  |
|                                  | Manufacturer  |                | Caution  |
|                                  | Consult Instructions for Use  | <b>LOT</b>     | Lot Number   |
| <b>REF</b>                       | Model number  |                | Keep Away From Sunlight  |
|                                  | Do Not Use if Packaging is Damaged  | <b>Rx ONLY</b> | Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. |
|                                  | <b>Only for EU member states:</b><br>Use of this symbol indicates that the product must be disposed of in a way that complies with local and national regulations. For questions regarding recycling of this device please contact your distributor |                |  |

**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 resterilized, 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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