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The PowerWire® 14 Radiofrequency (RF) Guidewire Kit includes the PowerWire® 14 RF Guidewire and the RFP-100A Connector Cable. Carefully read all instructions prior to use.

Instructions for Use

PowerWire® 14 Radiofrequency (RF) Guidewire Kit

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PowerWire 14 Radiofrequency Guidewire Kit

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 PowerWire 14 RF Guidewire Kit includes the PowerWire 14 RF Guidewire and the RFP-100A Connector Cable.

The PowerWire 14 RF Guidewire must be used with an approved Baylis Radiofrequency Puncture Generator (Baylis RF Generator) and Baylis Connector Cable.

The PowerWire 14 RF Guidewire delivers radiofrequency (RF) power in a monopolar mode between its distal electrode and a commercially available external Disposable Indifferent (Dispersive) Patch (DIP) Electrode, which is in compliance with IEC 60601-2-2 standards. The PowerWire 14 RF Guidewire is connected to the Baylis Radiofrequency Puncture Generator via the Baylis Connector Cable.

Dimensions for different models of the PowerWire 14 RF Guidewire are described on the product label. The insulation on the PowerWire 14 RF Guidewire body facilitates smooth advancement to the target location as well as providing electrical insulation. The distal portion of the PowerWire 14 RF Guidewire is flexible and the active tip is rounded to be atraumatic to vessel walls.

The RFP-100A Connector Cable connects the RFP-100A BMC Radiofrequency Puncture Generator (RFP-100A Generator) to the PowerWire 14 RF Guidewire. This Cable enables radiofrequency (RF) power to be delivered from the Generator to a PowerWire 14 RF Guidewire. Detailed information concerning the RFP-100A Generator is contained in a separate manual that accompanies the Generator (RFP-100A Generator Instructions for Use).

The dimensions for the PowerWire 14 RF Guidewire and the RFP-100A Connector Cable can be found on the device label and in Section VI "Product Specifications." The RFP-100A Connector Cable has a connector on one end that mates with the RFP-100A Generator and a connector at the other end, which mates with a PowerWire 14 RF Guidewire.

II. INDICATIONS FOR USE

The PowerWire 14 Radiofrequency Guidewire is intended to create a channel in totally occluded peripheral vessels 3 mm or greater, including vessels with stents.

Note: The intended use of the RFP-100A Connector Cable is to connect the RFP-100A BMC Radiofrequency Puncture Generator to a PowerWire 14 RF Guidewire.

III. CONTRAINDICATIONS

The RFP-100A Connector Cable included in the PowerWire 14 Kit is not recommended for use with any other RF generator or any other device.

IV. WARNINGS

- Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use the PowerWire 14 RF Guidewire. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures.
- The PowerWire 14 RF Guidewire is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged.
- The PowerWire 14 RF Guidewire and RFP-100A Connector Cable are intended for single patient use only. Do not attempt to clean, re-sterilize or re-use either device. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another.
- The PowerWire 14 RF Guidewire must be used with the Baylis Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.
- The RFP-100A Connector Cable must only be used with the RFP-100A Generator and the PowerWire 14 RF Guidewire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator.
- The active tip of the PowerWire 14 RF Guidewire is fragile. Be careful not to damage the tip while handling the PowerWire 14 RF Guidewire. If the tip becomes damaged, discard the PowerWire 14 RF Guidewire immediately.
- Do not attempt to shape or reshape the PowerWire 14 RF Guidewire by any means. Attempting to shape or reshape the PowerWire 14 RF Guidewire may result in damage to the guidewire.
- If the active tip of the PowerWire 14 RF Guidewire becomes bent at any time during its use, dispose of the PowerWire 14 RF Guidewire immediately. Do not attempt to straighten the active tip.
- If using with snare device, snare must be tightened midway along the radiopaque coil, at least 5mm from both the distal and proximal ends of the radiopaque coil. Snaring proximal or distal to the radiopaque coil may result in distal tip component separation.
- Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency cutting 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.
- Interaction with sharp edges may result in damage to device, which may lead to clinical adverse events requiring additional intervention.
- Navigation through occluded stents may result in device entanglement in stent.

V. PRECAUTIONS

* Do not attempt to use the PowerWire 14 RF Guidewire Kit or ancillary equipment before thoroughly reading the accompanying Instructions for Use.
* Radiofrequency interventional procedures should be performed only by physicians thoroughly trained in the technique in an operating room fully equipped for interventional procedures and/or 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 PowerWire 14 RF Guidewire and the RFP-100A Connector Cable to ensure there is no cracking or damage to the insulating material. Do not use if the equipment is damaged.
* Do not use the PowerWire 14 RF Guidewire Kit after the "Use By" date indicated on the label.
* The PowerWire 14 RF Guidewire is intended for use with only those devices listed in section VII "Equipment Required." The RFP-100A Connector Cable is intended for use with the PowerWire 14 RF Guidewire and PowerWire® Radiofrequency Guidewire Kit .
* Read and follow the manufacturer's instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements.
* Placement of the dispersive electrode on the thigh could be associated with higher impedance.
* In order to prevent the risk of ignition, make sure that flammable material is not present in the room during radiofrequency power application.
* 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.
* Careful manipulation of the PowerWire 14 RF Guidewire must be performed to avoid vessel trauma. PowerWire 14 RF Guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the PowerWire 14 RF Guidewire.
* Gently advance and withdraw the PowerWire 14 RF Guidewire to avoid device kinking.
* Do not use a metal torque device with the PowerWire 14 RF Guidewire. Use of a metal torque device may result in damage to the PowerWire 14 RF Guidewire.
* Excessive tightening of a plastic torque device onto the PowerWire 14 RF Guidewire may result in damage to the PowerWire 14 RF Guidewire.
* Do not attempt to reposition a torque device over the wire while it is tightened, as it may result in damage to the PowerWire 14 RF Guidewire.

* Do not attempt to deliver radiofrequency energy until the tip of the PowerWire 14 RF Guidewire is confirmed to be in good contact with the target biological material.
* Do not bend the PowerWire 14 RF Guidewire or the RFP-100A Connector Cable. Excessive bending or kinking of either device may damage the integrity of the device and may cause patient injury. Care must be taken when handling the PowerWire 14 RF Guidewire and the RFP-100A Connector Cable.
* Do not exceed 60 seconds of radiofrequency power applications per PowerWire 14 RF Guidewire.
* The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the PowerWire 14 RF Guidewire and/or DIP electrode, particularly when operating the device.
* During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.
* Do not activate RF whilst tip is within catheter.
* Care must be taken to verify the compatibility of the PowerWire 14 RF Guidewire when used with catheters.
* Never disconnect the RFP-100A Connector Cable from the RFP-100A Generator while the Generator is delivering RF power.
* Never disconnect the 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 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.
* Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor contact with the target biological material at the active tip. Check for obvious equipment defects or misapplications. Attempt to better position the active tip of the PowerWire 14 RF Guidewire against the target biological material.
* Baylis Medical Technologies relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of the radiofrequency interventional procedure.

VI. PRODUCT SPECIFICATIONS

Product	PowerWire 14 RF Guidewire	Product	RFP-100A Connector Cable
Useable Length	190 cm 300 cm	**Useable Length**	10 feet (3 m)
Outside Diameter	0.014” / 0.367 mm	**Generator Connector**	Multi-pin
Radiopaque Markers (ROM)	ROM1: 2 mm length at distal tip ROM2: 18 mm length at 4 mm proximal to ROM1	**Device Connector**	Push Button

The PowerWire 14 RF Guidewire is a defibrillation-proof type CF applied part.

VII. ADVERSE EVENTS

Adverse events that may occur while performing the radiofrequency cutting procedure include:

Thrombosis	Pain and Tenderness
Vessel perforation	Distal embolization
Vessel dissection	Sepsis/Infection
Hemorrhage	Hematoma
Tamponade	Arrhythmias
Effusion	Death
Damage to Stent	Entanglement of device in stent

VIII. EQUIPMENT REQUIRED

Radiofrequency cutting 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. Ancillary materials required to perform this procedure include:

- Baylis Radiofrequency Generator
- Disposable Indifferent (dispersive) Patch (DIP) electrode

IX. INSPECTION PRIOR TO USE

Prior to performing the radiofrequency cutting procedure, the individual components including the Baylis Radiofrequency Generator, PowerWire 14 RF Guidewire, and the RFP-100A Connector Cable should be carefully examined for damage or defects, as should all equipment used in the procedure.

Inspect the packaging of the PowerWire 14 RF Guidewire Kit to ensure the package has not been damaged, sterility has not been compromised, and that a product label is present. Ensure that the RFP-100A Connector Cable and the PowerWire 14 RF Guidewire have no visible damage, such as discoloration, cracks, label fading, splicing, or kinks. Do not use damaged or defective equipment. Do not reuse the PowerWire 14 RF Guidewire or the RFP-100A Connector Cable. In cases of use in vessels with stents, observe any significant stent irregularities (e.g. kinks, fractures, etc.) by angiography prior to insertion into vasculature.

X. DIRECTIONS FOR USE

All instructions for equipment required should be carefully read, understood, and followed. Failure to do so may result in complications.

* The PowerWire 14 RF Guidewire Kit is supplied sterile. Use aseptic technique when opening the package and handling the product in the sterile field.
* 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 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.
* Do not use excessive force in connecting the cable to the generator. Use of excessive force may result in damage to the connector pins.
* Once access to the target site has been gained using standard interventional techniques, the PowerWire 14 RF Guidewire can be introduced to the target site. To ensure PowerWire 14 RF Guidewire is centered within the vessel, confirm alignment under multiple imaging projections. A distal target may be used.
* Firmly grasp the catheter connector end of the cable in one hand. Using your thumb depress the red button on the top of the connector. Slowly insert the proximal end of the PowerWire 14 RF Guidewire into the opening of the catheter connector. Once the exposed portion of the proximal end of the device is no longer visible release the red button on the connector. Gently tug on the device to ensure that you have a secure connection.
* With the tip of the PowerWire 14 RF Guidewire in good contact with the target site, radiofrequency power can be delivered via the BMC Radiofrequency Generator to the distal tip. This results in thermal necrosis (cutting) of the target site. Please refer to the Generator Instructions for Use before using the Generator.
* Apply gentle pressure to the PowerWire 14 RF Guidewire during the application of radiofrequency energy to successfully advance it through the target site.
* Radiofrequency power delivery can be terminated by pressing the RF ON/OFF button on the Generator if the timer has not expired.
* Successful advancement of the PowerWire 14 RF Guidewire can be confirmed by monitoring the PowerWire 14 RF Guidewire under fluoroscopy in multiple imaging projections.
* If advancement across the occlusion is not successful after sixty (60) seconds of radiofrequency power applications, it is advised that the user utilize a new PowerWire 14 RF Guidewire device.
* The PowerWire 14 RF Guidewire can now be used to exchange for or place other interventional devices at the discretion of the physician.
* The PowerWire 14 RF Guidewire can also be used as a standard flexible mechanical Guidewire.
* To disconnect the PowerWire 14 RF Guidewire from the RFP-100A Connector Cable, depress the red button on the catheter connector and gently remove the proximal end of the puncture device from the connector cable.
* To disconnect the cable from the generator, grasp the connector firmly and gently pull it straight out of the socket.
* In cases of occluded stents, lack of advancement through occluded stents may be attributed to device interaction with strut of stent. In this case, halt application of radiofrequency energy,

reposition the distal end of the device by torquing and retracting slightly. Ensure good contact with the target site and then repeat application of radiofrequency energy while avoiding contact with stent struts.

* When device usage is complete, dispose of the device according to region biohazardous waste guidelines.

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XI. CLEANING AND STERILIZATION INSTRUCTIONS

The PowerWire 14 RF Guidewire Kit is intended for single use only. Do not clean or re-sterilize any device in the PowerWire 14 RF Guidewire Kit. Do not use solvents to clean the distal tip of the PowerWire 14 RF Guidewire.

The PowerWire 14 RF Guidewire Kit 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 Technologies equipment, contact technical support personnel.

NOTES:

In order to return products you must have a return authorization number before shipping the products back to Baylis Medical Technologies.

XIII. TROUBLESHOOTING

The following table is provided to assist the user in diagnosing potential problems.

PROBLEM	COMMENTS	TROUBLESHOOTING
Connector Cable does not fit into the **Isolated Patient Connector** on the front panel of the generator	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. Ensure that the connectors are clean and unobstructed.
Generator Error Messages	In order to successfully puncture biological material using RF energy, all devices must be properly connected and in good working order.	Ensure that all connections are made: - PowerWire 14 RF Guidewire to Connector Cable - Connector Cable to Generator - Generator to power outlet - Generator to DIP electrode Visually inspect the PowerWire 14 RF Guidewire or Cable for damage. Immediately discard any damaged equipment. If problem persists discontinue use. For error messages encountered while attempting radiofrequency cutting, refer to the Instructions for Use document that accompanies the Generator. If errors persist, attach a new connector cable. If this solves the problem, discard the damaged connector cable.
PowerWire 14 RF Guidewire breaks or kinks.	Breaks and kinks in the PowerWire 14 RF Guidewire are a potential cause of patient injury.	If observed, stop use immediately and return to manufacturer.

XIV. LABELING AND SYMBOLS

	**Manufacturer**
	**Sterile using ethylene oxide**
	**Use By**
	**Caution**
	**Follow instructions for use**
	**Model number**
Rx ONLY	**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	**Do not reuse**
	**Lot Number**
	**Do Not Use if Packaging is Damaged**
	**Keep Away From Sunlight**
	**Non-Pyrogenic***

*Note: Non-pyrogenic symbol applies only to the PowerWire 14 RF Guidewire.

XV. LIMITED WARRANTY – DISPOSABLES AND ACCESSORIES

Baylis Medical Technologies Inc. (BMT) warrants its Disposable and Accessory products against defects in materials and workmanship. BMT 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, BMT will replace or repair, in its absolute and sole discretion, any such product, less any charges to BMT 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. BMT's Limited Warranty shall not apply to BMT products which have been resterilized, repaired, altered, or modified in any way and shall not apply to BMT products which have been improperly stored or improperly cleaned, installed, operated or maintained contrary to BMT's instructions.

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No agent, employee or representative of Baylis Medical Technologies 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 Technologies products directly from a Baylis Medical authorized agent. The original purchaser cannot transfer the warranty.

Use of any BMT 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**