English CE 0344

INSTRUCTIONS FOR USE
Powerline™ PTCA Catheter

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1. DEVICE DESCRIPTION

The Powerline™ PTCA catheter is a rapid exchange semi-compliant PTCA catheter with an integrated shaft and a distal balloon. The shaft has one lumen to inflate/deflate the balloon and a second lumen about 28 cm from the balloon for advancement on a guidewire. The guidewire diameter should not exceed 0.014".

Two radio-opaque markers are positioned at each end of the balloon (distal and proximal shoulder) for easier positioning. On the shaft of the catheter, two markers are located 91 cm and 100 cm from the distal tip.

The balloon is designed to have a consistent balloon diameter increase at each increment of pressure (see compliance table). The inflation pressure for expanding the balloon to its nominal diameter is 6 atm.

At the proximal end of the balloon catheter is a female Luer hub for connecting an inflation device.

Table 1: Device Description

Balloon Diameters (mm):	1.5 - 4.0
Balloon Lengths (mm):	10; 15; 20; 25; 30
Delivery Catheter Working Length:	142 cm
Balloon material	Polyamide Elastomer
Balloon compliance	Semi-compliant
Balloon Inflation: Nominal Inflation Pressure: Rated Burst Pressure:	 6 atm / 608 kPa 14 atm / 1418 kPa

Table 2: Device specification:

Product Code	Nominal Expanded balloon diameter (mm)	Nominal unexpended balloon length (mm)
PWR-1510	1.5	10
PWR-1515	1.5	15
PWR-1520	1.5	20
PWR-1525	1.5	25
PWR-1530	1.5	30
PWR-2010	2.0	10
PWR-2015	2.0	15
PWR-2020	2.0	20
PWR-2025	2.0	25
PWR-2030	2.0	30
PWR-2510	2.5	10
PWR-2515	2.5	15
PWR-2520	2.5	20
PWR-2525	2.5	25
PWR-2530	2.5	30
PWR-2720	2.75	20
PWR-3010	3.0	10
PWR-3015	3.0	15
PWR-3020	3.0	20
PWR-3025	3.0	25
PWR-3030	3.0	30
PWR-3510	3.5	10
PWR-3515	3.5	15
PWR-3520	3.5	20
PWR-3525	3.5	25
PWR-3530	3.5	30
PWR-4010	4.0	10

PWR-4015	4.0	15
PWR-4020	4.0	20
PWR-4025	4.0	25
PWR-4030	4.0	30

2. INDICATIONS

The Powerline device is indicated for Percutaneous Transluminal Angioplasty (PTCA) procedures of lesions in coronary arteries.

3. CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Patients suffering from coronary artery spasms, in the absence of a significant stenosis.

4. WARNINGS

- This device should be used only by physicians who have received appropriate training, and are experienced in performing PTCA.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery (CABG) can be quickly performed in the event of a potentially life-threatening or other serious complication.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries additional risk.
- This device is intended for single patient use only.
- DO NOT resterilize and / or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient.
- Do not exceed the rated burst pressure as indicated on product label. Use of pressures higher than specified on the product label may result in a rupture of the balloon with possible intimal damage and vessel dissection.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should not exceed the diameter of the vessel just proximal and distal to the stenosis.
- When the catheter is exposed to the vascular system, it should be manipulated under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If there is resistance, determine and address its cause before proceeding. Continuing to advance or retract the catheter against resistance may result in damage to the vessels, and in damage or separation of the catheter.
- Never apply extreme bending or twisting force to any section of the catheter, in order to prevent kinking, damage, or separation of the shaft.
- The Powerline catheter is not intended for stent deployment.

5. PRECAUTIONS

- **For single use only**. Do not resterilize or reuse.
- Do not use a product that has reached or exceeded its labeled expiration date.
- Prior to angioplasty, the balloon catheter should be examined to verify its integrity and ensure that its size is suitable for the specific procedure for which it is to be used.
- During the procedure, provide as needed appropriate anti-coagulant and coronary vasodilator therapy to the patient. Continue this therapy for an appropriate period of time after the procedure.
- Always advance a balloon catheter over a guidewire that is positioned through the target stenosis and into a distal section of the coronary artery.
- When loading or exchanging the balloon catheter, the guidewire should be thoroughly wiped and cleaned for better balloon catheter movement on the wire.
- Do not force motion of the balloon catheter against significant resistance.

- After use, disposal of the device and of its packaging must be handled according to hospital policies and applicable laws and/or regulations.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- The products are contaminated during use and may present a biohazard. Handle and dispose of products in accordance with insight hospital policies, applicable laws and/or regulations.
- Do not expose delivery catheter to organic solvents, e.g. isopropyl alcohol. Such an exposure can degrade delivery catheter performance.

6. OPERATOR'S MANUAL

6.1 Inspection prior to use

- Prior to use, examine carefully the balloon catheter for bends, kinks, or other damage. Do not use any damaged equipment.
- Do not use if inner package is open or damaged.
- Do not use the device after the "Use by" date.
- Verify if the type, size and condition of the device is suitable for the procedure in which it is to be used.

6.2 Materials required

1000 IU	Sterile heparinized normal saline
1	Guiding catheter (femoral or brachial) in the appropriate size and configuration to select the coronary artery
1	Arterial sheath and dilatator set
1	Haemostatic valve(s)
N/A	Contrast medium diluted 1:1 with normal saline
1	20 cc Luer-lock syringe (optional)
1	Appropriately sized guidewire (diameter shall not exceed 0.014").
1	Guidewire introducer
1	Guidewire torque device
1	Inflation device

6.3 Catheter and inflation device preparation

Prepare each equipment to be used following instructions of its manufacturer.
Complete the following steps to prepare the Powerline for use:

1. Remove the balloon catheter from the package.
2. Remove the stylet and protective sheath from the distal end of the catheter.
3. Prepare the inflation device with an appropriate inflation medium (equivalent of 50:50 mixture of contrast medium and sterile saline)
4. Evacuate air from the balloon segment using the following procedure:
    a. Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommended inflation medium (usually corresponds to a 50:50 mixture of contrast medium and sterile saline).
    b. After attaching the syringe or inflation device to the balloon inflation lumen, orient the balloon catheter with the distal tip and the balloon pointing in a downward vertical position.
    c. Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the balloon catheter.
    d. Disconnect the syringe or inflation device from the inflation port of the balloon catheter.
    e. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the balloon catheter. Maintain negative pressure on the balloon until air no longer returns to the device. If air is continuously aspirated, verify that the balloon has no leaks by inflating the balloon with the inflation medium.
    f. Slowly release the device pressure to neutral.
    g. Disconnect the 20 cc syringe (if used) and connect the inflation device to the inflation port of the balloon catheter without introducing air into the system.

CAUTION: All air must be removed from the balloon and displaced with contrast prior to inserting into the body, (repeat steps 4c through 4f, if necessary); otherwise, complications may occur.

6.4 Insertion and use

a. Flush and fill the guidewire lumen of the balloon catheter with heparinized normal saline.

b. Insert the guidewire through the haemostatic valve on the guiding catheter, following the manufacturer's guidelines or standard practice. Under fluoroscopic guidance, carefully advance the guidewire into and through the guiding catheter, into the target vessel, across the stenosis, and into a distal vessel.
c. Prior to using the Powerline device, ensure that a guiding catheter is in place and offers support for advancing the catheter into the vessel, and that the guidewire is adequately positioned through the lesion.
d. Backload the guidewire into the distal tip of the balloon catheter guidewire lumen, and ensure that the guidewire exits the opening located approximately 28 cm proximal to the balloon.
e. Thoroughly aspirate and flush the hemostatic valve and the guiding catheter in preparation for introduction of the balloon catheter.
f. Advance the balloon catheter over the guidewire until it approaches the hemostatic valve of the guiding catheter. Loosen the hemostatic valve, insert the balloon catheter while maintaining the guidewire position; advance the balloon catheter about 30 to 40 cm into the guiding catheter, and tighten the hemostatic valve to create a seal around the balloon. Caution should be taken not to over-tighten the hemostatic valve around the balloon catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon. The movement of the balloon catheter within the guiding catheter should not be restricted.
g. Advance the balloon catheter until the appropriate proximal marker approaches the hub of the guiding catheter. Under fluoroscopy, continue to advance the balloon catheter over the guidewire and into the stenosis.
h. Verify the positioning of the balloon across the lesion prior to inflation, using the radio-opaque markers of the balloon for reference and inflate the balloon
i. After the lesion has been dilated, pull the plunger of the inflation device to create a vacuum, and control the deflation of the balloon under fluoroscopy.
j. After complete deflation, pull the balloon catheter back into the guiding catheter. A coronary angiography should be carried out for control purposes.
k. If the result is acceptable, withdraw the balloon catheter from the guiding catheter.
l. Remove the guiding catheter from the vessel.
m. Follow standard practice for management of the insertion site.

The physician should consult recent literature on current medical practice on PTCA such as published by ACC/AHA.

7. INDIVIDUALIZATION OF TREATMENT

The risks and benefits of balloons should be considered for each patient before use of the Powerline PTCA catheter. Physicians are responsible for assessing patient appropriateness for use of the balloon prior to procedure.

8. USE IN SPECIAL POPULATION

The safety and effectiveness of the Powerline PTCA catheter has not been established in the following patient populations.

• Pregnancy: There is no data available for use of Powerline in pregnant women.
• Pediatric use: The safety and efficacy of Powerline has not been established.

Carefully consider whether it is appropriate to use Powerline in the above patient populations.

9. POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with the use of a PTCA catheter in native coronary arteries, include but not limited to:

- Acute myocardial infarction
- Abrupt vessel closure or spasm
- Arrhythmias, including ventricular fibrillation, or other conduction disturbances
- Arteriovenous fistula
- Allergic reaction to anti-coagulation and/or anti-thrombotic therapy, contrast material, or delivery system materials
- Bleeding (in particular at puncture site)
- Coronary vessel dissection, perforation, rupture, or injury
- Cardiac tamponade
- Coronary thrombosis

- Coronary artery spasm
- Death
- Embolism
- Hypotension/hypertension
- Hemorrhage or hematoma
- Infection and/or pain at insertion site
- Restenosis of artery
- Renal failure
- Stroke / Cerebrovascular accident
- Total occlusion of the coronary artery or side branches
- Thrombosis
- Unstable angina

10. HOW SUPPLIED

STERILE, NON-PYROGENIC. This device is sterilized with ethylene oxide sterilization.
LATEX FREE. This device does not contain latex.
CONTENTS: One Powerline PTCA catheter.
STORAGE: Store in a cool, dark and dry place.
DISPOSAL: Dispose of device in accordance with local regulations.
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11. SYMBOLS USED IN LABELING

EC REP	Authorized representative in the European community
	Legal Manufacturer
	Date of Manufacture
REF	Catalog number
LOT	Batch code
	Caution, consult accompanying documents
	Consult instructions for use
	Do not reuse
	Do not re-sterilize
STERILE EO	This product has been sterilized using Ethylene Oxide
	Use by date Do not use this product after the indicated date (Year-month-day)
	Keep dry
	Keep away from sunlight or heat
	Do not use if package is damaged or opened
	Balloon Length
	Balloon Diameter (at nominal inflation pressure)
	Maximum Guidewire Outer Diameter (O.D.)
	Minimum Guiding Catheter Inner Diameter (I.D.)
NP	Nominal Inflation Pressure
RBP	Rated Burst Pressure

12. WARRANTY

Biosensors International™ warrants that its products are manufactured to the specifications set forth on its packaging, instructions for use and related literature.
This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Biosensors International neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

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