BARD | PERIPHERAL VASCULAR

English

PORTER GUIDEWIRE

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

CAUTION
This device should be used only by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA).

Do not use if package is damaged.

Do not re-sterilize or re-use.

Do not wipe with alcohol.

Single Use Only

Sterilized with ethylene oxide gas

Use the guidewire prior to the "Use before" date on the package label, preceded by the symbol

Refer to the instructions supplied with any interventional devices to be used in conjunction with the Guidewire for their intended uses, contraindications, and potential complications.

DESCRIPTION
The Porter Guidewire is a steerable guidewire available in several lengths and diameters. The distal tip is shapeable. Refer to the product label for product specifications (e.g. wire length, diameter and length of tip radiopacity).

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STORAGE Store in a cool, dark, dry place.

INDICATIONS FOR USE
The Porter Guidewires are intended for use in the coronary and peripheral vasculature.

CONTRAINDICATIONS
The Porter Guidewire is not intended for use in the cerebral vasculature.
Patients judged not acceptable for percutaneous intervention (PCI).

PRECAUTIONS
- Failure to follow the instructions may compromise guidewire performance and result in complications.
- Prior to use, confirm compatibility of guidewire outer diameter with the balloon catheter.
- The tip section of the guidewire has a proper orientation for shaping. Identify the flexing plane before shaping. Shape in the same plane as that for flexure.
- Guidewire advancement, withdrawal, and torquing should be monitored by fluoroscopy.
- These guidewires have stiff distal ends. Therefore the risk of perforation or injury when using these wires is higher. These wires must be operated carefully. Use the most flexible guidewire that will treat the lesion *i.e.* the guidewire with the smallest flexibility number and take due care to minimize the risk of perforation or other damage to the blood vessels.

DIRECTIONS FOR USE
A.Over-the-wire PTCA/PTA Balloon Catheters
1. Prepare the balloon catheter according to manufacturer's directions.
2. If desired, shape the guidewire tip using standard technique. When preparing to shape the tip section, hold the tip at the middle joint and between the two fingers. Gently "brush" the spring coil to identify the plane of flexure and complete the shaping procedure.
3. Moisten the guidewire with sterile saline to increase the surface lubricity
4. Place the guidewire into the dilatation catheter and advance it to the catheter lumen.
5. Remove the guidewire introducer by sliding it over the proximal end of the guidewire. Secure the guidewire within the haemostatic valve being careful not to over-tighten the compression fitting.
6. A torque application device may be applied to the proximal end of the guidewire.
7. Advance the guidewire into the target vessel and across the lesion using fluoroscopy to facilitate proper guidewire placement.
8. Holding the guidewire in position, advance the balloon catheter over the guidewire and into the target lesion.
9. Complete the procedure and remove the guidewire and balloon catheter according to procedural protocol.

B.Rapid Exchange Systems
1. If desired, shape the guidewire tip using standard technique. When preparing to shape the tip section, hold the tip at the middle joint and between the two fingers. Gently "brush" the spring coil to identify the plane of flexure and complete the shaping procedure.
2. Moisten the guidewire with sterile saline to increase surface lubricity.
3. Introduce the guidewire through the guiding catheter Y -adapter using a guidewire introducer.
4. Remove the guidewire introducer by sliding it over the proximal end of the guidewire. Secure the guidewire within the haemostatic valve being careful not to over-tighten the compression fitting.
5. Advance the guidewire into the target vessel and across the lesion using fluoroscopy to facilitate proper guidewire placement. A torque application device may be applied to the proximal end of the guidewire. Manifold flushing of the catheter lumen during guidewire advancement is recommended to remove any residual air.
6. Place the rapid-exchange balloon catheter on the guidewire and advance it into position according to manufacturer's instructions.
7. Holding the guidewire in position, advance the balloon catheter over the guidewire and into the target lesion.
8. Complete the procedure and remove the guidewire and balloon catheter according to procedural protocol.

WARNING
A guidewire is a delicate instrument and must not be advanced, withdrawn, or torqued if resistance is met. Guidewire manipulations must always be observed under fluoroscopy.
If the guidewire is removed and is to be re-inserted, it must be inspected for signs of damage (weakened or kinked segments) prior to re-introduction.
Do not re-introduce if guidewire is weakened or kinked.

Explanation of symbols used on the package labels:

D	Single use only
Y	See instructions for use before use
h	Reference number
g	Lot number
I Q	Sterilized with ethylene oxide gas
H	Use before
N	Date of Manufacture

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