INSTRUCTIONS FOR USE VERITHIN® PRESSURE GUIDE WIRE

PREPARATION FOR USE

1. Open the package and remove pressure guide wire and sterile introducer sheath.
2. Prepare the pressure guide wire under the conditions described below.
3. Use a separate wire to confirm engagement of the pressure guide wire into the system.

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CAUTION: 1. U.S. Federal Law restricts this device to sale by or on the order of a physician. 2. Prior to use, read this entire package insert.

INTERVIEW SIZE

The Verithin® pressure guide wire is indicated for use to measure pressure in small vessels, including both coronary and peripheral vessels, during diagnostic angiography and any interventional procedures. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

DESCRIPTION

The Verithin® pressure guide wire (hereafter referred to as "pressure guide wire") is a sterile guide wire with a non-stented balloon mounted on it. It is preformed to the "S"-shaped curve, and "The Verithin® wire" measures pressure when used with the Intravascular, Intramural, and CARDIAC systems. The pressure wire is a diameter of 0.014" (0.356 mm) and is available in lengths of 18" or 30" cm and in 0.5m or 1.0m lengths. The pressure guide wire is packaged according to the connector with a tension device to facilitate navigation through the vessel.

CONTRAINDICATIONS

The pressure guide wire is not intended for use in any vessel or ostium.

ADVERSE EFFECTS

As with all catheterization procedures, complications may be encountered with the use of the pressure-sensing wire. The major risks of coronary angiography and coronary angiography include: dissection, perforation, embolus, spasm, local and/or systemic infection, pneumothorax, retroperitoneal injury, serious arrhythmia and death. The major risks of peripheral angiography or peripheral angiography include: dissection, abrupt closure, perforation, embolus, and spasm.

WARNING:

• Do not use pressure guide wire with a different connector than the one supplied, unless provided as a part of the package.
• Do not use the proximal (electrical contact) end of the pressure guide wire when inserted into the connector. Incorrect handling may damage or contaminate the internal components of the connector, which is critical for the proper use of the device.

PRECAUTIONS

• Do not use any product that has been damaged in any way. For such reasons, damage may be a result of incorrect use or usage of the pressure guide wire. The user should also be aware that the pressure guide wire is a sterile product and must be stored properly.

• When advancing the pressure guide wire into a stented vessel, it is important to avoid contact with the stent struts. If contact is made with the stent struts, the pressure guide wire may become entangled in the stent struts of the stent. This may result in repositioning of the pressure guide wire, leading to the pressure guide wire being removed from the system and/or dilated.

• If the pressure guide wire is advanced into a stented vessel, do not allow the wire to come in contact with any stent wire. Subsequent advancement of the wire could cause creation of defects in the wire and/or complete disconnection of the guide wire from the system.

• Use caution when removing the pressure guide wire from a stented vessel in order to prevent patient risk.

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NOTE: The modular plug remains connected to the instrument's connector to prevent separation of the connector and the pressure guide wire.

Removing Guide Wire from Connector

1. Insert the pressure guide wire into the connector. Ensure that the connector is not touching the patient's skin or the inside of the connector.
2. Pull the pressure guide wire slowly to ensure that the pressure guide wire is removed from the connector.

NOTE: The connector is pre-attached to the package for use in the individual guide wire that is connected to it and should not be used with any other guide wire.

- Use before date
- Authorized European representative:
- Volume Corporation

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NOTE: The wire is used exclusively for diagnostic or therapeutic procedures, and the connector for any other purpose than this.

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