The PrimeWire® PLUS Pressure Guide Wire is a steerable guide wire with a pressure transducer mounted on the tip. Its PrimeWire PLUS pressure wire measures pressure with a silicone, polyurethane, and silicone rubber in the external components, ensuring accuracy and durability. The major risks of perforating angioplasty include: dissection, abrupt closure, perforation, embolus, and spasm.

**WARNING:**

- Use of a PrimeWire Prestige PLUS guide wire with a different connector than the wire supplied may result in inaccurate pressure measurements.
- Do not pass the proximal (electrical connection) end of the guide wire disconnected from the connector. Excessive friction may damage or break the external components.
- Never abuse, torque, or insert a guide wire which may cause significant stress.
- This product is supplied sterile. If the pouch is opened or damaged compromising the sterile barrier, discard the product. This product contains sterile saline used.
- The PrimeWire PLUS Pressure Guide Wire is designed for single use only. Volcano Corporation ("VOLCANO") makes no warranty, representation or condition, whether expressed or implied (including, without limitation, any warranty of merchantability or fitness for a particular purpose), with respect to the product.

**INSTRUCTIONS FOR USE:**

- Open the PrimeWire PLUS guide wire packaging using sterile technique and place the spiral on the wire.
- With the wire remaining in the spiral, flush the distal end of the guide wire with heparin solution.
- With the wire in the spiral, remove the guide from the spiral by pulling the modular plug and connect the modular plug to the connector. For all operations refer to the proper Operator’s Manual.
- Verify the need for Blue PTFE coating on the entire end of the guide wire aligned with the connector nose and is extended to the locked position.
- After the wire has been inserted, carefully remove the connector body from the spiral and withdraw the guide wire from the spiral.
- The connector provided in the package is unique to the individual Guide Wire and is connected to and should never be used with another Guide Wire.
- In the event the Guide Wire is Not Positioned, outside the use of the connector, remove the Guide Wire, insert the Guide Wire back into the connector and the wire is seated in the external components and rotate the wire to the locked position.
- If it is required, the 3 mm disposable guide wire may be easily removed using standard disposable pliers. For best results use a disposable sharp tip to the direction of the sensor housing opening. This will not use a disposable shape coating with a blade edge.
- When threading the length of wire with normal saline and insert the PrimeWire PLUS pressure wire through the appropriate introducer components and guiding catheter into the desired blood vessel. Slowly advance the guide wire until it is flush against the vessel or when the device is resistance.
- Ensure that the tip is centered and no friction or resistance is felt upon torque or advancement.
- Locate the pressure sensor (3 mm from tip) adjacent to the tip of the guide catheter and perform manual manipulation with the instrument.
- Advance the sensor to desired measurement location and perform pressure measurements with the instrument.
- After each procedure withdraw the pressure sensor, just distal to the guide catheter tip, and verify equal pressure.

**Advise:**

- Insert the proximal end of the guide wire into the external components and advance through mild resistance until a positive stop is felt with the blue PTFE coating is approximately aligned with the ventricular position.
- With the wire distal end against the internal wall, insert the connector in the locked position.
- Ensure the connector snaps in the socketed position.
- Do not grasp the tip of the guide wire to remove it from the dispenser.

**PRECAUTIONS:**

- Decreased Mechanical Performance (including but not limited to torqueability and trackability).
- Additional precautions regarding this product should be directed to VOLCANO CORPORATION in the USA.

**CAUTION:**

- Do not use the product that has been implanted in any way as it may result in erroneous pressure measurements.
- Avoid all catheterization procedures, complications may be encountered with the use of the PrimeWire Prestige PLUS guide wire which may include:

  - Coronary vessel dissection, occlusion, perforation, embolus, spasm, and vessel wall injury
  - Pericardial effusion
  - Nerve damage
  - Depression of myocardium

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