INSTRUCTIONS FOR USE
PrimeWire Prestige® PLUS Pressure Guide Wire

CAUTIONS:
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.

INTENDED USE:
The PrimeWire Prestige PLUS Pressure Guide Wire is intended for use to measure pressure in blood vessels including both coronary and peripheral vessels, during drug and angioplasty procedures. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

DESCRIPTION:
The PrimeWire Prestige® PLUS Pressure Guide Wire is a straight guide wire with a pressure transducer located 3 cm from the tip. The PrimeWire Prestige PLUS guide wire is available in 14 gauge (0.018" outer diameter) and is available in lengths of 181 cm (360 cm, and also in straight or pre-shaped tips). The PrimeWire Prestige PLUS guide wire is a packaged product intended for use with a temporary device to facilitate navigation through the vascular system.

Note: Do not use open or damaged packages.

AUTHORISED USES:
As with all catheterisation procedures, compilations may be accompanied with the use of the PrimeWire Prestige PLUS guide wire. The major risks of coronary angioplasty and coronary angiography include:
- coronary vessel dissection, occlusion, perforation, emboli, spasm, local and systemic infection, pancreatitis, endovascular, sepsis and death.
- the major risks of peripheral angioplasty and peripheral angiography include:
- dissection, abrupt closure, perforation, emboli, spasm, and death.

WARNING:
• Do not use the PrimeWire Prestige PLUS guide wire with a different connector than the one supplied. The connector provided in the package is unique to the individual Guide Wire it is connected to and the nose is rotated to the locked position.
• Verify the end of the blue PTFE coating on the proximal end of the wire is aligned with the connector nose.
• When re-advancing the pressure guide wire into a stented vessel, at no time should the wire come in contact with one or more stent struts. Subsequent advancement of the wire could cause entanglement.
• Ensure the connector nose is in the unlocked position.
• Do not insert the catheter with the pressure guide wire into blood vessels with severe tortuosity or significant narrowing.

PRECAUTIONS:
• If the modular plug remains connected to the instrument, it is not required to repeat zeroing and normalization of the system’s operations refer to the proper Operator’s Manual.
• When recommendations are made for this product, multiple studies may be combined using a systematic review approach. Differences in the methods used to conduct each study are noted. Subsequent analysis of the pooled data indicates no difference in effectiveness of the guide wire, whenewire and stent are co-implanted to guide wire, when wire is sliding, and without stent.
• Do not flex the proximal (electrical connector) end of the guide wire when disconnected from the connector because bending can damage the internal components.
• Do not use open or damaged packages.

STORAGE AND HANDLING:
• Do not use open or damaged packages.

MATERIALS:
• This product is supplied sterile; if the pouch is opened or damaged compromising the sterile barrier, the device should not be used.
• If claims under this warranty become necessary, contact VOLCANO for instructions and issuance of a Return Material Authorization number if the Wire is to be returned. Equipment will not be accepted for warranty purposes unless the return has been authorized by VOLCANO.

LIMITED WARRANTY:
VOLCANO warrants that the PrimeWire Prestige PLUS Pressure Guide Wire (the "Wire"), as so delivered, shall materially conform to VOLCANO’s specifications for the period of time specified herein except for any period of time from the date of manufacture.” ANY LIABILITY OF VOLCANO WITH RESPECT TO THE WIRE OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, HARGUIGE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO REPLACEMENT OR, IF REPLACEMENT IS UNAVALABLE, AS A REMEDY ON VOLCANO’S OPINION, IMPAIRMENT, OR TO REFUND OF THE PRICE PAID FOR THE WIRE. EXCEPT FOR THE FOREGOING, THE WIRE IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF FITNESS, MERCHANTABILITY, AND FOR A PARTICULAR PURPOSE OF NON-INFRINGEMENT. FURTHERMORE, VOLCANO HEREBY DISCLAIMS ALL IMPLIED WARRANTIES, REPRESENTATIONS REGARDING THE USE, OR THE RESULTS OF THE USE, OR THE WRITING MATERIALS OR INSTRUMENTS IN CONNECTION WITH THE USE OF THE WIRE. VOLCANO DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND/OR FITNESS FOR A PARTICULAR PURPOSE.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO VOLCANO CORPORATION IN THE USA.

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Use Before Date
Do not use open or damaged packages

Use of this product requires knowledge of the patient’s condition and the procedure. When recommendations are made for this product, multiple studies may be combined using a systematic review approach. Differences in the methods used to conduct each study are noted. Subsequent analysis of the pooled data indicates no difference in effectiveness of this product.