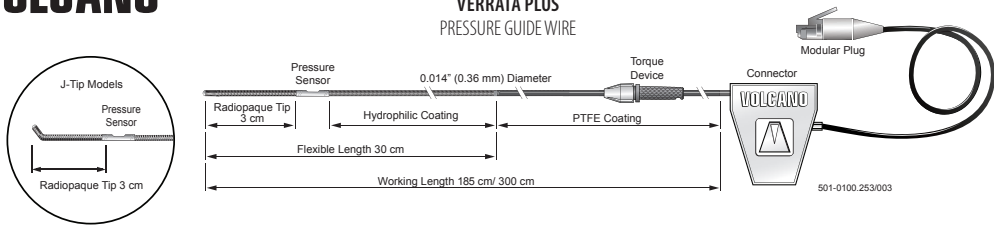




INSTRUCTIONS FOR USE  
VERRATA PLUS  
PRESSURE GUIDE WIRE

MODELS: 10185P/10185JP • 10300P/10300JP ENGLISH



**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.

**INDICATIONS FOR USE:**

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

**DESCRIPTION:**

The Verrata PLUS pressure guide wire (hereafter referred to as the "pressure guide wire") is a steerable guide wire with a pressure transducer mounted 3 cm proximal to the tip. The Verrata PLUS guide wire measures pressure when used with the SmartMap, ComboMap, s5 Series, and CORE Series of systems. The pressure guide wire has a diameter of 0.014" (0.36 mm) and is available in lengths of 185 cm or 300 cm\* and also in straight or pre-shaped tips. The pressure guide wire is packaged attached to the connector with a torque device to facilitate navigation through the vasculature.

\* Not available in all countries.

**CONTRAINDICATIONS:**

This pressure guide wire is not intended for use in crossing a total vessel occlusion.

**ADVERSE EFFECTS:**

**As with all catheterization procedures, complications may be encountered with the use of the pressure guide wire. The major risks of coronary angiography and coronary angioplasty include: coronary vessel dissection, occlusion, perforation, embolus, spasm, local and/or systemic infection, pneumothorax, myocardial infarction, serious arrhythmias and death. The major risks of peripheral angiography or peripheral angioplasty include: dissection, abrupt closure, perforation, embolus, and spasm.**

**WARNINGS:**

- Use of a pressure guide wire with a different connector than the one supplied may provide inaccurate pressure information.
- Do not flex the proximal (electrical connector) end of the pressure guide wire when not inserted in the connector. Excessive flexing can damage or break the internal components.
- Never advance, torque or retract a pressure guide wire which meets significant resistance.
- This product is supplied sterile. If the pouch is opened or damaged, compromising the sterile barrier, please discard the product. This product cannot be re-sterilized or re-used.
- The pressure guide wire is designed for single use only. Volcano Corporation ("VOLCANO") makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of the product.
- In addition, VOLCANO assumes no responsibility or liability for incidental or consequential damages which may result from such re-use. Re-use including re-sterilization of unused product may result in, but is not limited to the following:
  - Potential critical harm to patient due to device separation, material deformation or infection/sepsis;
  - Inaccurate pressure readings due to pressure sensor damage;
  - Decreased mechanical performance (including but not limited to torqueability and trackability).

**PRECAUTIONS:**

- Do not use product that has been damaged in any way as this may result in vessel damage, inaccurate pressure measurements and/or poor torque response.
- Do not grasp the tip of the pressure guide wire to remove it from the spiral.
- Do not withdraw or manipulate the blue PTFE-coated pressure guide wire in a metal cannula or sharp edged object.
- Always keep the connector bands at the proximal end of the pressure guide wire clean and dry.
- In both diagnostic and interventional procedures, clean pressure guide wire thoroughly with normal sterile heparinized saline before and after each insertion.
- The Volcano pressure guide wire should not be advanced if resistance is encountered. The wire should never be forcibly pushed into a vessel. Any time that resistance is encountered, the wire should be withdrawn under fluoroscopic guidance. In some instances, the wire may kink and must be removed.
- When advancing the pressure guide wire into a stented vessel, in the event that the stent is not fully apposed against the vessel wall, the pressure guide wire may become entangled in one or more stent struts. This may result in entrapment of the pressure guide wire, shredding of the pressure guide wire and/or stent dislocation.
- When re-advancing the pressure guide wire into a stented vessel, do not allow the wire to come in contact with any stent struts. Subsequent advancement of the wire could cause entanglement between the wire and the stent(s) resulting in entrapment of guide wire, guide wire shredding, and/or stent dislocation.
- Use caution when removing the pressure guide wire from a stented vessel to minimize patient risk.

**INSTRUCTIONS FOR USE:**

**Preparation For Use**

- Open the pressure guide wire packaging using sterile technique and place the tray on the sterile field.
- Prepare the guide wire for use following the numbers on the tray:
  1. Flush wire: Flush the guide wire with normal sterile heparinized saline (labeled #1) using the wire flush port on the spiral.
  2. Zero wire: Lift the flap in the center of the tray (labeled #2) flap and withdraw the cable. Connect the plug to a compatible instrument. This will automatically zero the guide wire. For system's operations refer to the proper Operator's Manual.
  3. Remove product from tray: Lift the flap on the right side of the tray (labeled #3) and Use the opening on the underside of the tray to assist with connector removal. Grasp the connector with thumb on top and a finger through the opening on the underside of the tray. Carefully lift the connector from the tray and slide the wire out of the spiral. Place wire and connector on the sterile field.

**NOTE:** When withdrawing the wire from the spiral, keep the connector and wire in the same plane to avoid kinking the wire.
- If indicated, the 3 cm shapeable guide wire tip may be carefully shaped using standard tip shaping practices. For best results, shape the tip in the direction of the sensor housing opening. DO NOT use a shaping instrument with a sharp edge.
- Wet the working length of the guide wire with normal sterile heparinized saline, and insert the pressure guide wire through the appropriate introducer components and guiding catheter into the desired blood vessel. Slowly advance the guide wire tip under fluoroscopy using contrast injections to verify location.
- Ensure that the tip is rotating freely and no resistance is felt when torque is applied.
- Position the pressure sensor (located 3 cm from tip) adjacent to the tip of the guide catheter and perform normalization procedure with the instrument. For system's operations refer to the proper Operator's Manual.
- In the event the guide wire is "Not Recognized", retract connector cover and realign the guide wire.
- Advance the pressure sensor to desired measurement location, and perform pressure measurements with the instrument.
- After every procedure, withdraw the guide wire until the pressure sensor is just distal to the guide catheter tip. Verify that the pressures measured by the guide wire and the guide catheter are equal.

**Removing Guide Wire from Connector**

- The pressure guide wire may be disconnected from the connector to facilitate wire maneuverability and to allow advancement of catheters and other components over the proximal end of the wire.

**NOTE:** If the modular plug remains connected to the instrument, it is not required to repeat zeroing and normalization.

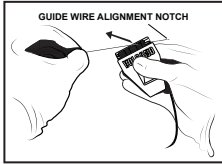
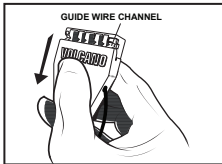
**NOTE:** The connector provided in the package is unique to the individual guide wire it is connected to and should not be used with any other guide wires.
- To remove the guide wire, retract the connector cover and carefully lift the proximal end of the wire from the guide wire channel.
- If desired, loosen the torque device and withdraw it from the proximal end of the guide wire.

**Catheter Insertion**

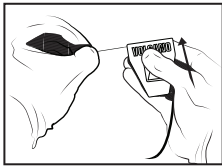
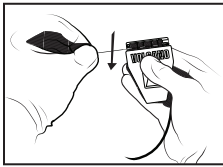
- Clean the proximal end of the guide wire with normal sterile heparinized saline.
- Thread catheter over guide wire taking care not to kink the proximal contact bands of the wire.
- Flush catheter with normal sterile heparinized saline.

**Attaching Pressure Guide Wire to Connector**

- Install the included torque device over the proximal end of the pressure guide wire. *The connector cannot be used to effectively torque the guide wire as the wire rotates freely inside the body of the connector.*
- Clean the proximal end of the guide wire with normal sterile heparinized saline. Dry the proximal end of the guide wire with a clean, dry cloth.
- Retract the connector cover to expose the guide wire channel.
- Hold the guide wire at a slight angle to the connector and place it in the channel with approximately 0.5 inches (1.3 cm) of the guide wire protruding from the connector.
- Maintaining the angle, slide the guide wire through the channel until the guide wire alignment notch catches. This will align the guide wire.



- Lower the guide wire into the channel.



- Close the connector cover to lock the guide wire in place.

- A pressure signal will now be present on the display instrument. It is not required to repeat zeroing and normalization as long as the modular connector has not been removed from the instrument.
- When the procedure is completed, remove and discard the pressure guide wire and connector in accordance with local regulations.

**STORAGE AND HANDLING:**

Products should be stored in a dry, dark, cool place in their original packaging.

**LIMITED WARRANTY:**

Subject to the conditions and limitations on liability stated herein, Volcano Corporation ("VOLCANO") warrants that the Verrata PLUS pressure guide wire (the "Wire"), as so delivered, shall materially conform to VOLCANO'S then current specification for the Wire upon receipt for a period of one year from the date of delivery. **ANY LIABILITY OF VOLCANO WITH RESPECT TO THE WIRE OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO WIRE REPLACEMENT OR, IF REPLACEMENT IS INADEQUATE AS A REMEDY OR, IN VOLCANO'S OPINION, IMPRACTICAL, TO REFUND OF THE FEE PAID FOR THE WIRE.**

**EXCEPT FOR THE FOREGOING, THE WIRE IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF FITNESS, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE OF NONINFRINGEMENT. FURTHER, VOLCANO DOES NOT WARRANT, GUARANTEE, OR MAKE ANY REPRESENTATIONS REGARDING THE USE, OR THE RESULTS OF THE USE, OF THE WIRE OR WRITTEN MATERIALS IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, OR OTHERWISE.** Licensee understands that VOLCANO is not responsible for and will have no liability for any items or any services provided by any persons other than VOLCANO. VOLCANO shall have no liability for delays or failures beyond its reasonable control. Additionally, this warranty does not apply if:

1. The Wire is used in other than a manner described by VOLCANO in the Instructions For Use supplied with the Wire.
2. The Wire is used in a manner that is not in conformance with purchase specifications or specifications contained in the Instructions For Use.
3. The Wire is re-used or re-sterilized.
4. The Wire is repaired, altered, or modified by other than VOLCANO authorized personnel or without VOLCANO authorization.

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.

PATENT [www.volcanocorp.com/patents.php](http://www.volcanocorp.com/patents.php)

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This product is licensed to the customer for single use only.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO VOLCANO CORPORATION IN THE U.S.A.:

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(916) 638-8008  
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|----------------------------|--------------------------------------------|
| <b>Use Before Date</b>     | <b>Do not use open or damaged packages</b> |
| <b>Content: One (1)</b>    | <b>Prescription Only</b>                   |
| <b>Single Use Only</b>     | <b>Sterilized using Ethylene Oxide</b>     |
| <b>Do not Re-Sterilize</b> | <b>Store in a dry, dark, cool place</b>    |
| <b>Nonpyrogenic</b>        | <b>Not made with Natural Rubber Latex</b>  |