COMBOWIRE®
PRESSURE/FLOW GUIDE WIRE
REF 9500 SERIES
COMBOWIRE® 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.

INTENDED USE:
The ComboWire® Pressure/Flow Guide Wire is indicated for use to measure simultaneous pressure and blood flow in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures.

Blood pressure measurements and blood flow velocity measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

DESCRIPTION:
The ComboWire is a steerable guide wire with a pressure transducer mounted proximal to the tip and a tip mounted ultrasound transducer. The ComboWire measures pressure and flow velocity when used with the ComboMap® Instrument. The ComboWire is available in a diameter of 0.014" (0.36 mm) with a length of 185 cm. The ComboWire is packaged preconnected to the connector with a torque device to facilitate navigation through vasculature.

CONTRAINDICATIONS:
This guide wire is not intended for use in crossing a total vessel occlusion. Refer to the device instructions for use and product labeling for any additional product specific contraindications which may apply.

ADVERSE EFFECTS:
As with all catheterization procedures, complications may be encountered with the use of the ComboWire. 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 ComboWire with a different Connector than the one supplied may provide inaccurate pressure and/or flow information.
- Do not flex the proximal (electrical connector) end of the ComboWire when disconnected from the Connector. Excessive flexing can damage or break the internal components.
- Never advance, torque, or retract a 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. This product 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 reuse. Re-use may result in, but is not limited, to the following:
  - Device Separation
  - Transducer Damage
  - Inaccurate Readings
  - Decreased Mechanical Performance (including but not limited to torquability and trackability)

PRECAUTIONS:
- Do not use product, which has been damaged in any way; which may result in vessel damage, inaccurate pressure and/or flow measurements and/or poor torque response.
- Do not grasp the tip of the guide wire to remove it from the dispenser.
- Do not withdraw or manipulate the PTFE-coated guide wire in a metal cannula or sharp edged object.
- Always keep the connector bands at the proximal end of the guide wire clean AND dry.
- In both diagnostic and interventional procedures clean guide wire thoroughly with heparinized saline before and after each insertion.
- The Volcano functional measurement (pressure or flow) wire should not be advanced if resistance is encountered. The wire should never be forcibly pushed into a vessel. Anytime that resistance is encountered, the wire should be withdrawn under fluoroscopic guidance. In some instances, the wire may kink and must be removed.

INSTRUCTIONS FOR USE:
Initial Use
Open the product packaging using sterile technique and place the spiral on the sterile field.

Place ComboMap PIM in sterile plastic sleeve or towel to locate PIM within sterile field.

With the wire in the spiral, remove the cables from the spiral by pulling on the plugs and connect to compatible Instrument. For system’s operations refer to the proper Operator’s Manual.

Verify the end of the blue PTFE coating on the proximal end of the wire is aligned with the connector nose and the nose is rotated to the locked position.

After the wire has been zeroed, 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 it is connected to and should not be used with any other Guide Wires.

In the event the Guide Wire is “Not Recognized”, unlock the nose of the connector, remove the Guide Wire, insert the Guide Wire back into the connector until the wire is seated against the internal wire stop and rotate the nose to the locked position.

If indicated, 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 saline and insert 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. Torque is approximately a one-to-one ratio.

Locate the pressure sensor (1.5 or 0.0 cm from tip) adjacent to the tip of the guide catheter and perform normalization procedure with the instrument.

Advance guide wire tip to desired measurement location. Doppler flow velocity is measured approximately 5 mm from the tip. The pulsed doppler beam angle is 45 degrees and insonifies a maximum diameter of approximately 4 mm.

Manipulate guide wire tip to insonify peak velocities and adjust instruments spectral display.

Perform pressure and/or flow velocity measurements with the instrument.

After every procedure withdraw the pressure sensor, just distal to the guide catheter tip, and verify equal pressure.

**Connector Removal**

The connector may be disconnected from the guide wire to facilitate the advancement of the catheters or other components over the proximal end of the wire.

Note: If the pressure plug remains connected to the Instrument, repeat zeroing and normalization is not required.

To remove the connector, rotate the connector nose to the unlocked position and withdraw the proximal end of the guide wire from the connector.

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

**Connector Attachment**

- Install the included torque device over the proximal end of the guide wire. The connector cannot be used to effectively torque the guide wire as the internal lock rotates inside the body of the connector. Clean the proximal end of the guide wire with the heparinized saline.
- Dry the proximal end of the guide wire with a clean, dry cloth.
- Ensure the connector nose is in the unlocked position.

- Insert the proximal end of the guide wire into the small hole in the end of the nose and advance through mild resistance until a positive stop is felt and the blue PTFE coating is approximately aligned with the nose.
- With the end of the wire seated against the internal wire stop, rotate the nose to the locked position.

A pressure signal will now be present on the display instrument. Repeat zeroing and normalization are not required as long as the modular connector has not been removed from the instrument.

When the procedure is completed, remove and discard the Wire and Connector.

**STORAGE AND HANDLING:**

Store in a cool, dry place.

**LIMITED WARRANTY:**

Subject to the conditions and limitations on liability stated herein, Volcano Corporation ("VOLCANO") warrants that the ComboWire (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.

This product, and the use thereof, may be covered by one or more of the following U.S. and international patents: 5163445; 5271404; 5348481; 5358409; 5413508; 5581144; 5668320; 5715827; 5743956; 5797856; 6025670; 6041862; 6106476; 6265792; 6585660; 6663570; 6767327; 6978965; 7097620; 7134994; 7274956; DE P6911406.2; DE P6941888.3; EP 0466424; EP 0726243; EP0778746; EP 0828164; JP 3235839; JP 3313723; JP 3619845; JP 3624200; JP4259880. Other U.S. and international patents pending.

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ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

Manufactured By:
Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670 USA
(800) 228-4728 (916) 638-8008 (916) 638-8112 fax
www.volcanocorp.com

Authorized European Representative:
Volcano Europe BVBA/SPRL
Excelsiorlaan 41
B-1930 Zaventem Belgium
+32.2.679.1076 +32.2.679.1079

STERILE EO
Sterilized with EtO

Each device is for one (1) use only

Read instructions prior to use

Keep cool

Keep dry

Instructions For Use visit
www.volcanocorp.com

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