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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.

INDICATIONS FOR USE:

The VISIONS PV .014P RX Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The VISIONS PV .014P RX Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

DESCRIPTION:

The VISIONS PV .014P catheter incorporates a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The VISIONS PV .014P catheter utilizes an internal lumen that allows the catheter to track over the 0.014" (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The catheter is introduced percutaneously or via surgical cutdown into the vascular system.

Three 1 mm-long radiopaque markers are incorporated on the internal lumen positioned 10 mm apart from distal edge to distal edge, starting 10 mm from the proximal edge of the portion of the scanner marker tube normally visible under fluoroscopy.

The VISIONS PV .014P catheter may only be used with Volcano sS Series and CORE Series of Systems. This catheter will not operate if connected to any other imaging system.

CONTRAINDICATIONS:

The VISIONS PV .014P Digital IVUS Catheter is generally contraindicated in situations presenting a reasonable probability of tissue or organ damage. This device is not currently indicated for use in cerebral vessels.

ADVERSE EFFECTS:

Possible adverse effects include, but are not limited to, the following: myocardial infarction; occlusion; coronary vessel dissection; perforation, rupture or injury; restenosis; hemorrhage or hematoma; unstable angina; arrhythmias; drug reactions; allergic reaction to contrast medium; hypo/hypertension; infection; vessel spasm; arteriovenous fistula; embolism; entry puncture site bleeding; vascular wall injury; vessel thrombosis; pseudoaneurysm (at site of catheter insertion); renal failure; coronary aneurysm; vessel trauma requiring surgical repair or intervention, death.

WARNINGS:

- Use of the VISIONS PV .014P catheter should be restricted to specialists who are familiar with, and have been trained to perform, the procedures for which this device is intended.
- The 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 VISIONS PV .014P catheter 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 catheter.
- In addition, VOLCANO assumes no responsibility or liability for incidental or consequential damages which may result from such re-use. Re-use including resterilization 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
 - Failure to Image or other device malfunctions
- The catheter transducer is a delicate electronic assembly, deliberate misuse by bending, twisting or any other severe physical manipulation will void the warranty.
- Do not use the device for purposes other than those indicated.
- The device may not be safe in those patients who cannot be properly anticoagulated or who cannot receive anti-platelet or anti-coagulation therapies.

PRECAUTIONS:

The VISIONS PV .014P device is a delicate scientific instrument and should be treated as such. Always observe the following precautions:

- Prior to use, carefully inspect the scanner and catheter body for bends, kinks or other damage. Do not use a damaged or suspected damaged catheter.
- Protect the catheter tip from impact and excessive force.
- Do not cut, crease, knot, or otherwise damage the catheter.
- Protect the electrical connections from exposure to fluid.
- Do not handle the transducer.
- The outside diameter along the entire length of the guide wire should not exceed the maximum specified.
- During use, ensure that the placement of the catheter does not preclude blood flow through the vessel.
- Clean guide wire and flush catheter thoroughly with heparinized saline before and after each insertion.
- When inserting the guide wire both catheter and wire must be straight with no bends or kinks, or damage to inner lumen may occur.
- Do not advance the guide wire against significant resistance. If binding occurs between the catheter and the guide wire while inside the patient, CAREFULLY REMOVE BOTH the wire and catheter and do not use. If binding occurs outside of the patient, remove the catheter and do not use.
- The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis.
- During the procedure, provide appropriate anticoagulation to the patient as needed.
- When advancing or re-advancing the catheter over a guide wire and through a stented vessel, in the event that the stent is not fully apposed against the vessel wall, the guide wire / and or catheter may become entangled in the stent between the junction of the catheter and guide wire or within one or more stent struts. This may result in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation. Never use force to advance the catheter.
- Use caution when re-advancing a catheter over a guide wire and into a stented vessel. Forceful advancement of the IVUS catheter could cause entanglement between the catheter and the stent(s) resulting in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation.
- Use caution when removing the catheter over the guide wire from a stented vessel to minimize patient risk.
- If resistance is encountered during pullback, remove the entire system (guide wire, IVUS catheter, sheath/guide catheter) at the same time.

INSTRUCTIONS FOR USE:

The VISIONS PV .014P catheter may be introduced into the vascular system percutaneously or surgically and advanced to the desired location. The frequency and duration of administration is subject to the discretion of the physician and depends upon the procedure and information required.

- Review the Volcano Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to the use.
- If using VH IVUS, review the Volcano Imaging System Operator's Manual prior to use.
- Remove the VISIONS PV .014P catheter from its sterile packaging when in a sterile field.
- Remove the stylet.
- Attach the flushing device to a 10 cc or larger syringe filled with heparinized normal saline. Insert the distal tip of the catheter into the device. Inject the saline into the lumen. Fluid should be observed flowing out of the Guide Wire Exit Port.
- Remove the clear/white cap from the PIM connector (if applicable).
- Connect the PIM connector of the VISIONS PV .014P catheter to the Patient Interface Module as described in the Volcano Imaging System Operator's Manual. Verify that the device is imaging.
- Place the VISIONS PV .014P catheter onto the intravascular catheter guide wire which has been previously positioned into the artery. A guide wire of 0.014" (0.36 mm) or smaller can be used.
- Advance the catheter over the guide wire to the site of the vasculature to be imaged.

- Check the Monitor for an image. Once the image has been obtained, the catheter can be advanced over the guide wire to image additional segments of vasculature.
- If an image is not obtained or is not satisfactory, consult the Volcano sS Series or CORE Series of Systems Operator's Manual.
- When the procedure is completed, remove and discard the catheter in accordance with local regulations.

STORAGE AND HANDLING:

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

PRODUCT SPECIFICATIONS:

Model	VISIONS PV .014P
Crossing profile at transducer	3.5F (0.046", 1.17 mm)
Maximum guide wire	0.014" (0.36 mm)
Minimum guide catheter O.D.	5F (0.066" 1.67 mm)
Minimum guide catheter I.D.	0.056", 1.42 mm
Usable length	150 cm

Acoustic Output Parameter	B-Mode	Chromafo
ISPTA.3 (mW/cm ²)*	2.93x10 ⁻³	7.98x10 ⁻²
ISPPA.3 (W/cm ²)*	7.5x10 ⁻³	175.0x10 ⁻³
Pr.3 (MPa)	20.0x10 ⁻³	81.5x10 ⁻³
PD (µs)	161.0x10 ⁻³	125.0x10 ⁻³
PRF (Hz)	53760	75368
Center Freq (MHz)	18.6	17.9
MI**	4.5x10 ⁻³	1.92x10 ⁻²
TI**	2.06x10 ⁻⁵	1.56x10 ⁻⁴

* Maximum overall uncertainty + 33.9% / - 30.5%

** As estimated in tissue

TI: Thermal Index defined as $TI = \frac{W_{0.1x1t}}{210}$

W_{0.1x1}: Bounded-square Output (mW)

f_c: Center Frequency (MHz)

MI: Mechanical Index defined as $MI = Pr.3 / (f_c^{1/2})$

ISPPA.3: Derated Intensity, Spatial Peak Pulse Average (W/cm²)

ISPTA.3: Derated Intensity, Spatial Peak Temporal Average (mW/cm²)

Pr.3: Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral (MPa)

W₀: Total Power (mW)

PD: Pulse Duration (µs)

PRF: Pulse Repetition Frequency (Hz)

LIMITED WARRANTY:

Subject to the conditions and limitations on liability stated herein, VOLCANO Corporation ("VOLCANO") warrants that the VISIONS PV .014P catheter (the "Catheter"), as so delivered, shall materially conform to VOLCANO'S then current specification for the Catheter upon receipt for a period of one year from the date of delivery. ANY LIABILITY OF VOLCANO WITH RESPECT TO THE CATHETER OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO CATHETER REPLACEMENT OR, IF REPLACEMENT IS INADEQUATE AS A REMEDY OR, IN VOLCANO'S OPINION, IMPRACTICAL, TO REFUND OF THE FEE PAID FOR THE CATHETER. EXCEPT FOR THE FOREGOING, THE CATHETER 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 NON-INFRINGEMENT. FURTHER, VOLCANO DOES NOT WARRANT, GUARANTEE, OR MAKE ANY REPRESENTATIONS REGARDING THE USE, OR THE RESULTS OF THE USE, OF THE CATHETER 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 Catheter is used in a manner other than described by VOLCANO in the Instructions For Use supplied with the Catheter.
2. The Catheter is used in a manner that is not in conformance with purchase specifications or specifications contained in the Instructions For Use.
3. The Catheter is re-used or re-sterilized.
4. The Catheter 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 Catheter 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

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

VISIONS is a registered trademark of Volcano Corporation in the United States and other countries.

Volcano and the Volcano logo are trademarks of Volcano Corporation and are registered in the United States and other countries.

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

Legal Manufacturer:

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Manufacturing Sites:

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Telephone: (800) 228-4728
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Use Before Date	Do not use open or damaged packages
Content: One (1)	Prescription Only
Single Use Only	Sterilized using Ethylene Oxide
Do not Re-Sterilize	Store in a dry, dark, cool place
Nonpyrogenic	Not made with Natural Rubber Latex