### Limitations and Precautions

**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 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.

**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; pseudoneurysm (at site of catheter insertion); renal failure; coronary aneurysm; vessel trauma requiring surgical repair or intervention, death.

**PREPARATIONS:**

- 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.
- 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.

**EXAMINATION:**

- **CAUTION:**
  - U.S. Federal Law restricts this device to sale by or on the order of a physician.
  - Prior to use, read this entire package insert.

**INDICATIONS FOR USE:**

The VISIONS PV .014P 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. The device is not currently indicated for use in central vessels.

**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.

**CONTRAINdications:**

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

**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 (0.064", 1.17 mm)
- **Maximum guide wire:** 0.014" (0.36 mm)
- **Minimum guide catheter O.D.:** 5F (0.086", 1.67 mm)
- **Minimum guide catheter I.D.:** 0.050", 1.42 mm
- **Usable length:** 150 cm

**Acoustic Output Parameter**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>B-Mode</th>
<th>ChromoTime</th>
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</thead>
<tbody>
<tr>
<td>Fumax (MHz)</td>
<td>7.9 x 10^{-2}</td>
<td>7.9 x 10^{-2}</td>
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<tr>
<td>Fmax (MHz)</td>
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<tr>
<td>PS (MPa)</td>
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<td>PD (mW)</td>
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<td>PRF (Hz)</td>
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<td>Center Freq (MHz)</td>
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<td>17.9</td>
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<tr>
<td>MV**</td>
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<tr>
<td>TV**</td>
<td>2.06 x 10^{-3}</td>
<td>1.15 x 10^{-3}</td>
</tr>
</tbody>
</table>

* Maximum overall uncertainty + 33.9% ~ 30.5%
** As estimated in tissue

**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 NONINFRINGEMENT. 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: Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670 USA
Telephone: (800) 228-4728
(916) 638-8008
Fax: (916) 638-8112

Manufacturing Sites:
Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670 USA
Or
Volcarica S.R.L.
Coyol Free Zone and Business Park
Building B17
Coyol, Alajuela, Costa Rica
Telephone: (800) 228-4728
(916) 638-8008
Fax: (916) 638-8112

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

www.volcanocorp.com