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 Instructions For Use.

INTENDED USE:
The Crux® VCF is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava (IVC) in the following situations:

• Pulmonary thromboembolism when anticoagulants are contraindicated
• Failure of anticoagulant therapy in thromboembolic diseases
• Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
• Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Crux® VCF may be removed according to the instructions contained in the section “Optional Retrieval of the Crux® VCF” in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard endovascular techniques for placement of vascular access sheaths, angiographic catheters and guidewires should be employed.

DESCRIPTION:
The Volcano Corporation Crux® Vena Cava Filter (Crux® VCF) is an endovascular medical device used in the prevention of recurrent pulmonary embolism (PE). The Crux® VCF Filter consists of a self-expanding nitinol filter delivered via a one-time-use disposable delivery catheter.

The filter is composed of two opposing, self-expanding nitinol wireforms and features cranial and caudal retrieval tails. Each retrieval tail has an atraumatic tip and a radiopaque tantalum marker band to facilitate visualization during retrieval. Five tissue anchors (2 cranial and 3 caudal) are attached to the wireforms. The clot trapping portion of the filter is formed from a web of ePTFE filaments attached to the wireforms using PTFE/FEP tubing. The Crux® VCF comes in two pre-loaded configurations for delivery of the filter by a femoral approach or a jugular approach. See Figure 1 and Figure 2 for further detail about the product.

The delivery catheter for the Crux® VCF is a disposable, 9Fr introducer-sheath-compatible, single-use device (see Figure 2). It is an 0.035” guidewire-compatible over-the-wire catheter and consists of a polycarbonate inner shaft and a nylon outer shaft. The inner shaft consists of the guidewire lumen and a flexible, radiopaque tracking tip. The outer shaft has a radiopaque distal marker band, a Tuffy-Borst hemostasis valve and a one-way check valve for flushing. The filter can be retrieved using commercially available snares and sheaths.

CONTRAINDICATIONS:
Filter Placement
• Average or Max Diameter of the IVC > 28 mm
• Diameter of the IVC < 17 mm
• Vena cava filters should not be implanted in patients with risk of septic embolism

Optional Filter Retrieval
• Retrieval of the filter with significant thrombus in or near the filter
• Retrieval of the filter for patients with an ongoing high risk for pulmonary embolism.

WARNINGS:
Filter Placement
• Do not deploy the filter unless the IVC has been properly measured using imaging.
• The Crux® VCF consists of nickel-titanium alloy which is generally considered safe. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies.
• All device manipulations should be under fluoroscopic guidance. Never advance or manipulate the devices or any accessories during deployment or retrieval without fluoroscopic guidance.
• Excessive force should not be used to place the filter.
• The Crux VCF is only intended for filter delivery via the femoral or jugular approach.
• Do not attempt to deliver the filter if large thrombus is present at targeted delivery site.
• Do not reuse, re-sterilize or reprocess. Impairment of structural integrity or function may result from reuse, re-sterilization or reprocessing of the device, possibly leading to adverse patient reactions.
• The filter may be positioned prior to drawing back the outer shaft or with only the first retrieval tail released from the outer shaft. Do not attempt to reposition or re-sheath the filter once you have passed this point.
• Filter fractures are a known complication of vena cava filters. There have been reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
• The movement, migration and/or tilt are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal filter migration. Migration may be caused by placement in IVCs with diameters exceeding the dimensions specified in the IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burden.
• Implantation of the Crux VCF can be done by either the Femoral (REF 7024) or Jugular (REF 7025) approach. Ensure you select the correct product for the intended approach.
• Do not disassemble the device. If any components are disassembled, do not reassemble for deployment.
• After use, the Crux VCF and accessories should be treated as a biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local state and federal laws and regulations.

**Optional Filter Retrieval**

• Excessive force should not be used to retrieve the filter.
• Do not remove the Crux VCF if thrombus is trapped within the filter.
• After filter implantation, any catheterization procedure requiring passage of a device may be impeded.

**PRECAUTIONS:**

• Possible allergic reactions should be considered. The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
• The decision to use any IVC filter must ultimately be made by the physician on an individual patient basis.
• Standard techniques for placement of vascular access sheaths, angiographic catheters and guidewires should be employed.

**Filter Placement**

- The Crux VCF is specific for a femoral or jugular vein approach.
- Maintain guidewire position, with anatraumatic, non-J guidewire tip preceding the delivery catheter while advancing.
- If the filter is deployed in an incorrect position or orientation, consider immediate retrieval using the Optional Filter Retrieval procedures. Do not reposition a deployed filter.
- The filter may foreshorten as it is deployed. Consider this when positioning the filter during the deployment procedure. For reference only see Table 1.
- Anatomical variances may complicate filter insertion and deployment.
- Do not abort deployment or re-sheath once filter deployment has been initiated.

**Optional Filter Retrieval**

- An inferior vena cavaogram evaluation for thrombus should be performed prior to attempted retrieval.
- Do not attempt retrieval if thrombus is present in the filter and/or caudal to the filter.
- Never redeploy a retrieved filter.
- Anatomical variances may complicate the removal procedure.
- The decision to remove a filter should be based on the patient’s individual risk/benefit profile. Retrieve the filter as soon as feasible and clinically indicated.

**NOTE:** The safety and effectiveness of the Crux VCF has been established for the cohort studied under the clinical investigation and has not been established for pediatric patients, pregnant females or suprarenal placement.

Standard and guidelines developed by the Society of Interventional Radiology recommend that patients with filters, permanent or retrievable, are tracked and should receive follow up visits subsequent to the placement of the filter. FDA recommends that implanting physicians responsible for the ongoing care of patients with retrievable IVC filters should consider removing the filter as soon as it is no longer needed. FDA encourages all physicians involved in the treatment and care of IVC filter recipients to consider the risks and benefits of filter removal for each patient.

**SOURCE:**

- 2012 American College of Radiology ACR Appropriateness Criteria™
- The Participants in the Vena Cava Filter Consensus Conference. J. Vasc Interv Radiol 2003; 14:S427-S432

**HOW SUPPLIED:**

- The Crux VCF is sterilized using ethylene oxide gas in peel-open packages, and is non-pyrogenic.
- The Crux VCF is sterile if package is unopened and undamaged.
MRI COMPATIBILITY:
Non-clinical testing has demonstrated that the Crux VCF is MR Conditional. Patients with a Crux vena cava filter can be scanned safely, immediately after implantation, under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 25 T/m (2,500 G/cm).
- Maximum specific absorption rate (SAR) of 2 W/kg in normal operating mode for 15 minutes of scanning at 1.5T and 3.0T.

3.0T RF Heating
In non-clinical testing with body coil excitation, the Crux vena cava filter produced a maximal differential temperature rise of 4.5°C at a maximum specific absorption rate (SAR) of 3.4 W/kg for 15 minutes of scanning in a 3.0-Tesla MR system (Siemens Tm, SYNGO MR A30 4V/3A0A software, Munich, Germany). Scaling of the SAR and observed heating indicates that a SAR of 2 W/kg would be expected to yield a localized temperature rise of 2.6°C.

1.5T RF Heating
In non-clinical testing with body coil excitation, the Crux vena cava filter produced a maximal temperature rise of 3.5°C at a maximum specific absorption rate (SAR) of 1.6 W/kg for 15 minutes of scanning in a 1.5-Tesla MR system (Siemens Espree, SYNGO MR B15 software, Munich, Germany). Scaling of the SAR and observed heating indicates that a SAR of 2 W/kg would be expected to yield a localized temperature rise of 4.4°C.

CAUTION: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifacts
In gradient and spin echo sequences, the image artifact extends approximately 8 mm from the Crux vena cava filter. It may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

OTHER:
Magnetically induced displacement force and torque testing indicated that the implant posed no known risks from magnetically induced displacement or force when subjected to the MR environment described in the conditions above:

Possible adverse effects associated with IVC filters include, but are not limited to, the following: arrhythmia, arteriovenous fistula, back or abdominal pain, contrast media extravasation at time of vena cavaogram, death, deep vein thrombosis, delivery system detachment or embolization, emboli (air, thrombotic or tissue), filter expansion failure, filter or device entanglement, fever, filter fracture, filter thrombosis or occlusion, filter malpositioned, mis-oriented or compressed, filter migration, filter embolization, guidewire entrapment, hematoma or nerve injury at the puncture site or subsequent retrieval site, hemorrhage with or without transfusion, hemothorax, inability to retrieve filter, infection, intimal tear, occlusion of small vessels, organ injury, pain or discomfort, perforation or other acute or chronic damage of the IVC wall, phlegmasia cerulea dolens, pneumothorax, post phlebitis syndrome, pulmonary embolism (recurrent or new), renal injury or failure, restriction of blood flow, stenosis at implant site, stroke, thrombosis, venous ulceration, vessel dissection, perforation, ulceration or rupture, vessel spasm.

CLINICAL STUDIES:
A multinational investigational study was conducted to assess the safety, performance and effectiveness of the Crux VCF as both retrievable and permanent device. The study was a prospective single-arm comparing the results to a pre-established performance goal. The primary endpoint was Clinical Success defined as a composite of technical success, and freedom from pulmonary embolism, migration or a device related adverse event requiring intervention. The study hypothesis of Clinical Success would be met if the lower limit of the one-sided 95% confidence interval was not below 80%.

Table 1 - Subject Accountability for the Crux Vena Cava Filter Study

<table>
<thead>
<tr>
<th>Time from Implantation to Retrieval</th>
<th>Eligible for Visit</th>
<th>Death</th>
<th>Lost to Follow-up</th>
<th>Retrieved</th>
<th>Not Due For Next Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>125</td>
<td>6</td>
<td>0</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>30 Days</td>
<td>105</td>
<td>6</td>
<td>1</td>
<td>16</td>
<td>2^</td>
</tr>
<tr>
<td>90 Days</td>
<td>70</td>
<td>2</td>
<td>1</td>
<td>16</td>
<td>2^</td>
</tr>
<tr>
<td>180 Days</td>
<td>49</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

1 Per protocol, two subjects entered at 30 days due to no implant (technical failures)
2 There was an additional withdrawal post retrieval for one subject which does not show up on this table.
N/A=Not applicable.

Figure 3 - Filter Time from Implantation to Retrieval. Average time to retrieval was 85 ± 58 days.

Subject Accountability for Crux Vena Cava Filter Study

One hundred and twenty-five (125) subjects at high risk for pulmonary embolism (PE) were enrolled. Of the 125, 73 (58%) male and 52 (42%) female were included with a mean age of 59.6 ± 17.2. The primary three reasons for filter implant were surgical risk (36%), presence of DVT (15%), and contraindication to anticoagulation (14%). The four primary thromboembolic risk factors were overall, thromboembolic risk factors DVT at baseline (58.4%), history of DVT (49.6%), contraindication to anticoagulation (37.6%) and history of PE (36.8%). All subjects had one or more thromboembolic risk factors.

During the course of the study, no embolization, migration or fractures were observed. Three subjects had pulmonary embolisms...
There were 8 subjects with thrombus observed in or near the filter (6%), primarily at retrieval evaluations, no subjects were symptomatic. The primary endpoint of Clinical Success was 96.0% (91.8% lower one-sided 95% CL exceeding the 80% Lower Limit). Retrieval success was 53/54 (98%) average time to retrieval was 85 + 58 days with 1 radiographic anomaly observed with no clinical sequelae. The clinical trial demonstrated the safe deployment, implant and retrieval of the filter. Technical and retrieval success are shown to be high, with a low rate of device related complications. The observed rates of filter migration and pulmonary embolization were consistent with published literature. For additional information on subject disposition (see Table 2).

**INSTRUCTIONS FOR USE:**

### For Deployment
- Standard micro-puncture set or seldinger needle to obtain percutaneous access
- 9F short introducer sheath if desired
- 0.035" (outer diameter) guidewire with a minimum length of 180 cm
- Angiographic catheter

### For Retrieval
- Standard micro-puncture set or seldinger needle to obtain percutaneous access
- 0.035" (outer diameter) guidewire with a minimum length of 180 cm
- Angiographic catheter
- 6F x 90cm tip sheath
- 10F x 80cm tip sheath

**Preparing the Crux VCF (Femoral REF 7024 or Jugular REF 7025) for the filter implantation procedure.**

### Inspection Prior to Use
Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, do not use and contact your Volcano Corporation representative.

### Preparation For Use
1. Open outer pouch at the guidewire port end, and transfer the inner pouch and device to sterile field using aseptic technique.
2. Open the inner pouch at the guidewire port end, and remove device from pouch.
3. Remove the stylet from the distal tip of the delivery catheter and discard.
4. Carefully remove the Crux VCF from the insert card and inspect the device for damage.

**WARNING:** Do not use the device if any damage exists on the device.

5. Tighten the hemostasis valve on the outer shaft handle.

6. Fasten check valve to outer shaft flush port.

7. Using normal sterile heparinized saline, flush the outer shaft lumen through the handle flush port while occluding the inner shaft guidewire port. Verify that the flush is observed exiting the distal end of the outer shaft of the delivery catheter.

8. Using normal sterile heparinized saline, flush the guidewire lumen through the guidewire port. Verify that the flush is observed exiting the distal end of the tracking tip of the delivery catheter.

**NOTE: All catheter or Crux VCF manipulations should be done while using fluoroscopy imaging guidance.**

9. Access either the femoral or jugular vein using standard percutaneous technique.
10. Place a 0.035” straight tipped guidewire into the vein and advance to target site.
11. Advance a multi-side hole angiographic catheter and remove the guidewire to perform diagnostic imaging of the vena cava using a contrast injection. Locate the renal veins and confirm that the vena cava diameter and anatomy are appropriate for IVC filter placement.

**NOTE:** Diagnostic imaging of the vena cava can also be performed via the Crux VCF Delivery Catheter. If this is done, the contrast injection should take place through the guidewire lumen of the delivery catheter. Contrast may come through the check valve if a stopcock or other device is not placed over it.

**WARNING:** Do not exceed maximum pressure rating of 500 psi and flow rate of 10 ml per second.

12. Proceed with deployment if the IVC target site measures 17mm to 28mm at its widest or average diameter. For reference only, estimates of deployed filter length are provided in Table 1.
13. Re-insert guidewire into the angiographic catheter and remove the catheter, leaving guidewire in place.
14. Using the Crux VCF delivery catheter indicated for the intended approach (Femoral REF 7024 or Jugular REF 7025), verify that the hemostasis valve on the outer shaft handle is tight.

(2.4%), confirmed by CT or perfusion lung scan, and 17 subjects had new DVT (14%).
15. Load and advance the delivery catheter over the guidewire under fluoroscopic guidance to the target site.

16. With the outer flush port of the delivery catheter pointed in the 12 o’clock position, using fluoroscopic guidance:
   a. **Femoral approach**: position the leading radiopaque marker band 4 cm above the lowest renal vein. Ensure that the cranial anchors are infrarenal post-deployment.
   b. **Jugular approach**: position the trailing radiopaque marker band 3 cm above the lowest renal vein. Ensure that the cranial anchors are infrarenal post-deployment.

17. Verify the Crux VCF delivery catheter positioning in the inferior vena cava and make adjustments as necessary.

18. Loosen the hemostasis valve.

**CAUTION:** Avoid rotating the outer shaft handle during shaft pullback as this can result in an inaccurate deployment.

19. If tissue anchors are unsheathed, it is possible to stop and re-position the delivery catheter during deployment. Never attempt to re-sheath the filter.

**CAUTION:** The filter may foreshorten as it is deployed:
   • **Femoral Approach**: the cranial filter tail may land up to 1.5 cm caudal to the initial deployment location.
   • **Jugular Approach**: the cranial tail may land up to 0.5 cm caudal to the initial deployment location.

20. Continue pulling back the outer shaft handle until the hemostasis valve contacts the distal edge of the guidewire port. Ensure that hemostasis valve is pulled completely back to allow full deployment of the filter.

**NOTE:** The Crux VCF will fully deploy and release from the delivery catheter once the hemostasis valve contacts the distal edge of the guidewire port.

**CAUTION:** Do not attempt to re-position a deployed filter.

22. Verify Crux VCF positioning in the inferior vena cava.

23. Tighten the hemostasis valve.

**Removal of the Delivery System Post Deployment**

1. Ensure the hemostasis valve has been tightened.
2. Using fluoroscopy, ensure the tracking tip is not seated against the outer shaft to prevent possible filter displacement.
3. Remove the delivery catheter from the patient such that the tip is carefully pulled through the deployed filter.

**CAUTION:** Do not attempt to re-position the inner shaft steady, and slowly pull back on the outer shaft handle to initiate deployment.

**CAUTION:** Do not push the outer sheath back over a partially deployed filter.

**Optional Retrieval of the Crux VCF**

**NOTE:** Retrieval of the Crux VCF can be accomplished via either the femoral vein or the jugular vein.

1. Access either the femoral or jugular vein using standard percutaneous technique.
2. Place a 0.035" guidewire into the vein and advance to target site.
3. Advance an angiographic catheter over the guidewire to the target site. Remove guidewire from angiographic catheter.
4. Perform a venogram of the IVC and filter for thrombus.
5. Reinsert guidewire into the angiographic catheter. Remove the angiographic catheter, leaving the guidewire in place.
6. Using a two sheath/catheter coaxial system (e.g., 6F x 90 cm tip inner sheath and 10F x 80 cm outer soft tip sheath) advance the coaxial system approximately 3 mm beyond the targeted filter retrieval tail (see Figure 4).
7. Advance and manipulate the snare until the retrieval tail is captured. Use care to not capture anchors with snare.
8. Pull tension on the snare while advancing 6F sheath until the retrieval tail has been captured within the 6F inner retrieval sheath (see Figure 5).
9. Keep tension on the snare wire, and move the torque device against the hub of the 6F inner retrieval sheath. This locks the filter tail inside of the 6F inner retrieval sheath.
10. While keeping 6F sheath and snare steady, advance 10F outer retrieval sheath over filter (see Figure 6) to completely re-sheath the filter under fluoroscopic guidance.
WARNING: Use of excessive force to retrieve the filter can result in damage to the retrieval devices and/or damage to the vena cava.

CAUTION: Avoid pulling filter into the outer sheath.

11. Remove retrieval sheaths and device from patient.

12. POST RETRIEVAL CARE - After retrieval of filter, standard of care should be followed for removing the sheaths and establishing hemostasis to prevent bleeding at the vascular access site.

STORAGE AND HANDLING:
Products should be stored in a dry, dark, cool place in their original packaging.

PRODUCT SPECIFICATIONS:

- Shaft outer diameter: 9Fr
- Usable length: 67 cm
- Maximum guide wire: 0.035"

LIMITED WARRANTY:
Subject to the conditions and limitations on liability stated herein, VOLCANO Corporation ("VOLCANO") warrants that the Crux VCF (the "Device"), as so delivered, shall be free from significant manufacturing defects in materials and workmanship during VOLCANO's standard manufacturer's warranty period. THE SOLE AND EXCLUSIVE REMEDY OF LICENSEE FOR VOLCANO'S BREACH OF THE FOREGOING WARRANTY WILL BE, AT VOLCANO'S OPTION, THE REPAIR OR REPLACEMENT OF A CONFIRMED DEFECTIVE DEVICE. EXCEPT WITH RESPECT TO CONFIRMED DEFECTIVE DEVICES IN BREACH OF THE FOREGOING WARRANTY, VOLCANO CONVEYS NO RIGHT OF RETURN TO LICENSEE AND NO RETURNS WILL BE ACCEPTED. EXCEPT FOR THE FOREGOING WARRANTY, VOLCANO MAKES NO WARRANTY, EXPRESS, IMPLIED OR STATUTORY, AS TO ANY MATTER WHATSOEVER, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. FURTHER, VOLCANO MAKES NO REPRESENTATIONS REGARDING THE CORRECTNESS, COMPLETENESS, ACCURACY OR RELIABILITY OF THE DEVICE OR ACCOMPANYING DOCUMENTATION. THE FOREGOING WARRANTY APPLIES ONLY IN FAVOR OF LICENSEE WHO IS THE END USER AND ORIGINAL LICENSEE OF THE DEVICE AND IS NOT TRANSFERABLE. RETURN OF DEFECTIVE DEVICES MUST BE MADE ACCORDING TO VOLCANO'S THEN-CURRENT RETURN GOODS AUTHORIZATION PROCEDURES. VOLCANO WILL NOT ACCEPT ANY RETURNS FOR STERILE DEVICES IF THE ORIGINAL PACKAGING HAS BEEN TAMPERED WITH OR OPENED WITHOUT VOLCANO'S PRIOR APPROVAL. 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 (and without limitation), this warranty does not apply if:

1. The Device is used by unauthorized or improperly trained personnel, or is used in a manner other than described by VOLCANO in the Instructions For Use supplied with the Device.
2. The Device is used in a manner that is not in conformance with purchase specifications or specifications contained in the Instructions For Use.
3. The Device is re-used, re-processed, repackaged, re-sterilized or used after its expiration date.
4. The Device is repaired, altered, or modified by other than VOLCANO authorized personnel or without VOLCANO's express written authorization.
5. The Device is subjected to unusual physical, electrical or environmental stress or is damaged during shipment to Licensee.

LIMITATION OF LIABILITY:
VOLCANO'S TOTAL AGGREGATE LIABILITY ARISING OUT OF THE SALE OR USE OF THE DEVICE WILL BE LIMITED TO THE AMOUNT OF THE PURCHASE PRICE FOR THE DEVICE IN QUESTION. UNDER NO CIRCUMSTANCES WILL VOLCANO BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, EXEMPLARY, PUNITIVE OR SPECIAL DAMAGES, INCLUDING DAMAGES FOR LOST REVENUE, PROFITS OR BUSINESS OPPORTUNITIES, THE COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES OR OTHER FINANCIAL LOSSES. THESE LIMITATIONS APPLY EVEN IF VOLCANO HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY AND REGARDLESS OF THE THEORY OF LIABILITY.

If claims under this warranty become necessary, contact VOLCANO for instructions and issuance of a Return Material Authorization number if the Device 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.

Crux is a registered trademark of Volcano Corporation.

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:

Legal Manufacturer: Volcano Corporation
- 2870 Kilgore Rd
- Rancho Cordova, CA 95670 USA
- Telephone: (800) 228-4728
- 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 B37
  - Coyol, Alajuela, Costa Rica
- Telephone: (800) 228-4728
- Fax: (916) 638-8008

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

Use Before Date
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Sterile by Sterilized using Ethylene Oxide
Not made with Natural Rubber Latex
Contains phthalate: benzyl butyl phthalate (BBP)
Nonpyrogenic

CE 0086

www.volcanocorp.com