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 cavogram, 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, guide wire 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 cerulean 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.

CONTRAINDICATIONS:
Do not use the Crux VCF in patients who do not meet the intended use and indications including: uncontrolled sepsis, risk of septic embolism, IVC diameter below 17 mm or above 28 mm, contraindications to endovascular procedures done under fluoroscopic guidance, sensitivity to any materials used in the Crux VCF, retrieval of the filter with significant thrombus in or near the filter, pregnant patients where fluoroscopy may endanger the fetus.

ADVERSE EFFECTS:
A full explanation of the risks and benefits should be discussed with each prospective patient prior to implantation. Adverse effects range from mild to serious. Serious adverse effects, sometimes leading to surgical intervention or death, have been associated with the use of IVC filters. In addition, complications due to individual patient reaction to an implanted device, or to physical or chemical changes in the components, may necessitate reoperation and replacement of the filter. 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 cavogram, 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, guide wire 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 cerulean 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.
The Crux VCF is supplied in two versions: Femoral vein delivery (REF 7024) and Jugular vein delivery (REF 7025).

The Crux VCF is sterile if package is unopened and undamaged.

The Crux VCF is sterilized using ethylene oxide gas in peel-open packages, and is non-pyrogenic.

Anatomical variances may complicate filter removal.

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 burdens.

The decision to use an IVC filter must ultimately be made by the physician on an individual patient basis after carefully evaluating the intended use and indications and the short and long term risks and benefits to the patient as compared to alternative methods of treatment.

For Vena Cava Filter Placement

- When using the femoral percutaneous approach, it may be preferable to use the right femoral vein due to the tortuosity of the left femoral vein.
- When using the jugular percutaneous approach, it may be preferable to use the right internal jugular vein.
- Use pressure contrast injections for IVC measurements. The IVC diameter must be 17mm to 28mm.
- The Crux VCF comes preloaded on a delivery catheter specific for either a femoral or a jugular approach. Do not disassemble.
- If any components are disassembled, do not reassemble for deployment.
- 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 the filter once you have passed this point.
- 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 (caudally for a femoral approach and cranially for a jugular approach). Consider this when positioning the filter during the deployment procedure (see Table 2).
- Following implantation of the filter, subsequent vena cava catheterization procedures may be impeded by the presence of the filter.
- Anatomical variances may complicate filter insertion and deployment.

For 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.
- Do not redeploy a retrieved filter. It should be handled and disposed of in accordance with accepted medical practice and applicable local state and federal laws and regulations.
- Anatomical variances may complicate the removal procedure.

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

NOTE: 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.


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.
- The Crux VCF is supplied in two versions: Femoral vein delivery (REF 7024) and Jugular vein delivery (REF 7025).
**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 25.1 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 Trix, SYNGO MR A30-W4A30A 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.

**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.

Physicians should encourage patients to register the above safe scanning conditions with MedAlert Foundation (www.medicalert.org) or equivalent organization.

**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%. Secondary endpoints included retrieval success, migration, IVCF thrombus and device integrity.

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 (19%). 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.

Filter deployment technical success occurred in 123/125 (98%). In two cases, the physicians choose to retrieve the filter immediately because of inaccurate deployment and replace with commercially available filters. There were no adverse clinical sequelae in those two subjects.

Fifty three (53) of 54 patients had their filter successfully retrieved. The average time to retrieval was 85 ± 58 days (see Figure 3). One (1) filter could be not retrieved at 167 days due to excessive force. A femoral retrieval approach was used in 37 procedures (78%). Retrieval Success was achieved in 98% with only 1 radiographic anomaly observed at retrieval with no clinical sequelae.

Forty-nine (49) subjects completed the study with a permanent filter in situ at 180 days. Twenty-two (22), (16%) did not complete the study: 14 (11%) patients died due to pre-existing or other reasons unrelated to the study, 6 (5%) subjects withdrew and 2(2%) were lost to follow up. No patient deaths were attributed to the filter, deployment or retrieval procedures based on independent Medical Monitor adjudication.

During the course of the study, no embolization, migration or fractures were observed. Three subjects had pulmonary embolisms (2.4%), confirmed by CT or perfusion lung scan, and 17 subjects had new DVT (14%). 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 95.2% (92% lower one-sided 95% Cl exceeding the 80% Lower Limit).

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

| Subject Accountability for the Crux Vena Cava Filter Study | Events Occurring Prior to Next Visit | Not Due for Next Visit | Withdrawal | Retrieved | Follow-up | Death | Last to Follow-up | Eligible for Visit | Baseline 125 | 6 | 0 | 14 | 0 | 20 | 35 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 30 Days 105 | 6 | 1 | 23 | 3 | 35 |
| 90 Days 70 | 2 | 1 | 16 | 2 | 21 |
| 180 Days 49 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

1. Per protocol, two subjects exited at 30 days due to no implantation failures.

2. There was an additional withdrawal past retrieval for one subject which does not show up on this table.

No patient deaths were attributed to the filter, deployment or retrieval procedures based on independent Medical Monitor adjudication.

During the course of the study, no embolization, migration or fractures were observed. Three subjects had pulmonary embolisms (2.4%), confirmed by CT or perfusion lung scan, and 17 subjects had new DVT (14%). There were 8 subjects with thrombus observed in or near the filter (6%), primarily at retrieval evaluations, no subjects were symptomatic.

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

For Deployment:

- Standard micro-puncture set to obtain percutaneous access
- 9F short introducer sheath if desired
- 0.035" (outer diameter) guide wire with a minimum length of 180cm
- Sizing angiographic catheter

For Retrieval:

- Standard micro-puncture set to obtain percutaneous access
- 0.035" (outer diameter) guide wire with a minimum length of 180cm
- Angiographic catheter
- 6F x 90cm tip sheath
- 10F x 80cm tip sheath

For additional information on subject disposition (see Table 1).
Preparing the Crux VCF (Femoral REF 7024 or Jugular REF 7025) for the filter implantation procedure. Implanting 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.

**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, contact your Volcano Corporation representative.

**Preparation For Use**
1. Open outer pouch at the guide wire 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 guide wire 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 guide wire lumen through the guide wire 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" guide wire into the vein and advance to target site.
11. Advance a measuring pigtail catheter over the guidewire to target site. Remove guide wire from pigtail catheter.
12. With power contrast injection, perform a venogram of the target site. Assess vena cava diameter.
13. Remove the pigtail catheter, leaving guide wire in place.
14. Proceed with deployment if the IVC target site measures 17mm to 28mm at its widest diameter. As a guideline, estimates of deployed filter length are provided in Table 2.
15. Verify that the hemostasis valve on the outer shaft handle is tight. Load and advance the Crux VCF delivery catheter indicated for the intended approach (Femoral REF 7024 or Jugular REF 7025) over the guide wire under fluoroscopic guidance to the target site.
16. Using fluoroscopic guidance, position the radiopaque marker band just above the renal veins if using the femoral approach; or, if using the jugular approach, position the loaded cranial retrieval tail at the level of the lowest renal vein.
17. Verify Crux VCF positioning in the inferior vena cava and make adjustments as necessary.

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<table>
<thead>
<tr>
<th>IVC Diameter (mm)</th>
<th>Overall Filter Length (mm)</th>
<th>Anchor to caudal tail length (mm)</th>
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</thead>
<tbody>
<tr>
<td>17</td>
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<td>46</td>
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<td>28</td>
<td>65</td>
<td>44</td>
</tr>
</tbody>
</table>

Table 2 - Estimated deployed length is derived from a benchtop IVC model.

18. Loosen the hemostasis valve.
19. Maintain position of the inner shaft steady, and slowly pull back on the outer shaft handle to initiate deployment.
20. Upon exposure of the retrieval tail during deployment:
   - It is possible to stop and re-position the filter.
   - Do not attempt to re-sheath the filter.
21. Verify Crux VCF positioning in the inferior vena cava and make adjustments as necessary.

**CAUTION:** The filter may shortens as it is deployed:
- **Femoral Approach:** the cranial filter tail may land up to 1.5cm caudal to the initial deployment location (see Figure 4).
- **Jugular Approach:** the cranial filter tail may land up to 0.5cm caudal to the initial deployment location (see Figure 5).

Consider this when positioning the filter during the deployment procedure.
22. Continue pulling back the outer shaft handle until the hemostasis valve contacts the distal edge of guide wire port. Ensure that hemostasis valve is pulled completely back to allow full deployment of the filter.
23. Tug the hemostasis valve.

**CAUTION:** Do not attempt to re-position the filter. Do not push the outer sheath back over the filter.
24. Proceed with deployment if the IVC target site measures 17mm to 28mm at its widest diameter. As a guideline, estimates of deployed filter length are provided in Table 2.
25. Verify that the hemostasis valve on the outer shaft handle is tight. Load and advance the Crux VCF delivery catheter indicated for the intended approach (Femoral REF 7024 or Jugular REF 7025) over the guide wire under fluoroscopic guidance to the target site.
26. Using fluoroscopic guidance, position the radiopaque marker band just above the renal veins if using the femoral approach; or, if using the jugular approach, position the loaded cranial retrieval tail at the level of the lowest renal vein.
27. Verify Crux VCF positioning in the inferior vena cava and make adjustments as necessary.

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[Table 2 - Estimated deployed length is derived from a benchtop IVC model.]

**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:** Ensure that the delivery catheter does not interact with the deployed filter during withdrawal, to prevent shifting of the filter.
4. After deployment of filter, standard care should be followed for removal of devices and establishing hemostasis to prevent bleeding at the vascular access site.

**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" guide wire into the vein and advance to target site.
3. Advance an angiographic catheter over the guide wire to the target site. Remove guidewire from pigtail catheter.
4. Perform a venogram of the IVC and filter for thrombus.
5. Reinsert guide wire into the angiographic catheter. Remove the angiographic catheter, leaving the guide wire in place.
6. Using a two sheath coaxial system (e.g. 6F x 90cm tip inner sheath and 10F x 80cm outer soft tip sheath) advance the coaxial system approximately 3 mm beyond the targeted filter retrieval tail (see Figure 6).

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 7).

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 8) 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 VFG (“the Device”), as so delivered, shall be free from significant defects in materials and workmanship for a period of one year from the date of delivery. 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. FURTHERMORE, 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 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 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, reprocessed or re-sterilized.
4. The Device is repaired, altered, or modified by other than VOLCANO authorized personnel or without VOLCANO authorization.
5. The Device is subjected to unusual physical, electrical or environmental stresses 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.

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