# Patient Device Information

COPY-CORDIS-23022 Rev.1

## Cordis OPTEASE® Retrievable Vena Cava Filter

### What the Cordis OPTEASE® Retrievable Vena Cava Filter is Used For

The OPTEASE® Retrievable Vena Cava Filter is indicated for the prevention of pulmonary embolism (PE) via percutaneous placement in the inferior vena cava (IVC) in patients considered at high risk of PE.

Deep vein thrombosis (DVT) is a serious medical condition that can cause swelling, pain, and tenderness in your leg. In some cases, a deep clot in a leg vein can break free and stick in a vessel in the lung. This can cause a blockage in the vessel called a pulmonary embolism. Pulmonary embolism can cause severe shortness of breath and even sudden death.

### Product Description

The OPTEASE® Retrievable Vena Cava Filter is laser cut from nickel titanium alloy tubing. It can be retrieved within a specified period after implantation.

**Active Ingredient**

• Nitinol (nickel titanium alloy)

### About Your Procedure

An IVC filter is one method to help prevent pulmonary embolism. Your inferior vena cava (IVC) is the major vein that brings oxygen-poor blood from the lower body back to the heart. The heart then pumps the blood to the lungs to pick up oxygen. An IVC filter is a small, wiry device. When the filter is placed in your IVC, the blood flows past the filter. The filter catches blood clots and stops them from moving up to the heart and lungs. This helps to prevent a pulmonary embolism.

It's important to understand that an IVC filters does not protect against DVT. You may still get a DVT. The filter helps to protect you from a life-threatening pulmonary embolism if you have a DVT.

The procedure usually takes about an hour. The procedure is performed in an Interventional Radiology Lab or a Cardiac Cath Lab. A typical case is performed with these steps:

- An IV (intravenous) line will be put in your arm or hand before the procedure starts. You'll be given sedation through the IV line. This will make you relaxed and sleepy during the procedure.
- Hair in the area of your procedure may be removed. The area may be numbed with a local anesthesia.
- Your doctor will make a small incision in this region to access a major vein leading to the IVC.
- A long thin tube (catheter) will be inserted into this vein.
- Using continuous X-rays (fluoroscopy), this tube will be moved up into the IVC. X-ray dye (contrast material) may be sent through into the catheter. This helps show the IVC clearly on the X-rays.
- Your doctor will release the filter into the IVC. Here the filter will expand and attach itself to the walls of your IVC.
- The catheter will be removed.
- Manual pressure will be applied for a couple of minutes and a bandaid or a dressing will be placed on the site.

### Caution

Patients with allergic reactions to nitinol (nickel titanium) may suffer an allergic response to this implant.

Before undergoing any surgical procedure, speak with your doctor if you plan to have any type of surgery that may require you to stop taking antiplatelet or blood thinning medications.

### Adverse Effects

The risks of using the OPTEASE® Retrievable Vena Cava Filter are similar to those that are associated with other non invasive procedures. For more information regarding the risks, consult your doctor.

### Device Interaction and MRI Information

If you require a magnetic resonance imaging **(MRI)** scan, tell your doctor or MRI technician that you have a stent implant. The OPTEASE® Retrievable Vena Cava Filter has been shown to be MRI conditional.

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### Post-Procedure Care

After the procedure, you will spend several hours in a recovery room. You may be sleepy and confused when you wake up. Your nurse will watch your vital signs, such as your heart rate and breathing. You'll be given pain medicine if you need it. You may have a headache or nausea, but these should go away quickly.

You may be able to go home the same day. Your doctor will tell you more about what to expect. When you're ready to go home, you'll need to have a family member or friend drive you.

You may have some pain after the procedure. You may notice a bruise where the catheter was inserted. You can take over-the-counter pain medicines if you need to. Get some rest and avoid strenuous exercise for at least 24 hours.

- Call your provider right away if you have any of the following:
- Coldness or numbness in one of your limbs
- Bleeding at the site that doesn't stop with pressure
- Swelling or pain at the incision site that gets worse
- Fluid leaking from the incision site
- Redness or warmth at the incision site
- Fever
- Chest pain
- Headache or nausea that don't go away
- Follow all of your doctor's instructions. This includes any advice about medications, exercise, and wound care. Your doctor may prescribe blood thinner medication to help prevent blood clots.

Talk to your doctor about returning to work, which depends on your type of work, your procedure, and any medication you may be taking.

**Precaution**

Any serious incident that occurs in relation to the device should be reported to Cordis US Corp. and to the Therapeutic Goods Administration (TGA).

Cordis Cashel, Cahir Road, Cashel, Co. Tipperary, Ireland
email: anz-product-complaints@cordis.com

TGA:
http://www.tga.gov.au/reporting-problems

### Discharge Information

You will be discharged to the care of your procedural doctor or primary doctor. You should be able to return to your normal activities soon.

You will need continued monitoring after your treatment. You may need follow-up imaging tests to make sure your filter is still in the correct location. If you have the type of IVC filter that can be removed, you may have a similar procedure in the future to remove the device. This may be done after your risk of DVT has decreased. In some cases, a removable filter is left in place. This may happen if scar tissue grows around the filter and it cannot be removed.

### Legal Manufacturer

Cordis Cashel, Cahir Road,
Cashel, Co. Tipperary, Ireland