Patient Information Leaflet

COPY-CORDIS-25029 REV.1

Cordis OPTEASE™ Retrievable Vena Cava Filter

Device Name and Model

Cordis OPTEASE™ Retrievable Vena Cava Filter

Device Description

The Cordis OPTEASE Retrievable Vena Cava Filter (Retrievable Filter) is designed for percutaneous delivery of a retrievable vena cava filter to the inferior vena cava (IVC).

The self-centering OPTEASE Retrievable Filter is laser cut from nickel titanium alloy (Nitinol) tubing. The proximal and distal baskets of the OPTEASE Retrievable Filter, which consist of struts in a six diamond shape configuration, are designed for optimal clot capture. The baskets are connected by six straight struts. A single row of fixation barbs is present at the cranial end
of the struts. These barbs, intended for fixation to the vessel wall, are extensions of the parallel struts. A hook is centrally located at the caudal basket extremity and allows for filter retrieval using a snare.

Intended Purpose

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

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the vena cava.

Patient Target Group

This device is intended for patients who are considered at high risk of pulmonary embolism (PE). It is placed percutaneously into the inferior vena cava (IVC) to prevent PE.

Operating Instructions

This device is intended to be implanted by trained healthcare professionals in a hospital or clinical setting. It is not operated or adjusted by the patient.

After the procedure, follow all instructions provided by your doctor regarding recovery, medications, and follow-up visits. Attend all scheduled check-ups so your doctor can monitor the device and ensure it is functioning correctly. Immediately contact your healthcare provider if you experience any new or unusual symptoms, such as pain, swelling, changes in sensation, or any symptoms your doctor has advised you to watch for. Always carry your patient implant card and show it to healthcare professionals when receiving medical care.

Residual Risks

Person with allergic reaction to nickel titanium (Nitinol) may suffer an allergic response to this implant.

Warnings and Precautions

This stent contains nickel and cobalt. These metals may cause allergic reactions in some people. Tell your doctor if you have any known allergies to metals.

Tell your doctor if you take antacids or stomach acid–reducing medicines, as these can interfere with the absorption of other medicines you may need after the procedure (such as aspirin).

If you feel any discomfort or experience unusual symptoms after the procedure, contact your doctor immediately.

Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during the procedure.

Possible procedure complications include, but are not limited to, the following:

- air embolism
- hematoma at the puncture site
- incorrect positioning of the filter
- incorrect orientation of the filter
- perforation of the vessel wall
- restriction of blood flow
- occlusion of small vessel
- distal embolization
- infection

- intimal tear
- filter fracture
- thrombus formation
- incomplete expansion of the filter.

If the filter is not removed within 12 days of implantation, the possible long-term complications associated with filter implantation include, but are not limited to the following:

- filter obstruction/thrombosis
- filter perforation of the vena cava wall
- filter migration
- filter fracture
- recurrent pulmonary embolism
- pain
- peripheral edema.

Lifetime of the Device

This device is a permanent implant device.

Materials and substances included in the device

The OPTEASE filter is made from a metal alloy called Nitinol, which is a combination of nickel and titanium.

Device Interaction and MRI Information

A patient with the OPTEASE Vena Cava Filter may be safely scanned under the limited conditions.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a filter implant.

Adverse Event Report

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

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

Sponsor:
Cordis Australia Pty Ltd.
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Manufacturer

Cordis Cashel
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Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, suggested procedure, warnings and precautions. Please contact your Cordis representative for additional product information.