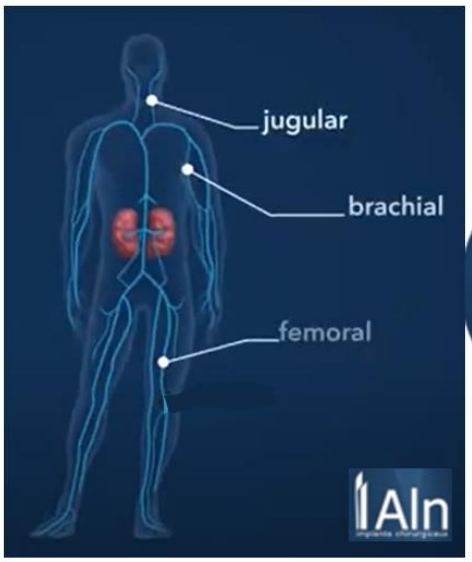
1. The device

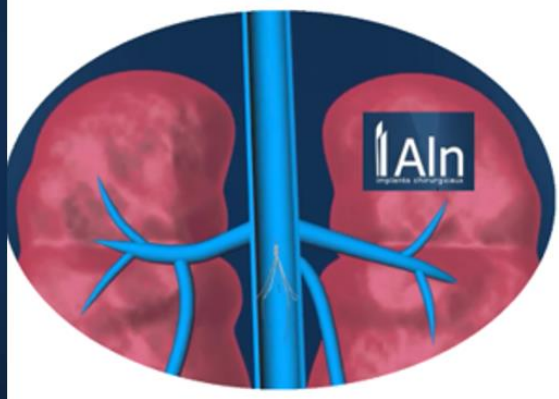
The ALN Optional Vena Cava Filter is used for protection against pulmonary embolism by thrombus migration stopping in the inferior vena cava.

The ALN Optional Vena Cava Filter is available with three introduction kits depending on the vascular approach of filter insertion: femoral, brachial or jugular approach.

Name and models of the device

Optional Vena Cava Filter, Jugular Approach:	FJ.120096
Optional Vena Cava Filter with Hook, Jugular Approach:	FJ.HOOK
Optional Vena Cava Filter, Brachial Approach:	FB.010500
Optional Vena Cava Filter with Hook, Brachial Approach:	FB.HOOK
Optional Vena Cava Filter, Femoral Approach:	FF.010995
Optional Vena Cava Filter with Hook, Femoral Approach:	FF.HOOK





2. Intended purpose and target population

The ALN Optional Vena Cava Filter is classed in the family of Optional Vena Cava Filters that can be removed when the evolution of the patient's condition allows it or left permanently in place if necessary.

Please, contact your doctor in order to know if an extraction of the filter is planned or if the filter will stay implanted permanently.

Several clinical studies have demonstrated the effectiveness and safety of the ALN Vena Cava Filter in the prevention of pulmonary embolism, whether implanted permanently or temporary.

The ALN Optional Vena Cava Filter is designed to be implanted in adult patients (not teenagers or children) whose vena cava diameter is less than or equal to 32 mm, from jugular, brachial and femoral route placement.

Absolute indications:

- Deep vein thrombosis (popliteal, femoral, iliac vein or vena cava), with or without pulmonary embolism in patients presenting with one or more of the following characteristics:

- anticoagulant treatment complications requiring interruption of treatment,
- symptomatic recurrence of acute pulmonary embolism under efficient anticoagulant treatment (this recurrence must be objectively confirmed),
- symptomatic extension of thrombosis under efficient anticoagulant treatment (this extension must be objectively confirmed),
- contraindications to high-dose anticoagulant treatments (temporary or definitive).

- Severe trauma (cranial or spinal) causing local diffuse hemorrhages, in patients for whom preventive mechanical intermittent venous compression means cannot be applied, in the demonstrated absence of pulmonary embolism or deep vein thrombosis.

- Prevention of pulmonary embolism during high thromboembolic risk surgical procedures in patients with recent history of deep vein thrombosis or pulmonary embolism.

Relative indications:

Prevention of pulmonary embolism during high thromboembolic risk surgical procedures in patients with history of deep vein thrombosis or pulmonary embolism.

Safety and efficiency of the device are not established for suprarenal placement or pregnancy.

3. Special operating instructions for the use of the device

Non applicable (the use of ALN filters is restricted to trained health professional).

4. Intended performance and undesirable effects

Intended performance:

The ALN Optional Vena Cava Filter is a metallic device that it is implanted percutaneously (using a small catheter) into the Vena Cava to provides effective protection against pulmonary embolism. Its role is to prevent the migration to the lungs of clots formed in the veins upstream. This filter lets the blood goes through and retains clots that will be dissolved – in most cases – by a natural process.

If you want to know the reason why the pose of a Vena Cava Filter is needed, please ask your doctor.

Undesirable effect: please discuss all risks with your doctor. Major risks associated with ALN Optional Vena Cava Filter include, but are not limited to:

- Incorrect filter placement or release,
- Incomplete filter deployment,
- Filter tilting
- Bruising or hemorrhage at the puncture site
- Insertion site infection
- Filter migration
- Occlusion of the vena cava
- Perforation of the vena cava, vessels or an adjacent organ
- Death caused by migration of a thrombus to the heart and lungs
- Puncture site thrombosis
- Implantation site thrombosis
- Fracture of a filter's element
- Recurrent pulmonary embolism
- Long-term deep vein thrombosis
- Arrhythmia
- Contact of the head of the filter with the vena cava wall
- Hemothorax
- Edema
- Pneumothorax
- Ulceration
- Lower extremities edema
- Vena cava stenosis
- Damage of the vena cava wall.

5. Any residual risks that could arise due to any shortcomings of the protection measures

Non applicable for the patient information leaflet.

6. Warnings and precautions

- **Very important: please inform health professional that you have a vena cava filter before any surgery, especially for abdominal one.**

- **Magnetic Resonance** Imaging: a patient implanted with this filter can safely undergo MRI examination under the following conditions:
  - **Static magnetic field of 3 Tesla or less.**
  - The quality of the MRI image may be impaired if the point of interest is located at the exact or approximate filter implantation site. In this case, it may be necessary to optimize the machine parameters in order to improve the image.

7. Follow-up of a patient with ALN Optional Vena Cava Filter

- Patient's follow-up should include the following points (a specific follow-up may be required based on physician judgment):
  - Examination of the catheter insertion site to make sure about a good healing.
  - Anterior posterior (AP) and lateral cavography should be performed before the patient's release and made every year.
  - The patient should attend a follow-up consultation, made by the physician who placed the filter or by his medical team, or by the clinician who referred the patient for the procedure within the first month.
- Circumstances in which the patient should contact a health professional in relation to the operation of the device are : shortness of breath, unusual pain or suspicious pain.
- There is no lifetime limit for the ALN Optional Vena Cava Filter.
- The patient can continue its activities of daily living and live normally. However, if the patient may practice specific hard activities (such as heavy lifting, pulling or pushing), he should ask for advice to its health professional.

8. Materials and Substances included in the device

The ALN Optional Vena Cava filter is made of 316 LVM stainless steel. The device does not contain:

- Any animal product
- Any product derived from human tissues
- Any product that could be considered as medicine
- Any phthalate or latex

No rejection or allergic reaction has been reported to date.

9. Implanted Device Identification Card

After an ALN Optional Vena Cava Filter implantation procedure, your health professional will give you an implanted device identification card that will list the following information:

- Type of device implanted
- Lot number of the device implanted
- Serial number of the device implanted
- Date of implant
- Your doctor's information
- **Magnetic Resonance Imaging** (MRI) information

10. Reporting of serious incident

Any serious incident occurring in connection with the device must be reported to the manufacturer and to the competent authority of the Therapeutic Goods Administration.

The address of the Therapeutic Goods Administration's website is as follows:

https://www.tga.gov.au

11. Contacting ALN

If you have any questions concerning an ALN Optional Vena Cava Filter manufactured by ALN, you should contact your doctor. If there is anything that we as a company can do to assist you, please feel free to contact us at:

Manufacturing site and offices
ALN S.A.R.L.
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83230 Bormes les Mimosas
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Fax: +33 (0)4 94 01 09 01
Website: http://www.aln2b.com
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