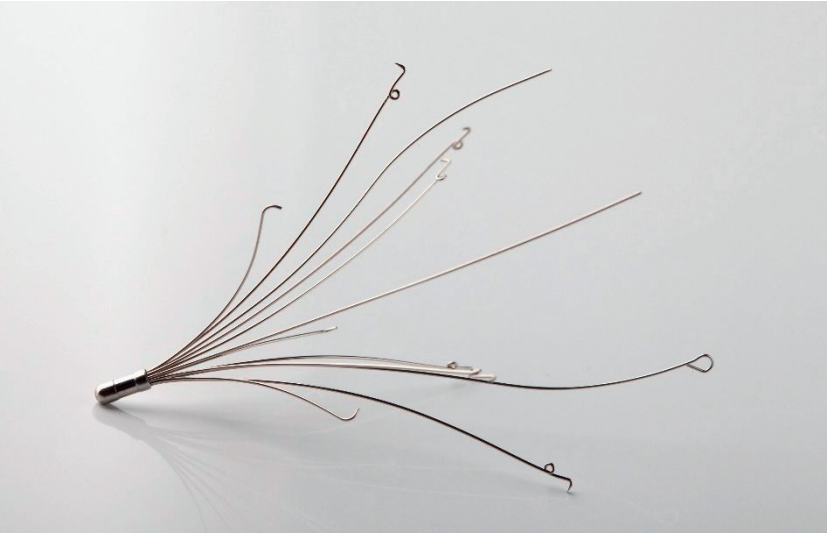
INSTRUCTIONS FOR USE
OF THE ALN OATF VENA CAVA FILTER
POPLITEAL APPROACH
(EN)



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Contents

1: General information **4**

2: Symbols **5**

3: Kit content **6**

4: Indications **7**

5: Contraindications **8**

6: Composition **8**

7: Warnings **9**

8: Complications **11**

9: Implantation procedure **13**

10: Patient's follow-up **19**

11: MRI **19**

12: Removal **20**

13: Packaging and handling **20**

14: Disposal of the device **20**

15: Warranty **20**

16: Duty to report incidents or risks of incident **21**

1: General information

The ALN OATF Vena Cava Filter is an optional filter (definitive and/or temporary). Its intended purpose is to provide effective protection against pulmonary embolism.

The ALN OATF Vena Cava Filter is made of twelve 316 LVM stainless steel legs. Six legs are fitted with hooks for anchoring in the vena cava, three legs serve to center the filter inside the vena cava and the other three anti-tilting legs serve to the centering optimization of the filter inside the vena cava.

The ALN OATF Vena Cava Filter has been tested and presents no additional risk for patients undergoing MRI examinations with magnetic forces of up to **3 Tesla**. The quality of MRI images may, however, be affected if the area of interest is at the exact (or close to) location of the ALN OATF Vena Cava Filter. See the MRI equipment manufacturer's precautions for use for imaging an implanted metallic prosthesis.

The ALN OATF Vena Cava Filter is a device intended to be implanted on patients whose inferior vena cava diameter is less than or equal to **32 mm.**

Read the instructions carefully before use. These instructions should be used only if you have opted for **popliteal approach** implantation. Do not use them for any other approaches (brachial, jugular or femoral).

The ALN OATF Vena Cava Filter is supplied sterile. It is intended for one-time use.

2: Symbols

This section presents the definitions of the symbols used on the product and its package.

REF	Catalog reference
LOT	Batch number
SN	Serial number
	Use by
	Date of manufacture
	Warning
	Read instructions before using
STERILE EO	Sterilized using ethylene oxide, double sterile barrier system
	Do not reuse
STERILIZE	Do not resterilize
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
MR	MR Conditional
	Non-pyrogenic
MD	Medical Device
UDI	Unique Device Identifier
	Manufacturer

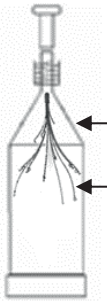
3: Kit content

Ensure that all kit components are present before starting the procedure. If an item is missing, use another kit.

The ALN OATF Vena Cava Filter popliteal approach device comprises the following elements:

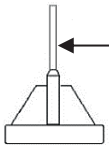
- The filter 6 cm high (1) placed in its filter holder (2).
- The filter holder itself consists of a conical tube, a protective cap, a clip and a piston (3). The piston serves to push the filter into the introducer sheath by means of a metal tube.
- An introduction system comprising a dilator 1260 mm long (4) (red luer lock tip) screwed onto the 7F introducer sheath 1200 mm long (5).
- A pushing catheter 1214 mm long (6). This element serves to push the filter into the introducer sheath.
- A 18-gauge, 70 mm puncture needle (7).
- A Teflon-coated 0.035'' diameter and 1800 mm length J-guidewire.

The ALN OATF Vena Cava Filter popliteal approach kit is supplied sterile. This device is intended for one-time use. It is sterilized using ethylene oxide.

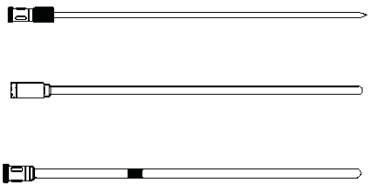


(2) Filter holder

(1) Filter positioned inside the filter holder for popliteal introduction



(3) Piston used to push the filter



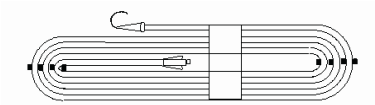
(4) Dilator

(5) Introducer sheath 7F *(internal diameter)*

(6) Pushing catheter

Introduction system

(7) Puncture needle



(8) Teflon-coated J-guidewire

4: Indications

The ALN OATF Vena Cava Filter should only be implanted for the indications listed in this section. The indications listed below are those acknowledged by the **SFICV[1].** They are based on the **SIR[2]** and **CIRSE[3]** agreements.

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.

Important note: The validation of preventive placement of a vena cava filter prior to a surgical procedure must be individualized to each patient and the various practitioners must be aware of the associated risks. The decision must be validated in collaboration with all concerned units.

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

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[1] SFICV (Société Française d'Imagerie Cardiaque et Vasculaire). Recommandations et Bonnes Pratiques en Radiologie Vasculaire Interventionnelle. Mars 2007. Pages 93-101.

[2] SIR (Society of Interventional Radiology). Guidelines for the use of retrievable and convertible vena cave filters: report from the Society of Interventional Radiology multidisciplinary consensus conference. J.A. Kaufman et al, Journal of Vascular Interventional Radiology 2006; 17 (3): 449-59.

[3] Guidelines CIRSE 2007 (Cardiovascular and Interventional Radiological Society of Europe). Quality Improvement guidelines for percutaneous inferior vena cave filter placement for the prevention of pulmonary embolism.

5: Contraindications

1. An ALN OATF Vena Cava Filter cannot be implanted on patients whose inferior vena cava diameter is greater than **32 mm** since the filter cannot be correctly anchored with an increased risk of migration.
2. Presence of thrombi:
   - In the upper chest region,
   - At the puncture site,
   - In the ipsilateral iliac vein,
   - In the inferior vena cava.

In all these cases, the thrombi can potentially be displaced, causing an embolism while manipulating the introduction system.

3. Percutaneous insertion in patients with abnormal coagulation time.
4. In all cases in which radioscopic control is contraindicated, in case of pregnancy in particular, the advantages and disadvantages of the filter implantation must be carefully assessed.
5. Known hypersensitivity to one of the components (Cf 6. Composistion) constitutes a contraindication to the placement of an ALN OATF Vena Cava Filter.
6. If there is a risk of septic embolism, placement of the ALN OATF Vena Cava Filter is contraindicated.
7. The implantation of an ALN OATF Vena Cava Filter is contraindicated in children and adolescents.

6: Composition

The ALN OATF Vena Cava Filter is made from 316LVM stainless steel and is composed as follows:

- Carbon (C) ≤ 0,030%
- Manganese (Mn) ≤ 2,00%
- Silicon (Si) ≤ 0,75%
- Phosphorus (P) ≤ 0,025%
- Sulphur (S) ≤ 0,010%
- Chromium (Cr) : 17,00-19,00%
- Nickel (Ni) : 13,00-15,00%
- Molybdenum (Mo) : 2,25-3,00%
- Copper (Cu) ≤ 0,50%
- Nitrogen (N) ≤ 0.10%
- Cobalt (Co) < 0.10 %
- Iron (Fe): balance

7: Warnings

General warnings relative to the use of the ALN OATF Vena Cava Filter

1. Read the instructions for use carefully. These instructions should be used only if you have opted for **popliteal approach** placement. Do not use them for any other approaches (brachial, jugular or femoral).
2. The ALN OATF Vena Cava Filter popliteal approach is provided ready to use, sterile (ethylene oxide sterilized) and non-pyrogenic. Do not use the product if its package is damaged or open, or if there is a doubt whether is sterile.
3. The product should be stored in a dry place and kept away from sunlight.
4. Do not use the ALN OATF Vena Cava Filter beyond the expiration date indicated on the label.
5. The ALN OATF Vena Cava Filter is intended for one-time use. It must not be reused and the kits components must not be re-sterilized.
6. Always use the **green** popliteal filter-holder of the introduction system for a popliteal approach.
7. The ALN OATF Vena Cava Filter should only be implanted using the introduction kit provided for this purpose by ALN.
8. The ALN OATF Vena Cava Filter should only be removed using one of the Extraction or Repositioning Kits sold for this purpose by ALN. It should not, under any circumstances, be removed with a snare.

General procedure-related warnings

9. ALN recommends that both the operating physicians and non-physicians performing the procedures should possess a level of expertise in accordance with **SFICV**[4] recommendations. This means that it is necessary to have implanted at least one permanent filter and at least one optional or temporary filter in order to implant the ALN filter under good conditions.

The **SFICV** recommends:

- That a junior operator should have performed 6 placements in a role of second operator and 6 placements himself/herself, under the supervision of a senior to be considered as competent.
- That a senior operator should perform at least 6 placements per year to maintain his/her level of expertise.
- That the electro radiology operator should possess basic vascular procedure training and that the nurses, including operating theatre nurses, have undergone specific training in invasive and interventional vascular imaging.

10. ALN warns users of the increased risk of migration in the following cases:

- major surgery (thorax, abdomen, etc.),
- procedures potentially modifying vascular hemodynamics,
- procedures that may cause contact with the inferior vena cava and/or the filter implantation site.

[4] SFICV (Société Française d'Imagerie Cardiaque et Vasculaire). Recommandations et Bonnes Pratiques en Radiologie Vasculaire Interventionnelle. Mars 2007. Pages 93-101.

11. Before the procedure, the elements of the kit - J-guidewire and introduction system (dilator + introducer sheath) - should be rinsed with a sterile heparinized physiological saline solution or similar isotonic solution.

12. Never advance the J-guidewire or the introduction system without medical imaging.

Cavography-related warnings

13. In case of pre-surgery preventive placement, we strongly recommend checking the filter by imaging both before and after surgery. These images should be archived and appended to the patient record for viewing whenever desired.

14. Ensure that the cavography can be performed without risk for the patient: take into account any problems associated with use of contrast media (allergy, renal failure).

15. Do not deploy the filter if any measurement of the inferior vena cava diameter has been made. The diameter of the inferior vena cava can be measured by anterior posterior (AP) and lateral cavography. It is important, however, to note that the cavography may over- or underestimate the actual diameter of the inferior vena cava. If megacava is suspected, the diameter of the inferior vena cava should be measured by ultrasound or scanner.[5]

General warnings relative to deploying the ALN OATF Vena Cava Filter

16. Take care to avoid deploying the ALN OATF Vena Cava Filter in a thrombus; this could prevent the filter from opening fully and from correctly anchoring in the inferior vena cava.

Other warnings

17. Any attempt to manipulate the ALN Vena Cava Filter using components or devices other than those provided is under the practitioner's entire responsibility.

18. Improper handling of the ALN vena cava filter may also expose the person to a risk of puncture/injury, or infection if the filter has been explanted.

19. Any contaminated or potentially contaminated product may present an infectious risk and must be disposed of through the appropriate disposal channel in accordance with standard medical practice and the regulations in force.

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[5] Value of frontal caval measurement in the placement of inferior vena cava filters. Deepak R. Kaura et al, Canadian Association of Radiologists Journal 1999; 5: 301-305.

8: Complications

There are some potential complications associated with the use of vena cava filters. Consequently, the insertion procedure must not be performed by practitioners unaware of these complications.

These complications can occur during and/or after the implanting procedure.

Clinical complications related to implantation include (but are not limited to):

1. Incorrect filter placement or release,
2. Incomplete filter deployment,
3. Filter tilting,
4. Bruising or hemorrhage at the puncture site,
5. Insertion site infection,
6. Filter migration,
7. Occlusion of the vena cava,
8. Perforation of the vena cava, vessels or an adjacent organ/structure,
9. Hematoma/Haemorrhage of an organ/structure,
10. Death caused by migration of a thrombus to the heart and lungs,
11. Puncture site thrombosis,
12. Implantation site thrombosis,
13. Fracture of a filter's element,
14. Recurrent pulmonary embolism,
15. Long-term deep vein thrombosis,
16. Arrhythmia,
17. Contact of the head of the filter with the vena cava wall,
18. Hemothorax,
19. Edema
20. Pneumothorax,
21. Ulceration,
22. Lower extremities edema,
23. Vena cava stenosis,
24. Damage of the vena cava wall,
25. Arteriovenous fistula,
26. Consumption coagulopathies.

Known (but rare) equipment-related technical complications that users may encounter include:

Problem	Cause	Prevention	Action
When pushing the filter through the introducer sheath, one or more filter's legs are bent inside the filter holder.	The filter has been pushed using the piston with too much strength.	Slowly and carefully push the filter fully using the piston, such that it comes through the conical part of the filter holder.	Leave the introduction system in place and use a new filter. ALN recommends to have at least two implantation kits available.
Inability to introduce the filter into the introducer sheath, filter misaligned from the plunger and blocked in the filter-holder.	The piston was released when pushing the filter into the introducer sheath.	Push the filter without releasing the piston so that it passes under the best conditions in the conicity of the filter-holder.	Leave the introduction system in place and use a new filter. ALN recommends to have at least two implantation kits available.
Failure to insert the filter into the introducer sheath and deformation of the filter.	The dilator was not removed.	Ensure that the J-guidewire and the dilator have been removed before inserting the filter into the introducer sheath.	Remove the damaged filter and the filter holder and ensure that the introducer sheath is not damaged. Use a new filter if necessary. If the introduction system is damaged, repeat the procedure. ALN recommends to have at least two implantation kits available.
The filter's leg perforated the introducer sheath when pushing the filter with the pushing catheter.	The sheath was kinked during the procedure.	Ensure that, once the dilator and the J-guidewire are removed, the introducer sheath is handled by its base and is not bent.	Remove the introduction system and use a new implantation kit. ALN recommends to have at least two implantation kits available.

9: Implantation procedure

1: Patient preparation

Disinfect and position sterile tissues. (1) (2)

(1)

(2)

2: Anesthesia and puncture

After local anesthetic, puncture the selected popliteal vein with the provided 18-gauge puncture needle. (3)

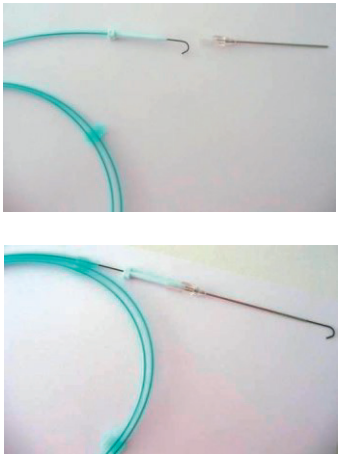
(3)

3: Inserting the J-guidewire and rinsing the introduction system

***Warning*: The J-guidewire should be used by a physician with appropriate cardiac catheterization training. Never advance the J-guidewire or the introduction system without radiological control.**

Flush the J-guidewire with sterile heparinized physiological saline or similar isotonic solution, fixing a syringe to the luer base of the J-guidewire's distributor (4). Insert the flexible end of the J-guidewire into the puncture needle. (5)

(4)

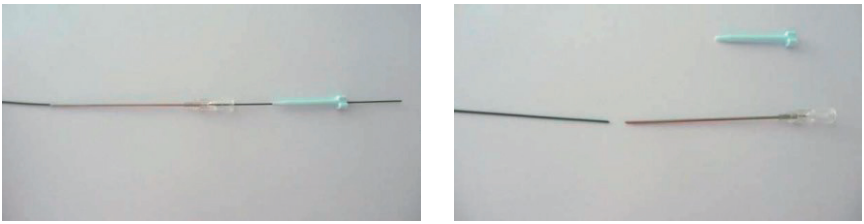

(5)

Advance the J-guidewire in the puncture needle. Place the end of the J-guidewire:

Lower approach: suprarenal.

Leave an appropriate length of the J-guidewire exposed.

Hold the J-guidewire in place and remove the puncture needle and the J-guidewire's stiffener. (6)



(6)

***Warning*: During J-guidewire progression, check for the absence of bends or loops under medical imaging. Always advance the J-guidewire further than the implantation site and ensure that 2 or 3 cm of J-guidewire extends beyond the proximal end of the introduction system.**

***Warning*: Do not attempt to advance or remove the J-guidewire in case of resistance. The cause of resistance should be determined by radioscopy. If the cause of resistance cannot be determined, remove the J-guidewire and the introduction system.**

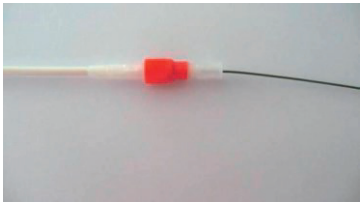
To facilitate the progression of the introduction system, we recommend making a sufficiently large incision to the tissues surrounding the J-guidewire.

Rinse the introduction system with a sterile physiological saline solution or similar isotonic solution.

4: Advancing the introduction system (introducer sheath + dilator) and performing a cavography.

Insert the outer part of the J-guidewire into the distal end of the introduction system.

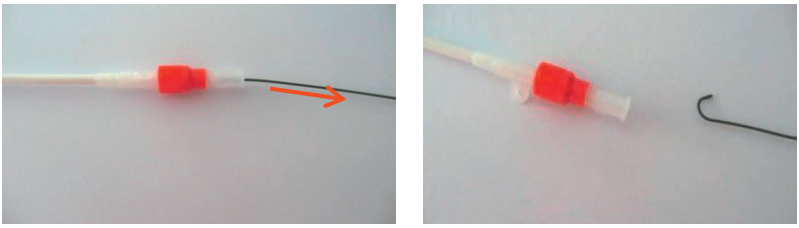
Advance the introduction system along the vein by sliding over the J-guidewire. (7)



(7)

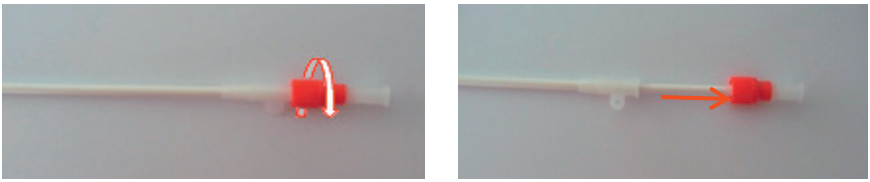
Advance the distal end of the introduction system until the tip of it lies just below the renal veins.

Remove the J-guidewire. (8)



(8)

Remove the dilator by rotating the red luer lock counter-clockwise. (9)



(9)

***Warning**: Be sure to remove the J-guidewire and the dilator before performing the cavography to avoid any type of trauma of the vena cava.*

Carefully advance the introduction system a few centimeters and perform a cavography to view the renal veins.

During all of these steps, check the procedure closely using medical imaging.

***Warning**: Anterior posterior (AP) and lateral cavography must be performed before placing an ALN OATF Vena Cava Filter in order to:*

- *Confirm the permeability and define the anatomy of the inferior vena cava, ipsilateral iliac veins and renal veins.*
- *Determine the length and the diameter of the subrenal inferior vena cava and detect any possible variations in IVC anatomy (double vena cava, left inferior vena cava, agenesis, etc.)*
- *Diagnose IVC disease (partial or total vena cava thrombosis, extrinsic adenopathy-related compression, tumor syndrome or aortic aneurysm).*
- *Determine the most suitable implantation site. For a normal IVC, the apex of the ALN OATF Vena Cava Filter should be below the lowest renal vein.*

***Warning**: If there is a doubt concerning the anatomy or the size of the vena cava, another cavography should be performed from different angles.*

***Warning**: Do not deploy the filter if any measurement of the inferior vena cava diameter has been made.*

***Warning**: An ALN OATF Vena Cava Filter cannot be implanted on patients whose inferior vena cava diameter is greater than 32 mm since a correct fixation of the latter is compromised with an increased risk of migration of the filter.*

5: Rinsing the introducer sheath

Rinse the introducer sheath with a sterile heparinized physiological saline solution or similar isotonic solution. (10)

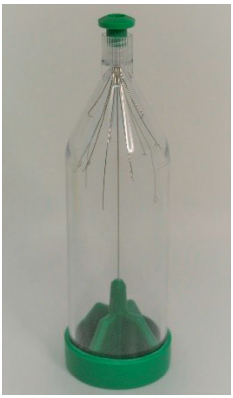
(10)

***Warning*: Insufficient rinsing of the introducer sheath may cause clot formation in it, leading to a poor filter's anchoring and thus increasing the risk of migration during the implantation procedure. If the implantation procedure is longer than expected, do not hesitate to rinse the introducer sheath regularly.**

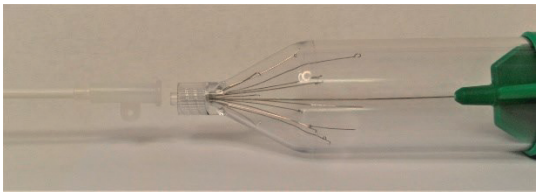
6: Inserting the filter into the introducer sheath

***Warning*: Ensure that the J-guidewire and the dilator have been removed before inserting the filter into the introducer sheath.**

Take the filter holder. Remove the protective cap and present the filter holder along the axis of the introducer sheath. (11) (12)



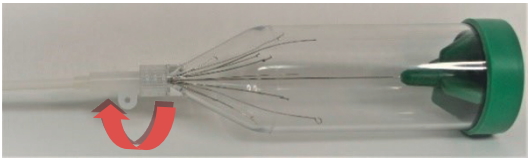
(11)



(12)

***Warning*: The filter is packed in its filter holder by ALN and is ready to use. Never use a filter that has been removed from its filter holder, nor attempt to re-insert it into the filter holder. Do not attempt to modify the filter in any way. In particular, do not increase or reduce its diameter, or change the orientation of the filter in its filter holder.**

Insert the tip of the filter holder into the base of the introducer sheath. Screw the filter holder (clockwise rotation) onto the base of the introducer sheath. (13)



(13)

<u>Warning</u>: Do not force or screw the filter holder too tightly onto the introducer sheath. If necessary, use another filter.

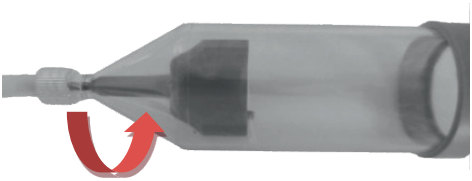
<u>Warning</u>: To avoid kinking the introducer sheath during the progression of the filter, ensure that the introducer sheath is handled by its base and is not bent.

Slowly and carefully push the filter fully using the piston, such that it comes through the conical part of the filter holder. The filter is now inside the introducer sheath. (14)

(14)

<u>Warning</u>: If one or more filter's legs are deformed in the filter holder, do not insist and use another filter.

Remove the empty filter holder by unscrewing it (counter-clockwise rotation). (15)



(15)

7: Advancing the filter to the implantation site

Under medical imaging, move the filter down using the pushing catheter. Align the pushing catheter's black mark with the base of the introducer sheath. (16)

(16)

<u>Warning</u>: If difficulties are encountered when pushing the filter through the introducer sheath, do not insist and repeat the procedure with a second implantation kit.

Confirm the appropriate position of the ALN OATF Vena Cava Filter in the inferior vena cava. For a normal IVC, the apex of the filter should be below the lowest renal vein. Position the radio-opaque band of the introducer sheath below the lowest renal vein (see figure 1).

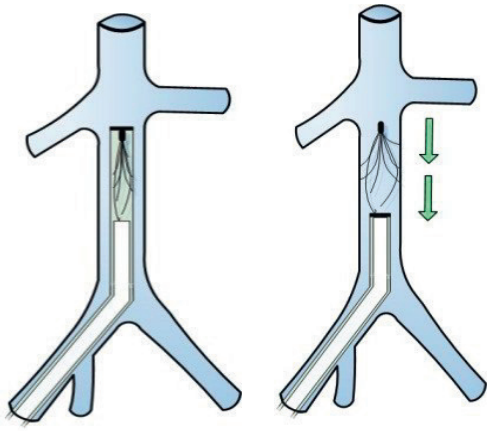


Figure 1: Positioning the ALN OATF Vena Cava Filter below the lowest renal vein following popliteal approach introduction.

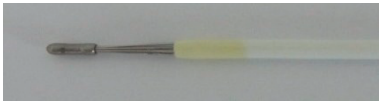
***Warning*: Do not release the filter until it is in its optimal position, the most appropriate implantation site being confirmed by cavography.**

8: Filter release at the implantation site

***Warning*: Do not deploy the filter if any measurement of the inferior vena cava diameter has been made. An ALN OATF Vena Cava Filter cannot be implanted on patients whose inferior vena cava diameter is greater than 32 mm since a correct fixation of the latter is compromised with an increased risk of migration of the filter.**

Withdraw the introducer sheath back over the pushing catheter with a slow and steadily movement, until the filter is released. (17) (18)

(17)



(18)

***Warning*: Once the pushing catheter's black mark is aligned with the base of the introducer sheath, release the filter by immobilizing the base of the pushing catheter, and slowly and steadily withdrawing the introducer sheath back. This ensures the optimal position of the filter.**

***Warning*: Do not attempt to remove or reposition the filter once the hooks have been engaged into the walls of a vessel except by using the ALN Extraction or Repositioning Kit intended for this purpose. The sharp hooks could cause severe damages to tissues.**

***Warning*: A misplaced filter which, nevertheless, protects the patient against a pulmonary embolism in an appropriate way, should be left in place. If a misplaced filter doesn't protect the patient against a pulmonary embolism in an appropriate way, it should be repositioned, or a second filter should be implanted. Removal, either by surgical way, or by using the ALN Extraction or Repositioning Kit intended for this purpose, is recommended for a misplaced filter that could cause cardio-respiratory consequences.**

9: End of procedure

Withdraw the pushing catheter and perform a post-operative control cavography with subtracted and non-subtracted images (anterior posterior (AP) and lateral cavography). All images should be archived and available on film or electronic media, appended to the patient's record.

Withdraw the introducer sheath.

Achieve hemostasis at the puncture site.

An X-ray imaging should be performed twenty four (24) hours after the filter's implantation.

This reference document with regard to filter's entirety and position should be available for later consultation (Appended to the patient's record).

10: Patient's follow-up

Considering the above-mentioned risks, patient's follow-up should include the following points:

- 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 practitioner who placed the filter or by his medical team, or by the clinician who referred the patient for the procedure within the first month.
- A written document stating:
  - ✓ Filter's type, batch and serial number,
  - ✓ Implantation date,
  - ✓ Hospital and department where the filter has been implanted

should be provided to the patient and his/her referring physician. The patient and the referring physician should be informed of the necessary follow-up and possible complications.

In this respect, it is imperative to give to the patient the implantation's card provided by ALN.

- Inferior vena cava permeability control imaging should be performed if there is the slightest suspicion of recurrent pulmonary embolism or phlebitis.

A Summary of Safety and Performance Characteristics will be available in the European Medical Device Database (EUDAMED) via this link: SS(C)P > SS(C)P: DOC-225 - EUDAMED.

The public website of Eudamed is: https://ec.europa.eu/tools/eudamed/#/screen/home.

An electronic copy of this user manual is available on ALN's website: www.aln2b.com.

11: MRI

A non-clinical test, conducted in accordance with the ASTM F2052 standard, has demonstrated that the ALN OATF Vena Cava Filter is "MR-conditional". A patient with this implant can be scanned safely in an MR system after placement under the following conditions:

- Static magnetic field of 3 Tesla or less,
- Spatial magnetic field gradient of 600-Gauss/cm or less,
- Maximum SAR of 2 W/kg for a 15-minute examination.

During the non-clinical test, the ALN OATF Vena Cava Filter generates a 2.2°C increase in temperature for a 2 W/kg SAR during 15 minutes, on a 3-Tesla MRI.

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. In all cases, see the MRI machine's user manual when conducting an examination on a patient implanted with an ALN OATF Vena Cava Filter.

12: Removal

When the risk of embolism or placement indications are no longer present, the ALN OATF Vena Cava Filter can be removed at any time, using the **ALN Extraction or Repositioning Kit** intended for this purpose.

The removal procedure is described in instructions for use of the **Extraction or Repositioning Kit for ALN Vena Cava Filter.**

Any attempt to manipulate the ALN OATF Vena Cava Filter using accessories other than those allowed is prohibited and under the practitioner's entire responsibility.

The ALN OATF Vena Cava Filter can also be implanted permanently. The decision to remove the filter should be taken individually for each patient according to his/her clinical condition.

13: Packaging and handling

The ALN OATF Vena Cava Filter is provided ready to use, sterile (ethylene oxide sterilized) and non-pyrogenic. Do not use the product if its package is damaged or open, or if there is a doubt whether is sterile.

The product must be handled under aseptic conditions.

The product should be stored a dry place and kept away from sunlight.

Do not use the ALN OATF Vena Cava Filter beyond the expiration date indicated on the label.

The ALN OATF Vena Cava Filter is intended for one-time use. It must not be reused and the kits components must not be re-sterilized.

14: Disposal of the device

A used device becomes infectious risk healthcare waste. It must undergo decontamination and be eliminated by the appropriate channel (example: incineration or pre-treatment by disinfection) in accordance with usual medical practices and according to the regulations in force.

An unused device must be disposed of as follows: the needle must be disposed of with waste from health care activities at risk of infection if it has been removed from its packaging because it may expose to a risk of injury. The cardboard box and the paper instructions are to be recycled. The rest of the device can be disposed of through the conventional waste stream of healthcare establishments.

15: Warranty

ALN declares to have manufactured this product with all necessary care. This guarantee replaces and excludes all other formal or tacit guarantees granted by virtue of any other provision not expressly stated in the present, in particular all tacit guarantees concerning the product's suitability for sale and for specific use, as inappropriate handling, storage, repeat cleaning and repeat sterilization of this product, along with certain factors related to the patient, diagnosis, treatment and surgical procedures, etc., beyond the control of ALN have an impact on this product and on the results achieved with it.

ALN cannot be held responsible for any fortuitous or indirect damage, nor for losses or costs resulting, either directly or indirectly, from the use of this product. It shall, however, be obliged to replace it.

Certain countries do not allow the exclusion of implicit guarantees, or accessory or indirect damage. You may have access to other legal action in accordance with the laws of your country.

Furthermore, ALN accepts no other additional commitments or responsibilities in relation to this product, and does not authorize any third parties to do so.

16: Duty to report incidents or risks of incident

To the attention of the user and/or patient: any serious incident occurring in connection with the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

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