INSTRUCTIONS FOR USE:

ALN VENA CAVA FILTER EXTRACTION AND/OR REPOSITIONING KIT

ALN Straight RS

EN

Reference : FT.902010

JUGULAR ROUTE
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1. General information

The ALN Vena Cava Filter Extraction and/or repositioning kit is intended only to remove the ALN Vena Cava Filter with or without a hook when the filtration indication no longer exists for a patient (see section 4 ALN Vena Cava Filter withdrawal indication and 5 Warnings)

- This medical device is available under three references:
  - ALN Straight RS Extraction and/or Repositioning kit: reference FT.902010
  - ALN Pre-curved RS Extraction and/or Repositioning kit: reference FT.902010/VS2.
  - ALN 2in1 RS Vena Cava Filter Extraction and/or Repositioning kit: reference RK-2010

- The choice of device to use is individual to each patient. Nevertheless, ALN strongly recommends ensuring that both the straight and curved references, or the curvable reference, are available.

- The ALN Vena Cava Filter is an optional filter (definitive and/or temporary). Its efficacy and safety having been confirmed1, it must be kept in mind that it can be permanently implanted and there is no obligation to remove it.

- The decision to remove the ALN Vena Cava Filter is made individually for each patient (benefit/risk ratio for the patient). Before making a withdrawal decision, the degree of withdrawal urgency must be determined.

- The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit can only be used via the jugular route.

- Read the instructions carefully before use.

- The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit is supplied sterile (ethylene oxide sterilisation). It is intended for single use and must not be re-sterilised.
## 2. Symbols

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

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<tr>
<th>Symbol</th>
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<td><img src="image" alt="Warning" /></td>
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<td><img src="image" alt="Keep in a dark place" /></td>
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*Table 1: List of symbols used in the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit*
### 3. Kit contents

The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit comprises the following items:

- A Clamp Catheter, comprising:
  - a 7F sheath with two black marks (1)
  - a basket-shaped clamp comprised of eight 316LVM stainless steel strands (2), connected by a central 316LVM stainless steel bar to a yellow cast-moulded handle (3)
  - a three-way rinse valve (4)
- A dilator with red Luer Lock end piece (5)
- A 9F introduction sheath with radio-opaque marker (6)
- A puncture needle (7)
- A Teflon-coated J-guide, designed for use in the context of percutaneous catheter insertion. (8)

The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit is provided sterile (ethylene oxide sterilisation). It is intended for single use and must not be re-sterilised.

| Clamp Catheter | (1) 7F sheath (inner diameter: 7F; outer diameter: 9F; length: 600mm) for Clamp Catheter with two black marks |
| (2) 8-strand clamp | (2) 8-strand clamp |
| (3) Cast-moulded handle | (3) Cast-moulded handle |
| (4) 3-way valve | (4) 3-way valve |
| (5) Dilator (inner diameter: 3F; outer diameter: 9F; length: 630mm) | (5) Dilator (inner diameter: 3F; outer diameter: 9F; length: 630mm) |
| (6) 9F introduction sheath (inner diameter: 9F; outer diameter: 11F; length: 570mm) with radio-opaque marker | (6) 9F introduction sheath (inner diameter: 9F; outer diameter: 11F; length: 570mm) with radio-opaque marker |
| (7) Puncture needle | (7) Puncture needle |
| (8) Teflon-coated J-guide (0.035"; maximum diameter of the flexible J end: 9F; length: 150cm) | (8) Teflon-coated J-guide (0.035"; maximum diameter of the flexible J end: 9F; length: 150cm) |
4. ALN Vena Cava Filter extraction indications

The indications for withdrawing the ALN Vena Cava Filter using the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit listed below are approved by the SFICV². They are based on the SIR and CIRSE³ agreements:

- The permanent filtration indication is no longer present
- The risk of symptomatic pulmonary embolism is acceptably low after successful initial anticoagulant treatment (therapeutic or preventive) or on change in the patient's clinical status.
- The patient is not likely to return to a high risk of pulmonary embolism following interruption of initial anticoagulant therapy and new clinical conditions.

In particular, do not remove the ALN Vena Cava Filter if the patient is to eventually undergo a high thromboembolic-risk surgical procedure.

- The patient's life expectancy is sufficiently long to achieve the estimated benefit from terminating filtration;

In particular, patients with a life expectancy of less than 6 months are not indicated for Vena Cava Filter removal.

- Extraction may be performed in a risk-free manner if the patient has no prior history of severe reaction to contrast agents, difficult venous approach, and if the extraction does not present significant risks for the inferior vena cava due to the nature, condition or position of the filter.
- The patient is aware of the potential risks associated with removal and agrees to the procedure being performed.
- The patient is aware that, in certain circumstances, the ALN Vena Cava Filter cannot be removed (technical or therapeutic impossibility) and accepts this risk.
- The patient is aware that the ALN Vena Cava Filter is an optional filter (permanent and/or temporary) and that is has been designed to be implanted permanently should the removal procedure be impossible.

5. Warnings

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

1. Read the instructions for use carefully.

2. The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit is intended only to remove and/or reposition the ALN Vena Cava Filter when the filtration indication no longer exists for a patient (see section 4 ALN Vena Cava Filter extraction indication)

3. ALN declines all liability in the event of attempted removal of a medical device using the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit.

4. ALN declines all liability in the event of attempted removal of the ALN Vena Cava Filter using a device other than the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit provided for this purpose.

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

6. The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit is provided ready to use, sterile (ethylene oxide sterilised) and non-pyrogenic. Do not use the product if its packaging is damaged or open.
7. The product should be stored in a cool, dry and dark place.

8. Do not use the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit after its use-by date.

9. The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit is intended for a single use. It must not be reused and the kit’s components must not be re-sterilised.

10. The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit can only be used via the jugular route.

11. The ALN Vena Cava Filter is an optional filter (definitive and/or temporary). Its efficacy and safety having been confirmed, it must be kept in mind that it can be permanently implanted and there is no obligation to remove it.

12. The decision to remove the ALN Vena Cava Filter is made individually for each patient (benefit/risk ratio for the patient). Before making a withdrawal decision, the degree of withdrawal urgency must be determined.

General warnings relative to the patient’s clinical condition

13. Patients with still active thromboembolic disease undergoing anticoagulant treatment:

✓ The time during which the patient is exposed to the risk of relapse of pulmonary embolism must be individualised to each patient (integration of known risk factors).

✓ Patients receiving anticoagulants for whom ALN Vena Cava Filter removal is planned must have undergone tests (International Normalized Ratios assay) with standards-compliant results for at least 7 days prior to removal, in order to avoid any risk of haemorrhage.

✓ Any suspicion of failure or complication of the anticoagulant treatment must be eliminated prior to considering removal of the ALN Vena Cava Filter.

14. Patients with no thromboembolic disease:

✓ Removal of the ALN Vena Cava Filter, for patients at risk of thromboembolic disease, with no diagnosis of thromboembolic disease, for whom a filter has been implanted for preventive purposes, may be considered once the initial prevention has been successfully completed and is likely to be maintained, or once the high risk of pulmonary embolism has been reduced.

✓ There should be no obvious evidence of development of thromboembolic disease before removing the ALN Vena Cava Filter.

15. Other cases:

✓ If, for specific reasons, the ALN Vena Cava Filter is no longer able to play its preventive role with respect to pulmonary embolism, or if it represents a hazard to the patient, removal must be considered.

✓ If the filtration indication is still present, another ALN Vena Cava Filter should be implanted.

Warnings relative to checks to be performed before removal of the ALN Vena Cava Filter

16. Control imaging and a precise blood evaluation must be performed.

Control imaging:

Check the Inferior Vena Cava and ALN Vena Cava Filter using a diagnostic imaging system:

✓ Patient with no suspicion of thromboembolic disease relapse: perform a cavography.
Patient with suspicion of thromboembolic disease relapse: Appropriate imaging should be performed before extracting the ALN Vena Cava Filter (pulmonary angiogram).

In all cases, before any ALN Vena Cava Filter removal procedure, check the permeability of the inferior vena cava and ensure there are no thrombi in the vicinity of the ALN Vena Cava Filter. This examination can be performed via Doppler ultrasound, CT scan with injection, or cavography.

If a thrombus is found to be trapped in the ALN Vena Cava Filter, its size and type must be determined prior to making the removal decision. Indeed, the presence of a thrombus trapped in the ALN Vena Cava Filter may indicate that the filter has played its role perfectly (in this case, ensure that the disease is not progressive), or that the ALN Vena Cava Filter presents a thrombosis problem.

Before removal, it is essential to ensure that the patient is not in thromboembolic disease relapse.

Discovery of thromboembolic disease in these patients will require postponement of the procedure and implementation of anticoagulant therapy, if there are no contraindications for the patient. In order to reconsider ALN Vena Cava Filter removal, biological test results must conform to standard values for at least 3 weeks previously.

If, after clinical tests, it is accepted that the patient is not in thromboembolic relapse, removal of the ALN Vena Cava Filter may be considered provided that the size of the thrombus does not represent a significant clinical risk.

- If the trapped thrombus is too large (excessive risk of thrombus migration during the procedure and potential pulmonary embolism), further anticoagulant treatment may be implemented (if not contraindicated for the patient) and an examination may be conducted several weeks after initiation of this therapy in order to reconsider removal.

- Decisions shall be made individually for each patient.

**Blood evaluation:**

- Patients undergoing anticoagulant treatment must undergo blood tests to confirm the absence of haemorrhagic problems for at least 7 days prior to removal. A biological examination on the day of the procedure shall serve to confirm the validity of the removal procedure.

- Biological tests:
  - Measurement of prothrombin level (expressed in INR): as an indication, the conventionally recommended INR values fall between 2 and 3 - concerning prophylaxis or treatment of vein thrombosis –
  - Complete blood examination with platelet count: for information: 150,000 – 400,000 /mm3
  - Creatinaemia: for information, creatinine levels in blood should not exceed 115 micromoles/litre, i.e. 7 to 13 mg; before injection of iodinated contrast medium.
  - Partial thromboplastin time (PTT).

Continuation or termination of anticoagulant treatment should be determined on a per case basis by the medical team.

**Cavography-related warnings**

17 A frontal and lateral cavography must be performed before the removal procedure. The purpose of this examination is to check:

- The permeability and anatomy of the inferior vena cava.
- The absence of thrombi,
- The position of the ALN Vena Cava Filter
The result of the cavography in terms of inferior vena cava anatomy, along with the position of the ALN Vena Cava Filter, shall assist the practitioner in selecting the type of Extraction and/or Repositioning kit to use (straight, reference FT.902010, curved, reference FT.902010/VS2, or 2IN1, reference RK-2010).

18 During injection of contrast medium into the 9F introduction sheath, do not exceed a pressure of 450 psi.

19 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).

20 If there is any doubt concerning the anatomy of the vena cava and/or the position of the ALN Vena Cava Filter new pictures should be taken with different incident angles.

21 A control cavography may be performed after the extraction procedure.

22 If the ALN sheath and dilator system is used to perform a control cavography, ensure that the dilator has been removed before performing the cavography. Failure to remove the dilator could damage the vena cava.

23 If the control cavography is performed using the 9F ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit introduction sheath, ensure that the distal end of this sheath does not enter into contact with the implanted ALN Vena Cava Filter. This could modify the filter's position (risk of tilting or migration).

**General procedure-related warnings**

24 The expertise of physician and non-physician operators who will be performing the procedures must conform to the recommendations of the SFICV2.

- A Junior Operator must have previously assisted a senior during at least 6 removals (as 2nd operator) and must have removed at least 6 filters himself/herself under the supervision of a senior to be deemed competent.

- A senior may maintain his/her skill by removing at least 6 filters per year without incident.

- The electroradiology operator should possess basic vascular procedure training, as defined by the SFICV2.

- Nurses, including operating theatre nurses, must have undergone specific invasive and interventional vascular imaging training.

In case of preventive indication for ALN Vena Cava Filter placement - in particular prior to surgery with a high risk of pulmonary embolism - it is essential to ensure that the surgical team in charge of the patient is aware of the presence of the ALN Vena Cava Filter.

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

- Major surgery (thorax, abdomen, etc.),
- procedures potentially modifying haemodynamics,
- procedures that may cause contact with the inferior vena cava and/or the filter placement site.

Being aware of the above-mentioned potential risks, it is important to ensure that all elements pertaining to ALN Vena Cava Filter placement are logged in the patient record, which should be checked prior to each procedure.

26 Operators must wear sterile clothing.

27 Before the procedure, the elements of the kit (J guide and introduction system (dilator + 9F introduction sheath) should be rinsed with a sterile physiological saline solution or similar isotonic solution.
28 The entire procedure must be conducted under medical imaging (preferably fluoroscopy).

**Warnings relative to use of the J guide**

29 The J guide should be used by a physician with appropriate cardiac catheterisation training. Never advance the J guide or introduction system without radiological control.

30 During J guide progression, check for the absence of bends or loops, monitoring the progress under medical imaging. Always ensure that 2-3cm of J guide extend beyond the proximal end of the introduction system.

31 Do not attempt to advance or remove the guide in the event of resistance. The cause of resistance should be determined by radioscopy. If the cause of resistance cannot be determined, remove the guide and catheter together.

32 Make sure to remove the J guide and dilator before performing the control cavography in order to avoid causing any trauma to the vena cava.

33 Radiographs performed without radio contrast medium, that do not clearly show the anatomy of the inferior vena cava, may be misinterpreted.

34 A certain number of potential J guide-related complications exist when used on patients with Vena Cava Filters. Consequently, the withdrawal procedure must not be performed by practitioners unaware of these complications. These complications include, in particular, a risk of migration, of tilting and the possibility of the J guide becoming trapped in the filter.

**Warnings relative to implementation of the 9F introduction sheath**

35 Ensure that the distal end of the 9F introduction sheath does not enter into contact with the implanted ALN Vena Cava Filter. This could modify the filter's position (risk of tilting or migration).

36 Before inserting the Clamp Catheter into the introduction sheath, the radio-opaque ring on the sheath's distal end must be positioned 2cm above the Filter head. This distance is essential to start the procedure under optimum conditions.

**Warnings relative to insertion of the Clamp Catheter into the 9F introduction sheath.**

37 Ensure that the J guide and dilator have been removed before inserting the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit.

38 To avoid puncturing the 9F introduction sheath, ensure that the 9F introduction sheath is handled by its base and is not bent.

39 Always ensure that the 9F introduction sheath is adequately rinsed with a sterile heparinised physiological saline solution or similar isotonic solution. Insufficient equipment rinsing may lead to clot formation in the introduction system. If the removal procedure is longer than planned, rinse the 9F introduction sheath regularly.

40 Never insert the Clamp Catheter into the 9F introduction sheath before having retracted the Clamp of the Clamp Catheter into its sheath. For this, turn the yellow Luer Lock handle left to unlock and pull for approximately 5cm.

41 Ensure that the base of the 9F introduction sheath is in contact with the base of the Clamp Catheter.

42 Use the yellow handle Luer Lock and never unlock the Luer Lock screwed onto the Clamp Catheter sheath.

43 Lock the Clamp Catheter Luer Lock by rotating the yellow handle right, causing the clamp to open.

44 In the event of a long and difficult procedure (several attempts to capture the filter head and clamp movement inside the vena cava) and to avoid any trauma to the vena cava wall, ALN recommends
reducing clamp opening - or even closing it completely - by sliding the 9F introduction sheath over the clamp's hooks.

**Warnings relative to capturing the ALN Vena Cava Filter**

45 Never attempt to remove the ALN Vena Cava Filter by one of its strands. The ALN Vena Cava Filter must strictly be removed by its head.

46 To remove the ALN Vena Cava Filter under optimum conditions, the Filter head must be fully engaged into the Clamp of the Clamp Catheter.

47 In the event that it is difficult (or even impossible) to insert the filter head fully into the Clamp, use the ANGLED Extraction and/or Repositioning kit. It is still possible to bend the STRAIGHT Extraction and/or Repositioning kit, without using steam (cold operation) and without the risk of plication. Nevertheless, ALN strongly recommends ensuring both references are available.

48. To bend the STRAIGHT Extraction and/or Repositioning kit, the following procedure must be followed: Leave the 9F introduction sheath in place (radio-opaque strip 2cm from the filter head). Remove the Clamp Catheter after ensuring that the clamp has been correctly retracted into its sheath. On the table, remove the clamp from its sheath and rinse the device thoroughly via the 3-way valve. Apply the necessary angle at a distance of approximately 5cm from the distal end of the sheath. Rinse the device once more, retract the clamp and reinsert. This procedure can be repeated several times, though any subsequent manipulations will be less easy to perform.

49 When the Filter is ready to be captured, do not pull on the Clamp Catheter until the filter is completely captured.

50 If the position of the Filter does not allow easy removal (filter head against the wall of the vena cava for example), the degree of urgency and the operator's experience should be taken into account before performing any further endovascular manoeuvres.

51 As losing the filter during the procedure is a possible risk, the recommendations made by ALN must be followed.

**Filter recovery-related warnings**

52 Do not pull on the Clamp Catheter if the coloured Clamp Catheter is not visible or has been passed.

53 Carefully monitor filter, Clamp Catheter and 9F introduction sheath progression via medical imaging.

54 To remove the ALN Vena Cava Filter from the 9F introduction sheath and to use the sheath for postoperative control cavography (recommended), sufficient tension must be applied to the filter.

**Warnings relative to checks to perform after removing the ALN Vena Cava Filter**

55 Imaging is essential after removal of the ALN Vena Cava Filter to confirm the absence of trauma to the inferior vena cava or vena cava thrombus.

This imaging is all the more essential if the procedure was long and difficult, or if the patient complained of pain during or after this procedure.

If inferior vena cava trauma is observed, additional procedures and close clinical monitoring will be necessary.

56 Filter integrity must be confirmed.

Should a piece of the filter be missing, check the sheath and check the abdomen under imaging to locate and document the missing filter elements.

57 Therapeutic follow-up after ALN filter removal
Patients should be treated according to the diagnosis of their thromboembolic disease, with no specific treatment and continuing their therapy if applicable.

All patients should be monitored for the appearance of a new, relapse or progressive deep vein thrombosis and/or pulmonary embolism.

**Other warnings**

58 After use, the kit components should be discarded as per usual medical practice and according to applicable regulations.

**6. Necessary resources**

1. Human resources:

The expertise of physician and non-physician operators who will be performing the procedures must conform to the recommendations of the SFICV².

A Junior Operator must have previously assisted a senior during at least 6 removals (as 2nd operator) and must have removed at least 6 filters himself/herself under the supervision of a senior to be deemed competent.

A senior may maintain his/her skill by removing at least 6 filters per year without incident.

The electroradiology operator should possess basic vascular procedure training, as defined by the SFICV².

Nurses, including operating theatre nurses, must have undergone specific invasive and interventional vascular imaging training.

2. Material resources:

Vena Cava Filter removal should be conducted as any other vascular interventional procedure, under resource and organisation conditions as defined by the SFICV².

During the procedure, all patients must be placed under continuous cardiac and intermittent blood pressure monitoring. Vital signs should be recorded. An intravenous route should be set up for all patients for administering solutes and drugs as required. The equipment and drugs required for emergency resuscitation must be immediately available and staff trained in their use.

Necessary equipment not provided by ALN:

- Sterile physiological saline solution or similar isotonic solution for system rinsing.
- Sterile syringe for perfusing the sterile physiological saline solution
- Contrast medium used for cavography
- Local anaesthetic
- Basic catheterisation materials and miscellaneous consumables.
7. ALN Vena Cava Filter extraction procedure

Warning: The entire procedure must be conducted under medical imaging.
Warning: Before starting the ALN Vena Cava Filter removal procedure, several checks need to be performed. See the section "Warnings relative to checks to perform before removal of the ALN Vena Cava Filter" in this manual. In particular, imaging is essential to check for the presence of a thrombus in the ALN Vena Cava Filter. If a thrombus is present, do not extract the ALN Vena Cava Filter.
Warning: The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit can only be used via the jugular route.

1: Patient preparation:

Disinfect and use sterile sheets (1). The necessary equipment is carefully prepared (2) (extraction kit, sterile heparinised physiological saline solution or similar isotonic solution for rinsing the system, etc.; see section 6.2. Material resources).

After local anaesthetic, puncture the right internal jugular vein using the puncture needle (3) provided.

2: Inserting the J guide and rinsing the introduction system

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

Warning: A certain number of potential J guide-related complications exist when used on patients with Vena Cava Filters. Consequently, the withdrawal procedure must not be performed by practitioners unaware of these complications. These complications include, in particular, a risk of migration, of tilting and the possibility of the J guide becoming trapped in the ALN Vena Cava Filter.

Flush the J guide with sterile physiological saline or similar isotonic solution, fixing a syringe to the Luer Lock base of the guide's distributor.(4) Insert the flexible end of the guide (5) into the puncture needle in place on the patient.
Under medical imaging, lower the J guide through the needle using the stiffener until it is positioned above the filter. Leave a suitable length of guide exposed. Hold the guide in place and remove the puncture needle and guide stiffener (6). To facilitate the manipulation, a slight incision can be made to the tissues surrounding the guide.

**Warning:** During J guide progression, check for the absence of bends or loops, monitoring the progress under medical imaging. Always ensure that 2-3cm of J guide extends beyond the proximal end of the introduction system (7).

**Warning:** Do not attempt to advance or remove the guide in the event of resistance. The cause of resistance should be determined by radioscopy. If the cause of resistance cannot be determined, remove the guide and catheter together.

### 3: Advancing the Dilator and 9F introduction sheath

Under medical imaging, slide the Dilator + 9F introduction Sheath assembly (8) over the J guide and position the radio-opaque ring 2cm above the filter head (9).
Warning: Ensure that the distal end of the 9F introduction sheath does not enter into contact with the implanted ALN Vena Cava Filter. This could modify the ALN Vena Cava Filter's position (risk of tilting or migration).

Warning: Before inserting the Clamp Catheter into the 9F introduction sheath, the radio-opaque ring on the sheath's distal end must be positioned 2cm above the head of the ALN Vena Cava Filter. This distance is essential to start the procedure under optimum conditions.

Warning: To avoid puncturing the 9F introduction sheath, ensure that the 9F introduction sheath is handled by its base and is not bent.

Remove the J guide. (10)

Remove the dilator by unscrewing the red Luer Lock connector by one quarter turn left. (11)

4: Inserting the Clamp Catheter into the 9F introduction sheath

Warning: Ensure that the J guide and dilator have been removed before inserting the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit.

Before inserting the Clamp Catheter into the 9F introduction sheath, the sheath should be rinsed with heparinised physiological saline.

Warning: Insufficient equipment rinsing may lead to clot formation in the system. If the removal procedure is longer than planned, rinse the 9F introduction sheath regularly.
Move the clamp inside its 7F sheath by rotating the yellow Luer Lock left to unlock, then pulling it for approximately 2cm (12).

*Warning:* Never insert the Clamp Catheter into the 9F introduction sheath before having retracted the Clamp of the Clamp Catheter into its sheath.

*Warning:* Use the yellow handle Luer Lock and never unlock the Luer Lock screwed onto the Clamp Catheter sheath (13).

Under frontal and lateral imaging, fully insert the Clamp Catheter into the 9F introduction sheath (14).

*Warning:* Ensure that the base of the 9F introduction sheath is in contact with the base of the Clamp Catheter (15).
Push, then lock the Clamp Catheter's yellow Luer Lock handle, rotating it to the right (16) in order to release the curved section, which is then in curved position, along with the clamp's hooks.

5: Capturing the ALN Vena Cava Filter

*Warning:* Never attempt to remove the ALN Vena Cava Filter by one of its strands. The ALN Vena Cava Filter must strictly be removed by its head. (17)

Slowly lower the Clamp Catheter over the head of the ALN Vena Cava Filter and ensure that the Clamp Catheter is fully in contact with the head of the ALN Vena Cava Filter (18) (under medical imaging, preferably from a lateral or three quarter angle).

*Warning:* In the event that it is difficult (or even impossible) to insert the ALN Vena Cava Filter head fully into the Clamp, use the ANGLED Extraction and/or Repositioning kit. It is still possible to bend the STRAIGHT Extraction and/or Repositioning kit, without using steam (cold operation) and without the risk of plication (see warning no. 47). Nevertheless, ALN strongly recommends ensuring both references are available.

*Warning:* If the position of the ALN Vena Cava Filter does not allow easy removal (filter head against the wall of the vena cava for example), the degree of urgency and the operator's experience should be taken into account before performing any further endovascular manoeuvres.
Initially, continue to slowly lower the 9F introduction sheath over the ALN Vena Cava Filter until the coloured mark on the 7F Clamp Catheter sheath is visible. This mark indicates that the filter has been replaced in the 9F sheath (19).

**Warning:** Do not pull on the Clamp Catheter if the coloured Clamp Catheter is not visible or has been passed.

Secondly, with a slow movement, remove the Clamp Catheter until the second, black mark (20) becomes visible. Extract the filter from the 9F introduction sheath by pulling on it firmly (21).

**Warning:** Carefully monitor ALN Vena Cava Filter, Clamp Catheter and 9F introduction sheath progression via medical imaging.

Perform a control cavography using the 9F introduction sheath left in place.

**Warning:** To remove the ALN Vena Cava Filter from the 9F introduction sheath and to use the sheath for postoperative control cavography (recommended), sufficient tension must be applied to the ALN Vena Cava Filter.

**6: End of procedure**

Remove the 9F introduction sheath from the inferior vena cava and stem the bleeding at the puncture point.

**Warning:** After use, the kit components should be discarded as per usual medical practice and according to applicable regulations

**8: ALN Vena Cava Filter repositioning procedure**

We recommend repositioning the ALN Vena Cava Filter in the event of:
- Premature ALN Vena Cava Filter deployment during placement.
- ALN Vena Cava Filter deployment in a position different to that initially planned.
- Significant tilting, reducing the ALN Vena Cava Filter’s filtration capacity.

1: Removing the ALN Vena Cava Filter

Slowly lower the Clamp Catheter over the head of the ALN Vena Cava Filter and ensure that the Clamp Catheter is fully in contact with the head of the ALN Vena Cava Filter (24) (under medical imaging, preferably from a lateral or three quarter angle).

**Warning:** In the event that it is difficult (or even impossible) to insert the ALN Vena Cava Filter head fully into the Clamp, use the ANGLED Extraction and/or Repositioning kit. It is still possible to bend the STRAIGHT Extraction and/or Repositioning kit, without using steam (cold operation) and without the risk of plication (see warning no. 47). Nevertheless, ALN strongly recommends ensuring both references are available.

**Warning:** If the position of the ALN Vena Cava Filter does not allow easy removal (filter head against the wall of the vena cava for example), the degree of urgency and the operator’s experience should be taken into account before performing any further endovascular manoeuvres.

To reposition the ALN Vena Cava Filter, slowly lower the 9F introduction sheath onto the ALN Vena Cava Filter until the black mark on the 7F Clamp Catheter sheath appears. This mark indicates that the filter has been replaced in the 9F sheath (23).

**Warning:** Once the ALN Vena Cava Filter is inside the 9F introduction sheath, a solution of sterile physiological saline must be injected regularly to avoid the formation of blood clots that could compromise correct filter deployment.

2: Positioning the 9F introduction sheath at the implant site

Position the radio-opaque ring of the 9F introduction sheath approximately 55mm below the lowest renal vein if prior tests have confirmed possible placement beneath the lowest renal vein. (24)
Warning: Do not release the filter until it is in its optimum position, the most appropriate placement site being confirmed by cavography.

Warning: Deliberate positioning of the filter above the renal veins should only be performed after checking compatibility of the suprarenal vena cava (maximum 32mm) and if the available space between renal veins and cardiac atrium is of at least 55mm (filter height).

3: Advancing the filter to the placement site

While immobilising the clamp handle, slide the 9F introduction sheath over the Clamp Catheter by imparting a slow and smooth retrieval motion (towards yourself) until the clamp is free of the 9F introduction sheath. The clamp should now be fully open and the filter completely deployed. (25)

Next, pull the handle in a slow and straight motion to move the clamp away from the filter head. The clamp should be 2cm away from the filter head. (26) The 9F introduction sheath should be pulled at the same time as the handle.
Warning: The withdrawal movement should be slow and straight to avoid tilting the filter.

Warning: Do not pull the Clamp Catheter relative to the 9F introduction sheath, but rather with the 9F introduction sheath, or the clamp may be closed over the filter head.

Warning: A poorly positioned filter, but that nevertheless confers adequate protection against pulmonary embolism, should be left in place. If the filter is not positioned in such a manner as to protect against pulmonary embolism, it must either be repositioned, or a second filter implanted. Removal, either by surgical means, or using the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit, is recommended for an incorrectly positioned filter that could have cardiorespiratory effects.

4: Removing the Clamp Catheter

To remove the Clamp Catheter, slowly lower the 9F introduction sheath onto the Clamp Catheter until it is completely covered (2cm). (27)

Warning: The procedure must be monitored under medical imaging to ensure that the clamp is fully inserted into the 9F introduction sheath.

Remove the Clamp Catheter by imparting a slow retrieve motion until the clamp exist the base of the 9F introduction sheath.

Warning: Monitor Clamp Catheter retrieval carefully under medical imaging.

Perform a control cavography using the 9F introduction sheath left in place.
5: End of procedure

Remove the 9F introduction sheath from the inferior vena cava and stem the bleeding at the puncture point.

**Warning:** After use, the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit components should be discarded as per usual medical practice and according to applicable regulations.

9: Patient follow-up

In light of the risks mentioned, we recommend conducting a patient follow-up, involving the following points:

- Examine the catheter insertion point to ensure it is healing correctly.
- Imaging is essential after removal of the ALN Vena Cava Filter to confirm the absence of trauma to the inferior vena cava or vena cava thrombus.

This imaging is all the more essential if the procedure was long and difficult, or if the patient complained of pain during or after this procedure. If inferior vena cava trauma is observed, additional procedures and close clinical monitoring will be necessary.

- The integrity of the ALN Vena Cava Filter must be confirmed. Should a piece of the filter be missing, check the sheath and check the abdomen under imaging to locate and document the missing filter elements.
- An additional procedure is left to the decision of the physician who conducted the initial procedure.

- Therapeutic follow-up after ALN Vena Cava Filter removal
  Patients should be treated according to the diagnosis of their thromboembolic disease, with no specific treatment and continuing their therapy if applicable.
  All patients should be monitored for the appearance of a new, recurrent or progressive deep vein thrombosis and/or pulmonary embolism.

The resumption of anticoagulant treatment must be adapted by the medical team to each patient.

10: Clinical data

A clinical trial, involving 123 patients, was conducted at 3 centres (Bellevue University Hospital in Saint-Etienne, Georges Pompidou European Hospital in Paris and Lille University Hospital) between November 2003 and June 2006 in order to assess removal of the ALN Vena Cava Filter. The trial was conducted on 123 patients who had received an indication for removal of their ALN Vena Cava Filter following a placement period ranging from 6 to 722 days. The mean age of patients who received an indication for removal of their vena cava filter was of 66.8 ±16.5 years (interval: 19-96 years).

The ALN Vena Cava Filter placement indications for these patients were a contraindication to treatment by anticoagulants (recent surgery, haemorrhage or coagulopathy), complications to or failure of anticoagulant treatment (extension of deep vein thrombosis, new deep vein thrombosis and/or pulmonary embolism, haemorrhage, etc.) or other prophylactic indication.

Filters that were implanted due to temporary contraindication to anticoagulant treatment were removed on resumption of treatment. Filters that were implanted due to extension of an existing deep vein thrombosis, or a new deep vein thrombosis under anticoagulants, were removed after 6 months without
clinical signs of recurrence. Filters implanted due to complications to anticoagulant treatment were removed 3 to 6 months post-placement, corresponding to the time required to consider the deep vein thrombosis or pulmonary embolism event as being chronic, with a low risk of recurrence. In the event of prophylactic indication, filters were removed after completion of surgery.

The ALN Vena Cava Filters were removed after a mean placement time of 93 ±15 days (interval: 6-722 days). The ALN Vena Cava Filters were removed using an ALN extraction and/or repositioning kit, introduced via the internal jugular vein.

122 of the 123 filters were successfully removed (success rate: 99%). The case of failed removal concerns a filter that had been implanted for 45 days and that was severely tilted (>15°). The filter head was in contact with the vessel wall and entirely encased in fibrous tissue.

For 4 patients, a thrombus was present in their filter on removal. These patients were administered anticoagulant therapy for 3 weeks before their filter could be removed.

Moderate tilting (<15°) was observed in 37 patients and severe tilting (>15°) in 6 patients. In two cases of severe tilting (placement period between 38 and 81 days), the filter head was in contact with the vessel wall. Both of these filters, however, were successfully removed.

During the removal procedure, two patients presented with bruising at the puncture site, but with no other major complications.

No migration, breakage or filter strand penetration was detected in these patients. The removal procedures did not cause any vessel wall damage.


### 11: Packaging and handling

The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit is provided ready to use, sterile (ethylene oxide sterilised) and non-pyrogenic. Do not use the product if its packaging is damaged or open.

The product should be stored in a cool, dry and dark place.

Do not use the ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit after its use-by date.

The ALN Straight RS Vena Cava Filter Extraction and/or Repositioning kit is intended for a single use. It must not be reused and the kits components must not be re-sterilised.

After use, the kit components should be discarded as per usual medical practice and according to applicable regulations.

### 12: Guaranty

ALN declares to have manufactured this product with all necessary care. This guaranty replaces and excludes all other formal or tacit guaranties granted by virtue of any other provision not expressly stated hereto, in particular all tacit guaranties concerning the product's suitability for sale and for specific use, due to handling, storage, cleaning and sterilisation 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 liable 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.

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

**References**


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