



**INSTRUCTIONS FOR USE  
OF  
THE ALN EXTRACTION AND/OR REPOSITIONING KIT**

**ALN Pre-Curved RS**

**US**



**Reference: FT.902010/VS2**

**Ed. 03/2026**



**STERILE EO**



**JUGULAR APPROACH**



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# 1. General information

The ALN Extraction and/or repositioning kit is intended **only** to remove and/or reposition the ALN Optional Vena Cava Filter with or without a hook when the filtration indication no longer exists for a patient (see section 5: ALN Optional Vena Cava Filter retrieval considerations and section 6: 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 2 in 1 RS 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 RS and Pre-Curved RS references, or the 2 in 1 RS reference, are available.

The ALN Optional Vena Cava Filter is an optional filter (permanent and/or temporary). The ALN Optional Vena Cava Filter is designed to act as a permanent filter or retrievable filter. When clinically indicated it may be retrieved according to the instructions provided under the section "ALN Optional Vena Cava Filter Extraction procedure."

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

The ALN Pre-Curved RS Extraction and/or Repositioning kit can only be used via the **jugular approach**.

Read the instructions for use carefully before use.

The ALN Pre-Curved RS Extraction and/or Repositioning kit is supplied sterile (ethylene oxide sterilization). It is intended for single use and must not be re-sterilized.

## 2. Symbols

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

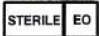
|                                                                                     |                                    |
|-------------------------------------------------------------------------------------|------------------------------------|
|    | Product reference                  |
|    | Batch Code                         |
|    | Serial Number                      |
|    | Use-by Date                        |
|    | Date of Manufacture                |
|    | Caution                            |
|    | Consult Instructions For Use       |
|    | Sterilization Using Ethylene Oxide |
|    | Do Not Reuse                       |
|   | Do Not Resterilize                 |
|  | Do Not Use if Package is Damaged   |
|  | CE mark                            |
|  | Keep Dry                           |
|  | Keep Away from Sunlight            |
|  | Non-Pyrogenic                      |

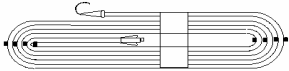
*Table 1: List of symbols used in the ALN Pre-Curved RS*

### 3. Kit contents

The ALN Pre-Curved RS Extraction and/or Repositioning kit comprises the following items:

- A Pincer Catheter, comprising:
  - A 7F sheath with two black marks. (1)
  - A basket-shaped pincer comprised of eight 316LVM stainless steel strands connected by a central 316LVM stainless steel bar to a yellow handle. (2)
  - Moulded handle. (3)
  - A three-way rinse valve. (4)
- An Introduction system comprising a dilator with red luer lock end piece (5) screwed onto the 9F extraction sheath with radio-opaque marker band. (6)
- A puncture needle. (7)
- A Teflon-coated J-guidewire.

The ALN Pre-Curved RS Extraction and/or Repositioning kit is supplied sterile (ethylene oxide sterilization). It is intended for single use and must not be re-sterilized.

| Pincer Catheter                                                                     |                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | <p>(1) 7F sheath (inner diameter: 7F; outer diameter: 9F; length: 596 mm) for a pincer catheter with two black marks</p> <p>(2) 8-strand pincer</p> <p>(3) Cast-moulded handle</p> <p>(4) 3-way rinse valve</p> |
|  | <p>(5) Dilator curved 145° (inner diameter: 3F; outer diameter: 9F; length: 630 mm)</p>                                                                                                                         |
|  | <p>(6) 9F extraction sheath (inner diameter: 9F; outer diameter: 11F; length: 570 mm)</p> <p>With radio-opaque marker band</p>                                                                                  |
|  | <p>(7) Puncture needle</p>                                                                                                                                                                                      |
|  | <p>(8) Teflon-coated J- guidewire (0.035"; length: 150 cm)</p>                                                                                                                                                  |

## 4. Indications for use

The ALN Optional Vena Cava Filter and the ALN Optional Vena Cava Filter with Hook are indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The ALN Optional Vena Cava Filter and the ALN Optional Vena Cava Filter with Hook may be retrieved with the ALN Extraction and/or Repositioning Kit according to the Instructions for Use of these devices.

The ALN Optional Vena Cava Filter with Hook may be also retrieved with a Standard Gooseneck Snare according to the Instructions for Use of this medical device.

The ALN Extraction and/or Repositioning Kit is indicated for the removal of an implanted ALN Optional Vena Cava Filter and ALN Optional Vena Cava Filter with Hook in patients who no longer require a filter. The retrieval of the filter can be performed only by jugular approach.

## 5. ALN Optional Vena Cava Filter retrieval considerations

The considerations for retrieving the ALN Optional Vena Cava Filter using the ALN Straight RS listed below are approved by the SFICV<sup>1</sup>. They are based on the SIR and CIRSE<sup>2</sup> guidelines:

- 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 Optional 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 Optional Vena Cava Filter cannot be removed (technical or therapeutic impossibility) and accepts this risk;
- The patient is aware that the ALN Optional Vena Cava Filter is an optional filter (permanent and/or temporary) and that it has been designed to be implanted permanently should the removal procedure be impossible.

## 6. Warnings

### **General warnings relative to the use of the ALN Optional Vena Cava Filter**

1. Read the instructions for use carefully.
2. The ALN Pre-Curved RS Extraction and/or Repositioning kit is intended **only** to remove and/or reposition the ALN Optional Vena Cava Filter when the filtration indication no longer exists for a patient (see section 4 ALN Optional Vena Cava Filter extraction indication).
3. ALN declines all liability in the event of attempted removal of a medical device using the ALN Pre-Curved RS Extraction and/or Repositioning kit.
4. ALN declines all liability in the event of attempted removal of the ALN Optional Vena Cava Filter using a device other than the ALN Pre-Curved RS Extraction and/or Repositioning kit supplied for this purpose.
5. Any attempt to manipulate the ALN Optional Vena Cava Filter using accessories other than those supplied is prohibited and under the practitioner's entire responsibility.
6. The ALN Pre-Curved RS Extraction and/or Repositioning kit is supplied ready to use, sterile (ethylene oxide sterilized) 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 Pre-Curved RS Extraction and/or Repositioning kit after its use-by date.
9. The ALN Pre-Curved RS 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-sterilized.
10. The ALN Pre-Curved RS Extraction and/or Repositioning kit can only be used via the jugular approach.
11. The ALN Optional Vena Cava Filter is an optional filter (permanent and/or temporary). The ALN Optional Vena Cava Filter is designed to act as a permanent filter or retrievable filter. When clinically indicated it may be retrieved according to the instructions provided under the section "ALN Optional Vena Cava Filter Extraction procedure."
12. The decision to remove the ALN Optional Vena Cava Filter is made individually for each patient (benefit/risk ratio for the patient). Before making a removal decision, the degree of removal 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 individualized to each patient (integration of known risk factors).
- Patients receiving anticoagulants for whom ALN Optional 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 hemorrhage.
- Any suspicion of failure or complication of the anticoagulant treatment must be eliminated prior to considering removal of the ALN Optional Vena Cava Filter.

#### **14. Patients with no thromboembolic disease:**

- Removal of the ALN Optional 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 Optional Vena Cava Filter.

#### **15. Other cases:**

- If, for specific reasons, the ALN Optional 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 Optional Vena Cava Filter should be implanted.

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

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

- In all cases, before any ALN Optional 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 Optional Vena Cava Filter. This examination can be performed via Doppler ultrasound, CT scan with injection, or cavogram.
- If a thrombus is found to be trapped in the ALN Optional 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 Optional 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 Optional Vena Cava Filter presents a thrombosis problem.
- Continuation or termination of anticoagulant treatment should be determined on a per case basis by the medical team.

### **Cavogram-related warnings**

17. Cavogram: A frontal and lateral cavogram 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 Optional Vena Cava Filter,
  - The result of the cavogram in terms of inferior vena cava anatomy, along with the position of the ALN Optional Vena Cava Filter, shall assist the practitioner in selecting the type of Extraction and/or Repositioning kit to use (Straight RS, reference FT.902010, Pre-Curved RS, reference FT.902010/VS2, or 2 in 1 RS, reference RK-2010).
18. During injection of contrast medium into the 9F extraction sheath, do not exceed a pressure of 450 psi.
19. Ensure that the cavogram 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 Optional Vena Cava Filter new pictures should be taken with different incident angles.
21. A control cavogram may be performed after the extraction procedure.
22. If the ALN sheath and dilator system is used to perform a control cavogram, ensure that the dilator has been removed before performing the cavogram. Failure to remove the dilator could damage the vena cava.
23. If the control cavogram is performed using the 9F extraction sheath supplied in the ALN Pre-Curved RS Extraction and/or Repositioning kit, ensure that the distal end of this sheath does not enter into contact with the implanted ALN Optional 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 SFICV<sup>1</sup>.
  - 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 SFICV<sup>1</sup>.
  - Nurses, including operating theatre nurses, must have undergone specific invasive and interventional vascular imaging training.

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 Optional 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-guidewire and introduction system (dilator + 9F extraction 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-guidewire**

29. The J-guidewire should be used by a physician with appropriate cardiac catheterization training. Never advance the J-guidewire or introduction system without radiological control.
30. During J-guidewire progression, check for the absence of bends or loops, monitoring the progress under medical imaging. Always ensure that 2-3 cm of J-guidewire extend beyond the proximal end of the introduction system.
31. Do not attempt to advance or remove the J-guidewire in the event of resistance. The cause of resistance should be determined by radioscopy.
32. Make sure to remove the J-guidewire and dilator before performing the control cavogram 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.

#### **Warnings relative to implementation of the 9F extraction sheath**

34. Ensure that the distal end of the 9F extraction sheath is not in contact with the implanted ALN Optional Vena Cava Filter. This could modify the filter's position (risk of tilting or migration).
35. Before inserting the Pincer Catheter into the extraction sheath, the radio-opaque marker band on the sheath's distal end must be positioned 2 cm above the Filter's apex. This distance is essential to start the procedure under optimum conditions.

#### **Warnings relative to insertion of the Pincer Catheter into the 9F extraction sheath.**

36. Ensure that the J-guidewire and dilator have been removed before inserting the ALN Pre-Curved RS Extraction and/or Repositioning kit.
37. To prevent kinking of the 9F extraction sheath, ensure that the 9F extraction sheath is handled by its base and is not bent.

38. Always ensure that the 9F extraction sheath is adequately rinsed with a sterile heparinized physiological saline solution or similar isotonic solution. Insufficient equipment rinsing during the procedure may lead to clot formation in the introduction system.
39. Never insert the Pincer Catheter into the 9F extraction sheath before having retracted the Pincer of the Pincer Catheter into its sheath. For this, turn the yellow luer lock handle counterclockwise to unlock and pull for approximately 2 cm.
40. Ensure that the base of the 9F extraction sheath is in contact with the base of the Pincer Catheter.
41. Use the yellow handle luer Lock and never unlock the luer lock screwed onto the Pincer Catheter sheath.
42. Lock the Pincer Catheter luer Lock by rotating the yellow handle clockwise, causing the pincer to open.

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

43. Never attempt to remove the ALN Optional Vena Cava Filter by one of its legs. The ALN Optional Vena Cava Filter must strictly be removed by its apex.
44. To remove the ALN Optional Vena Cava Filter under optimum conditions, the filter's apex must be fully engaged into the Pincer of the Pincer Catheter.
45. In the event that it is difficult (or even impossible) to insert the filter's apex fully into the Pincer, use the Straight RS Extraction and/or Repositioning kit or 2 in 1 RS Extraction and/or Repositioning kit. It is still possible to bend the Pre-Curved RS Extraction and/or Repositioning kit, without using steam and without the risk of plication. Nevertheless, ALN strongly recommends ensuring that at least two of these three references are available.
46. To bend the Pre-Curved RS Extraction and/or Repositioning kit, the following procedure must be followed: Leave the 9F extraction sheath in place (radio-opaque marker band 2 cm from the filter's apex). Remove the Pincer Catheter after ensuring that the pincer has been correctly retracted into its sheath. On the table, get the pincer out of its sheath again and rinse the device thoroughly via the 3-way rinse valve. Apply the necessary angle at a distance of approximately 50 mm from the distal end of the sheath. Rinse the device once more, retract the pincer and reinsert. This procedure can be repeated several times, though any subsequent manipulations will be less easy to perform.
47. When the Filter is ready to be captured, do not pull on the Pincer Catheter until the filter is completely captured.
48. If the position of the Filter does not allow easy removal (filter's apex 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 maneuvers.
49. As losing the filter during the procedure is a possible risk, the recommendations made by ALN must be followed.

### **Filter recovery-related warnings**

50. Do not pull on the Pincer Catheter if the first black mark of the 7F Pincer Catheter is not visible or has not been passed.

51. Carefully monitor the ALN Optional Vena Cava Filter, the Pincer Catheter and the 9F extraction sheath progression under medical imaging.
52. To remove the ALN Optional Vena Cava Filter from the 9F extraction sheath and to use the sheath for postoperative control cavogram (recommended), sufficient tension must be applied to the filter.

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

53. Imaging is essential after removal of the ALN Optional Vena Cava Filter to confirm the absence of trauma to the inferior vena cava or vena cava thrombus.
  - If inferior vena cava trauma is observed, additional procedures and close clinical monitoring will be necessary.
54. 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.
55. 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**

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

## 7. Potential Complications

Procedural complications reported with filter retrieval include (but are not limited to):

- Migration of filter fractured components
- Thrombus migration during filter retrieval
- Caval injury such as laceration, development of a pseudoaneurysm, rupture and intussusception,
- Pulmonary embolism,
- Deep vein thrombosis,
- Caval collapse at the point of prior prolonged filter endothelialization,
- Acute caval thrombus.

A certain number of potential J-guidewire-related complications exist when used on patients with Vena Cava Filters. These complications include, in particular, a risk of migration, of tilting and the possibility of the J-guidewire becoming trapped in the filter.<sup>3</sup> Consequently, the extraction procedure must be performed by practitioners with appropriate cardiac catheterization training.

## 8. ALN Optional Vena Cava Filter extraction procedure

### Warning:

The entire procedure must be conducted under medical imaging.

### Warning:

Before starting the ALN Optional Vena Cava Filter removal procedure, several checks need to be performed. See the section " **Warnings relative to checks to be performed before removal of the ALN Optional Vena Cava Filter** " in this manual (page 7). In particular, imaging is essential to check for the presence of a thrombus in the ALN Optional Vena Cava Filter. If a thrombus is present, do not extract the ALN Optional Vena Cava Filter.

### Warning:

The ALN Pre-Curved RS Extraction and/or Repositioning kit can only be used via the **jugular approach**.

### 1: Patient preparation:

- Disinfect and use sterile sheets. (1) The necessary equipment is carefully prepared (2) (extraction kit, sterile heparinized physiological saline solution or similar isotonic solution for rinsing the system, etc.; see section 7.2. Material resources).



(1)



(2)

- After local anesthetic, puncture the right internal jugular vein using the puncture needle (3) supplied.



(3)

### 2: Inserting the J-guidewire and rinsing the introduction system

#### Warning relative to the use of the J-guidewire:

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

Make sure to remove the J-guidewire and dilator before performing the control cavogram in order to avoid causing any trauma to the vena cava.

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

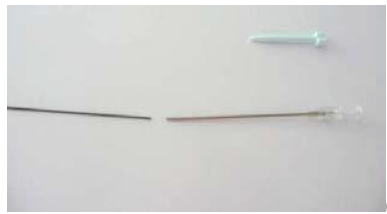


←  
(4) Rinse here



(5)

- Under medical imaging, advance the J-guidewire through the needle using the stiffener until it is positioned above the filter.
- Hold the J-guidewire in place and remove the puncture needle and J-guidewire's stiffener. (6)
- To facilitate progress of the introduction system, ALN recommends making a sufficiently large incision to the tissues surrounding the J-guidewire.



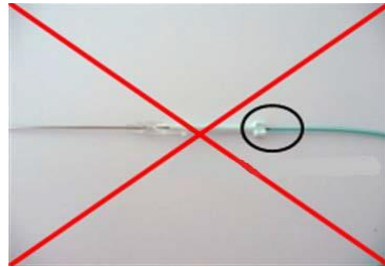
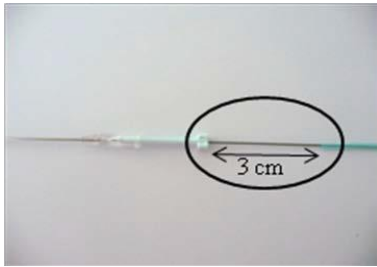
(6)

**Warning:**

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

**Warning:**

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



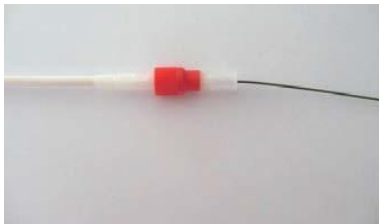
(7)

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

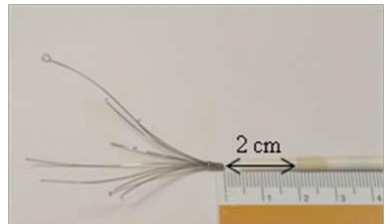
### 3: Advancing the introduction system (Extraction sheath + dilator)

**Note:** During the following steps, monitor the procedure closely using fluoroscopy guidance.

- Insert the outer part of the J-guidewire into the distal end of the introduction system.
- Advance the introduction system (Dilator + 9F extraction sheath) (8) over the J- guidewire and position the radio-opaque marker band 2 cm above the filter's apex. (9) If this distance is not respected, the pincer of the pincer catheter may open inside the filter.



(8)



(9)

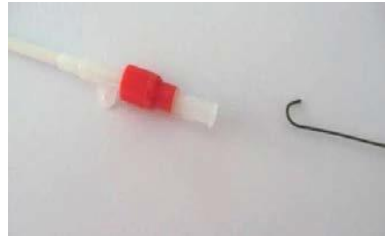
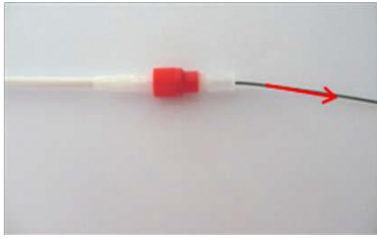
#### Warning:

Ensure that the distal end of the dilator is not in contact with the implanted ALN Optional Vena Cava Filter. This could modify the ALN Optional Vena Cava Filter's position (risk of tilting or migration).

#### Warning:

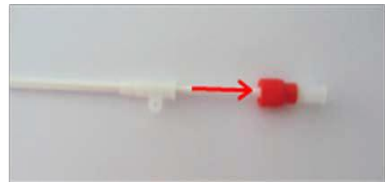
To prevent kinking of the 9F extraction sheath, ensure that the 9F extraction sheath is handled by its base and is not bent.

- Remove the J-guidewire. (10)



(10)

- Remove the dilator by rotating the red luer lock counterclockwise. (11)



(11)

#### 4: Inserting the Pincer Catheter into the 9F extraction sheath

##### Warning:

Ensure that the J-guidewire and dilator have been removed before inserting the ALN Pre-Curved RS Extraction and/or Repositioning kit Pincer Catheter.

##### Warning:

Before inserting the Pincer Catheter into the 9F extraction sheath, rinse the sheath and rinse the Pincer catheter using the 3-way valve with heparinized physiological saline. Insufficient equipment rinsing may lead to clot formation in the system

- Move the pincer inside its 7F sheath by rotating the yellow luer lock counterclockwise to unlock (12), then pulling it for approximately 2 cm. (13)



(12)



(13)

##### Warning:

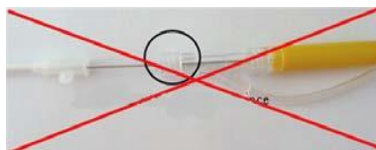
Never insert the Pincer Catheter into the 9F extraction sheath before having retracted the Pincer of the Pincer Catheter into its sheath.

##### Warning:

Use the yellow handle luer lock and never unlock the luer lock screwed onto the Pincer Catheter sheath. (14)

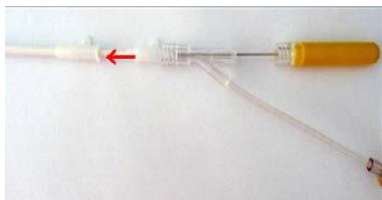


The yellow handle luer lock



The luer lock screwed onto the Pincer Catheter sheath

- Under frontal and lateral imaging, fully insert the Pincer Catheter into the 9F extraction sheath. (15)



(15)

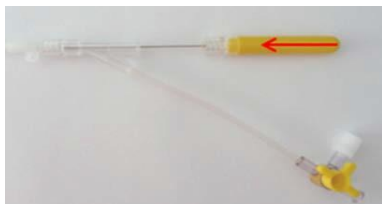
**Warning:**

Ensure that the base of the 9F extraction sheath is in contact with the base of the Pincer Catheter. (16)



(16)

- Push, then lock the Pincer Catheter's yellow luer lock handle, rotating it clockwise (17) to release the pincer.



(17)

## 5: Capturing the ALN Optional Vena Cava Filter

**Warning:**

Never attempt to remove the ALN Optional Vena Cava Filter by one of its legs. The ALN Optional Vena Cava Filter must strictly be removed by its apex. (18)



(18)

- Slowly lower the Pincer Catheter over the apex of the ALN Optional Vena Cava Filter and ensure that the Pincer Catheter is fully in contact with the apex of the ALN Optional Vena Cava Filter (19) (under medical imaging, preferably from a lateral or three-quarter angle).



(19)

**Warning:**

In the event that it is difficult (or even impossible) to insert the filter's apex fully into the Pincer, use the Straight RS Extraction and/or Repositioning kit or 2 in 1 RS Extraction and/or Repositioning kit. ALN strongly recommends ensuring that at least two of these three references are available.

**Warning:**

If the position of the ALN Optional Vena Cava Filter does not allow easy removal (filter's apex 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 maneuvers.

- At this step of the procedure, slowly lower the 9F extraction sheath over the pincer, then over the ALN Optional Vena Cava Filter until the first black mark appears on the 7F Pincer Catheter sheath. This mark indicates that the filter has been fully positioned in the 9F extraction sheath. (20)

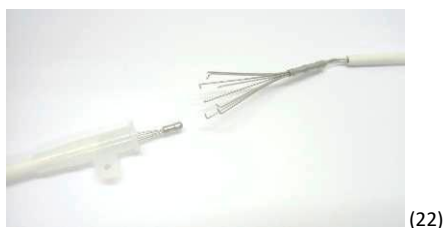


(20)

**Warning:**

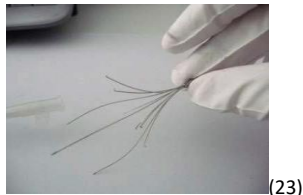
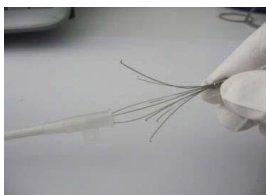
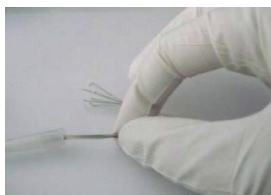
Do not pull on the Pincer Catheter if the first black mark of the 7F Pincer Catheter is not visible or has not been passed.

- If you want to use the 9F extraction sheath to perform a control cavogram after the removal of the ALN Optional Vena Cava Filter, pull back the pincer catheter with a slow and steady movement until the second black mark appears (21). Then, pull back firmly to remove the pincer catheter and the filter from the 9F extraction sheath. (22)

**Warning:**

Carefully monitor the ALN Optional Vena Cava Filter, the Pincer Catheter and the 9F extraction sheath progression under medical imaging.

- Delicately remove the ALN Optional Vena Cava Filter from the 9F extraction sheath. (23)



- Perform a control cavogram using the 9F extraction sheath left in place.

**Warning:**

To remove the ALN Optional Vena Cava Filter from the 9F extraction sheath and to use the sheath for postoperative control cavogram (recommended), sufficient tension must be applied to the ALN Optional Vena Cava Filter.

## 6: End of procedure

- Remove the 9F extraction sheath.

Note: Hospital standard of care should be followed for removing the introducer sheath and providing hemostasis to prevent bleeding at the vascular access site.

### **Warning:**

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

## 9. ALN Optional Vena Cava Filter repositioning procedure

ALN recommends repositioning the ALN Optional Vena Cava Filter in the event of:

- Premature ALN Optional Vena Cava Filter deployment during placement.
- ALN Optional Vena Cava Filter deployment in a position different to that initially planned.
- Significant tilting, reducing the ALN Optional Vena Cava Filter's filtration capacity.

### 1: Capturing the ALN Optional Vena Cava Filter

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



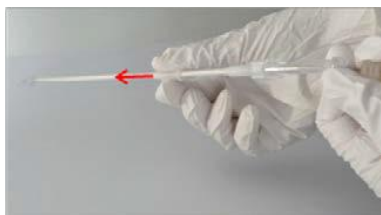
### **Warning:**

In the event that it is difficult (or even impossible) to insert the filter's apex fully into the Pincer, use the Straight RS Extraction and/or Repositioning kit or 2 in 1 RS Extraction and/or Repositioning kit. It is still possible to bend the Pre-Curved RS Extraction and/or Repositioning kit, without using steam and without the risk of plication (see warning no 47). Nevertheless, ALN strongly recommends ensuring that at least two of these three references are available.

### **Warning:**

If the position of the ALN Optional Vena Cava Filter does not allow easy removal (filter's apex 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 maneuvers.

- To reposition the ALN Optional Vena Cava Filter, slowly lower the 9F extraction sheath over the pincer, then over the ALN Optional Vena Cava Filter until the first black mark appears on the 7F Pincer Catheter sheath. This mark indicates that the filter has been fully positioned in the 9F extraction sheath. (25)



(25)

**Warning:**

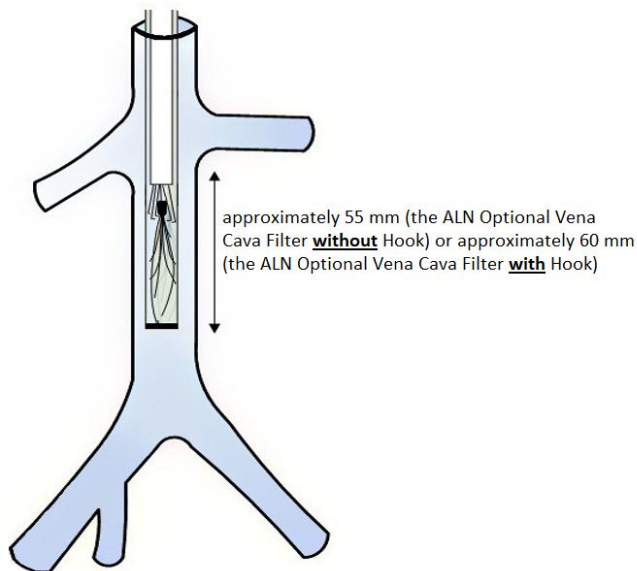
At this step of the procedure, never pull on the Pincer Catheter.

**Warning:**

Once the ALN Optional Vena Cava Filter is inside the 9F extraction 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 extraction sheath at the implantation site

- Position the radio-opaque marker band of the 9F extraction sheath approximately 55 mm (the ALN Optional Vena Cava Filter **without** Hook) or approximately 60 mm (the ALN Optional Vena Cava Filter **with** Hook) below the lowest renal vein if prior tests have confirmed possible placement below the lowest renal vein. (26)



(26)

**Warning:**

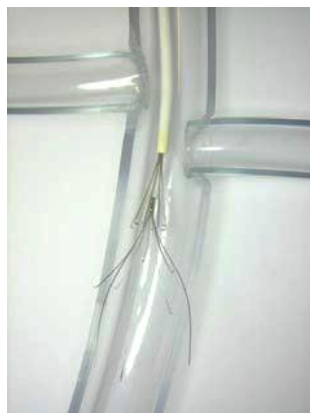
Do not deploy the filter until it is in its optimum position, the most appropriate placement site being confirmed by cavogram.

**Warning:**

Deliberate positioning of the filter above the renal veins should only be performed after checking diameter size of the suprarenal vena cava (maximum 32 mm) and if the available space between the highest renal vein and the atrium is of at least 55 mm (filter's length) for the Filter without Hook and 59 mm (filter's length) for the Filter with Hook.

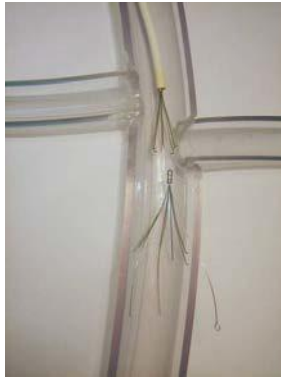
### 3: Releasing the filter at the implantation site

- While immobilizing the pincer handle, slide the 9F extraction sheath over the Pincer Catheter by imparting a slow and smooth retrieval motion (towards yourself) until the pincer is free of the 9F extraction sheath. The pincer should now be fully open and the filter completely deployed. (27)



(27)

- Then, pull the handle in a slow and straight motion to move the pincer away from the filter's apex. The pincer should be 2 cm away from the filter's apex. (28) The 9F extraction sheath should be pulled at the same time as the handle.



(28)

**Warning:**

The removal movement should be slow and straight to avoid tilting the filter.

**Warning:**

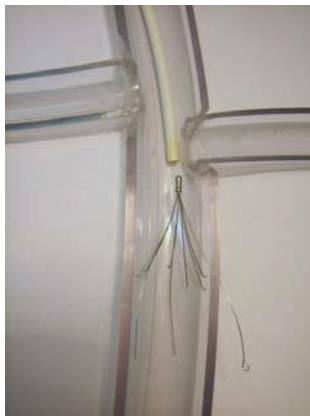
Do not only pull the Pincer Catheter itself but pull both the Pincer Catheter and the 9F extraction sheath together, if not the Pincer may be closed on the filter's apex.

**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 surgically or using the ALN Pre-Curved RS Extraction and/or Repositioning kit, is recommended for an incorrectly positioned filter that could have cardiorespiratory effects.

#### 4: Removing the Pincer Catheter

- To remove the Pincer Catheter, slowly lower the 9F extraction sheath onto the Pincer Catheter until it is completely covered (2 cm). (29)



(29)

**Warning:**

The procedure must be monitored under medical imaging to ensure that the pincer is fully inserted into the 9F extraction sheath.

- Remove the Pincer Catheter by imparting a slow retrieve motion until the pincer exist the base of the 9F extraction sheath.

**Warning:**

Monitor Pincer Catheter retrieval carefully under medical imaging.

- Perform a control cavogram using the 9F extraction sheath left in place.

**5: End of procedure**

- Remove the 9F extraction sheath.

Note: Hospital standard of care should be followed for removing the introducer sheath and providing hemostasis to prevent bleeding at the vascular access site.

**Warning:**

After use, the ALN Pre-Curved RS Extraction and/or Repositioning kit components should be discarded as per usual medical practice and according to applicable regulations.

## 10. Patient follow-up

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

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

This imaging is even 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 Optional 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 Optional 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.

## 11. Packaging and handling

The ALN Pre-Curved RS Extraction and/or Repositioning kit is supplied ready to use, sterile (ethylene oxide sterilized) and non-pyrogenic. Do not use the product if its packaging is damaged or open.

The product must be handled under aseptic conditions.

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

Do not use the ALN Pre-Curved RS Filter Extraction and/or Repositioning kit after its use-by date.

The ALN Pre-Curved RS Extraction and/or Repositioning kit is intended for a single use. It must not be reused and the kits components must not be re-sterilized.

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

## 12. Warranty

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 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 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 authorize any third parties to do so.

## References

1. SFICV (Société Française d'Imagerie Cardiaque et Vasculaire - French Society for Cardiac and Vascular Imaging). Interventional Vascular Radiology Recommendations and Best Practices. Pages 93 - 101, 2007.
2. CIRSE guidelines (Cardiovascular and Interventional Radiological Society of Europe). Quality Improvement guidelines for percutaneous inferior vena cave filter placement for the prevention of pulmonary embolism, 2007.
3. Guide Wire Entrapment by Inferior Vena Cava filters: an experimental study. M.J. Rosen et al, Journal of American College of Surgeons, Vol 201, No3, 2005.
4. Early and Late Retrieval of the ALN Removable Vena Cava Filter: Results from a Multicenter Study. Pellerin O. et al. Cardiovascular and Interventional Radiology. 2008; 31(5):889-896.



**FDA Cleared**



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