



INSTRUCTIONS FOR USE
VENA CAVA FILTER REMOVAL KIT
JUGULAR APPROACH
(EN)

ALN Pre-curved RS



CE
0297

CE marking since 2010

Product reference: FT.902010/VS2

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1: General information

The Removal Kit ALN is intended **only** to remove the ALN Vena Cava Filter with or without a hook when the indication of filtration no longer exists for a patient (see section 4. *ALN Vena Cava Filter removal indications* and 5. *Warnings*).

This medical device is available under three references:

- ALN Straight RS: reference FT.902010,
- ALN Pre-curved RS: reference FT.902010/VS2,
- ALN 2in1 RS: reference RK-2010.

The choice of device to use is individual to each patient. Nevertheless, ALN strongly recommends ensuring that both the Straight and Pre-curved references or the 2 in 1 reference are available.

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

The decision to remove the ALN Vena Cava Filter should be taken individually for each patient according to his / her clinical condition (benefit / risk ratio for the patient). Before making the decision to remove the filter, the degree of removal's urgency must be determined.

ALN Pre-Curved RS can only be used via the **jugular approach**.

Read the instructions carefully before use.

ALN Pre-Curved RS is supplied sterile (*ethylene oxide sterilization*). It is intended for one-time use and its components must not be re-sterilized.

¹ A prospective long-term study of 220 patients with a retrievable vena cava filter for secondary prevention of venous thromboembolism. P. Mismetti et al, *en el pecho*, 131 / 1, 2007.

2: Symbols

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

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

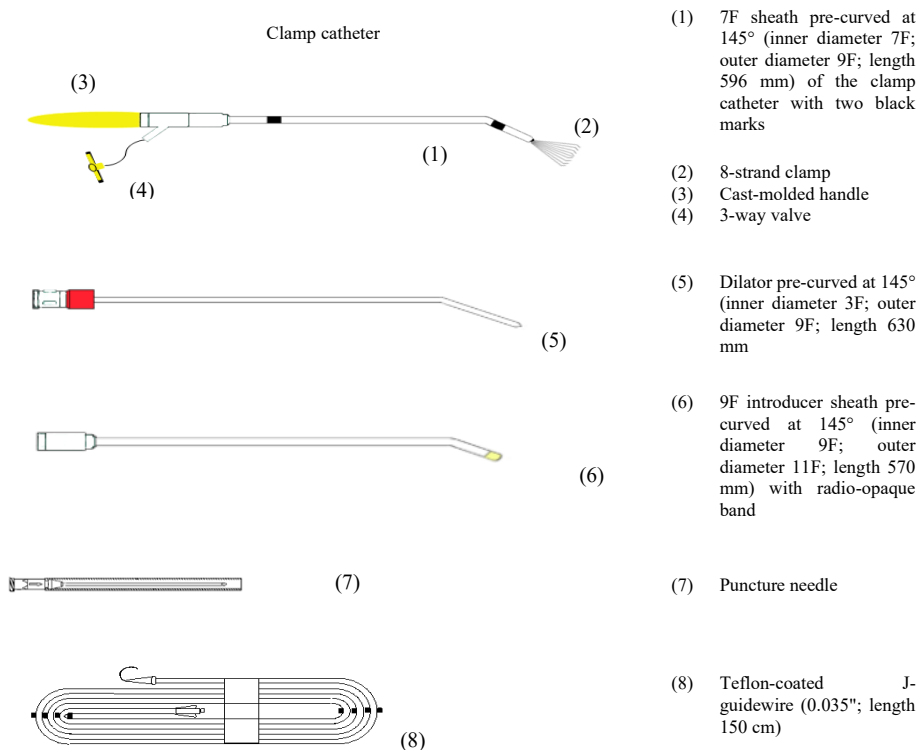
3: Kit content

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

ALN Pre-Curved RS comprises the following elements:

- A clamp catheter including:
 - a 7F sheath with two black marks (1),
 - a basket-shaped clamp consisting of eight 316 LVM stainless steel strands (2) connected by a central 316LVM stainless steel bar to a yellow cast-molded handle (3),
 - a three-way rinse valve (4),
- A dilator with red luer lock end piece (5),
- A 9F introducer sheath with radio-opaque marker (6),
- A puncture needle (7),
- A Teflon-coated J-guidewire (8).

ALN Pre-Curved RS is provided sterile (*ethylene oxide sterilization*). It is intended for one-time use and must not be re-sterilized.



4: ALN Vena Cava Filter removal indications

The indications for removal of the ALN Vena Cava Filter using the ALN Pre-Curved RS listed below are approved by the SFICV². They are based on the SIR³ and CIRSE⁴ 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.

- Removal 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 removal 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 it has been designed to be implanted permanently should the removal procedure be impossible.

5: Warnings

General warnings relative to the use of the ALN Pre-Curved RS

1. Read the instructions for use carefully.
2. ALN Pre-Curved RS is intended **only**:
 - ✓ To remove the ALN Vena Cava Filter when the filtration indication no longer exists for a patient (see section 4. *ALN Vena Cava Filter removal indications*).
 - ✓ Or to reposition the ALN Vena Cava Filter.

² SFICV (Société Française d'Imagerie Cardiaque et Vasculaire). Recommandations et Bonnes Pratiques en Radiologie Vasculaire Interventionnelle. Mars 2007. Pages 93-101.

³ 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.

⁴ 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, 2007.

3. ALN declines all liability in case of attempt to remove any other medical device using the Removal Kit ALN.
4. ALN declines all liability in case of attempt to remove the ALN Vena Cava Filter using a device other than the Removal Kit ALN 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. ALN Pre-Curved RS 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.
7. The product should be stored in a dry place and kept away from sunlight.
8. Do not use ALN Pre-Curved RS beyond the expiration date indicated on the label.
9. ALN Pre-Curved RS is intended for one-time use. It must not be reused and the kit's components must not be re-sterilized. Reuse even after a new cleaning and a new sterilization could expose the patient to an infectious risk and a potential malfunction of the device (device not controlled by the manufacturer).
10. ALN Pre-Curved RS can **only** be used via the **jugular approach**.
11. The ALN Vena Cava Filter is an optional filter (definitive and / or temporary). Its efficacy and safety having been confirmed¹, the ALN Vena Cava Filter can also be implanted permanently and there is no obligation to remove it.
12. The decision to remove the ALN Vena Cava Filter should be taken individually for each patient according to his / her clinical condition (benefit / risk ratio for the patient). Before making the decision to remove the filter, the degree of removal's 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).
 - ✓ The anticoagulation of a patient for whom removal of the ALN Vena Cava Filter is planned must be taken into account or monitored/evaluated before the intervention so as to avoid any hemorrhagic risk.
 - ✓ 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.

Warning before considering the removal of the ALN Vena Cava Filter

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

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.

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

Cavography-related warnings

17. Anterior posterior (AP) 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 Removal kit to use (Straight - reference FT.902010, Pre-curved - reference FT.902010/VS2, or 2 in 1 - reference RK-2010).

18. During injection of contrast medium into the introducer 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 cavography should be taken with different incident angles.
21. A control cavography may be performed after the removal procedure.
22. If the ALN introduction system (introducer sheath and dilator) is used to perform a control cavography, **ensure that the dilator has been removed before performing the cavography**. Not removing the dilator could damage the vena cava.
23. If the control cavography is performed using the introducer sheath of ALN Pre-Curved RS, 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 **SFICV**⁵.
- ✓ 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.

⁵ SFICV (Société Française d'Imagerie Cardiaque et Vasculaire). Recommandations et Bonnes Pratiques en Radiologie Vasculaire Interventionnelle. Mars 2007. Pages 93-101.

- ✓ A senior may maintain his/her skill by removing at least 6 filters per year without incident.
 - ✓ The electro radiology operator should possess basic vascular procedure training, as defined by the **SFICV**.
 - ✓ 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 implantation site.

Being aware of the above-mentioned potential risks, it is important to ensure that all elements pertaining to ALN Vena Cava Filter implantation are reported 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 + introducer sheath)) should be rinsed with a sterile physiological saline solution or similar isotonic solution.
28. The entire procedure must be performed 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 under medical imaging. Always ensure that 2-3cm of J-guidewire extend beyond the proximal end of the introduction system.
31. Do not attempt to advance or remove the J-guidewire in case of resistance. The cause of resistance should be determined by radioscopy.
32. Make sure to remove the J-guidewire and dilator before performing the cavography in order to avoid any trauma to the vena cava.
33. Radiographies 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 introducer sheath

34. Ensure that the distal end of the introducer sheath does not enter contact with the implanted ALN Vena Cava Filter. This could modify the filter's position (risk of tilting or migration).
35. Before inserting the clamp catheter into the introducer sheath, the radio-opaque 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 optimal conditions.

Warnings relative to insertion of the clamp catheter into the introducer sheath.

36. Ensure that the J-guidewire and the dilator have been removed before inserting the clamp catheter.
37. To avoid kinking the introducer sheath, ensure that the introducer sheath is handled by its base and is not bent.

38. Always ensure that the introducer sheath is adequately rinsed with a sterile heparinized physiological saline solution or similar isotonic solution. Insufficient rinsing of the introducer sheath during the procedure may cause clot formation in it.
39. Never insert the clamp catheter into the introducer sheath before having retracted the clamp of the clamp catheter into its catheter. For this, move back the clamp inside its sheath by rotating the yellow luer lock left to unlock, then pulling it for approximately 2 cm.
40. Ensure that the base of the introducer sheath is in contact with the base of the clamp catheter.
41. Use the yellow handle luer lock and never unlock the luer lock screwed onto the clamp catheter.
42. Lock the clamp catheter luer lock by rotating the yellow handle right, causing the clamp to open.

Warnings relative to capturing the ALN Vena Cava Filter

43. Never attempt to remove the ALN Vena Cava Filter by one of its legs. The ALN Vena Cava Filter must strictly be removed by its apex.
44. To remove the ALN Vena Cava Filter under optimal conditions, the filter's apex must be fully engaged into the clamp of the clamp catheter.
45. In the case where it is difficult (or even impossible) to insert the filter's apex fully into the clamp, use the PRE-CURVED Removal Kit (ALN Pre-curved RS), or the 2 in 1 Removal Kit (ALN 2 in 1 RS). It is still possible to bend the STRAIGHT Removal Kit (ALN Straight RS) without using steam (cold operation) and without the risk of kinking it. Nevertheless, ALN strongly recommends ensuring that at least both references are available.
46. To bend the STRAIGHT Removal Kit (ALN Straight RS), the following procedure must be followed: leave the introducer sheath in place (radio-opaque band 2 cm from the filter's apex). Remove the clamp catheter after ensuring that the clamp has been correctly retracted into its catheter. On the table, move the clamp inside its catheter by rotating the yellow luer lock left to unlock, then pulling it for approximately 2 cm and rinse the device thoroughly via the 3-way valve. Apply the necessary angle at a distance of approximately 5 cm from the distal end of the catheter. Rinse the device once again, retract the clamp in its catheter and reinsert into the introducer sheath. 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 clamp catheter until the filter is completely captured.
48. If the position of the filter does not allow easy removal (filter' 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. Losing the filter during the procedure being a possible risk, the recommendations made by ALN must be followed.

Filter recovery-related warnings

50. Do not pull on the clamp catheter until the first black mark on the clamp catheter is not visible or has been passed.
51. Check the progression of the filter and the clamp catheter in the introducer sheath under medical imaging.
52. In order to remove the ALN Vena Cava Filter from the introducer sheath and to use the sheath for postoperative cavography (recommended), sufficient tension must be applied to the ALN Vena Cava Filter.

53.

54. Incorrect handling of the ALN vena cava filter may expose the patient to a risk of sting/injury or infection.

Warning after the removal of the ALN Vena Cava Filter

55. A medical imaging is essential after the removal of the ALN Vena Cava Filter in order to confirm the absence of inferior vena cava injuries, or the presence of a thrombus in the vena cava.

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

56. The integrity of the ALN Vena Cava Filter must be confirmed.

Should a part of the filter be missing, check the sheath and check the abdomen with radiology images to locate and document the missing filter elements.

57. Therapeutic follow-up after the removal of the ALN Vena Cava Filter.

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 followed up for a new, recurrent, or progressive deep vein thrombosis and/or pulmonary embolism.

Other warnings

58. 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.

6: 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.⁴ Consequently, the removal procedure must be performed by practitioners with appropriate cardiac catheterization training.

7: ALN Vena Cava Filter removal 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 "**Warning before considering the removal of the ALN Vena Cava Filter**" in this manual. In particular, a medical imaging is essential in order to check 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: ALN Pre-Curved RS can only be used via the **jugular approach**.

1: Patient preparation:

Disinfect and position sterile tissues (1). The necessary equipment is carefully prepared (2) (the removal kit, the sterile heparinized physiological saline solution or the similar isotonic solution for rinsing the system, etc.).



(1)



(2)

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

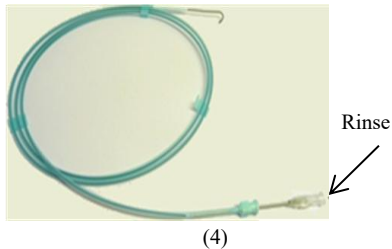


(3)

2: 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.

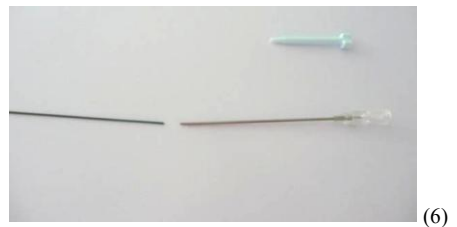
Flush the J-guidewire with the sterile physiological saline or similar isotonic solution, fixing a syringe to the luer lock base of the J-guidewire's distributor (4). Insert the flexible end of the J-guidewire (5) into the puncture needle.



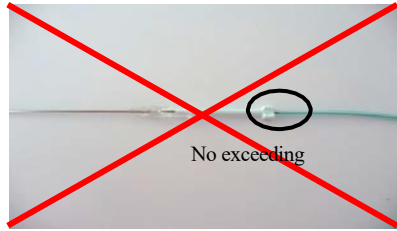
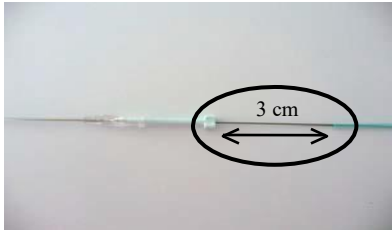
Under medical imaging, introduce the J-guidewire through the needle using the stiffener and advance the J-guidewire until it is positioned above the filter.

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

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



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

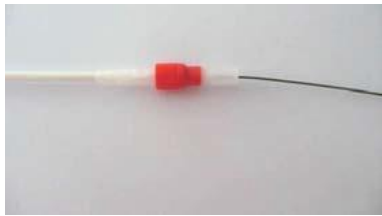


(7)

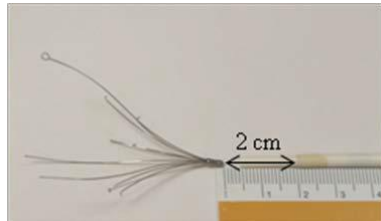
Warning: Do not attempt to advance or remove the J-guidewire in case of resistance. The cause of resistance should be determined by radioscopy. If the cause of the resistance cannot be determined, remove the J-guidewire and the introduction system.

3: Advancing the introduction system (introducer sheath + dilator)

Under medical imaging, slide the introduction system (8) over the J-guidewire and position the radio-opaque band 2 cm above the filter's apex (9). This distance is essential to start the procedure under optimal conditions.



(8)

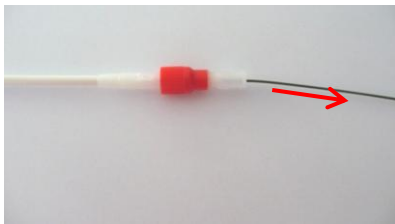


(9)

Warning: Ensure that the distal end of dilatator 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).

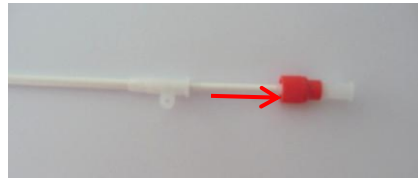
Warning: To avoid kinking the introducer sheath, ensure that the introducer sheath is handled by its base and is not bent.

Remove the J-guidewire. (10)



(10)

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



(11)

4: Inserting the clamp catheter into the introducer sheath

Warning: Ensure that the J-guidewire and the dilator have been removed before inserting the clamp catheter.

Before inserting the clamp catheter into the introducer sheath, rinse the sheath and rinse the clamp catheter using the 3-way valve with heparinized physiological saline.

Warning: Insufficient rinsing of the introducer sheath during the procedure may cause clot formation in it.

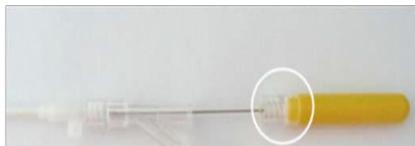
Move back the clamp inside its catheter by rotating the yellow luer lock left to unlock, then pulling it for approximately 2 cm (12).



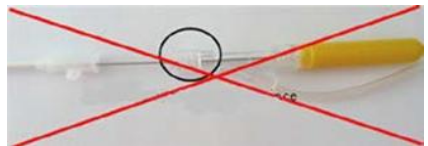
(12)

Warning: Never insert the clamp catheter into the introducer sheath before having retracted the clamp of the clamp catheter into its catheter.

Warning: Use the yellow handle luer lock and never unlock the luer lock screwed onto the clamp catheter (13).

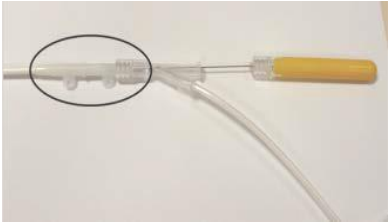
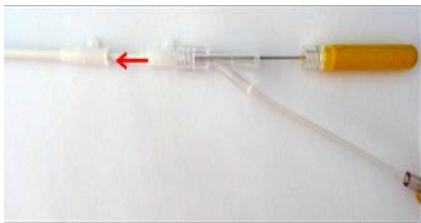


Luer lock of the yellow handle



Luer lock screwed onto the clamp catheter

Under frontal and lateral imaging, fully insert the clamp catheter into the introducer sheath (14).



(14)

Warning: Ensure that the base of the introducer sheath is in contact with the base of the clamp catheter (15).



(15)

Push, then lock the clamp catheter's yellow luer lock handle, rotating it to the right (16) in order to release the clamp's hooks.



(16)

5: Capturing the ALN Vena Cava Filter

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



(17)

Slowly move down the clamp catheter over the filter's apex and ensure that the clamp catheter is fully in contact with the apex of the ALN Vena Cava Filter (18) (under medical imaging, using preferably a lateral or a three-quarter angle).



(18)

Warning: If the position of the ALN Vena Cava Filter does not allow an 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.

First, move down the introducer sheath slowly over the ALN Vena Cava Filter until the black mark on the clamp catheter is visible. This mark indicates that the filter has entered into the introducer sheath (19).



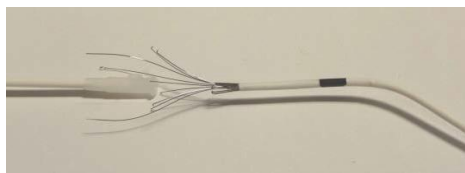
(19)

Warning: Do not pull on the clamp catheter until the first black mark on the clamp catheter is not visible or has been passed.

Secondly, with a slow movement, move back the clamp catheter until the second black mark (20) becomes visible. Take out the filter from the introducer sheath by pulling on it firmly (21).



(20)



(21)

Warning: Check the progression of the filter and the clamp catheter in the introducer sheath under medical imaging.

Perform a cavography using the introducer sheath left in place.

***Warning:** In order to remove the ALN Vena Cava Filter from the introducer sheath and to use the sheath for postoperative cavography (recommended), sufficient tension must be applied to the ALN Vena Cava Filter.*

6: End of procedure

Remove the introducer sheath from the inferior vena cava and achieve hemostasis at the puncture site.

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

8: Patient's follow-up

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

- ✓ Examination of the catheter insertion site to make sure about a good healing.
- ✓ A medical imaging is essential after the removal of the ALN Vena Cava Filter in order to confirm the absence of inferior vena cava injuries, or the presence of a thrombus in the vena cava.

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

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

- ✓ The integrity of the ALN Vena Cava Filter must be confirmed.

Should a part of the filter be missing, check the sheath and check the abdomen with radiology images to locate and document the missing filter elements.

An additional procedure is possible by the decision of the physician who conducted the initial procedure.

- ✓ Therapeutic follow-up after the removal of the ALN Vena Cava Filter.

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 followed up for of a new, recurrent, or progressive deep vein thrombosis and/or pulmonary embolism.

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

A Summary of Safety and Performance Characteristics is available in the European Medical Device Database (EUDAMED) via this link: [SS\(C\)P > SS\(C\)P: DOC-226 - EUDAMED](https://ec.europa.eu/tools/eudamed/#/screen/home).

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

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

9: Packaging and handling

ALN Pre-Curved RS 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 should be stored in a dry place and kept away from sunlight.

The product must be handled under aseptic conditions.

Do not use ALN Pre-Curved RS beyond the expiration date indicated on the label.

ALN Pre-Curved RS is intended for one-time use. It must not be reused and the kits components must not be re-sterilized.

10: 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.

11: 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 will, 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.



FDA Approval



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