INSTRUCTIONS FOR USE
OF THE ALN OPTIONAL VENA CAVA FILTER

BRACHIAL APPROACH

US

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Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

1. Device description

The ALN Optional Vena Cava Filter is an optional filter (permanent and/or temporary). It is intended for the prevention of recurrent pulmonary embolism.

The ALN Optional Vena Cava Filter is made of nine 316 LVM stainless steel legs. Six legs are fitted with hooks for anchoring in the vena cava. The other three legs serve to center the filter inside the vena cava.

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

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

The ALN Optional Vena Cava Filter is supplied sterile. It is intended for single use.

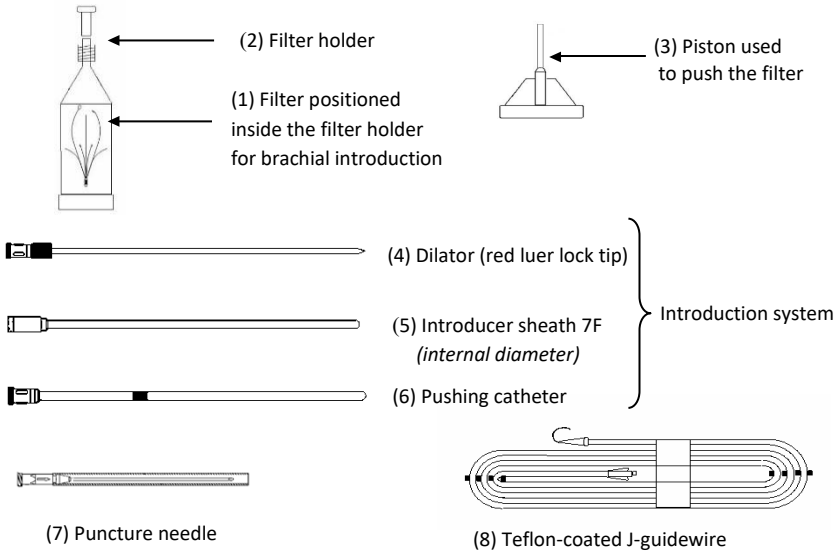
2. Kit content

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

The ALN Optional Vena Cava Filter brachial approach device comprises the following elements:

- The filter (1) prepackaged in its filter holder. (2)
- The filter holder itself consists of a conical tube, a protective cap, a clip and a piston. (3) The piston serves to push the filter into the introducer sheath by the metal rod.
- An introduction system comprising a dilator (4) (red luer lock tip) screwed onto the introducer sheath 7F. (5)
- A pushing catheter. (6) This element serves to push the filter into the introducer sheath.
- A puncture needle. (7)
- A Teflon-coated J-guidewire. (8)

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



3. Indications for use

The ALN Optional Vena Cava Filter with Hook and without 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.

ALN Optional Vena Cava Filters with Hook and without Hook, may be retrieved with the ALN Extraction Kits according to the instructions included in 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 included in the Instructions For Use of this medical device.

4. Contraindications

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

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

3. In all cases in which radioscopic monitoring is contraindicated, in the event of pregnancy in particular, the advantages and disadvantages of filter implantation must be carefully assessed.
4. Known hypersensitivity to one of the components constitutes a contraindication to the placement of an ALN Optional Vena Cava Filter.
5. If there is a risk of septic embolism, placement of the ALN Optional Vena Cava Filter is contraindicated.

5. Warnings and precautions

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

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

2. The ALN Optional Vena Cava Filter brachial approach is supplied ready to use, sterile (ethylene oxide sterilized) and non-pyrogenic. Do not use the product if its packaging is damaged or open.

3. The ALN Optional Vena Cava Filter is intended for a single use. It must not be reused and the kit components must not be re-sterilized.

4. Always use the femoral introduction system for a femoral approach, the jugular introduction system for a jugular approach and the brachial introduction system for a brachial approach.

5. The femoral kits are distinguished from the jugular and brachial kits by the orientation of the filter in its filter holder. The kits are also distinguished by color coding (green for the femoral kits, yellow for the brachial and jugular kits).

6. The brachial kits are distinguished from the femoral and jugular kits by the length of the introduction system elements and of the J-guidewire.

7. The ALN Optional Vena Cava Filter should only be implanted using the introduction kit supplied for this purpose by ALN.

8. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.

9. The entire procedure must be conducted under medical imaging.

10. Before placing the filter in the inferior vena cava, it is important that the emboli originate from the lower limbs, the filter being ineffective if the emboli are of cardiac or upper limb origin.

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

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

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

Removal of the ALN Optional Vena Cava Filter:

13. The ALN Optional Vena Cava Filter can be removed using one of the three extraction kits sold for this purpose by ALN. (see “Optional retrieval procedure” section of this IFU).

Precautions

1. Physicians should be properly trained prior to using the ALN Optional Vena Cava Filter.
2. The product should be stored in a cool, dry and dark place.
3. Do not use the ALN Optional vena cava filter after its use-by-date.
4. In case of preventive indication for ALN Optional vena cava filter implantation - 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 Optional vena cava filter.

6. MRI safety information

A non-clinical test, conducted in accordance with the ASTM F2052 standard, has demonstrated that the ALN Optional Vena Cava Filter is “MR-Conditional”. A patient implanted with this filter can safely undergo MRI examination after placement under the following conditions:

- Static magnetic field of 3 Tesla or less.
- Spatial magnetic field gradient of 720 Gauss/cm or less.
- Maximum SAR of 3 W/kg for a 15-minute examination.

During the non-clinical test, the ALN Optional Vena Cava Filter generates a 0.7°C increase in temperature for a 3 W/kg SAR during 15 minutes, on a 3-Tesla MRI.

The quality of the MRI image may be impaired if the point of interest is located at the exact or approximate filter placement site. In this case, it may be necessary to optimize the machine parameters in order to improve the image. In all cases, see the MRI machine’s user manual when conducting an examination on a patient implanted with an ALN Optional Vena Cava Filter.

7. Potential adverse events

Clinical adverse events

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

These complications must be explained to the patient prior to implanting the ALN Optional Vena Cava Filter.

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

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

Technical complications

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

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

8. Clinical data

A clinical trial[1], involving 123 patients, was conducted at 3 centers (Bellevue University Hospital in Saint-Etienne, Georges Pompidou European Hospital in Paris and Lille University Hospital) between November 2003 and June 2006 in view of assessing removal of the ALN Optional Vena Cava Filter. The trial was conducted on 123 patients who had received an indication for the removal of their ALN Optional Vena Cava Filter following an implantation 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 Optional Vena Cava Filter placement indications for these patients were a contraindication to treatment by anticoagulants (recent surgery, hemorrhage or coagulopathy), complications to or failure of anticoagulant treatment (extension of deep vein thrombosis, new deep vein thrombosis and/or pulmonary embolism, hemorrhage, 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-implantation, 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 Optional Vena Cava Filters were removed after a mean implantation time of 93 ±15 days (interval: 6-722 days). The ALN Optional 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's apex 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 (implantation period between 38 and 81 days), the filter's apex 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, fracture or filter leg penetration was detected in these patients. The removal procedures did not cause any vessel wall damage.

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[1] *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.*

PRESERVE Study

- ***Objectives and Design***

PRESERVE (Predicting the Safety and Effectiveness of Inferior Vena Cava Filters) was a multi-center, prospective, open-label investigation of commercially available inferior vena cava (IVC) filters that were placed in subjects for the prevention of pulmonary embolism (PE). The study enrolled 1,429 subjects at 54 US sites. All treated subjects were scheduled for evaluation at procedure and at 3, 6 (phone), 12, 18 (phone), and 24 months post-procedure.

The primary objective of this investigational device exemption (IDE) study was to evaluate the safety and effectiveness of commercially available IVC filters (retrievable and permanent) in subjects with a clinical need for mechanical prophylaxis of PE with an IVC filter.

The following filters were evaluated in the PRESERVE Study:

1. ALN Vena Cava Filter (with and without hook; ALN Implants Chirurgicaux).
2. Option™ Elite Retrievable Vena Cava Filter (Argon Medical Devices Inc., designed and manufactured by Rex Medical).
3. VenaTech® LP and VenaTech® Convertible™ Vena Cava Filter (B Braun Interventional Systems, Inc.).
4. DENALI™ Vena Cava Filter (DL900F, DL900J; Bard Peripheral Vascular, Inc.).
5. Günther Tulip® Vena Cava Filter (Cook Medical).
6. Cordis OPTEASE™ Retrievable Vena Cava Filter and Cordis TRAPEASE™ Permanent Vena Cava Filter (Cordis Corporation).
7. Crux® Vena Cava Filter System (Volcano Corporation; discontinued after only 7 subjects were enrolled).

The Primary Safety Endpoint was a composite that included freedom from:

- clinically significant perforation after successful vena cava filter placement (protrusion of filter legs through the wall of the IVC causing hemorrhage or hematoma or touching, impressing, or perforating another organ [e.g., liver, bowel, aorta, psoas muscle, vertebral body, or lymph nodes] or that triggers the decision to remove the filter or requiring the other intervention; confirmed by imaging) within the first 12 months.
- vena cava filter embolization (movement of the filter or its components to a distant anatomic site completely out of the target zone after successful vena cava filter placement; confirmed by imaging) within the first 12 months.
- caval thrombotic occlusion (presence of an occluding thrombus in the IVC after filter insertion and documented by ultrasound, computed tomography, magnetic resonance imaging, venography, or autopsy; this may be symptomatic or asymptomatic after successful vena cava filter placement) within the first 12 months.
- new deep vein thrombosis (DVT; lower extremity DVT that is confirmed present where it had not been present previously and that occurs after the placement of the vena cava filter) within the first 12 months.
- filter-related serious adverse events (SAEs) within the peri-operative period (the peri-operative period was ≤ 30 days post-filter placement).

The hypothesis for primary safety was that at 12-months post-procedure, the rates of freedom from clinically significant perforation, freedom from filter embolization, freedom from caval thrombotic occlusion, freedom from new DVT and freedom from filter-related SAEs will be above the prespecified performance goal of 80%.

The Primary Effectiveness Endpoint was a composite of the following components assessed at 12 months in subjects with an IVC filter in-situ or at 1-month post-retrieval (whichever occurred first):

- Procedural and technical success (deployment of the initial vena cava filter such that the vena cava filter is judged suitable for mechanical protection against PE, and placement of second vena cava filter to address any anatomic variation without clinically significant perforation, vena cava filter embolization, or insertion problems).
- Freedom from clinically significant PE (new symptomatic PE confirmed by appropriate imaging).

The hypothesis for primary effectiveness was that at 12-months post-procedure in-situ or 1-month post-retrieval (whichever comes first) the rates of procedural/technical success and freedom from PE will be above the prespecified performance goal of 90%.

Both hypotheses were tested using the one-sided exact binomial test. For each hypothesis, success would be considered if the lower limit of the one-sided 95% exact binominal confidence interval was above the performance goal.

Various secondary endpoints, including several device safety measures, procedure related complications, and filter retrieval, were also evaluated.

All endpoint assessments were based on site reported events. A Clinical Events Committee was responsible for standardized adjudication of the following safety events: PE, caval thrombotic occlusion, DVT, clinically significant perforation, retroperitoneal hematoma, adjacent organ penetration, unanticipated adverse device effects. CEC adjudications were used if there was a discrepancy with the site reported data. Death, filter embolization, and peri-operative SAEs were not adjudicated by the CEC.

- ***Subject Accountability***

In total, 1,421 of 1,429 enrolled subjects had IVC filters placed. Two (2) subjects died after enrollment, but before filter placement, and 6 subjects experienced treatment failures (i.e., failure to implant the IVC filter). Patient accountability is shown in **Table 1.** Results for the 1,421 patients that underwent IVC filter placement are summarized below.

Subjects with IVC filter retrieval: Forty-nine percent (49%) of 1,421 subjects underwent filter retrieval prior to 2-years of follow-up (690/1,421), and compliance with the 1-month post-retrieval visit was 86% (585/690). Fifty one percent (51%) of these filter retrievals took place prior to the 3-month follow-up visit (351/690), and 94% occurred prior to 12 months of follow-up (647/690).

Subject deaths: Almost 24% of subjects died prior to the 24-month follow-up or 1-month post-retrieval visit (337/1,421). Fifty two percent (52%) of these deaths occurred prior to the 3-month visit (174/337), and 85%, prior to 12 months of follow-up (286/337). Deaths were assessed for relatedness; 321 deaths were determined to not be device-related, 14 deaths were determined to be possibly device-related, 1 death was determined to be definitely device-related, and 1 death had missing relatedness information.

Consent withdrawal or lost-to-follow-up: Fifteen percent (15%) of subjects withdrew consent or were lost-to-follow-up (207/1,421), with 52% occurring within the first 3 months (108/207) and 85% (176/207) prior to 12 months follow-up. Over the course of the study, 110 subjects withdrew consent, and 99 were lost-to-follow-up.

12 Month Patient Accountability – CT Imaging:

Subjects receiving a filter at the index procedure were to complete a CT scan at 12 months if the filter was not retrieved. Approximately 22% (312/1,421) of subjects remained in the study with a filter in place at 12 months. Among these 312 subjects, 199 (63.8%) had a CT scan at 12 months. Among all subjects that received a filter, 14.0% (199 subjects) of subjects had a CT scan at 12 months.

24 Month Patient Accountability – CT Imaging:

Subjects receiving a filter at the index procedure were to complete a CT scan at 24 months if the filter was not retrieved. Just under 14% (193/1,421) of subjects remained in the study with a filter in place at 24 months. Among these 193 subjects, 104 (53.9%) had CT scans at 24 months. Among all subjects that received a filter, 7.3% (104 subjects) of subjects had a CT scan at 12 months.

Table 1: Patient Accountability

Patient Censoring	Procedure (n[a]=1429)	3 Months (n=788)	6 Months (n=501)	12 Months (n=312)	18 Months (n=241)	24 Months (n=193)	1-Month Retrieval (n=684)	Total
Treatment Failure	6							6
Death	174	54	58	29	18	0	4	337
Filter Retrieval	351	200	96	31	12	0	0	690
Withdrew Consent/ Lost to Follow Up	108	33	35	11	18	0	2	207
Total	**639**	**287**	**189**	**71**	**48**	**0**	**6**	**1240**

All counts in the table reflect subject disposition at the end of the respective visit window.
[a] At each time, n reflects the number of patients eligible for the follow-up.

- ***Results***

Baseline Demographics

The mean age of subjects was 62.7 years, 53% were male, and 78% were white. Seventy-one percent (71.7%) of subjects had current venous thromboembolism (VTE) and 34.3% of subjects had a history of VTE. **Table 2** shows patient baseline demographics.

Table 2: Baseline Demographics

Characteristic	N = 1421
Age, Yrs. [Mean (SD, Range)]	62.7 (14.7; 18.5 - 98.4)
Gender, Male (%, n)	759 (53.4%)
Race	
White	1,102 (77.6%)
Black	213 (15.0%)
Other	106 (7.5%)
Baseline Venous Thromboembolism Status	
Current VTE	1,019 (71.7%)
History of VTE	488 (34.3%)
Neither current nor a history of VTE	127 (8.9%)

[a] Other race includes: Asian (n=11), Native American or Alaskan Native (n=1), Native Hawaiian or Pacific Islander (n=1), other (n=70), more than one race (n=2), and unknown (n=21).

Indication for Filter Placement

In total, 1,421 of the 1,429 subjects had study filters placed. **Table 3** shows the indication for filter placement, the majority of which were for contraindication to anticoagulation (71.8%).

Table 3: Indication for Filter Placement

Indication	Total Number of Subjects (n=1421)
Contraindication to or complication of anticoagulation	72.2% (1,026)
Failure of anticoagulation	9.4% (133)
Prophylaxis in the absence of DVT or PE	8.9% (126)
Placed as part of thrombolysis procedure	6.3% (90)
Additional protection for patient receiving anticoagulation	3.2% (46)

- ***Primary Endpoint Results***

Primary Safety Endpoint Results

Primary safety event rates were calculated for living subjects with the IVC filter in-situ at 12-months (i.e., IVC filter not removed, and patient had not died, withdrawn, or been lost to follow-up).

The prespecified performance goal for the primary safety endpoint was 80%. In total, 293 subjects were evaluable for the primary safety endpoint when evaluating living subjects who reached 12-months follow-up, excluding subjects who died, were withdrawn, were lost to follow-up or had their IVC filter removed prior to 12-months (whether or not they had a prior safety event). The primary safety endpoint rate was 89.4%, with a lower 95% confidence interval of 85.3%, meeting the performance goal (see **Table 4**).

Table 4. Primary Safety Endpoint Results*

Primary Safety Endpoint Event	***Rate****	***95% CI****
Freedom from Primary Safety Event Rate at 12-months	**89.4% (262/293)**	**(85.3%, -)**
Freedom from Clinically Significant Perforation	98.6% (289/293)	(96.5%, 99.6%)
Freedom from Filter Embolization	100.0% (293/293)	(98.8%,100.0%)
Freedom from Caval Thrombotic Occlusion	98.6% (289/293)	(96.5%, 99.6%)
Freedom from New Deep Vein Thrombosis	91.5% (268/293)	(87.7%, 94.4%)
*Freedom from SAEs possibly, probably or definitely related to filter within Peri-Operative Period****	97.8% (1264/1292)	(96.9%, 98.6%)

*Excludes subjects who had died, withdrawn, or been lost to follow-up or had the IVC filter removed prior to 12-months (whether or not they had a prior safety event).
**The Exact binomial test model was used for analyses. The denominators are the number of subjects evaluable for the endpoint.
***SAEs possibly, probably or definitely related to the filter.

Primary Effectiveness Endpoint Results

Primary effectiveness event rates were calculated for living subjects with the IVC filter in-situ at 12-months or 1-month post-retrieval, whichever occurred first (i.e., patient had not died, withdrawn, or been lost to follow-up prior to the 12-month visit or had their filter retrieved within 12 months and did not miss the 1-month post-retrieval visit).

The pre-defined performance goal for the primary effectiveness endpoint event rate was 90%. In total, 829 subjects were evaluable for the primary effectiveness endpoint. The primary effectiveness endpoint rate was 96.4%, with a lower 95% confidence interval of 94.9%, meeting the performance goal (see **Table 5**).

Table 5: Effectiveness Endpoint Rate

Endpoint Event	**Rate***	**95% CI***
Primary Effectiveness Event Rates at 12-months in-situ or 1-month post-retrieval	**96.4% (799/829)**	**(94.9%, -)**
Procedural and technical success at time of procedure	98.0% (1,393/1,421)	(97.2%, 98.7%)
Freedom from clinically significant PE	98.3% (815/829)	(97.2%, 99.1%)
*The Exact binomial test model was used for analyses. The denominators are the number of subjects evaluable for the endpoint.		

Additional Measures

The secondary measures reported include individual components of the primary effectiveness endpoint and primary safety endpoint, as well as other device-related measures. These individual outcome measures included freedom from clinically significant pulmonary embolism, freedom from caval thrombotic occlusion, freedom from new deep vein thrombosis, freedom from clinically significant perforation, freedom from adjacent organ perforation, freedom from filter perforation >5 mm outside the cava wall, freedom from filter fracture, freedom from filter embolization, freedom from filter migration >20 mm, and freedom from SAEs possibly, probably, or definitely related to the filter within the peri-operative period.

Notably, the primary safety endpoint analysis did not include all safety events that occurred since subjects who died, were withdrawn, were lost to follow-up, or had a filter removed prior to 12 months were not counted towards the primary safety endpoint rate. Therefore, **Table 6** shows Kaplan-Meier estimates, as well as the number of patients at risk and the number of events, for the individual outcome measures at the protocol-defined follow-up time points; Kaplan-Meier analysis provides an estimate of cumulative survival (i.e., the probability that a patient is event-free over time). For freedom from clinically significant pulmonary embolism, Kaplan-Meier analysis indicated a 98.7% probability that a patient is free from experiencing clinically significant pulmonary embolism at 3 months (with 819 patients at risk or still in the study and not yet experienced clinically significant pulmonary embolism, and 16 events of clinically significant pulmonary embolism through 3 months) and a 96.2% probability that a patient is free from experiencing clinically significant pulmonary embolism at 24 months (with 192 patients at risk and 27 events of clinically significant pulmonary embolism through 24 months).

Finally, filter retrieval measures were reported. In total, 693 filters were retrieved; 690 of 706 retrieval attempts (assessed per subject) were successful. Some subjects underwent multiple retrieval attempts due to deferred or unsuccessful retrieval attempts, thus a subject may have one or multiple failed retrieval attempts. Failed retrieval attempts (39 attempts in 36 subjects) were attributed to an inability to engage the filter (n=13), an inability to detach the filter hook from the wall (n=8), thrombus detected in the filter or components (n=12), filter unable to be removed using planned approach (n=2), unsuitable position of filter (n=2), required imaging could not be obtained (n=1), or physician decision not to remove (n=1). Among the 693 IVC filter retrievals, there was one death resulting from an innominate vein injury.

Table 6: Kaplan-Meier Estimates for Secondary Endpoints

	Kaplan-Meier Estimate (Number of patients at risk, Number of events)				
Endpoint	**3 months**	**6 months**	**12 months**	**18 months**	**24 months**
Freedom from clinically significant pulmonary embolism	98.7 (819, 16)	97.8 (505, 22)	96.9 (310, 25)	96.6 (237, 26)	96.2 (192, 27)
Freedom from clinically significant perforation	99.9 (830, 1)	99.7 (516, 2)	99.2 (319, 4)	97.7 (242, 8)	96.2 (196, 11)
Freedom from adjacent organ perforation	100 (830, 0)	99.8 (516, 1)	99.3 (319, 3)	98.6 (243, 5)	97.6 (198, 7)
Freedom from filter perforation >5mm outside apparent cava wall	99.7 (829, 3)	99.3 (516, 6)	98.4 (318, 9)	94.6 (239, 20)	93.7 (194, 22)
Freedom from filter embolization	99.7 (828, 3)	99.6 (517, 4)	99.6 (321, 4)	99.6 (246, 4)	99.6 (201, 4)
Freedom from caval thrombotic occlusion	99.0 (822, 11)	98.3 (510, 15)	98.3 (317, 15)	97.9 (242, 16)	97.1 (197, 18)
Freedom from new deep vein thrombosis	95.2 (789, 55)	93.3 (477, 67)	91.8 (294, 73)	89.2 (217, 80)	89.2 (179, 80)
Freedom from SAEs possibly, probably or definitely related to filter within peri-operative period	97.9 (815, 28)	97.9 (507, 28)	97.9 (315, 28)	97.9 (241, 28)	97.9 (196, 28)

	Kaplan-Meier Estimate (Number of patients at risk, Number of events)				
Endpoint	**3 months**	**6 months**	**12 months**	**18 months**	**24 months**
Freedom from filter fracture	99.7 (828, 3)	99.5 (517, 4)	99.5 (321, 4)	99.5 (246, 4)	99.1 (201, 5)
Freedom from filter migration >20mm	99.8 (829, 3)	99.8 (516, 3)	99.8 (320, 3)	99.8 (245, 3)	99.8 (200, 3)

- ***Study Conclusions and Strengths/Limitations***

The PRESERVE Study provides safety and effectiveness data for up to two years of follow-up on 1,421 subjects treated with commercially available retrievable and permanent IVC filters in US subjects. This large, multicenter study was intended to address FDA questions related to observed safety events for IVC filters.

The primary safety endpoint rate was 89.4% (262/293), which met the prespecified performance goal of 80%. However, it is important to note that this rate excluded subjects who died, were withdrawn, were lost to follow-up or had the IVC filter removed prior to 12-months (whether or not they had a prior safety event). Thus, there was extensive censoring due to patient death, IVC filter retrieval, and subject lost-to-follow-up, which resulted in only 293 of 1,421 subjects (21%) evaluable at 12-months to assess the primary safety endpoint event rate. Given that only subjects who were still in the study at 12 months were included, subjects who experienced a primary safety endpoint event and then had a filter removed were not counted against the primary safety endpoint. For example, there were 4 instances of embolization of IVC filters or filter components, but this is not reflected in Table 4, which reports Freedom from Filter Embolization as 100% (293/293), since these filter embolizations occurred before IVC filter removal prior to 12-months. Kaplan Meier estimates for freedom from secondary measures for all subjects are shown in **Table 6**. Study endpoints were determined by site assessment, which could underestimate outcomes. Another limitation of the study is that only 14.0% of the 1421 subjects that received a filter (or 63.8% of subjects still in the study at 12 months) had CT scans at 12 months and only 7.3% (or 53.9% of subjects still in the study at 24 months) had CT scans at 24 months.

The Primary Effectiveness Endpoint rate was 96.4% (799/829) and met the prespecified performance goal of 90%. Of note, the 12-month rate of freedom from new pulmonary embolism was 98.3% (815/829) and contributed to the primary effectiveness outcome.

The results from the PRESERVE Study, especially when assessed for the full population and not just those in the study at 12 months, are consistent with previously reported rates for filter complications, including filter embolization, clinically significant perforation, new DVT, caval thrombotic occlusion, and SAEs.

9. Instructions for use

Choice of insertion technique and location

The ALN Optional Vena Cava Filter can be implanted by percutaneous or surgical approach. (see figure 1)

Upper route access (in order of preference):

- Right internal jugular vein
- Left internal jugular vein
- Left subclavian vein
- Basilic vein

Lower route access (in order of preference):

- Right femoral vein
- Left femoral vein

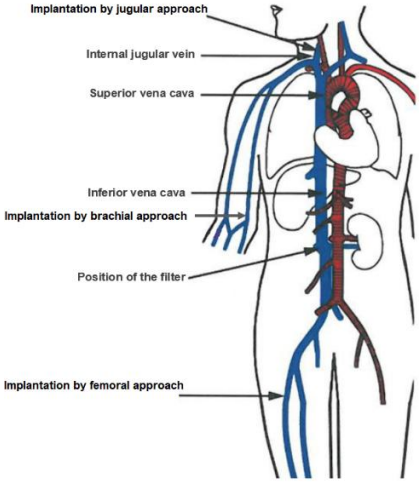


Figure 1: Different approach routes available for ALN Optional Vena Cava Filter implantation.

The approach route is selected according to clinical presentation, the chosen insertion technique and the practitioner's experience.

When employing a surgical approach, the right internal jugular vein is the most commonly selected approach.

The practitioner's choice of approach route is based on clinical circumstances.

Placement site: Inferior Vena Cava without any anatomic abnormalities, the apex of the ALN Optional Vena Cava Filter should be placed below the lowest renal vein. (see figure 2).

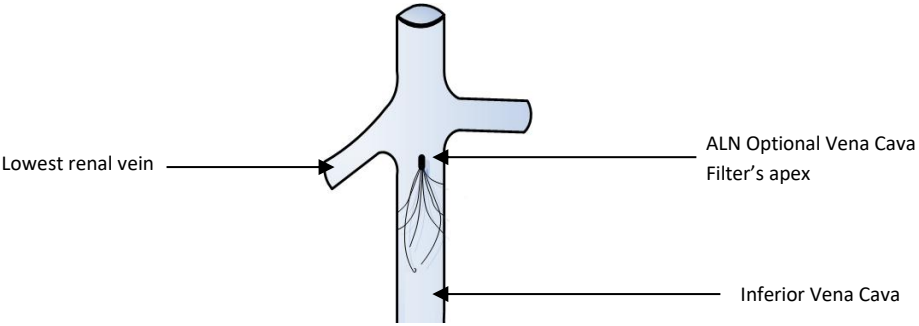


Figure 2: ALN Optional Vena Cava Filter placement site.

Necessary resources

The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.

Equipment Required:

- Sterile physiological saline solution or similar isotonic solution for system rinsing.
- Sterile syringe for perfusing the sterile physiological saline solution.
- Contrast medium used for cavogram.
- Local anesthetic.
- Basic catheterization materials and miscellaneous consumables.

Note: All catheter manipulations should be done while using fluoroscopy imaging guidance**.**

Insertion procedure

Warning:
The packaging should not be damaged. The device is sterile. Do not use if sterile barrier is damaged.

Warning:
The brachial and jugular kits are distinguished from the femoral kit by the orientation of the filter inside the filter holder. The kits are also distinguished by color coding (yellow for the brachial and jugular kits, green for the femoral kit). The brachial kit is distinguished from the femoral and jugular kits by the length of the introduction system elements and of the J-guidewire.

1: Patient preparation

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

(1)

(2)

2: Anesthesia and puncture

- After local anesthesia, puncture the selected basilic vein. (3)

(3)

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

Warnings relative to use of the J-guidewire*:*

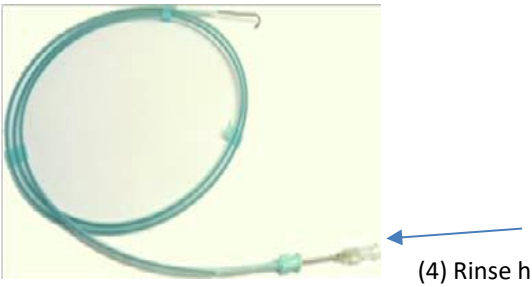
The J-guidewire should be used by a physician with appropriate cardiac catheterization training. Never advance the J-guidewire or introduction system without radiology control.

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 base of the J-guidewire's distributor (4). Insert the flexible end of the J-guidewire into the needle (5).
- Under medical imaging, advance the J-guidewire through the needle using the stiffener. Place the end of the J-guidewire:

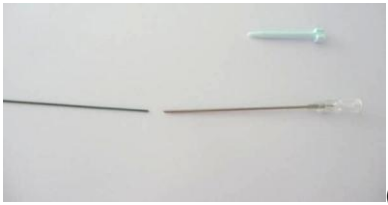
  Upper route – subrenal

- Leave enough length of the J-guidewire exposed.


(4) Rinse here

(5)

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


(6)

To facilitate progress of the introduction system, ALN recommends making a sufficiently large incision to the tissues surrounding the J-guidewire.

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

Warning:
Do not attempt to advance or remove the J-guidewire in 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.

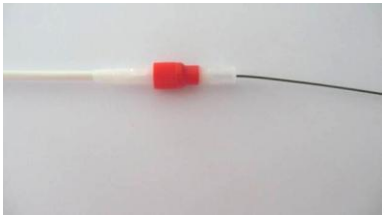
- Rinse the introduction system with a sterile physiological saline solution or similar isotonic solution.

4: Advancing the introduction system (introducer sheath + dilator) and cavogram

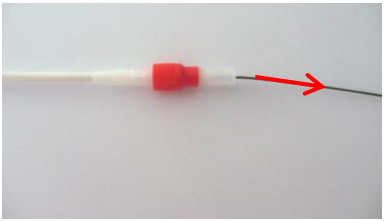
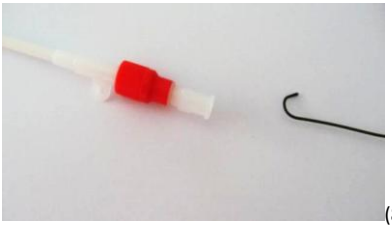
Note: During the following steps, monitor the procedure closely using fluoroscopy guidance

- Insert the outer part of the J-guidewire into the distal end of the introduction system.
- Advance the introduction system (Dilator + 7F introducer sheath) over the J-guidewire. (7)

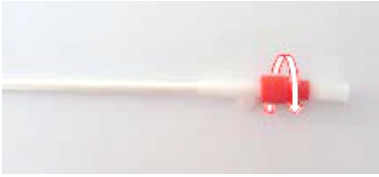
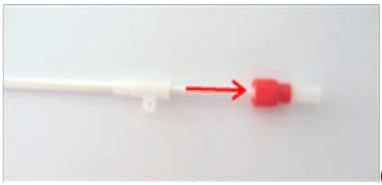
Warning:
To prevent kinking of the 7F introducer sheath, ensure that the 7F introducer sheath is handled by its base and is not bent.


(7)

- Advance the end of the introduction system to the vicinity of the iliac bifurcation.
- Remove the J-guidewire. (8)



(8)

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



(9)

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

Note: It is recommended that frontal and lateral cavogram is performed before placing an ALN Optional Vena Cava Filter. The purpose of this examination is to:

- Check the permeability and anatomy of the inferior vena cava, ipsilateral iliac veins and renal veins.
- Measure the length and diameter of the subrenal inferior vena cava and detect any possible variations in IVC anatomy (double vena cava, left inferior vena cava, agenesis, etc.).
- Diagnose IVC disease (partial or total vena cava thrombosis, extrinsic adenopathy-related compression, tumor syndrome or aortic aneurysm, etc.).
- Determine the most suitable placement site. Inferior Vena Cava without any anatomic abnormalities: the apex of the ALN Optional Vena Cava Filter should be placed below the lowest renal vein.

Warning:
If there is a doubt concerning the anatomy or size of the vena cava, new shots should be taken from different angles.

Do not deploy the filter if no prior diameter measurements have been made.

Patients whose inferior vena cava diameter is greater than 32 mm cannot be implanted with an ALN Optional Vena Cava Filter as this latter cannot be correctly anchored and there is an increased risk of filter migration.

- After localization, the renal veins can be marked by placing a metallic instrument on the operative field.

5: Rinsing the introducer sheath

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

(10)

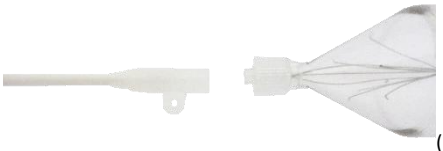
Warning:
Insufficient equipment rinsing may cause clot formation in the introduction system, leading to poor filter anchoring and thus increasing the risk of migration on placement. If the implantation procedure is longer than expected, do not hesitate to rinse the introducer sheath regularly.

6: Inserting the vena cava filter into the introducer sheath

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

- Remove the filter holder from its sterile bag. Remove the protective cap, then present the filter holder along the axis of the introducer sheath. (11) (12)

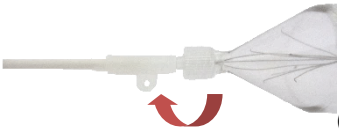
(11)


(12)

Warning:
The filter is prepackaged in its filter holder by ALN and is ready to use. Never use a filter that has been removed from its filter holder, nor attempt to re-insert it into this latter. Do not attempt to modify

the filter in any way. In particular, do not increase or reduce its diameter, or change the orientation of the filter in its filter holder.

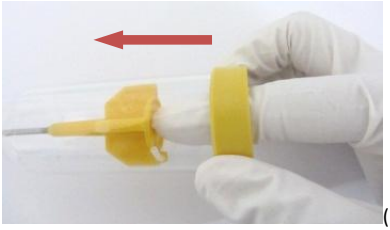
- Insert the tip of the filter holder into the base of the introducer sheath. Screw the filter holder (clockwise rotation) onto the base of the introducer sheath. (13)


(13)

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

To prevent kinking of the introducer sheath during filter progression, ensure that the introducer sheath is handled by its base and is not bent.

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


(14)

Warning:
If one or more filter legs are deformed in the filter holder, do not insist and use another filter.

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

(15)

7: Advancing the filter to the placement site

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

(16)

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

- If possible, adjust the position of the filter in the inferior vena cava: the filter's apex below the lowest renal vein. Position the radio-opaque marker band of the 7F introducer sheath approximately 55 mm below the lowest renal vein if prior tests have confirmed possible placement below the lowest renal vein. (see figure 3)

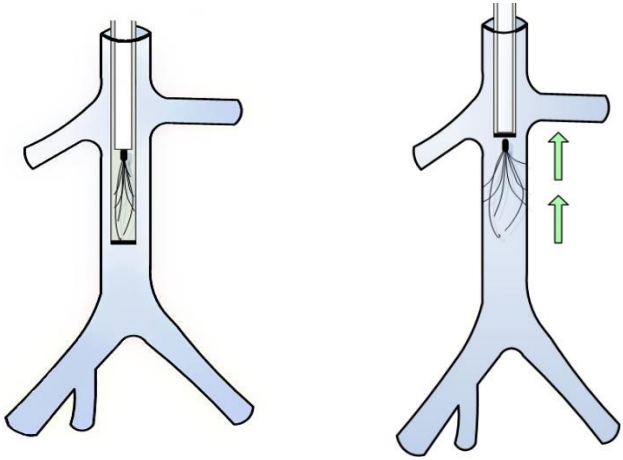


Figure 3: Positioning the ALN Optional Vena Cava Filter below the lowest renal vein

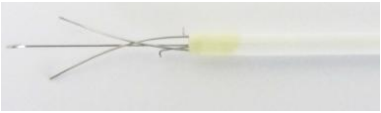
Warning:
Do not deploy the filter until it is in its optimum position, the most appropriate placement site being confirmed by cavogram.

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 at least 55 mm (filter's length).

8: Releasing Filter at the implantation site

Warning:
Do not deploy the filter if no prior diameter measurements have been made. Patients whose inferior vena cava diameter is greater than 32 mm cannot be implanted with an ALN Optional Vena Cava Filter since a correct fixation of the latter is compromised with an increased risk of migration of the filter.

- Slide the introducer sheath over the pushing catheter by a slow upwards removal movement, without jerking, until the filter is released (approximately 55 mm). (17) (18)

(17)  (18)

Warning:
Once the base of the introducer sheath reaches the black pusher marker, deploy the filter by immobilizing the base of the pushing catheter and slowly sliding the introducer sheath out. This ensures optimum filter positioning.

Do not attempt to remove or reposition the filter once the hooks have been engaged into the walls of a vessel except by using the ALN extraction and/or repositioning kit intended for this purpose. The sharp hooks could cause severe tissue damage.

A poorly positioned filter (tilted filter but with all legs in contact with the vena cava wall), which 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. Retrieval, either surgically, or using the ALN Extraction and/or Repositioning kit intended for this purpose, is recommended for an incorrectly positioned filter that could have cardio-respiratory effects.

9: End of procedure

- Remove the pushing catheter and perform a post-operative control cavogram with subtracted and non-subtracted images (frontal and lateral). All images should be archived and available on film or electronic medium, appended to the patient record.
- Remove the 7F introducer 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.

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

A PA (Plain Abdomen) X-ray image should be taken 24 hours after filter placement.

This reference document relating to filter stability, integrity and positioning should be made available for subsequent viewing (included in the patient record).

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.
- A frontal and lateral PA image should be taken before patient release, then each year thereafter.
- The patient should attend a follow-up consultation within the first month, by the radiologist who implanted the filter, or by his/her medical team or by the clinician who referred the patient for the procedure.

- A written document stating:
  - the type of filter (filter type and batch number),
  - placement date,
  - hospital and unit where the filter was implanted,

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

  In this respect, it is imperative to give to the patient the implantation's card provided by ALN.
- Inferior vena cava permeability control imaging should be performed if there is the slightest suspicion of recurrent pulmonary embolism or phlebitis.

10. Optional retrieval procedure

When the risk of embolism or placement indications are no longer present, the ALN Optional Vena Cava Filter is intended to be retrievable at any time, using the ALN Extraction and/or Repositioning Kits intended for this purpose (Product references FT.902010, FT.902010/VS2, RK-2010).

The retrieval procedure using the ALN Extraction and/or Repositioning kit is described in the instructions for use of the ALN Extraction and/or Repositioning kits.

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.

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

11. Packaging and handling

The ALN Optional Vena Cava Filter 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 Optional Vena Cava Filter after its use-by date.

The ALN Optional Vena Cava Filter 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. Symbols

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

REF	Product Reference
LOT	Batch Code
SN	Serial Number
	Use-by Date
	Date of Manufacture
	Caution
	Consult Instructions For Use
STERILE EO	Sterilization Using Ethylene Oxide, double sterile barrier system
	Do Not Reuse
STERILIZE	Do Not Resterilize
	Do Not Use if Package is Damaged
	Keep Dry
	Keep Away from Sunlight
CE	CE mark
MR	MR Conditional
	Non-Pyrogenic
MD	Medical device
UDI	Unique device identification
	Manufacturer

13. Warranty

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

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

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

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

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FDA Cleared

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