Octoparms Vena Cava Filter

Instructions for Use

Kossel Medtech (Suzhou) Co., Ltd.

Contents

Caution: Carefully read all instructions prior to use. Failure to observe all warnings and precautions may result in complications.

Please refer to *https://www.kossel-medical.com/* for e-IFU.
Recommend using browser Google Chrome or Microsoft Edge and keep the network connectivity.

I. Device description

1. Product Structure

The Octoparms Vena Cava Filter consists of a filter and a delivery system comprising a delivery sheath, dilator, introducer, and pusher.

The filter is laser-cut and expanded from a nickel-titanium alloy tubing. The filter, which consisting of a retrieval hook, four balance arms and four support legs, are designed for optimal clot capture. A retrieval hook is designed for filter retrieval using a snare. These anchors, which is located on support legs, are intended for filter fixation to the vessel wall.

The delivery sheath has a length of 55 cm and has an inner diameter of 2.2 mm, and its distal end has a radiopaque marker band; the dilator can use a 0.035-inch guidewire; the introducer has an inner diameter of 2.1 mm, and the filter is pre-installed inside the introducer. The body of the introducer has text and colored arrows printed on it that identify assembly orientation: “femoral” is printed in green and “jugular” in blue. The arrow of the desired access site will point toward the hub of delivery sheath. The specific structure and composition of each part are shown in Figure 1 and Figure 2.

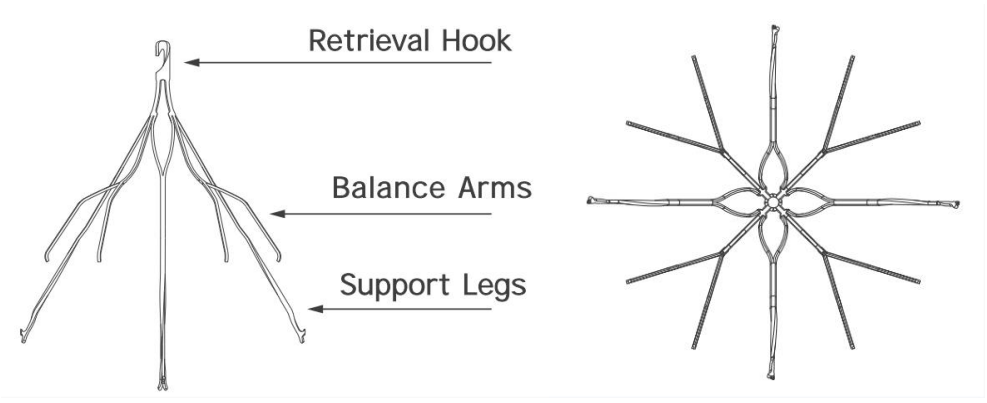
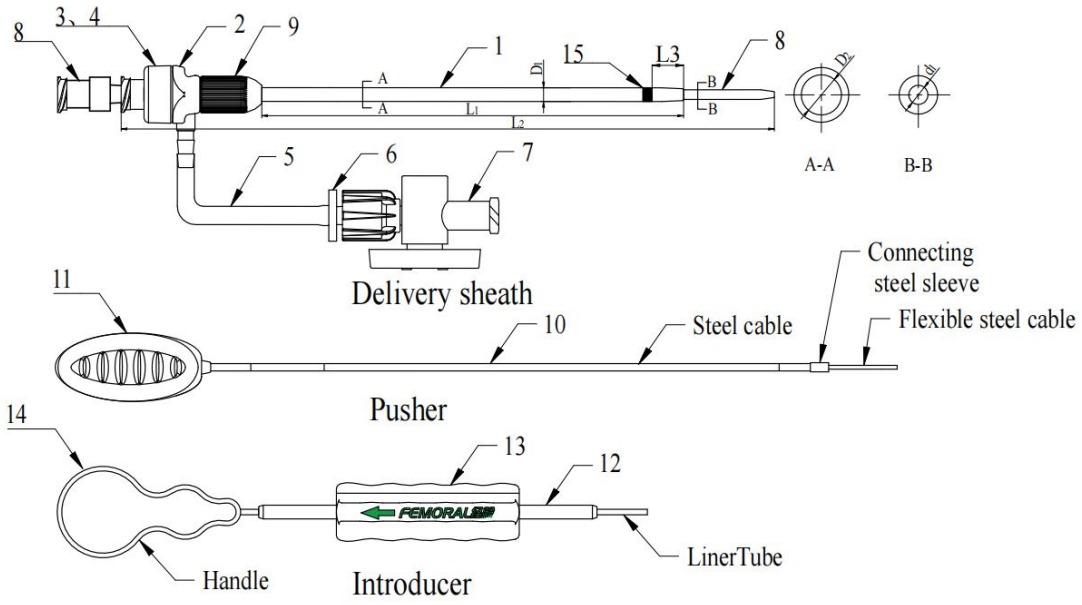


Figure 1: The front view and top view diagrams of the filter

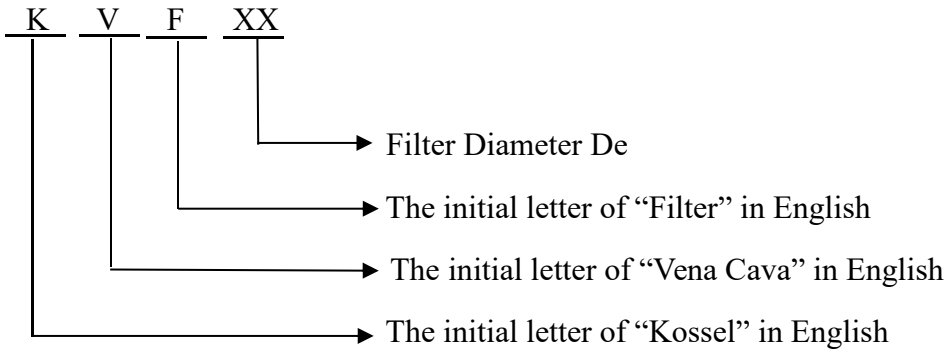


Note：1-Sheath 2-Tee connector 3-Luer cover 4-Silicone pad 5-Hose 6-Luer connector 7-Two-way straight valve 8-Dilater 9-Nut 10-Pusher body 11-Pusher handle 12-Introducer steel pipe 13-Rotating luer lock 14-Liner Tube (with handle) 15-Mark band

Figure 2: Schematic diagram of the delivery system

2. Device specifications and models

2.1 Naming Rules



2.2 Detailed specifications and models of the devices

Table 1: Filter specifications and models and dimensions list

Device models	Filter diameter (De) at 37℃ (mm)
KVF34	34±3
KVF40	40±3

Table 2: Dimensions of the delivery system

Effective length of the delivery sheath L_1（cm）	Outer diameter of the delivery sheath D_1（mm）	The inner diameter of the delivery sheath D_2（mm）	Effective length of the dilator L_2（cm）	The inner diameter of the the dilator d_1（mm）	The distance from the end of the mark band to the end of the sheath L_3（mm）
55±5	2.7±0.5	2.1±0.5	63±5	1.05±0.1	4±1

II. Intended Use/Purpose

The Octoparms Vena Cava Filter is implanted percutaneously via the femoral vein or the jugular vein, and is used to prevent pulmonary embolism (PE) caused by emboli that detach from the inferior vena cava system.

III. Intended users

The device is intended for use by physicians trained and experienced in diagnostic and interventional techniques.

IV. Patient target group

The patient population diagnosed as being at risk of thromboembolism.

V. Indications

A. Absolute indications for filter implantation

The product is implanted percutaneously via the femoral vein or the jugular vein, and is used to prevent pulmonary embolism (PE) caused by emboli that detach from the inferior vena cava system. Including:

1. Patients who have already developed PE or have thrombosis in the inferior vena cava and the iliac, femoral, and popliteal veins have any of the following conditions:

(1) Have contraindications to anticoagulant therapy;

(2) Have complications such as bleeding during anticoagulant therapy;

(3) Have recurrence of PE after adequate anticoagulation and cannot achieve adequate anticoagulation for various reasons.

2. PE, in patients with deep vein thrombosis of the lower extremities simultaneously.

3. Free-floating or extensive thrombi in the iliac, femoral, or inferior vena cava vein.

4. Diagnosed with thrombophilia and recurrent PE.

5. Acute deep vein thrombosis of the lower extremities, intending to undergo transcatheter thrombolysis and thrombus removal.

B. Relative indications for filter implantation

Primarily for prophylactic filter placement. The choice should be made with caution.

1. Severe trauma, accompanied by or potentially leading to acute lower extremity DVT, including:

(1) Closed head injury;

(2) Spinal cord injury;

(3) Multiple long bone fractures or pelvic fractures in the lower limbs, etc.

2.Critical cardiac and pulmonary reserve with acute lower extremity DVT.

3.Chronic pulmonary arterial hypertension with hypercoagulable state.

4.Patients with high-risk factors for thrombosis, such as long-term limb immobilization or critically ill patients.

5.Elderly or long-term bedridden patients with hypercoagulable state.

C. The indications for filter retrieval

1. Temporary filter or retrievable filter.

2. The filter has been implanted for a duration not exceeding the time limit specified in the instructions for use (within 90 days).

3. Angiography confirmed that there were no free-floating or fresh thrombi in the popliteal, femoral, iliac veins and inferior vena cava, or the thrombi in these vessels disappeared after treatment.

4. For patients who no longer require filter protection after preventive filter implantation and have undergone other treatments.

VI. Contraindications

A. Contraindications for filter implantation

1. Absolute contraindications

- Patients with chronic inferior vena cava thrombosis and severe stenosis of the inferior vena cava.
- The diameter of the inferior vena cava exceeds the maximum applicable diameter of the available filter.

2. Relative contraindications

- Patients with severe extensive PE, critical condition and at the verge of death.
- With bacteremia or septicemia.
- Minors.

B. Contraindications for filter retrieval

1. The angiography confirmed that there were still free-floating thrombi or many fresh thrombi in the popliteal, femoral, iliac veins and inferior vena cava.

2. The filter retrieval hook has penetrated the wall of the inferior vena cava. CT venography (CTV) confirmed that forcibly removing the filter might cause severe damage to the inferior vena cava.

VII. Warnings

1. The filter contains nickel-titanium alloy and is generally regarded as safe. However, people allergic to nickel may develop an allergic reaction after implantation, especially those with a history of metal allergy. Some patients may develop nickel allergy after implantation. Some allergic reactions may be severe. Devices that release nickel are not expected to cause breathing difficulties, facial inflammation or throat inflammation. If these symptoms occur, patients should be informed to seek medical attention immediately. Some forms of nickel may also be associated with carcinogenicity (the ability to cause cancer) in animal models. It is unknown whether the nickel released by the implant will increase the risk of cancer in patients.
2. The device is intended for single-use only. The reuse of the medical device may lead to cross-infection among patients. For medical devices, especially those with long and narrow lumens, joints and/or gaps between components, cleaning them becomes extremely difficult or almost impossible after a certain period of contact with body fluids or tissues that may contain potential heat sources or microbial contamination.
3. Because the filter cannot be safely reinserted into the introducer, it must not be released until it is correctly positioned in the inferior vena cava. Do not release the filter if the size of the inferior vena cava has not been accurately measured. Do not reinsert a filter that has been removed.
4. Do not perform sterilization again. After repeated sterilization, the contamination level of potential pyrogenic substances or biological contamination cannot be determined, and the sterility of the product cannot be guaranteed either. This may lead to infectious complications. Due to the adverse effects caused by heat and/or mechanical changes, the cleaning, repeated processing and/or repeated sterilization of existing medical devices will increase the possibility of failures.
5. The delivery of the filter along the delivery sheath is carried out only by means of propulsion. During the delivery process, the retraction of the pusher may cause the displacement of the filter. Crossing of the legs or arms may hinder the further advancement of the filter within the delivery sheath.

6. The filter can be inserted through the jugular vein or femoral vein access. Once the access is determined, please correctly connect the introducer to avoid the filter being inserted in the wrong direction in the inferior vena cava.

7. If the diameter of the vena cava is greater than 30mm, do not insert a filter.

8. If a large blood clot is found at the initial delivery site, it is not allowed to attempt to deliver the filter through this site, as the clot and/or the filter may shift. Instead, another delivery site should be selected to deliver the filter. Small blood clots can be treated by using a bridging technique to insert the guidewire and the delivery sheath.

9. Without fluoroscopic guidance, do not advance the guidewire, deliver the sheath/dilator, or release the filter.

10. Filter fracture is one of the known complications of inferior vena cava filter. There have been some reports indicating that inferior vena cava filter can cause severe cardiovascular and pulmonary complications, and removal of the fragments requires either interventional procedures or surgical methods.

11. Displacement, skewing or tilting of the filter is a known complication of the inferior vena cava filter. There have been reports indicating that the filter may shift into the heart or lungs. Other reports have stated that the tail of the filter may shift. If the diameter of the inferior vena cava exceeds the corresponding size determined in the instructions for use, the implantation will result in displacement in this case. Displacement may also be caused by incorrect implantation and the presence of blood clots, and the large burden may lead to dislocation.

12. After use, the filter and the delivery system may pose potential biological hazards. They should be disposed of in accordance with recognized medical practices and applicable local laws and regulations.

13. After the filter is inserted, it may interfere with the catheter operation passing through the filter, or the filter may get tangled.

14. If a large amount of thrombus has been accumulated in the filter, or if the retrieval hook is embedded in the wall of the vena cava, the filter must not be attempted to be removed.

15. Only use the intravascular retrieval device to remove the filter. For detailed

information, please refer to the content of the "Instruction for Use - Retrieval" section.

16. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Notes:

1. Strictly adhere to applicable clinical guidelines and consensus during use.
2. Remove the filter whenever possible after completion of venous thrombosis embolism (VTE) treatment.
3. Removal method: The filter can be retrieved via the jugular vein when no longer clinically required.
4. If the filter cannot be retrieved and remains implanted long-term, the following complications may occur:

- Migration of the filter
- Penetration of support legs or retrieval hook throught the vessel wall
- Filter fracture or component detachment/embolization
- Infeior vena cava (IVC) occlusion.

Refer to the “Potential Complications and Adverse Affects” section for detailed information.

5. If the filter cannot be retrieved and remains implanted long-term, the following complications may occur:

- Patients with advanced cancer and VTE
- Refractory thrombophilia
- Elderly VTE patients (≥80 years)

The device lacks clinical data supporting safety beyond 90 days. Use with caution as a permanent implant.

VIII. Precautions

1. The device is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. The safety and effectiveness of the device have not been established for pregnancy, nor in suprarenal placement position.
3. The safety and effectiveness of the device have not been established for pediatric patients.
4. The safety and effectiveness of the device have not been established for morbidly obese patients. Abdominal procedures such as bariatric surgery may affect the integrity and stability of the filter.
5. Anatomical variations may complicate filter insertion, deployment and removal. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
6. Procedures or activities that lead to changes in intra-abdominal pressure could affect the integrity and stability of the filter.
7. Position the filter retrieval hook 1cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading.
8. When measuring dimensions of vena cava, consider an angiographic catheter or Intra Vascular Ultrasound (IVUS) if there is any question about morphology of vena cava.
9. If misplacement, sub-optimal placement, or tilting of the filter occurs, consider immediate removal. Do not attempt to reposition the filter.
10. Spinal deformity: If it is considered to implant in patients with severe spinal kyphosis, special attention should be paid as the path of the inferior vena cava may be affected by such anatomical deformities. This may require highly skilled interventional techniques to remove the filter.
11. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to antithrombotic therapy as soon as it is deemed safe.

12. If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is present, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and delivery sheath.

13. It is very important to maintain delivery sheath with a saline flush to prevent occlusion of the sheath, which may interfere with delivery device advancement.

14. Do not attempt to attach a syringe or power injection line to the proximal end of the delivery sheath hub.

15. It is important to ensure that the delivery sheath is tightly connected to the introducer; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

16. Do not advance the filter beyond the distal end of the delivery sheath for deployment. To achieve proper placement, unsheath the stationary filter by withdrawing the delivery sheath. Do not twist the pusher at anytime during this procedure.

17. Withdrawing the delivery sheath while leaving the guidewire in place may lead to the introduction of air into the system.

18. If accidentally deployed, do not attempt to reinsert the filter into the introducer as damage to the balance arms and the support legs can occur.

19. Care should be taken when advancing a guidewire or angiographic catheter through a filter to prevent entanglement.

20. When using the device, it is necessary to administer heparin simultaneously. The recommended dosage is 100 U/kg per dose, with 1 to 2 times per day.

IX. MRI Safety

Non-clinical testing demonstrated that the Octoparms Vena Cava Filter is MR Conditional.

- Static magnetic field of 3-Tesla
- Under the static magnetic resonance condition of 3.0 Tesla, the Octoparms Vena Cava Filter produced a maximum temperature rise of 3.0°C at a maximum MR system reported whole body averaged specific absorption rate (SAR) of 2.0W/kg for 15 minutes of continuous MR scanning.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Octoparms Vena Cava Filter. Therefore, optimization of MR imaging parameters to compensate for the presence of the implant may be necessary.

Artifact Information:

Under the static magnetic resonance condition of 3.0 Tesla, the unilateral artifacts obtained using the spin echo sequence are no more than 15mm, and those obtained using the gradient echo sequence are also no more than 15mm. The artifacts can be optimized by adjusting the image parameters.

X. Potential Complications and Adverse Effects

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Migration or tilt of the filter are known complications of vena cava filter. Migration of filters to the heart or lungs has been reported. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and a large clots burden.
- Filter fractures are a known complication of vena cava filter. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Perforation or other acute or chronic damage of the IVC wall
- Extravasation of contrast material at time of venacavogram
- Vessel or organ injury
- Deep vein thrombosis
- Acute or recurrent pulmonary embolism. It has been reported that the complication can occur even without the use of a filter. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion
- Air embolism
- Hemorrhage
- Infection
- Stenosis at implant site
- Hematoma or nerve injury at the puncture site or subsequent retrieval site
- Insertion site thrombosis
- Incorrect placement of the filter or incorrect insertion direction

All of the above complications may be associated with serious adverse events such as

medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Before the operation, necessary imaging examinations need to be conducted to understand the condition of the inferior vena cava and the VCF insertion pathway; during the operation, necessary inferior vena cava angiography and the implementation of operation key points are required; and after the operation, strict anticoagulation treatment is necessary. These are the key to ensuring the success of VCF insertion, effectively preventing the occurrence of PE, and avoiding or reducing the occurrence of complications.

XI. Clinical Studies

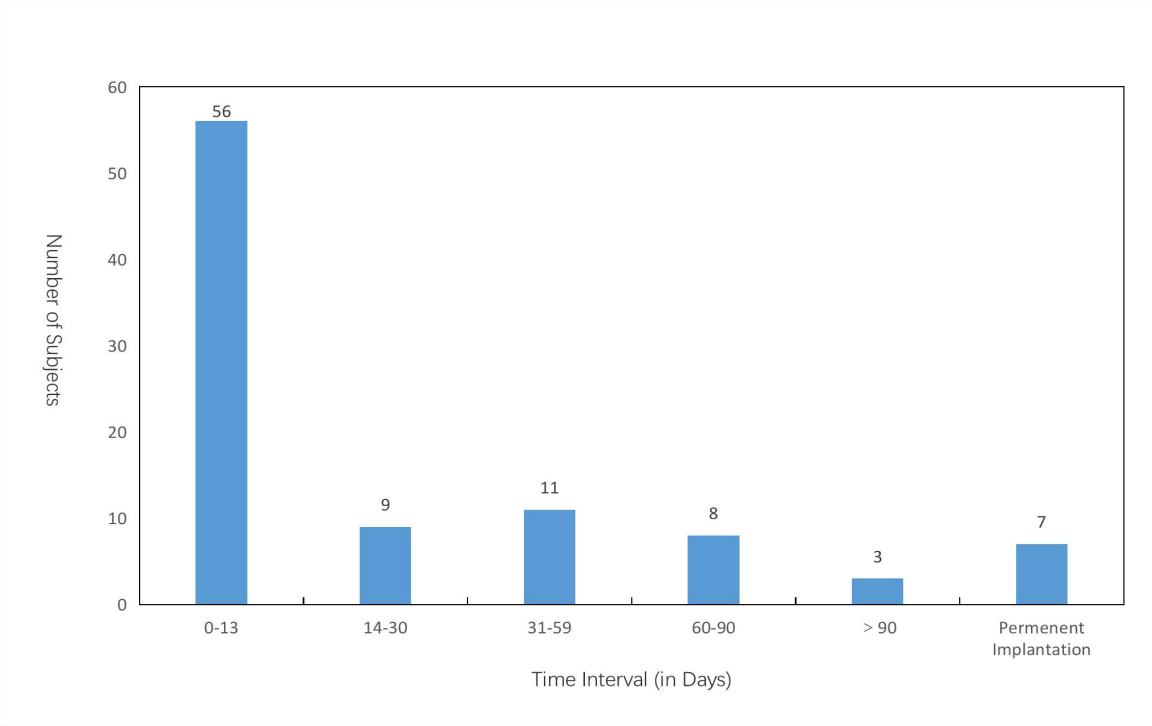
In a multicenter, randomized, parallel, positive control, non-inferiority clinical trial, there were 94 cases in each of the experimental group and the control group. The study evaluated the effectiveness and safety of the experimental product.

All 94 filters in the group were successfully implanted. Based on clinical needs, the doctors decided to either perform an elective retrieval of the filters or choose to permanently implant them. In clinical practice, filters were retrieved from 87 patients. During the retrieval process, the angiographic images showed no signs of perforation of the inferior vena cava. The filters of all 87 patients were successfully retrieved.

The summary of the placement time of the filter is as follows:

Filter implantation period	**Statistics of the number of cases in the experimental group**	**Ratio**
The number of cases with the filter implantation period less than 14 days	56	59.57%
The number of cases with a filter implantation period ranging from 14 days to 30 days	9	9.57%
The number of cases with a filter implantation period ranging from 30 days to 60 days	11	11.70%
The number of cases with a filter implantation period ranging from 60 days to 90 days	8	8.51%
The number of cases with filter implantation duration exceeding 90 days (retrieved)	3	3.19%
Number of permanent implant cases (implantation period: 195 - 265 days)	7	7.45%

Note: The implantation period for the permanent implant cases was calculated from the time of filter implantation in the patients until the end of the clinical trial follow-up.



The results of the current clinical studies for the product show that for the majority of cases, the implantation period was within 90 days and filter retrieval surgery was performed; for a few cases, the filters were not retrieved.

XII. Clinical Benefits

The vena cava filter can prevent pulmonary embolism (PE) caused by dislodged thrombi from deep vein thrombosis (DVT) in the inferior vena cava system. Additionally, it can be retrieved within three months after implantation, avoiding complications associated with long-term placement.

No.	Intended Clinical Benefit	Clinical Outcome Parameters
1	Prevent pulmonary embolism (PE)	Clinical success rate*
2	Brings benefits to users and patients	Device related death Incidence of PE Incidence of fracture Incidence of dislocation (>20mm) of filter Obliqueness of the filter (>15°), tilt Vessel wall penetration/ perforation

*Clinical success of filter placement was determined by evaluating whether the filter was appropriately positioned in the IVC to provide sufficient mechanical interruption to prevent incident symptomatic PE and by the absence of adverse events related to filter placement.

XIII. Summary of Safety and Clinical Performance

The Summary of Safety and clinical performance (SSCP) is available in the European database on medical device (EUDAMED), where it is linked to the Basic UDI-DI(697159176KVFVS).

The link to products summary of safety and clinical performance is as below:

https://webgate.ec.europa.eu/eudamed/secure#/actors/registrations/home

XIV. Instructions for Use - Implantation

Filter implantation via the bilateral femoral veins and the internal jugular vein access.

A. Procedure for femoral vein implantation:

1. Collect and prepare the following equipment for use.

- One Octoparms Vena Cava Filter System that contains:
  - One 55cm, 2.2mm I.D. delivery sheath/dilator kit
  - One introducer with preloaded filter
  - One pusher
- 0.035″ straight guidewire, 110cm long or longer
- 18G puncture needle
- Saline
- Contrast medium, angiographic catheter
- Syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

2. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's position or anatomy, operator's preference or location of venous thrombosis.

3. Prepare, drape and anesthetize the skin puncture site in standard method.

4. Open the vena cava filter system pouch using sterile technique.

5. Incise the skin with a #11 blade and perform venipuncture with an 18G puncture needle.

6. Insert the 0.035″ straight guidewire and gently advance it into the vena cava. Remove the 18G puncture needle over the straight guidewire.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side.

7. Perform standard inferior vena cava angiography using an angiography catheter (typically 30mL of contrast medium at 15mL/s). Check for caval thrombi, position of renal veins, and congenital anomalies.

8. Flush the dilator and the delivery sheath with saline. Slowly insert the dilator through the delivery sheath. Advance the delivery sheath together with dilator over the 0.035″ guidewire and into the vena cava.

PRECAUTION: It is very important to maintain delivery sheath patency with a saline flush to prevent occlusion of the delivery sheath which may interfere with delivery device advancement.

9. Remove the dilator and guidewire.

10. After inserting the flexible steel cable of the pusher into the liner tube in the introducer from the correct direction, then remove the liner tube.

Note: For femoral vein insertion, the direction of flexible steel cable insertion into the introducer is shown in Figure 3.

Warning: For femoral access, always insert the flexible steel cable first before removing the liner tube.

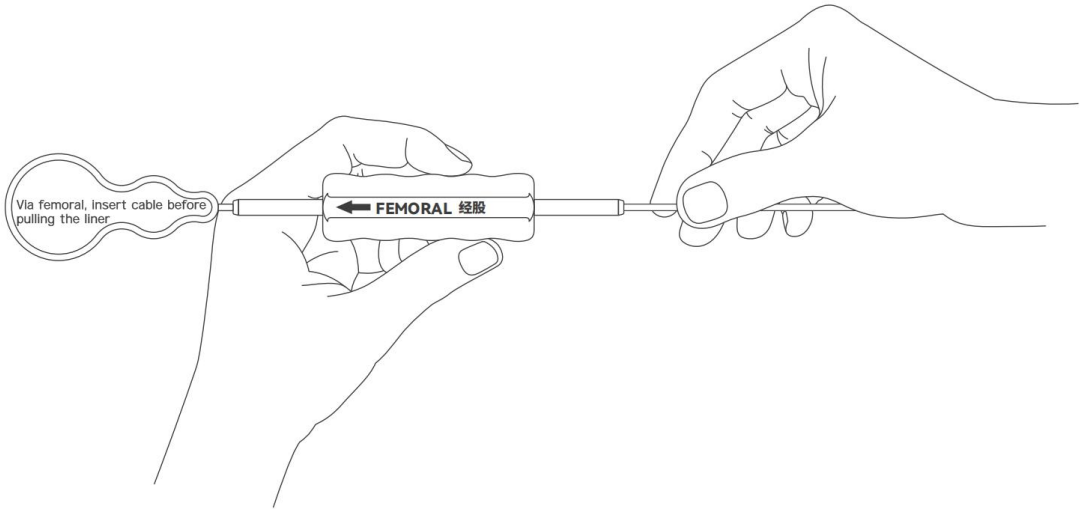


Figure 3: Diagram of steel cable insertion into the introducer (deployment via femoral vein)

11. Insert the introducer into the delivery sheath and tighten the rotating luer lock (Figure 4).

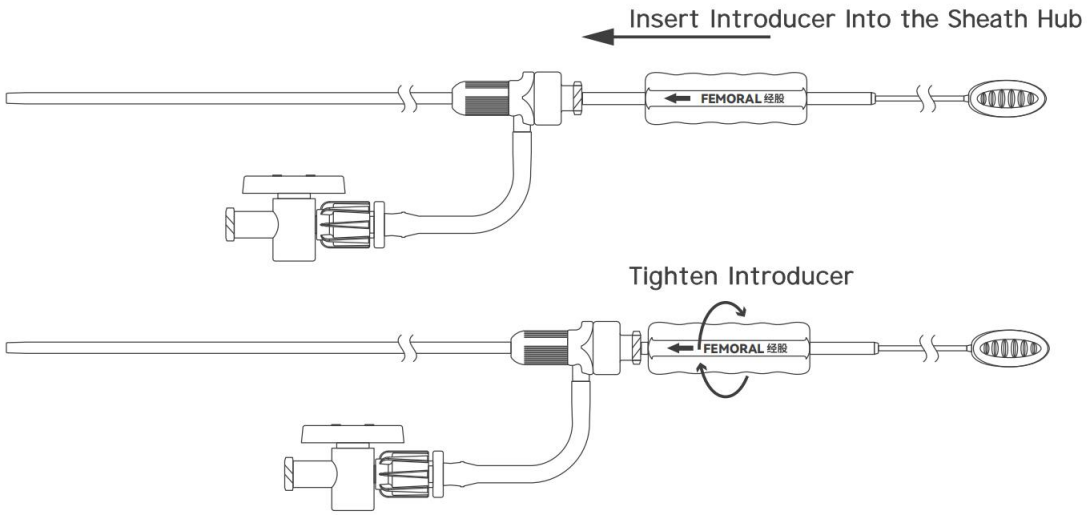


Figure 4 Schematic diagram of the connection to the delivery sheath (deployment via the femoral vein)

PRECAUTION: Care should be taken to ensure the connection between the delivery sheath hub and the introducer is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

Warning: During the connection of the introducer to the delivery sheath, it is necessary to avoid the pusher from falling out of the introducer.

12. Advance the pusher to deliver the filter into the delivery sheath. Do not retract the pusher during the advancing process.

13. Keep advancing the pusher until the filter reaches the tip of the sheath but is not exposed, holding the putter still. Before release, fluoroscopy was used to determine the position of the filter and confirm that the filter retrieval hook was in the expected position of the inferior vena cava.

14. Under fluoroscopic guidance, hold the pusher firmly and begin to remove the sheath. Then the filter is unfolded (shown in the left and middle pictures of Figure 5), and the sheath is removed continuously until the filter is released (shown in the right picture of Figure 5).

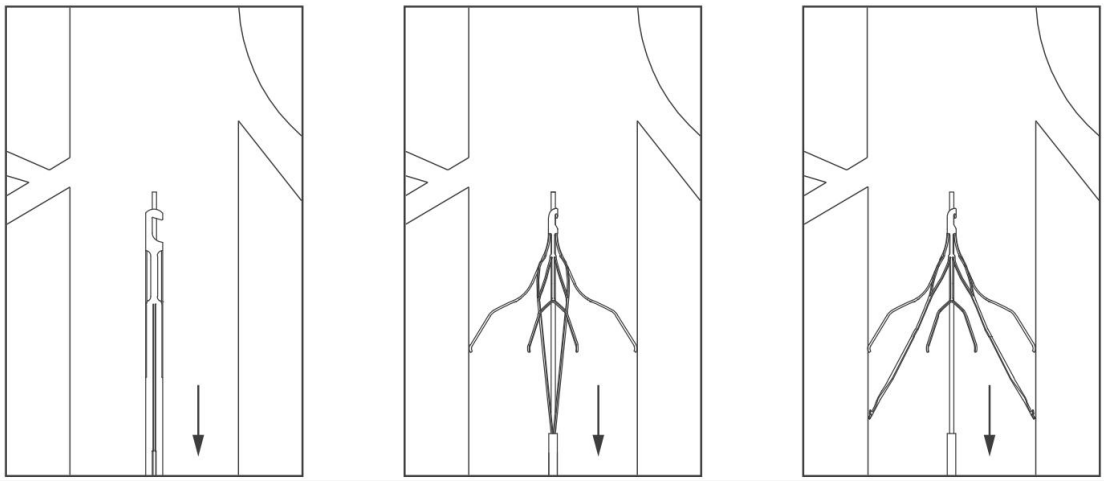


Figure 5: Deployment schematic diagram of the filter (inserted via the femoral vein)

15. Slowly pull back the pusher and withdraw; remove the introducer.

16. Cavography may be performed to confirm satisfactory deployment before completing the implantation procedure (typically 30mL of contrast medium at 15mL/s).

17. Remove the delivery sheath and apply routine compression over the puncture site to achieve hemostasis.

B. Procedure for jugular vein insertion:

1. Collect and prepare the following equipment for use.

- One Octoparms Vena Cava Filter System that contains:

- One 55cm, 2.2cm I.D. delivery sheath/dilator kit

- One introducer with preload filter

- One pusher

- 0.035″ straight guidewire, 110cm long or longer
- 18G puncture needle
- Saline
- Contrast medium, angiographic catheter
- Syringe of saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

2. Select a suitable jugular venous access route, on either the right of left side, depending upon the patient's position or anatomy, operator's preference or location of venous thrombosis.

3. Prepare, drape and anesthetize the skin puncture site in standard method.

4. Open the vena cava filter system pouch using sterile technique.

5. Incise the skin with a #11blade and perform venipuncture with an 18G puncture needle.

6. Insert the 0.035″ straight guidewire and gently advance it into the vena cava. Remove the 18G puncture needle over the straight guidewire.

PRECAUTION: If resistance is encountered during the insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side.

7. Perform standard inferior vena cava angiography using an angiography catheter (typically 30mL of contrast medium at15mL/s). Check for caval thrombi, position of renal veins, and congenital anomalies.

8. Flush the dilator and the delivery sheath with saline. Slowly insert the dilator through the delivery sheath. Advance the delivery sheath together with dilator over the 0.035″ guidewire and into the vena cava.

PRECAUTION: It is very important to maintain delivery sheath patency with a saline flush to prevent occlusion of the delivery sheath which may interfere with delivery device advancement.

9. Remove the dilator and guidewire.

10. Pull out the liner tube first, and then insert the steel cable of the pusher into the introducer from the correct direction.

Note: For jugular vein insertion, the direction of flexible steel cable insertion into the introducer is shown in Figure 6.

Warning: For jugular vein access, always remove the liner tube first before inserting the flexible steel cable.

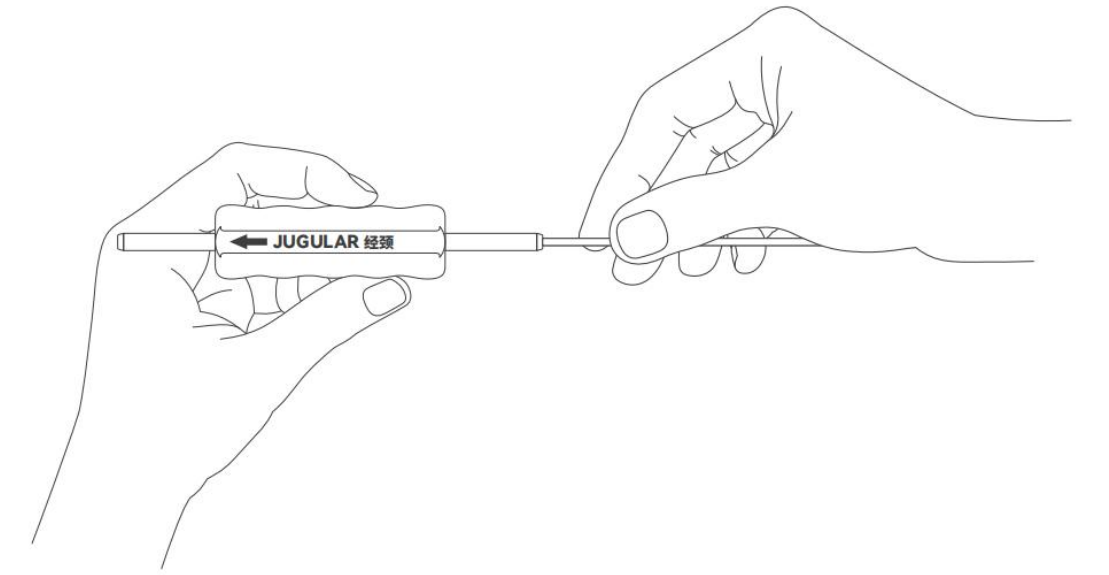


Figure 6: Diagram of steel cable insertion into the introducer (Deployment via jugular vein insertion)

11. Insert the introducer into the delivery sheath and tighten the rotating luer lock (Figure 7).

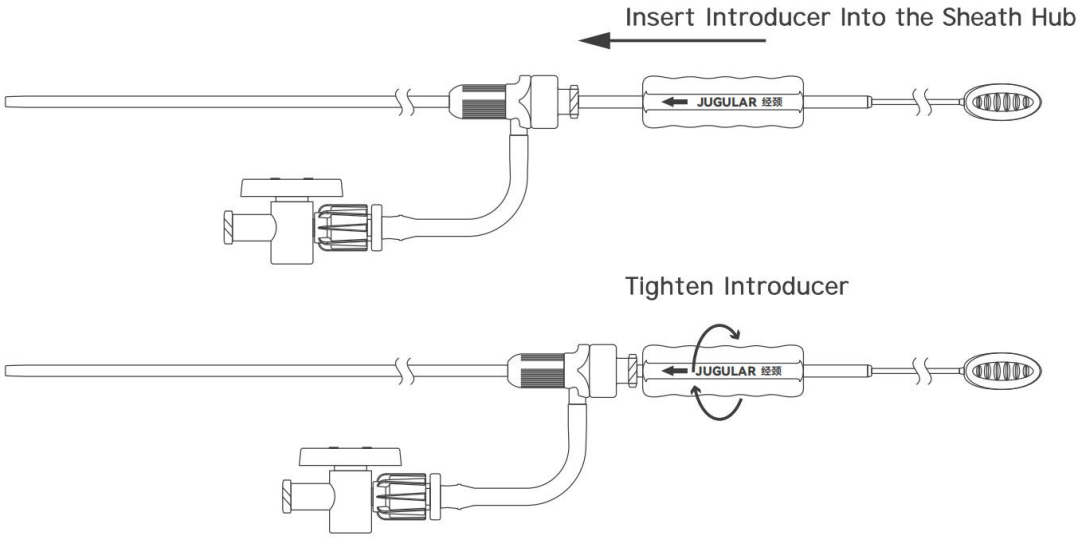


Figure 7 Schematic diagram of the connection to the delivery sheath (Deployment inserted via the jugular vein)

PRECAUTION: Care should be taken to ensure the connection between the delivery sheath hub and the introducer is tight; however, the use of excessive force which can cause slippage of the threads and/or breakage of the hub should be avoided.

Warning: During the connection of the introducer to the delivery sheath, it is necessary to avoid the pusher from falling out of the introducer.

12. Advance the pusher to deliver the filter into the delivery sheath. Do not retract the pusher during the advancing process.

13. Keep advancing the pusher until the filter reaches the tip of the sheath but is not exposed, holding the putter still. Before release, fluoroscopy was used to determine the position of the filter and confirm that the filter retrieval hook was in the expected position of the inferior vena cava.

14. Under fluoroscopic guidance, hold the pusher firmly and begin to remove the sheath. Then the filter is unfolded (shown in the left and middle pictures of Figure 8), and the sheath is removed continuously until the filter is released (shown in the right picture of Figure 8).

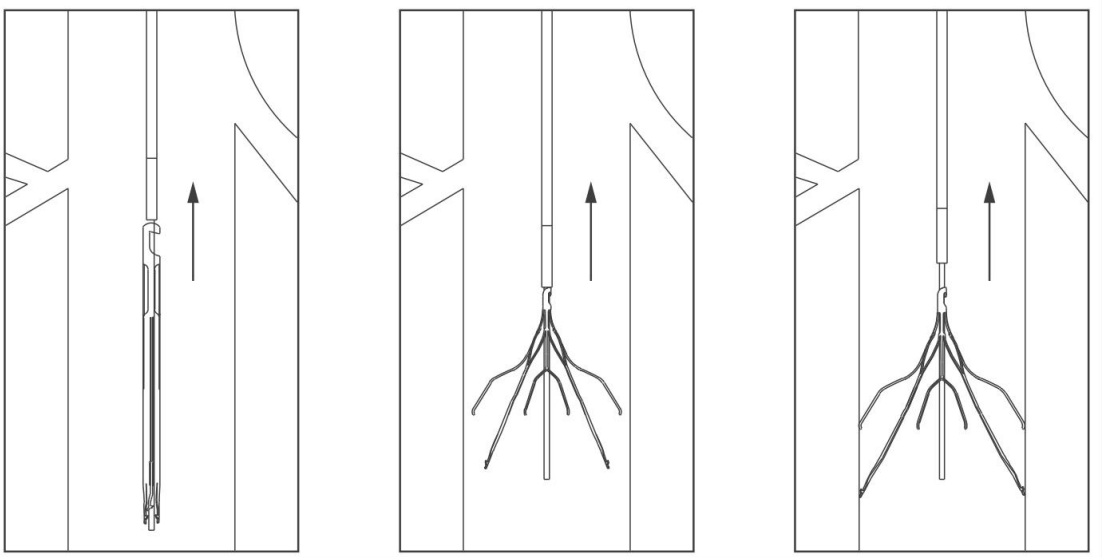


Figure 8: Deployment schematic diagram of the filter (Deployment via the jugular vein)

15. Slowly pull back the pusher and withdraw; remove the introducer.

16. Cavography may be performed to confirm satisfactory deployment before completing the implantation procedure (typically 30mL of contrast medium at 15mL/s)..

17. Remove the delivery sheath and apply routine compression over the puncture site to achieve hemostasis.

XV. Instructions for Use - Retrieval

Filter retrieval via the internal jugular vein access.

Collect and prepare the following equipment for use:

- One intravascular snare
- 18G puncture needle
- Saline
- Contrast medium
- Syringe of saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.
- Angiographic catheter

WARINING: Remove the filter using an intravascular loop snare only. Do not attempt to remove the filter if significant amounts of thrombus are trapped within the filter or if the retrieval hook of filter is embedded within the vena cava wall.

PRECAUTION: Care should be taken when advancing a guidewire or angiographic catheter through a filter to prevent entanglement.

Procedural Instructions

1. Select a suitable jugular venous access route, on either the right of left side, depending upon the patient's position or anatomy, operator's preference or location of venous thrombosis. (The right jugular vein is preferred)
2. Prior to use, remove the retrieval sheath from packaging and flush them with heparinized saline or suitable isotonic solution.
3. Prepare all other procedure components according to the manufacturer's Instructions for Use.
4. Observe the vena cava from anteroposterior (AP) and lateral angles to confirm the orientation and configuration of the filter. Exercise caution to avoid damaging the filter during traversal. Additionally, use appropriate methods to verify the absence of thrombus in the jugular retrieval path, inferior vena cava, and the filter itself.
5. Select an intravascular snare retrieval device with an appropriate loop diameter

size.

6. Assemble the intravascular snare according to the Instructions for Use provided by its manufacturer.

7. Assemble the components of retrieval sheath and ensure all components are flushed.

8. Carefully advance the guidewire into the IVC under fluoroscopic, positioning it close to the filter.

9. Advance the retrieval sheath and dilator over the guidewire until the tip of the sheath is approximately 3cm cephalad to the filter retrieval hook.

10. Remove the guidewire and dilator.

11. Insert and advance the intravascular snare through the retrieval sheath until its tip is exposed, ensuring that the marker band of the snare catheter is cephalad to the filter retrieval hook.

12. The retrieval of the filter using an intravascular snare is illustrated below.

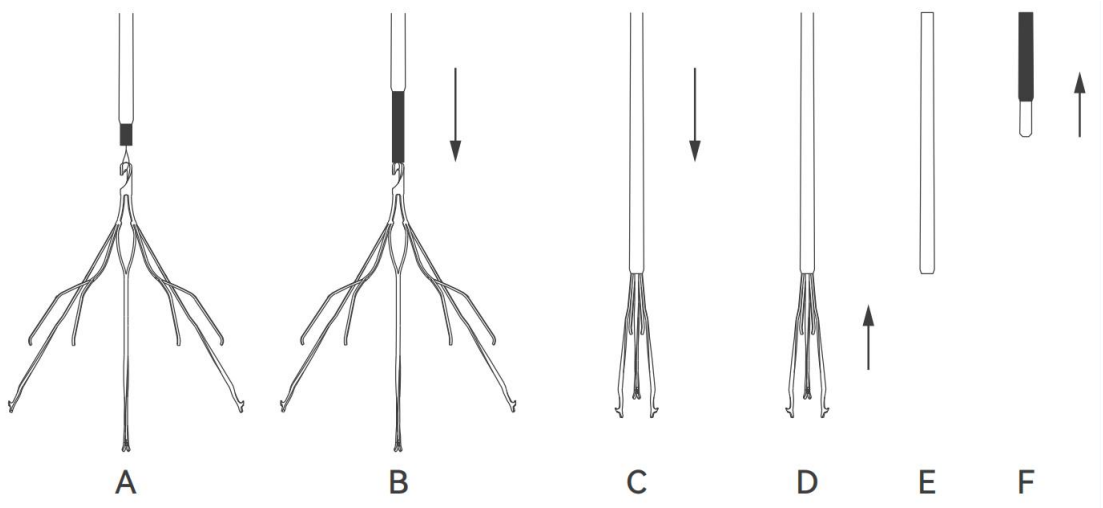


Figure 9: Retrieval of filter using an Intravascular Snare

Figure 9A: Slowly advance the loop forward over the filter retrieval hook.

Figure 9B: Reduce the loop diameter by advancing the snare catheter while simultaneously pulling the snare backwards until loop engages the filter retrieval hook.

Note: Under fluoroscopic guidance, ensure that the loop of the snare has properly engaged the filter retrieval hook and that the filter retrieval hook, retrieval sheath and

snare are aligned. Be careful to snare the top of the retrieval hook; not the side. The marker tip of the snare catheter must be cephalad to the filter retrieval hook.

Note: Always maintain tension on the snare to prevent disengagement of the snare loop from the filter retrieval hook.

Figure 9C: Advance the retrieval sheath in the caudal direction until it covers half of the filter.

Figure 9D: While keeping tension of the snare, hold the retrieval sheath stationary and withdraw the filter into the sheath by retracting the intravascular snare.

Figure 9E: Retract the snare until the filter is completely contained inside the retrieval sheath.

Figure 9F: Once the filter is fully collapsed inside the retrieval sheath, retract the filter, the snare, and the retrieval sheath as one unit out through the retrieval sheath.

13. Remove the filter from the retrieval sheath and examine the filter to assure that the complete filter has been removed.

14. A follow-up venacavogram should be performed prior to withdrawing the retrieval sheath (typically 30mL of contrast medium at 15mL/s)

PRECAUTION: Do not use the retrieval sheath for contrast injection or flushing once the filter has been removed.

15. Remove the retrieval sheath and apply routine compression over the puncture site in the usual way to achieve hemostasis.

XVI. Shelf Life

The validity period specified for the product is from the date of sterilization at the factory of the vena cava filter until 36 months later. That is to say, the validity period of the vena cava filter is three years. The label of the vena cava filter indicates the safe usage period. Vena cava filter that has expired must not be used.

XVII. Storage

1. Store the device in a dry area away from sunlight.
2. It is not allowed to perform high-temperature and high-pressure sterilization or re-sterilization through any other methods.
3. Do not come into contact with organic solvents.
4. If you have any doubts about the product before use, you can directly contact the agent or the manufacturer.
5. To prevent waste from polluting the environment, it is necessary to handle it properly.

XVIII. Transportation

The device should be protected from heavy pressure, direct sunlight and rain and snow immersion during transportetion.

XIX. Explanation of symbols on labels and packaging

	Manufacturer
	Authorized representative
	Date of manufacture
	Sterilized using ethylene oxide
	Do not re-use
	Caution
	Keep away from sunlight
	MR conditional
	Keep dry
	Catalogue number
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
	Batch code
	Use-by date
	Single sterile barrier system with protective packaging inside
	Serial number
	Consult instructions for use or consult electronic instructions for use

Kossel Medtech (Suzhou) Co., Ltd.

ADD: Building 6, No.8, Jinfeng Road, Suzhou New District, Jiangsu, 215163, China

Tel: +86 512 8717 4080

Fax: +86 512 8717 4081

Zip: 215163

MedPath GmbH

ADD: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Tel: +49(0)89 8130 6837

Fax: +49(0)89 5485 8884

【Document Numbers】TS30500053

【Revision Numbers】T01

【Revised Date】January 2026