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V-SAILING® Peripheral Thrombectomy System

Instruction for Use

(Please read this manual carefully before use, paying special attention to all warnings and precautions)

Shanghai EndoVas Medical Technology Co., Ltd.

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【Warning】

- Before use, carefully read this IFU to avoid adverse effects, paying special attention to all warnings and precautions.
- Physicians must receive appropriate professional training before using this product and have a clear understanding of the principles, clinical applications, complications, side effects, and hazards of deep vein thrombectomy.
- This product has been sterilized with ethylene oxide before leaving the factory and is intended for single use only (the stent retriever shall not be used more than four times during a single surgical procedure). Reprocessing and re-sterilizing a used product for another surgery is prohibited.
- If the packaging is found to be open, broken, or leaking before use, do not use the product.
- Check the product expiration date carefully before use. If expired, do not use the product.
- Handle the delivery system with care. Avoid excessive bending or twisting, which may prevent the stent from being deployed properly.
- Rotational operation of the product is not permitted.
- Do not advance the device without guidewire guidance.
- Do not use this product for thrombectomy in vessels with a diameter less than 6 mm.
- Pay attention to all warnings and precautions.

【Packing list】

1. V-SAILING® Peripheral Thrombectomy System product one set
2. A copy of instruction of use

【Description】

Peripheral Thrombectomy System is used for interventional procedures via popliteal/femoral vein access to remove thrombi from deep veins. It mainly consists of a stent retriever and a sheath. The stent retriever and sheath must be used together and are intended for combined use only.

The stent retriever includes a 16 mm diameter stent and a delivery catheter. The distal end of the stent retriever is fixedly connected to the TIP tip and the core shaft tube, while the proximal end is fixedly connected to the inner tube. The pushrod moves the core shaft tube to adjust the stent configuration. The stent retriever is assembled and retracted into the outer tube before use, as shown in Figure 1. Rotation of the pushrod is prohibited to avoid kinking of the stent retriever configuration.

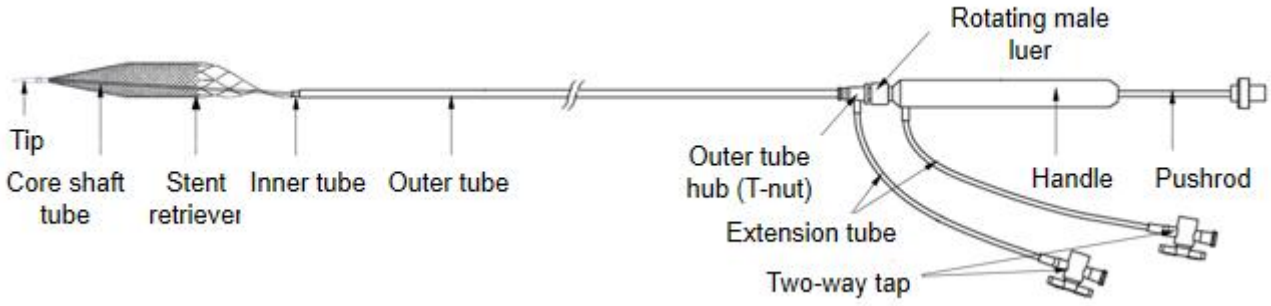

Figure 1. Stent retriever schematic diagram

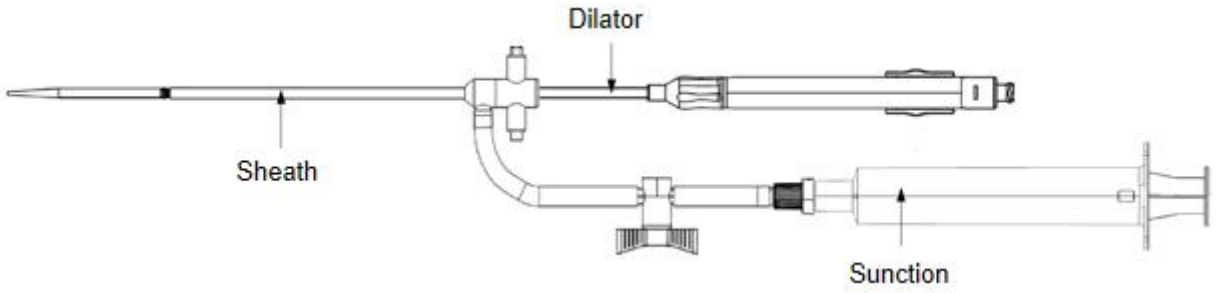

Figure 2. Sheath and dilator assembly schematic diagram

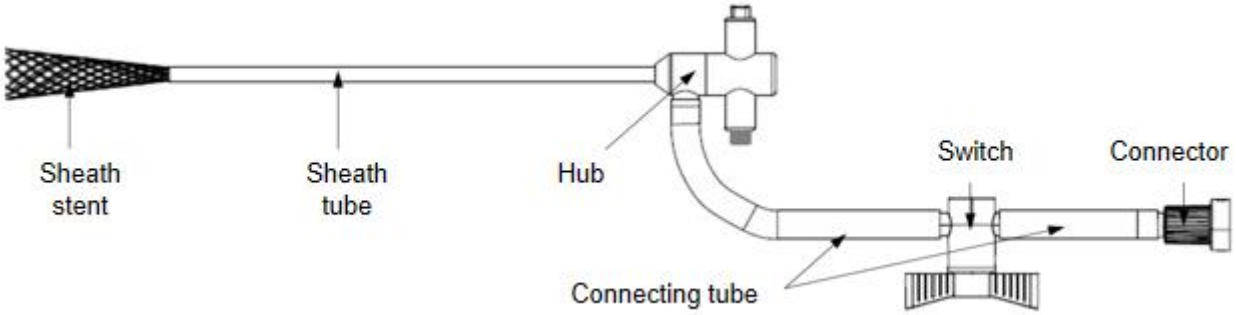

Figure 3. Sheath structure schematic diagram

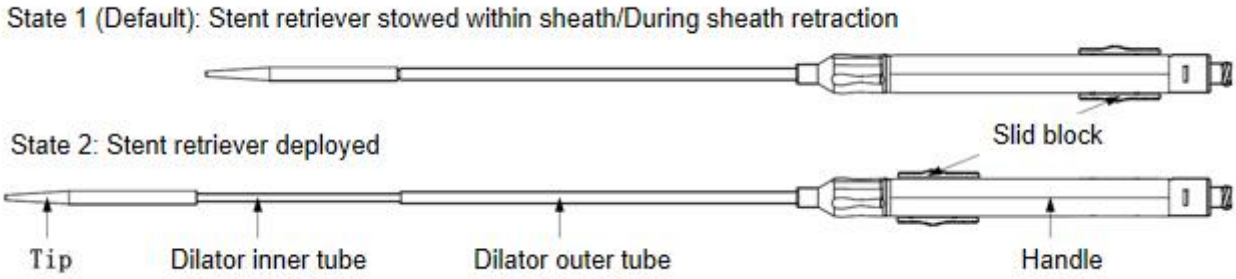

Figure 4. Dilator schematic diagram

The sheath includes an aspirator, sheath tube, dilator, etc. As shown in Figures 2 – 4.

The sheath consists of a sheath stent, sheath tube, sheath hub, connecting tube, aspiration switch, connector, and other components. The sheath and dilator are assembled as a set. During final assembly, the dilator is inserted into the sheath, and the sheath stent is pre-installed into the tip at the front end of the dilator. During the surgical procedure, the dilator and

sheath are advanced along a guidewire to the target position within the blood vessel. The dilator handle and slid block are then pushed to release the sheath stent, and the dilator is withdrawn.

During the surgical procedure, after the dilator is removed from the sheath, the stent retriever catheter is advanced along the guidewire through the sheath to the target vascular area. The handle is then pushed to deploy the stent retriever. The stent retriever catheter is then retracted through the sheath and removed from the body to complete the thrombectomy.

The sheath can be connected to an aspirator via the connector for negative pressure aspiration.

【Product specification】

The Peripheral Thrombectomy System is divided into three models based on the combination of the sheath and the stent retriever: composite type, stent retriever, and sheath. Among them:

The composite type is divided into 5 specifications based on the combination of the inner diameter of the sheath and the length of the stent retriever: CSS13-150, CSS13-100, CSS13-080, CSS10-150, CSS10-100.

The stent retriever is divided into 5 specifications based on the outer diameter of the stent retriever outer tube and the length of the stent retriever: T150, T100, T080, TS150, TS100.

The sheath is divided into 2 specifications based on its inner diameter: A13, A10.

The specific labeling method for product models and specifications is as follows:

Composite type

CSS13 - 150

- Length of the stent retriever
- Inner diameter of the sheath (Fr)
- Composite type code

Stent retriever

T/TS150

- Length of the stent retriever
- Stent retriever code (T indicates compatible with 13 Fr sheath, TS indicates compatible with10 Fr sheath)

Sheath

A13

- Inner diameter of the sheath (Fr)
- Sheath code

The Peripheral Thrombectomy System is compatible with a maximum guidewire size of 0.035 inches.

The stent retriever of each model and specification has the same diameter and is suitable for removing thrombi in blood vessels with a diameter of ⩾6 mm.

【Indication】

This product is designed for transcatheter thrombectomy in patients with deep vein thrombosis (DVT) of the lower extremities under the following conditions: (1) acute-phase iliac, femoral and popliteal vein DVT; (2) subacute-phase iliac and femoral vein DVT.

【Contraindications】

1. Not for use in blood vessels with a diameter of less than 6 mm.
2. Patients with contraindications to anticoagulants, antiplatelet agents, salicylates, or similar medications.
3. Loss of local hemostatic function at the puncture site.
4. Complete venous occlusion that prevents the establishment of an introducer system or guidewire passage via dilation.

【Precautions】

1. This product must be used under high-resolution fluoroscopic guidance.
2. Before the procedure, the patient's underlying conditions should be evaluated to determine suitability for the intended surgery.
3. Use of this product is not recommended for patients with a history of sensitivity to contrast media.
4. Do not use any instrument whose packaging has been opened or damaged.
5. Use the product before the "expiration date".
6. Before use, the instrument must be flushed and wetted with saline solution.。

【Potential complications and adverse events】

Possible complications and adverse events include, but are not limited to:

1. Allergic reactions to contrast media and nickel-titanium alloy (Nitinol);
2. Hematoma at the puncture site;
3. Intimal injury;
4. Vessel dissection;
5. Infection;
6. Death.

【Accessories associated with the device】

There are no accessories for Peripheral Thrombectomy System.

【Accessories not included but necessary for use】

- 0.035” compatible guidewire;
- Puncture instrument;

- Saline solution and syringe;
- Contrast medium and syringe.

【Application steps】

Preparation Before Use:

a. Material preparation: heparin, contrast medium, angiographic catheter, puncture instrument, 0.035'' guidewire, etc.;

b. Based on preoperative ultrasound or other examination results, combined with patient body position and size, anatomical structure, location of thrombosis, effective length of the instrument, etc., select an appropriate venous access route;

c. Prepare, drape, and anesthetize the skin puncture site.

Procedure：

1. Carefully check the integrity of the sterile packaging. If damaged, do not use. Using aseptic technique, open the inner packaging bag and remove the liner containing the Peripheral Thrombectomy System. Carefully remove the stent system from the liner.
2. Flush the dilator, sheath tube, outer tube, inner tube, etc. with saline solution until saline drips from the distal end.
3. Incise the skin with a blade and use the puncture instrument.
4. Under DSA guidance, insert the 0.035'' guidewire and slowly advance it at least 30 cm beyond the occlusion site within the vessel.
5. Deliver the sheath-dilator assembly along the guidewire into the vessel (if necessary, pre-dilate the punctured vessel due to the large outer diameter of the sheath).
6. Press the white ON button on the sheath hub to open the sheath hub switch. Slowly push the slid block on the dilator handle to its uppermost limit. Continue pushing the dilator handle until the sheath stent is fully deployed. Pull the slid block back to the lowest position, then continue pulling the slid block to withdraw the dilator from the sheath assembly. Keep the sheath hub stable throughout the procedure.
7. Advance the stent retriever along the guidewire into the sheath and continue pushing slowly until the TIP (radiopaque) reaches the target position (ensure the stent retriever is positioned above the intended thrombus to be removed). If the patient has a large volume of long-segment thrombus, the procedure may be performed in 2–3 segments: first position the stent at the distal thrombus segment for removal, then gradually move to the proximal thrombus segment in stages.
8. Fix the handle and inner tube, then slowly retract the outer tube until the outer tube contacts the handle. Tighten the movable male luer on the handle to the outer tube hub to complete stent retriever unsheathing. Pull the pushrod to adjust the deployed configuration of the stent retriever so that it apposes the vessel wall. Do not rotate

the push rod to avoid twisting the stent retriever configuration.

9. Slowly retract (recommended speed: 1 – 2 cm/s) the stent retriever catheter assembly until it enters the sheath stent. During this process, the thrombus within the vessel will be separated and collected.
10. When the TIP of the stent retriever enters the sheath stent opening, push the pushrod to the bottom of the handle to collapse the stent, then pull the handle to withdraw the stent retriever catheter from the sheath, completing one thrombectomy pass.
11. Depending on the patient's condition, after cleaning the thrombus from the stent retriever, the stent may be retriever retracted back into the outer tube (rotating the stent retriever 90° relative to the previous pass each time the outer tube is retracted may achieve better thrombectomy results). Then repeat steps 10 to 13 for additional thrombectomy passes.

    Note: The maximum number of thrombectomy passes is 4.
12. Connect the aspirator to the connector on the sheath. Use the aspirator to apply negative pressure to the sheath, thereby aspirating the thrombus from inside the sheath stent. If the sheath becomes clogged during aspiration of residual thrombus, remove the sheath tube from the patient. While removing the sheath, maintain vacuum negative pressure using the aspirator. If another treatment pass is required, flush the residual thrombus from the sheath, manually reload the sheath stent, and re-advance along the guidewire.

    Note: The maximum number of sheath stent redeployments is 4.
13. After completing thrombectomy, withdraw the sheath from the body and achieve hemostasis at the puncture site.

【Sterilization】

The Peripheral Thrombectomy System has been sterilized with ethylene oxide before leaving the factory.

【Transport condition】

During transportation, the product should be protected from high temperatures, heavy pressure, direct sunlight, and getting wet from rain, or handled according to the order contract.

【Storage condition】

Store at room temperature.

【Shelf life】

When stored under the specified conditions, the shelf life is three years. Please use this product within the indicated expiration date.

【Symbol Description】

1）		Do not re-use
2）		Consult instructions for use or consult electronic instructions for use
3）		Protect from heat and radio-active sources
4）		Keep dry
5）		Date of manufacture
6）		Use-by date
7）		Batch code
8）		Catalogue number
9）		Sterilized using ethylene oxide
10）		Do not use if package is damaged and consult instructions for use
11）		Number of products contained in the box is one
12）		Temperature limit
13）		Do not re-sterilize
14）		Keep away from sunlight

【Post sale service】

For any other questions about the product, just ask the company directly.

【Declaration】

Shaghai EndoVas Medical Technology Co., Ltd. (hereinafter referred to as 'EndoVas Medical') expressly states that the Peripheral Thrombectomy System manufactured by our company is for single use only and must not be reused. EndoVas Medical shall not be held liable for any product damage, surgical failure, or other incidents arising from improper product specification selection, operational errors, or any other man-made accidents. Regarding the reusability of the system, EndoVas Medical does not recommend, indicate, or imply in any way, and shall not be held responsible for any accidents or product damage caused by reuse.

【Manufacturer】

Legal Manufacturer：Shaghai EndoVas Medical Technology Co., Ltd.

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