EndoVas
恩盛医疗

Venous Stent System

Instruction For Use

Please read the instruction carefully before using this product. If not operated correctly according to instructions, warnings, and precautions, it may result in serious surgical consequences or cause serious harm to patients.

Shanghai EndoVas Medical Technology Co., Ltd.

Venous Stent System

【Product Components】

The venous stent is a self-expanding nitinol superelasticity alloy stent, the stent is pre-compressed into the outer sheath of the conveyor, when entering the lesion area, through the external sheath of the retraction delivery system, the stent is self-expanding and expanding, and the stent structure is shown in Figure 1.

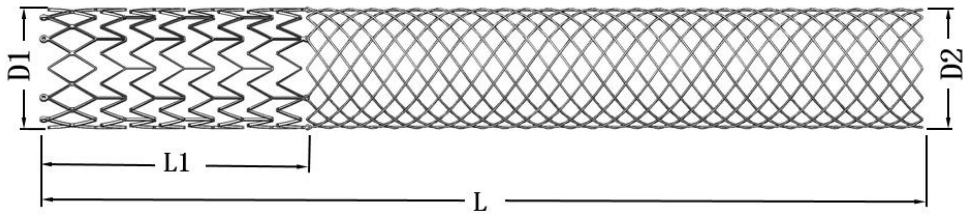

Figure 1. Schematic diagram of the stent structure

The stent delivery system is a quick-exchange type, and the guidewire enters through the tip cavity of the end and exits from the end of the pusher tailstock, as shown in Figure 2. The maximum acceptable gauge guidewire is 0.035". The stent is compressed and pre-placed in the distal outer sheath of the delivery system, and the distal and proximal radiopaque bands on the inner tube mark the two ends of the stent to help the stent be accurately positioned.

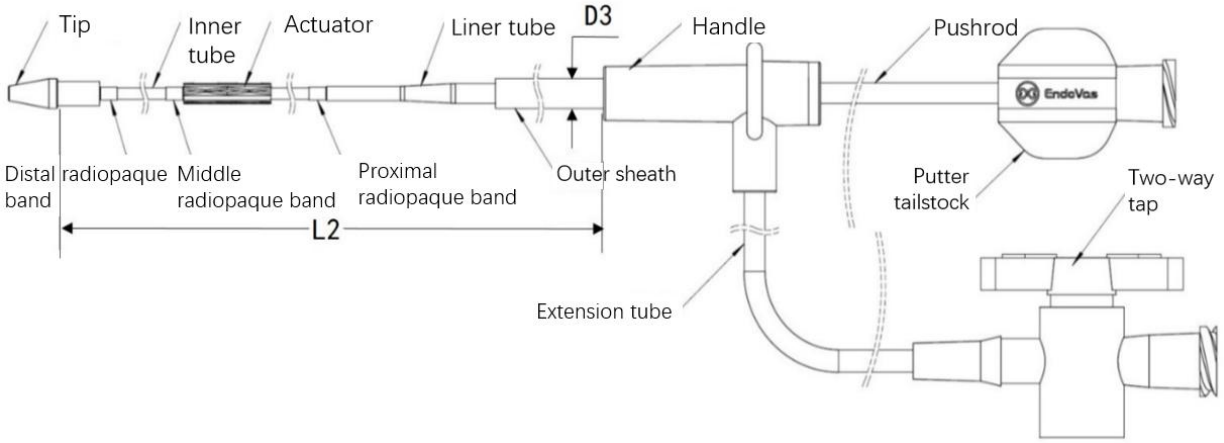

Figure 2. Schematic diagram of the delivery system structure

After the stent system is venipunctured into the intended diseased vessel, the external sheath is withdrawn and the stent is slowly released until the stent is fully released. Depending on the vascular lesion, the doctor may use a balloon to pre-expand or post-expand. The detail model please refer to the attachment.

Product model list

Stent diameter（mm）	Stent cutting section length L1（mm）	Stent length L（mm）	Effective length of the outer sheath of Delivery system L2（cm）	Outer diameter of the outer sheath of Delivery system D3
10、12、14、16、18、20	37	60、80、100、120、150	80	10F
	47	80、100、120、150		
	57	80、100、120、150		

【Intended Purpose】

This venous stent system is intended for use in the iliofemoral vein for the treatment of non-thrombotic iliac vein compression syndrome, deep vein thrombosis and post-deep vein thrombotic syndrome.

【Intended User】

The product should be used by a professional surgeon with special training of installing venous stent system operation.

【Indication】

The venous stent is designed to be used in the iliofemoral venous for the treatment of symptomatic venous outflow obstruction.

【Intended patient population】

The patients who with iliac venous occlusion.

【Contraindication】

- Cannot be used with anticoagulants, antiplatelet drugs and salicylates.
- Cannot be used with the patients who are allergic to nitinol.
- Lose local hemostasis at the puncture site.
- Complete occlusion of the veins that cannot establish the introducer system or guidewire channel by dilation.
- Patients who are not suitable for interventional surgery.
- Patients whose iliac vein size is not suitable for the iliac vein stent system specifications.

【Warnings】

- Before using the product, it is necessary to have a clear understanding of other devices and accessories used with it, and read the relevant instruction manual.
- This product is for one-time use only, it is forbidden to re-sterilize the used product and use it

again.

- Do not use if the package is found to have been opened, cracked, or leaked before use.
- Carefully check the expiration date of the product before use, if it has exceeded the expiration date, do not use it.
- The delivery system should be handled with care to avoid excessive bending or twisting, which may cause the stent inside to not be released normally.
- When using multiple stents, the stent material must be the same material.
- Do not move the instrument forward without guidewire guidance.
- When the force required for stent release is abnormally large, do not release the stent and replace the product.
- When the stent has been partially released, it is strictly forbidden to push the conveyor forward or retract as a whole.
- Ensure that the stent is in the correct position before it is released, and once the stent is released, it can no longer be retracted or adjusted.
- In order to avoid adverse consequences, please read this instruction manual carefully before use, and pay special attention to various warnings and precautions.
- This device is for single patient use only and should not be reused.
- There is not enough clinical data for the overlapping use of this product, and it is not recommended to overlap the use of stents.
- There is not enough clinical data for the use of this product in other joints, and it is not recommended to use it in other joints.

【Possible complications】

Potential complications that may exist with the use of Venous Stent System in arterial vessels include, but are not limited to:

- Allergic reaction to contrast agent and nitinol
- Hematoma at the puncture site
- Distal limb vascular embolism
- Acute vascular occlusion
- Deformation, collapse and displacement of the stent
- Infection
- Death
- Other complications such as iliac and femoral pain

【Main safety and performance criteria】

- Sealing strength is ≥2.25N per test strip.
- There should be no leakage of liquid from the delivery system seat or connecting assembly or other parts of the delivery system; air should not enter the delivery system assembly during continuous pumping.
- Smoothly passes through all parts of the vascular simulation.
- Should be sterile. (Use ethylene oxide sterilised bioculture indicator).

【Accessories associated with the device】

There are no accessories for Venous Stent System.

【Accessories not included but necessary for use】

a. This product needs to be used under the digital subtraction angiography machine (DSA);

b. This product requires an auxiliary device with a 0.035-inch guidewire and a syringe for injecting contrast solution. (the hospital is used as a supporting device)

【Application steps】

- Angiography

Angiography is performed with standard methods. Assess the target lesion site, look at the most severe obstruction and mark it.

- Correct selection of stent system specifications

Based on the imaging information, determine the diameter of the reference vessel (the diameter of the normal vessel at the proximal end). Judge the target lesion length and determine the appropriate stent length required to cover the entire lesion area.

Recommendations for stent diameter selection	
Refer to the diameter of the blood vessel (mm)	Stent nominal diameter (mm)
8~9	10
9~11	12
11~13	14
13~15	16
15~17	18
17~19	20

- Preparation of the iliac venous stent system

1. Open the box and remove the bag containing the stent system, inspect the integrity of the sterile packaging carefully and do not use if damaged.
2. Tear off the seal of the pouch and remove the tray containing the iliac venous stent system.
3. Remove the stent system from the tray carefully, and inspect the iliac venous stent system for any

damage.

4. Do not use if there is a suspicion that the sterility and function of this stent system is compromised, focus on checking the tip of the stent system, the stent should be completely placed in the outer sheath, if the stent is partially exposed, please do not use it.
5. Prior to use, the stent system should be rinsed until saline drip out of the tip.
6. The puncture sheath and catheter should be suitable for the stent corresponding to the diameter of the outer sheath, 0.035" guidewire can be used with this stent system.

- Induct of the stent

Sacculus pre-dilation: before the stent is used, the doctor can select a sacculus that matches the reference vessel of the target lesion for vascular pre-dilation. After pre-dilation, the stent system is inserted anterograde along the guidewire into the target lesion site and secured to pass through the guide catheter.

- Positioning and release of the stent

1. Adjust the position of the initiating site at the tip of the stent system at the beginning of the expected implantation of the blood vessel, and make sure that the guidewire is about 20cm beyond the tip of the stent and release the stent.
2. During the whole release operation, hold the putter tailstock with one hand, and pull the handle of the outer sheath to the outside of the body with the other hand, and the stent can be exposed from the sheath under X-ray, and continue to retract the outer sheath until the distal end of the stent is separated from the sheath, then the release of the stent is completed.
3. Pay attention to the relative position of the stent and the target lesion to ensure that the stent completely covers the target lesion. At the end of the release, the Delivery system is withdrawn from the body along the guidewire.

- Operation of sacculus dilation

According to the vascular lesion, the doctor can use a sacculus to post-dilate the stent, and should ensure that the venous stent is well adhered to the wall according to the reference vessel size and venous stent specifications.

【Shelf life and storage condition】

- This product is sterilized by ethylene oxide and is valid for three years.
- Manufacture date and expiration date refer to label.
- Avoid sunlight and store at room temperature in a dry place.
- Storage temperature: 10℃~30℃; Storage humidity: 10%~60% .

【Packaging】

- The product is supplied in a sterile state.
- Product components are fixed and protected in coil and packaged in single layer Tyvek® dialysis bags for sealing.

【Sterilization】

This product is sterilized by ethylene oxide and shall not undergo secondary sterilization. The sterilization method of this product is ethylene oxide sterilization, Tyvek® bag is recognized in the industry suitable for ethylene oxide sterilization packaging materials. The Tyvek® bag is suitable to ethylene oxide sterilization method.

【Post sale service】

For other questions related to the product, please contact Shanghai EndoVas Medical Technology Co., Ltd. directly, and the contact information can be found in the manufacturer's information.

【Declaration】

Shanghai EndoVas Medical Technology Co., Ltd. (hereinafter referred to as 'EndoVas Medical') clearly indicates that the venous stent system produced by the company is one-time and shall not be reused. EndoVas Medical will not be responsible for any product damage, surgical failure caused by improper selection of product specifications, operation errors, or any other man-made accidents. With regard to the reusability of the system, EndoVas Medical does not recommend, express, or imply in any way, and the company is not responsible for accidents or product damage caused by repeated use.

Shanghai EndoVas Medical Technology Co., Ltd.

Building 3, No.356, Zhengbo Road, Pilot Free Trade Zone Lingang Special Area, Shanghai, China

pearl.ding@endovasmedical.com

+86 13774226625

EC REP

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

+31644168999

Explanation of Symbols and Abbreviations Used on Product Labels

	Manufacturer
	Date of manufacture
	Do not re-use
	Batch code
	Operating instructions
	Use-by date
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from rain
	Keep away from sunlight
	Catalogue number
	Number of products contained in the box is one
	Medical Device
QTY:1	Quality is 1

Attachment. Product detail model

Specification	Stent diameter (mm)	Stent cutting section length L1 (mm)	Stent length L (mm)	Delivery system effective length of the outer sheath L2 (cm)	Delivery system outer sheath outer diameter D3
F1010060-37-080-P10	10	37	60	80	10F
F1010080-37-080-P10	10	37	80		
F1010100-37-080-P10	10	37	100		
F1010120-37-080-P10	10	37	120		
F1010150-37-080-P10	10	37	150		
F1212060-37-080-P10	12	37	60		
F1212080-37-080-P10	12	37	80		
F1212100-37-080-P10	12	37	100		
F1212120-37-080-P10	12	37	120		
F1212150-37-080-P10	12	37	150		
F1414060-37-080-P10	14	37	60		
F1414080-37-080-P10	14	37	80		
F1414100-37-080-P10	14	37	100		
F1414120-37-080-P10	14	37	120		
F1414150-37-080-P10	14	37	150		
F1616060-37-080-P10	16	37	60		
F1616080-37-080-P10	16	37	80		
F1616100-37-080-P10	16	37	100		
F1616120-37-080-P10	16	37	120		
F1616150-37-080-P10	16	37	150		
F1818060-37-080-P10	18	37	60		
F1818080-37-080-P10	18	37	80		
F1818100-37-080-P10	18	37	100		
F1818120-37-080-P10	18	37	120		
F1818150-37-080-P10	18	37	150		
F2020060-37-080-P10	20	37	60		
F2020080-37-080-P10	20	37	80		
F2020100-37-080-P10	20	37	100		
F2020120-37-080-P10	20	37	120		
F2020150-37-080-P10	20	37	150		
F1010080-47-080-P10	10	47	80		
F1010100-47-080-P10	10	47	100		
F1010120-47-080-P10	10	47	120		
F1010150-47-080-P10	10	47	150		
F1212080-47-080-P10	12	47	80		
F1212100-47-080-P10	12	47	100		
F1212120-47-080-P10	12	47	120		
F1212150-47-080-P10	12	47	150		
F1414080-47-080-P10	14	47	80		
F1414100-47-080-P10	14	47	100		

F1414120-47-080-P10	14	47	120		
F1414150-47-080-P10	14	47	150		
F1616080-47-080-P10	16	47	80		
F1616100-47-080-P10	16	47	100		
F1616120-47-080-P10	16	47	120		
F1616150-47-080-P10	16	47	150		
F1818080-47-080-P10	18	47	80		
F1818100-47-080-P10	18	47	100		
F1818120-47-080-P10	18	47	120		
F1818150-47-080-P10	18	47	150		
F2020080-47-080-P10	20	47	80		
F2020100-47-080-P10	20	47	100		
F2020120-47-080-P10	20	47	120		
F2020150-47-080-P10	20	47	150		
F1010080-57-080-P10	10	57	80		
F1010100-57-080-P10	10	57	100		
F1010120-57-080-P10	10	57	120		
F1010150-57-080-P10	10	57	150		
F1212080-57-080-P10	12	57	80		
F1212100-57-080-P10	12	57	100		
F1212120-57-080-P10	12	57	120		
F1212150-57-080-P10	12	57	150		
F1414080-57-080-P10	14	57	80		
F1414100-57-080-P10	14	57	100		
F1414120-57-080-P10	14	57	120		
F1414150-57-080-P10	14	57	150		
F1616080-57-080-P10	16	57	80		
F1616100-57-080-P10	16	57	100		
F1616120-57-080-P10	16	57	120		
F1616150-57-080-P10	16	57	150		
F1818080-57-080-P10	18	57	80		
F1818100-57-080-P10	18	57	100		
F1818120-57-080-P10	18	57	120		
F1818150-57-080-P10	18	57	150		
F2020080-57-080-P10	20	57	80		
F2020100-57-080-P10	20	57	100		
F2020120-57-080-P10	20	57	120		
F2020150-57-080-P10	20	57	150		