心脉医疗™ Endovastec

A-C1F01-009 Rev.B

# *Castor*™

## Branched Aortic Stent-Graft System

**CUSTOM-MADE DEVICE**

# Instructions for Use

Shanghai MicroPort Endovascular MedTech (Group) Co., Ltd.

## [WARNING]

- Please read the instruction for use carefully before using. Failure to follow the instruction for use can result in serious surgical consequences.
- Only professional and interventional surgeons can perform the operation. The surgical operation can only performed by professional physicians and physicians who have been trained in interventional therapy. Physicians must undergo systematic training in the proper use of the product before use.
- The operation site must be equipped with a doctor with traditional surgical operation qualification to deal with emergencies during the operation.
- Do not forcibly introduce or retract the delivery system during the operation, otherwise the blood vessels or delivery system may be damaged.
- The product is for single use only. The product after use should be properly disposed of in accordance with local laws and regulations to prevent cross-infection.
- Do not use if the inner packing is damaged.
- Repeatable sterilization is not allowed.
- Do not use the product if it has expired.

## [PACKING LIST]

- A set of Castor™ branched aortic stent-graft system; one guide catheter.
- One copy of instruction for use.

## [PRODUCT PERFORMANCE, MAIN STRUCTURE COMPOSITION]

Castor™ system is mainly composed of a delivery system and a self-dilation stent graft, which has been preinstalled in the delivery system.

Castor™ stent graft is made of permeable polyester (PET) membrane and multiple self-dilating nickel-titanium alloy stent segments by non-absorbable suture. Nickel-titanium alloy support has excellent superelasticity and radial support strength. PET materials for laminating have good biocompatibility. These materials are widely used in implantable devices and have a long history of application. Castor™ stent

graft is stitched by the main stent graft and the side branched stent graft. Radiopaque markers are marked on the main and the side branched stents, including 3 proximal, 2 distal, 4 side branch and 2 side branch root. The schematic diagram is shown in Figure I.

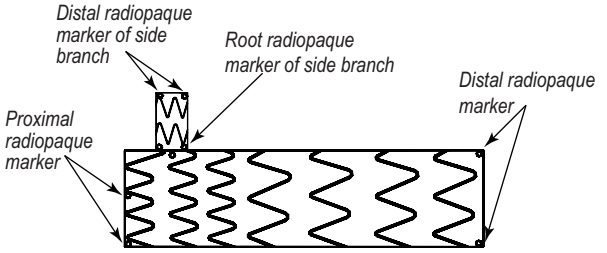



*Figure* I *Schematic Diagram of Stent Graft Structure*

## [MODEL, SPECIFICATION]

The specifications of Castor™ system are expressed by C (Castor™ for short) in combination with six parameters: the proximal diameter D1 of the stent graft main body, the distal diameter D2, the distal diameter D3 of side branch, the length L1 of the main body, the length L2 of side branch, and the backward length L3 of side branch, as shown in figure II. The designation symbol of the product specifications and instructions are as follows. This product has no model division.

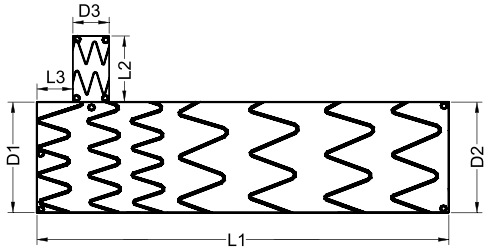
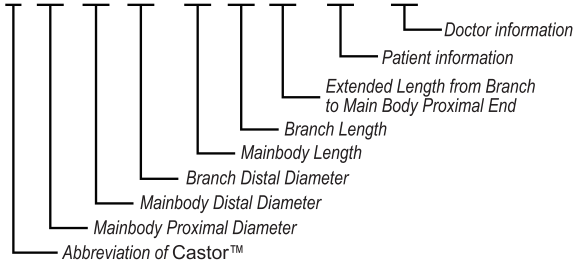


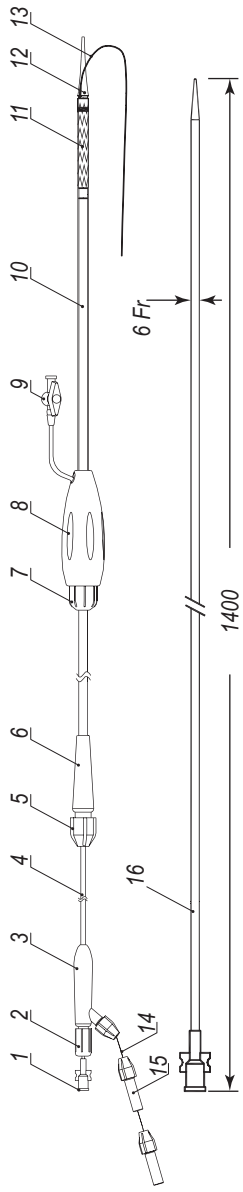

*Figure* II *Schematic Diagram of Stent Graft Marking*

Designation symbol: C D1 D2 D3-L1 L2 L3-xxx-xxx



For example: C 32 30 08 – 120 30 30 – FGR – JP

The suggested correspondence between the target vessel diameter and the proximal diameter of the main stent is shown in Table 1. The outer diameter of the delivery System is 24Fr and the main composition in shown in Figure III.




| No. | Name of Part | No. | Name of Part | No. | Name of Part | No. | Name of Part |
|---|---|---|---|---|---|---|---|
| 1 | Inner tubeend connector | 5 | Lock nut of soft inner sheath handle | 9 | Infusion valve | 13 | Branch guidewire |
| 2 | Lock nut of pushrod handle | 6 | Soft inner sheath handle | 10 | Outer catheter | 14 | Control guidewire |
| 3 | Pushrod handle | 7 | Lock nut of outer catheter handle | 11 | Stent graft | 15 | Guidewire twister |
| 4 | Pushrod | 8 | Outer catheter handle | 12 | Tapered tip | 16 | Guide catheter |

*Figure* III *Castor™ Branched Aortic Stent-Graft System Schematic Diagram*

*Table 1 Suggested Correspondence between the Target Vessel Diameter and the Proximal Diameter of the Main Stent*

| Diameter of Target Vessel (mm) | Proximal Diameter of the Stent Main Body (mm) |
|---|---|
| 23 | 26 |
| 24 | 26 |
| 25 | 28 |
| 26 | 28 |
| 27 | 30 |
| 28 | 30 |
| 29 | 32 |
| 30 | 34 |
| 31 | 34 |
| 32 | 36 |
| 33 | 36 |
| 34 | 38 |
| 35 | 38 |
| 36 | 40 |
| 37 | 40 |
| 38 | 42 |
| 39 | 42 |
| 40 | 44 |
| 41 | 44 |

*The distal diameter D3 of the side branch should be 0~2mm larger than the diameter of the branch vessel. In practice, the diameter and length of the stent graft should be chosen by experienced experts.*

## [CONTRAINDICATION]

This product is prohibited for use in patients with the following circumstances:

- Patients allergic to the materials of the device;
- Patients with severe or potentially systemic infections that increase the chance of graft infection.
- Minors and pregnant women.

## [COMPLICATION]

Using Castor™ systems can result in the following or other complications:

**Clinically related complications**

- Skin complaint;
- Admission infection;
- Incision site hematoma;
- Prolonged fever;

- Difficulty in breathing;
- Hemorrhage;
- Injury to the iliac artery, femoral artery or other blood vessels;
- Heart diseases;
- Lymph leakage;
- Arteriovenous thinness;
- Renal obstruction;
- Stent thrombosis;
- Distal limb vascular embolism;
- Graft infection;
- Tumor rupture;
- Paralysis or paraplegia;
- Death.

**Product-related complications**

- Internal hemorrhage;
- Stent displacement and the seal failure;
- The lateral branch opening deviates from the branch vessels and affects the branch blood flow.

## [INSTRUCTIONS FOR USE]

- **User training and experience**

The following skills are required for the operation of stent graft implantation:

1) Arterial dissection and suture;
2) Arterial anatomy;
3) Anatomical repair of arteries;
4) Percutaneous angiography;
5) Principle of fluorescence imaging;
6) Interventional technology applying X-ray;
7) Vascular bypass process.

**All surgical personnel involved in the use of the product must be trained in the full use of Castor™ system.**

- **Instructions for use**

***Caution:It is strongly recommended to equip the surgical site with the physicians familiar with interventional angiography and the physicians familiar with traditional vascular surgery.***

***Instruction:This instruction for use only recommends***

***general operating procedures and sequences.***

**Necessary equipments and accessories include:**

1) Free angle C-arm equipped with:
   High resolution fluoroscopy equipment;
   High-quality angiography equipment;
   Digital subtraction angiography (DSA);
2) Surgical equipment in case of emergency;
3) Tweezers;
4) Guidewire. It is recommended to use 0.035″ J-shaped super-stiff guidewire, with the length no less than 2.6 meters;
5) Vascular dilation device;
6) Balloon catheter;
7) Angiographic catheter;
8) Contrast agent;
9) Heparin saline.

- **Surgical procedures**

1) Preoperative assessment is performed to evaluate clinical operation conditions, determine lesion location, measure lesion size, determine product size and ideal release location, and verify the C-arm angle to fully open the left subclavian artery through three-dimensional reconstruction image of the aorta.
2) Preoperative arteriography. Further evaluate the clinical operation conditions, determine the lesion location, measure the size of the lesion, and determine the product size and ideal release location. Adjust the C-arm angle to enable the left subclavian artery to be fully opened.
3) Stent system preparation.
   - Take out the Castor™ system in a predetermined specification from the sealed package.
   - Remove air bubbles: The delivery system is inclined to make the tapered tip point obliquely upward. No less than 100ml of heparin saline is injected into the delivery system through the infusion valve. Meanwhile, slightly tap the outer catheter of the delivery system to exhaust the air bubbles, make sure that heparin saline can fill the whole outer catheter and discharge from the proximal

end of the tapper tip.

- Close the infusion valve of the delivery system.
- Heparin saline is injected into the delivery system from the distal end of the inner catheter until the heparin saline is discharged from the proximal end of the tapered tip.

4) Establish branch guidewire channel.

- Perform arterial puncture on the left brachial artery (6F hard sheath) ;cut open one side femoral artery for delivery system;
- Cut open the other side femoral artery for intraoperative angiography.
- The hydrophilic guidewire and guiding catheter is introduced from the left brachial artery, and exported from the femoral artery. Finally, completely pull out the hydrophilic guidewire leaving the catheter inside as a channel from brachial artery to femoral artery. (see Figure 1)

***Caution: The guiding catheter should be leaving inside to avoid it from injury by branch stent guidewire.***

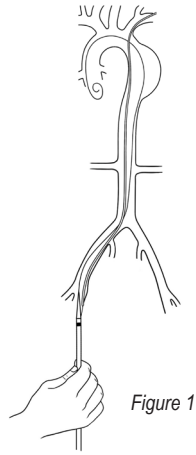


*Figure 1*

5) Introduce the delivery system.

- The super-stiff guidewire is introduced from femoral artery to the ascending aorta.
- Advance branch stent guidewire along the channel established by the catheter from the femoral artery to left branchial artery, then pull it out from the left brachial artery.

- The delivery system is advanced slowly over the super-stiff guidewire until the tappered tip reached the beginning point of descending aortic.

***Caution:Ensure that the infusion valve of the***

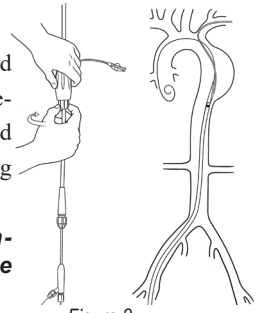


*Figure 2*

***delivery system points to the left of the patient during the introduction of the delivery system, as the infusion valve is in the same direction of branch stent.***

***Caution:Clamp the guiding catheter and branch stent guidewire with hemostatic forceps so as to keep the guiding catheter tip nearby the tapper tip of delivery system.***

6) Adjust the delivery system

- Observe the position of the "8" shape radiopaque marker on soft inner sheath, rotate the delivery system in the descending aorta until it is in align with the inner curve of aorta. At that moment, the marker will appear as the shape of "|".
- Loosen the lock nut of the outer catheter handle, hold the blue outer catheter handle stationary and push forward the white soft inner sheath handle with right hand until the distal end of the tapered tip is in align with LSA.

***Caution: If the winding exists, hold the outer catheter handle stationary, pull down the white soft inner sheath handle so as to retract the soft inner sheath back into the outer catheter. Remember to lock the outer catheter handle. Rotate the whole delivery system until the winding is relieved.***

***Caution: After advancing the soft inner sheath to the aortic arch, observe if the "8" shape marker remains as the "I" shape and in align with the inner curve to make sure that the branch stent graft is in the same orientation of left subclavian artery which is on the top of aortic arch. If deviation occurs, hold the outer catheter handle stationary, pull down the white soft inner sheath handle so as to retract the soft inner sheath back into the outer catheter. Remember to lock the outer catheter handle. Rotate the whole delivery system to the left until the "8" shape turns to position appeared on the aortic arch.***

***Caution: In the process of rotating the delivery system, it may be subject to great resistance. At this time, it is necessary not to forcibly rotate, but to push and pull the delivery system up and down slowly at the same time to reduce resistance.***

7) Adjust stent position

- The stent system is pushed to the proximal end so that the distal end of the tapered tip was flush with the branch vessel. (see Figure 3)
- After confirming that the guidewire is not wound, observe the “8” shaped radiopaque marker position at the nearest end of the delivery system under X-ray. If deviation from the side of small bend is found, the position of the sheath connector can be adjusted by rotating until the side branch stent is on the side of the branch vessel under X-ray. Push up the sheath connector so that the proximal end of the stent under X-ray is located in the target position. (as shown in Figure 4)

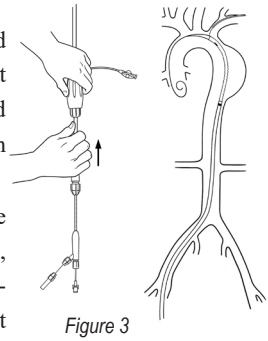


*Figure 3*

***Caution: When rotating the sheath connector, if there is a large resistance, the stent should be retracted into the outer tube and rotated again to adjust the direction of the stent.***

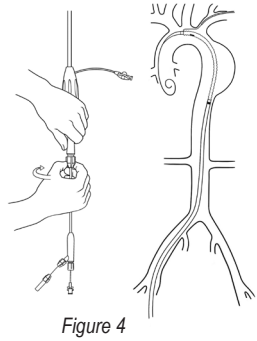


*Figure 4*

***Caution: The “8” shaped radiopaque marker at the nearest end of the delivery system under X-ray before release is always located at the side of small bend.***

8) Release the inner soft sheath

- Hold the white handle stationary and loosen soft inner sheath lock nut. (see Figure 4)
- With an assistant holding the blue outer catheter handle stationary, hold the pushrod handle stationary with right hand, and retract the white soft inner sheath handle with left hand to the limit position, then tighten the lock nut. (see Figure 6)
- Push forward the soft inner sheath handle, at the same time cooperated pull branch stent guidewire, so as to introduce the branch stent into LSA.

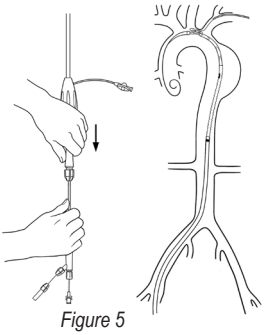


Figure 5

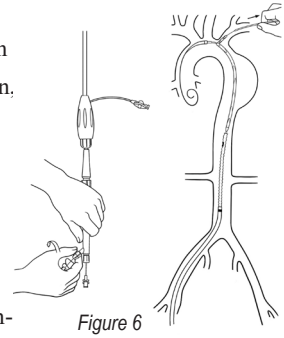


Figure 6

- Intraoperative angiography is recommended to determine the opening of LSA and the position of branch stent.
- The “o” shape markers on radiopaque metal ring cling to the opening of LSA, the 2 “o” shape markers will be quite close or overlap.
- Hold the pushrod connector with right hand, withdraw the outer catheter handle backward until the marker band of the outer catheter falls within 2cm to the distal end marker on the stent graft, then tighten the outer catheter connector lock nut.

***Caution: Pls. NOT rotate the delivery system after releasing the soft inner sheath.***

***Caution: The whole system cling to the outer curve.***

9) Deploy the mainbody stent graft

- Control the patient’s blood pressure at about 90mmHg;
- After accurately positioning the stent graft, hold the pushrod connector of the delivery system without move-

ment, loosen the control guidewire lock nut.(see Figure 6)

***Caution:After the accurate positioning of the stent graft, the relative position of each part of the delivery system should be kept still, otherwise it may lead to the displacement of the stent.***

- With an assistant pulling the branch stent guidewire, hold the outer catheter handle and try to make the whole system cling to the outer curve of the aorta. Hold the pushrod handle stationary with left hand, loosen the control guidewire lock nut with right hand and quickly pull out the control guidewire so as to deploy the mainbody stent graft. (see Figure 7)
- After deployment of mainbody stent , pull the branch stent guidewire and guiding catheter to deploy the branch stent. (see Figure 8)

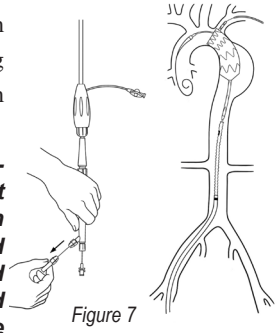


*Figure 7*

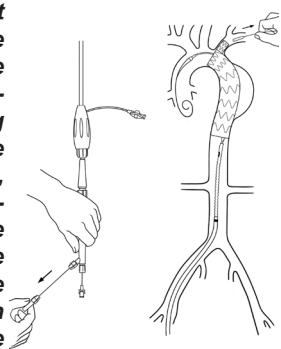


*Figure 8*

***Caution:After accurate positioning of the stent graft, the position of the pushrod connector should remain unchanged until the complete release of the stent raft. Otherwise, the positioning of the stent may be inaccurate, and during the release of the control guidewire, the branch guidewire should be pulled at the same time to make the root of the branch stent close to the opening of the aortic branch.***

***Caution:After the guidewire is completely pulled out, if the end segment of the stent does not spring open, hold the pushrod connector and***

***slowly pull down the entire delivery system by about 10mm to release the end segment of the stent from the cup sleeve. If resistance is encountered during the process or the tail segment cannot spring apart, slightly rotate the pushrod connector and then cooperate with the pull-down.***

***Caution:The guiding catheter shall keep close to branch stent sheath so as to protect the LSA and avoid it from injury by branch stent guidewire. Pull the branch stent guidewire under the protection of guiding catheter will also minimize the resistance.***

***Caution:The patient's left arm should be fully extended to reduce the resistance when deploying branch stent.***

10) Retract the delivery system.

- Hold the outer catheter handle stationary and pull the pushrod connector backward into the outer catheter until the taper tip coincides with the maker band of the outer catheter. (see figure 9)
- Finally, the entire delivery system is slowly removed from the patient body along the super-stiff guidewire. (see Figure 10)

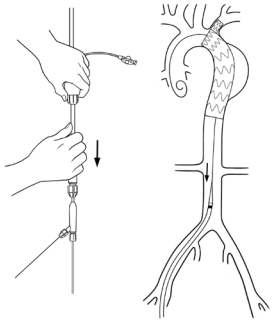


*Figure 9*

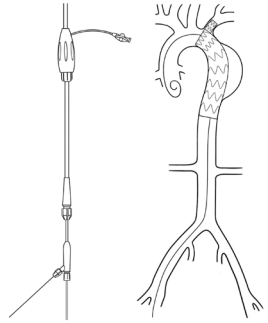


*Figure 10*

***Caution:When retracting the delivery system to the outside of the body, the action should be gentle and slow to avoid excessive force. Otherwise, the stent may be deformed, displaced, or even the cone head may fall off. When the delivery system meets great resistance in retracting, the delivery system should be sent back slightly and pulled down tentatively while rotating until the delivery***

***system is completely retracted from the body.***

***Caution:When retracting the delivery system, the super-stiff guidewire should be retained in the body for further operation.***

11) Arteriography is performed to evaluate the effect. According to the angiography, the isolation effect of the stent graft on tumor cavity/rupture is evaluated, and appropriate follow-up measures are taken when necessary. Follow-up measures include:

- If the side stent is show to be not fully opened, balloon dilatation should be performed as appropriate.
- If the distal end of the main stent is shown to be fully open, but not effectively covering the tumor cavity/rupture, an appropriate CUFF should be placed on the distal end;
- If the side branches are not properly opened or positioned, a bare stent should be added to the side branches for fixation as appropriate.

12) All the accessories are removed, the incision is closed, and the operation is completed.

## [MAGNETIC RESONANCE IMAGING (MRI)]

Non-clinical test showed that the MRI results of Castor™ after stent implantation under the following conditions are as follows:

In static state, the magnetic field strength is equal to 3T;

The spatial magnetic field gradient is no more than 720 Gauss/cm;

The average whole-body specific absorption rate (W-SAR) does not exceed 2.9W/kg, and the scanning time does not exceed 15 minutes.

In the above conditions, a single Castor™ stent has a deflection angle of 4° and does not produce torsion.

In normal scan pattern, under the condition that W-SAR is 2.9W/kg and the scanning time is 15 minutes, the local temperature rise generated for single Castor™ stent is 2°C. The results do not take into account the cooling effect of blood flow.

**Artifact information:**

If the imaging region of interest is close to or at the stent im-

plantation site during MRI scan, artifacts will have an impact.

## [STERILITY]

Castor™ system has been sterilized by ethylene oxide before delivery.

## [STORAGE AND TRANSPORTATION]

The product should be stored in normal temperature, corrosive gas-free, cool, dry, well-ventilated, and clean environment.

## [PRODUCTION DATE AND EXPIRATION DATE]

The dates of production and expiration can be found on the packaging label.

## [PERIOD OF VALIDITY]

The valid period is two years while complying with storage provisions.

## [SYMBOL DESCRIPTION]

| | | |
|---|---|---|
| 1) |  | Do not re-use |
| 2) |  | Consult instructions for use |
| 3) |  | Protect from heat and radioactive sources |
| 4) |  | Keep dry |
| 5) |  | Use-by date |
| 6) |  | Date of manufacture |
| 7) |   | Batch code |
| 8) |   | Catalogue number |
| 9) |   | Sterilized using ethylene oxide |
| 10) |  | Do not use if package is damaged |

| | | |
|---|---|---|
| 11) |  | Content: 1 |
| 12) |  | Authorized representative in the European |

## [AFTER SALES SERVICE]

The mission statement of Shanghai MicroPort Endovascular MedTech (Group) Co., Ltd. (hereinafter referred to as "Endovastec™") is "to provide the medical community with quality and highly effective medical products" as it guarantees that its products are free of material and manufacturing defects. For questions regarding the product, please feel free to make inquiries with the company directly.

## [SOLEMN STATEMENT]

Shanghai MicroPort Endovascular MedTech (Group) Co., Ltd. explicitly specifies that Castor™ Branched Aortic Stent-Graft System produced by Endovastec™ is designed for single use only and shall not be repeatedly used. Endovastec™ does not recommend, represent, or imply in any way the reusability of this system and does not accept liability for accidents or product damage associated with repeated use.



***DATE COMPILED:2022-08***

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