TJWY MEDICAL

CE 2292

Disposable Embolic Protection Device

Instructions for Use

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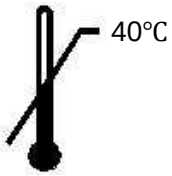
MR Conditional

No secondary sterilization

Table 1 The specification of DEPD

Specification	Filter diameter (mm)	Length of delivery wire (cm)	Delivery end ID of sheath	Delivery end OD of sheath	Recovery end ID of sheath	Recovery end OD of sheath
TJEP03-320	3	190/320	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP04-320	4	190/320	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP05-320	5	190/320	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP06-320	6	190/320	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP07-320	7	190/320	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP08-320	8	190/320	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP03-190	3	190	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP04-190	4	190	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP05-190	5	190	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP06-190	6	190	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP07-190	7	190	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm
TJEP08-190	8	190	0.032″ /0.82mm	3.2F/1.05mm	0.042″ /1.08mm	4.2F/1.38mm

The delivery wire of specification TJEP0X-320 can be snapped from 320cm to 190cm according to physician’s preference.



Upper limit of temperature is 40℃

Do not re-use

Do not use if package is damaged

Attention, see Instruction for Use

Keep away from sunlight and keep dry

Sterilized by ethylene oxide

No secondary sterilization

1. DEVICE DESCRIPTION

The Disposable Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The Embolic Protection Device is composed of a Capture Wire and a Delivery and Recovery Catheter (See **Fig. 1**). The Device Capture Wire is used as the 0.014″wire for interventional device delivery. The Device can be delivered over any 0.014 ″primary wire used to gain access to the lesion site.

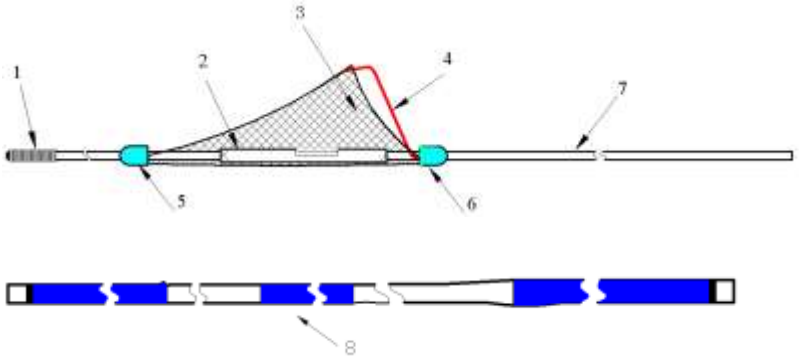


Fig.1 schematic diagram of Proender® Device

1. Distal Delivery Wire; 2.Fixed Cannula; 3. Filter; 4. Gold Loop; 5. Distal Marker; 6. Proximal Marker; 7. Proximal Delivery Wire; 8. Deivery and Recovery Catheter

The Capture Wire is composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a convertible 320/190cm PTFE-coated 0.014″stainless steel wire. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014″wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange

systems, if desired. The distal portion of the Capture Wire for rapid exchange use is yellow, and the proximal portion for standard over-the-wire use is black.

The Delivery and Recovery Catheter is used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.

2. INDICATIONS FOR USE

The Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries.

3. POTENTIAL COMPLICATIONS

The complications irrelevant with the device may occur during or after the procedure:

Complications related with Puncture

- Hematoma at the puncture site
- Hemorrhage at the puncture site
- Local or distal thromboembolism
- Thrombosis
- Arteriovenous fistula
- Pseudoaneurysm
- Puncture site infection

Complications related with Operation

- Artery dissection
- Vessel wall perforation or aneurysm rupture
- Long time vasospasm
- Acute occlusion required for surgical intervention

Complications related with Device

The anticipated adverse reactions related with the device are minimal (pyrogen reaction, infection, etc.), but it cann't completely exclude the possibility of occurrence of adverse reactions.

catheter in the sterile field. DO NOT DISCARD THE CATHETER. The Recovery End (blue) is required for Capture Wire recovery.

(19) Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

(20) After completion of the interventional procedure, wet the distal 20 cm of the Catheter with heparinized saline. Flush the distal tip of the Recovery End (blue) to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

(21) Advance the Catheter under fluoroscopy until the distal tip marker aligns with the proximal marker on the Filter.

(22) There are two methods for Filter Recovery:

A – Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, asindicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.

B – Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.

(23) Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

8. STORAGE

The Embolic Protection Device should be stored in a cool, dry, clean and well ventilated place with the relative humidity no more than 80%, temperature below 40 ℃, no toxic and corrosive gas.

9. STERILIZATION VALID PERIOD

The Embolic Protection Device is aseptic and pyrogen-free, and the sterilization validity is three years.

(12) Gently advance the Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the Radiopaque Marker at the distal tip of the Delivery End is at least 4-5 cm beyond the distal edge of the lesion.

CAUTION: Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the Catheter, which can cause the wires to wrap around the Catheter.

(13) Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.

(14) Hold the Catheter stationary, and gently advance the Capture Wire until the Distal Radiopaque Marker on the Filter aligns with the Radiopaque Marker on the Catheter distal tip.

WARNING: Do not place the Capture Wire in a vessel that does not allow wire movement. This may lead to embolization of debris, and vessel and/or device damage.

(15) Observe the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker is at least 2 cm distal to the lesion being treated. Gently advance the entire Delivery End assembly if necessary so the Proximal Radiopaque Marker is at least 2 cm beyond the lesion distal edge.

CAUTION: Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.

(16) Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.

(17) A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.

(18) Once the Filter is deployed in the desired location, carefully remove the Catheter from the patient. Keep the

4. CONTRAINDICATION

No special contraindications are known with the Device, and its clinical contraindications are the same with the general endovascular interventional operation.

(1) Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated.

(2) Do not use in vessels with excessive tortuosity and serious calcification.

(3) Do not use in patients with renal impairment, who are allergic to contrast medium.

5. WARNINGS

(1) Before the percutaneous intervention, make sure the patients are not allergic to contrast medium.

(2) Only physicians who have experience with interventional procedures should use this device.

(3) The device is sterile and make sure the package is intact before use.

(4) Prohibition of the use of the device if the inner package is open or damaged.

(5) Check the device before use in order to make sure the size or spec meet the requirements of operation.

(6) Consistently follow the general technical requirements of the use of the device, including the systematic heparinization, and flushing all the devices which need to be inserted into blood vessel with aseptic heparinized saline solution or similar isotonic solution.

(7) Choose the technical method according to different conditions of patients and the experience of physicians, as the device has different applications.

(8) Don’t insert the device through the sheath or guiding catheter of the minimum dimension.

(9) The device is intended for one use only and don’t re-sterilize or reuse this device, otherwise the device may be damaged and increase the risk of cross infection.

(10) The device should be used under X-ray condition.
(11) The device position should only be changed by capture wire, and moving the device during Carotid Artery Stent Operation or other intervention procedures is prohibited.
(12) Never withdraw or move the device against any resistance until the cause is confirmed.
(13) Use the device before the expiry date.

6. DEVICE COMPONENTS

Delivery End: The Delivery End has an embedded radiopaque marker at the distal tip, a Primary Wire Exit Port, a Capture Wire Exit Port, and a Clear Segment. The Delivery End is green. The Filter portion is deployed at the distal targeted location by the Delivery End of the Catheter.

Filter: The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip. The Capture Wire has a Nitinol mesh Filter with a two markers at both ends and a Distal Floppy Tip, mounted on a PTFE-coated 0.014 in. stainless steel wire.

Recovery End: It is designed as a rapid exchange Catheter, which could recover the Filter with embolus. The Recovery End has a Capture Wire Exit Port, about 25cm from the soft distal end with a marker. The Recovery End is blue, and the schematic diagram of the Delivery and Recovery Catheter is shown in Fig.2.

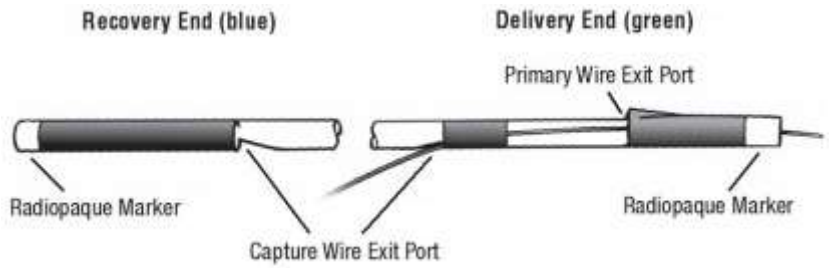


Fig.2 Schematic diagram of Delivery and Recovery Catheter

7. Application Techniques

(1) Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
(2) Perform angiography.
(3) Identify the location within the vessel where the Filter of the Embolic Protection Device will be deployed, and select the appropriate Filter diameter size (see Table 1).
(4) Using sterile technique, remove the Device compone -nts from the packaging, and place in a sterile work area.
(5) Remove the colored portion of the hoop to expose the Filter and the Delivery End of the Catheter.
(6) Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.
(7) Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.
WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker and/or inner lumen of the Catheter.
(8) Continue holding the Catheter near the distal tip to provide support to the catheter shaft. Pull the Capture Wire proximally until the Filter portion stops in the Clear Segment of the Catheter.
(9) Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter).
(10) Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to catheter distal tip).
(11) Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the distal edge of the lesion being treated.
NOTE: When loading the primary guidewire, gently bend the Catheter at the Primary Wire Exit Port to create a 2.5 cm radius.

APPROPRIATE SIZE SELECTION

The appropriate size selection should be in accordance with the vessel diameter. The length of delivery wire is chosen by physician in accordance with the length from puncture site to lesion site.

Table 2 Filter Diameter Sizing Recommendation

Specification	Filter diameter size	Recommended vessel size
TJEP03-320 TJEP03-190	3mm	2.0mm<Vessel≤2.5mm
TJEP04-320 TJEP04-190	4mm	3.0mm<Vessel≤3.5mm
TJEP05-320 TJEP05-190	5mm	3.5mm<Vessel≤4.5mm
TJEP06-320 TJEP06-190	6mm	4.5mm<Vessel≤5.5mm
TJEP07-320 TJEP07-190	7mm	5.5mm<Vessel≤6.5mm
TJEP08-320 TJEP08-190	8mm	6.5mm<Vessel≤7.5mm