Nanoparasol™

Embolic Protection System

INSTRUCTIONS FOR USE

TERUMO

PM-08956

DEVICE DESCRIPTION

The Terumo Nanoparasol™ Embolic Protection System (EPS) is designed to capture and remove dislodged debris during a carotid interventional procedure. It consists of three basic components and additional accessories: 1) an embolic protection device (EPD) consisting of a nitinol braided mesh filter with an atraumatic distal tip built on an integrated .014" PTFE coated stainless steel capture delivery wire, 2) a 3.5F delivery catheter with 165 cm length, and 3) a 4.5F retrieval catheter with 150 cm working length. Accessories include a wire introducer, EPD loading cover, sheath introducer and a torque device. Catheters are provided in two separate dispenser coils. The Nanoparasol EPS is used in conjunction with a primary .014" compatible wire (not included in package) with the rapid exchange port to gain access across the lesion site. The .014" integrated Capture delivery wire is used as the primary guidewire for interventional devices such as a stent or PTA balloon catheter compatible with a .014" or .018" wire. The EPD loading cover protects the filter, is used to flush and load the filter into the delivery catheter.

Figure 1.
Nanoparasol EPD and Delivery Catheter Set-up

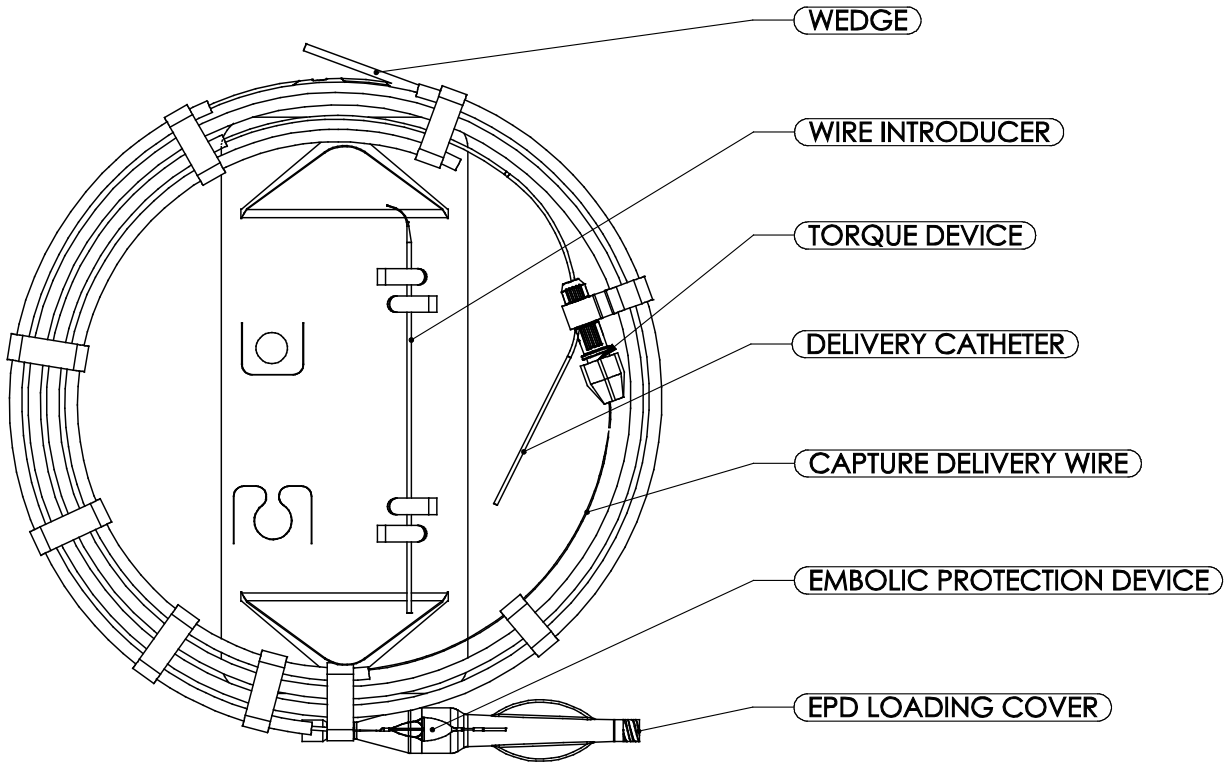


Figure 2.
Nanoparasol Retrieval Catheter Set-up

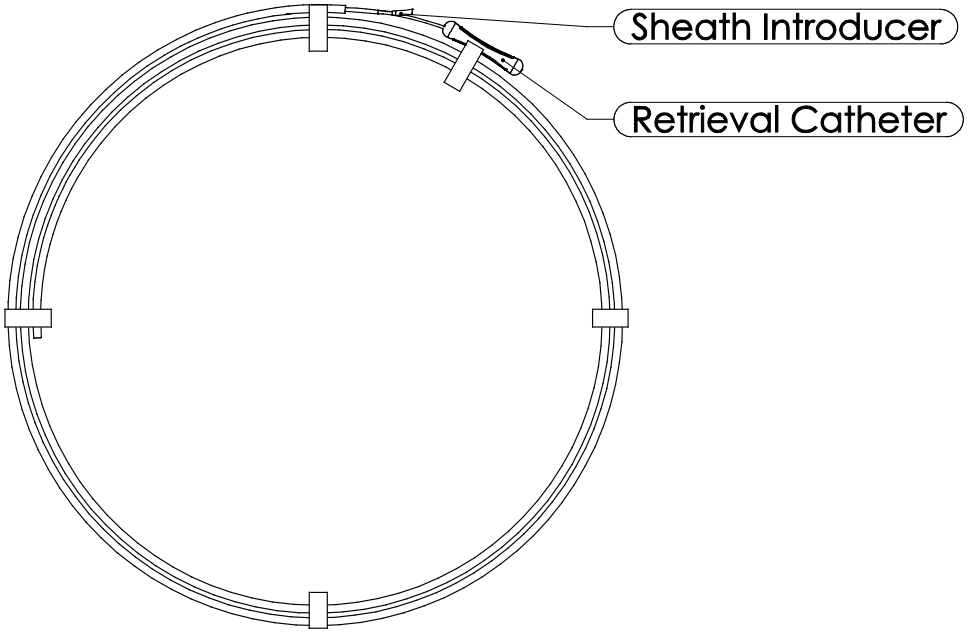
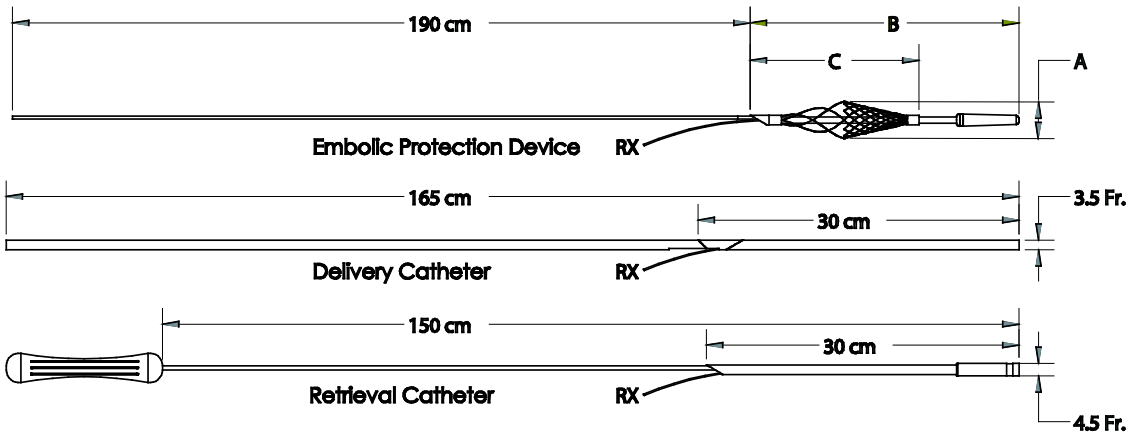


Figure 3.
Nanoparasol Dimensions



System Size	Reference Vessel Size (mm)	A (mm)	B (mm)	C (mm)
Small	3.0 – 4.5	5.2	36.3	19.6
Large	4.5 – 6.5	7.2	42.7	23.1

INDICATIONS

The Nanoparasol EPS is indicated for use as a guidewire to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of the filter placement should be between 3.0 and 6.5 mm.

CONTRAINDICATIONS

The Nanoparasol EPS is contraindicated for use in:

- Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs is contraindicated
- Patients with known hypersensitivity to nickel-titanium
- Patients with severe vascular tortuosity or anatomy that would preclude the landing zone requirement or the safe introduction of a guide wire, guide catheter, introducer sheath, an embolic protection device, delivery catheter, or retrieval catheter.
- Patients with uncorrected bleeding disorders
- Lesions in the ostium of the common carotid artery

WARNINGS

Only physicians who have had appropriate training for carotid artery stenting and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

Refer to instructions supplied with all interventional devices to be used with the Nanoparasol EPS for their intended uses, contraindications, and potential complications.

Safety and effectiveness of this device as an embolic protection system has not been established in coronary, cerebral or peripheral vasculatures.

The Nanoparasol EPS is intended for one time use only. DO NOT re-sterilize and/or reuse it because it can potentially result in compromised device performance and risk of cross contamination.

The appropriate antiplatelet, anticoagulant and if necessary, vasodilator therapy, must be used during the pre- and post-procedure to minimize the risk of embolism and thrombus.

Avoid using power injection in the cerebral circulation.

Introduce and advance devices slowly to prevent the embolism or trauma to the vasculature.

Do not oversize or undersize the filter relative to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the filter. Undersizing or oversizing could cause no-flow or slow flow and/or embolism of debris.

Overstretching of the artery may result in rupture and life-threatening bleeding.

Minimize movement of the Nanoparasol EPS after initial placement. Excessive movement of the capture delivery wire may lead to embolization of debris, and vessel and/or device damage.

Torqueing the capture delivery wire against resistance may cause filter damage, wire damage, delivery tip separation and wire whipping.

Never withdraw or move an intravascular device against any resistance until the cause is determined. Applying excessive force during delivery or retrieval of the systems can potentially result in loss or damage to the devices and delivery components.

Allow for and maintain adequate distance between the filter (no less than 2.5 cm), the stent delivery system or deployed stent to avoid potential entanglement.

Do not attempt to reposition or remove the capture delivery wire without the use of the retrieval catheter. This may lead to embolization of debris, and vessel and/or device damage.

The maintenance of blood flow through the filter device should be observed throughout the procedure by use of fluoroscopy.

Nanoparasol EPS has only been studied for compatible use with the Roadsaver stent and the safety and effectiveness of the device use with other stents has not been demonstrated.

PRECAUTIONS

Carefully inspect the sterile package and the Nanoparasol EPS prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components, or if the package is opened or damaged.

See the product label for shelf life. Do not use the Nanoparasol EPS beyond the labeled use by date.

Confirm the compatibility of the Nanoparasol EPS with the interventional devices before actual use.

Fully flush the Nanoparasol EPS filter and rapid exchange (Rx) guidewire lumen of the delivery catheter. Do not use the delivery system if flush is not observed exiting at the Rx delivery catheter proximal port location.

Identify the delivery catheter and the primary 0.014” guidewire while advancing. Do not rotate the delivery catheter which can cause the primary wire to wrap around the catheter.

Use caution when withdrawing the Nanoparasol EPS through the deployed stent. This may cause stent/filter entanglement, rupture and/or stent dislocation.

After use, dispose in accordance with hospital, administrative and/or local government policy.

Store in a cool and dry location.

POTENTIAL COMPLICATIONS

Possible complications include but are not limited to the following:

- Aneurysm and pseudoaneurysm formation
- Allergic reactions (including to antiplatelet agents, contrast medium or stent materials)
- Arteriovenous fistula
- Bacteremia or septicemia
- Bleeding from anticoagulation/antiplatelet medication
- Bradycardia and hypotension
- Cerebral edema
- Congestive Heart Failure
- Coronary ischemia

- Death
- Disseminated intravascular coagulation
- Emboli (air, tissue, plaque, thrombus, device or other)
- Emergent or urgent surgery
- Fever
- Filter thrombosis/occlusion
- Fluid overload
- Headache
- Hematoma
- Hemorrhagic or embolic stroke/Transient ischemic attack (TIA)
- Hyperperfusion syndrome
- Hypertension or Hypotension
- Infection and/or pain at insertion site/sepsis
- Intimal tear/dissection
- Ischemia/Infarction of tissue/organ
- Loss of all or part of the filter element
- Myocardial infarction (MI)
- New or worse encephalopathy
- Renal failure/insufficiency
- Respiratory arrest
- Seizure
- Stent/filter entanglement/damage
- Stroke or other neurological complications
- Thrombophlebitis
- Tissue necrosis
- Unstable angina pectoris
- Vascular access complications (e.g. loss of pulse, femoral artery pseudoaneurysm and infection)
- Vasospasm
- Vessel injury/dissection/perforation/rupture/trauma
- Vessel occlusion or thrombosis

SYMBOLS

	Caution		Manufacturer
	Lot Number		Non-pyrogenic
	Catalog Number		For Prescription Use Only
	Content		Do Not Resterilize
	Sterilized Using Ethylene Oxide		Do Not Use if Package is Damaged
	Do Not Reuse		Consult Instructions for use
	Use-by Date		Keep Dry
	Date of Manufacture		Keep Away from Sunlight

CLINICIAN USE INFORMATION

Materials

The following parts are required to use the Nanoparasol EPS:

Accessories for performing a procedure but NOT supplied should be selected based on the physician's experience and preferences:

- Appropriate guiding sheath or catheter with a minimum internal diameter (I.D.) of .074 in. (1.9 mm).
- .014" guidewire compatible with the Nanoparasol EPS
- Saline solution/heparin-saline solution (sterile)
- 5 cc luer-lock syringe for flushing the Nanoparasol EPS
- Contrast solution
- Rotating Hemostatic Valve (RHV)
- The Nanoparasol EPS does not contain latex or PVC materials.

PACKAGING AND STORAGE

The Nanoparasol EPS is placed inside a protective package which includes two (2) sterile sealed pouches and unit carton. The Nanoparasol EPS will remain sterile unless the package is opened, damaged, or the expiration date has passed. Store in a cool and dry place.

SHELF LIFE

See the product label for the device shelf life. Do not use the device beyond the labeled use by date.

PREPARATION FOR USE

Device and Delivery System Selection

Appropriate selection of the Nanoparasol EPS is important for patient safety. In order to choose the optimal Nanoparasol EPS filter size for any given carotid artery, examine pre-treatment angiograms for correct and accurate vessel measurements. Reference the Fig. 3 chart within the Instructions For Use or see the box label.

Directions for Use

Nanoparasol EPS Preparation

Note: Only prepare and flush the delivery system within the provided packaging.

1. Remove the two pouches enclosing the Nanoparasol EPS components from the carton.

   Pouch 1: EPD, delivery catheter, wire introducer, torque device, EPD loading cover and dispenser coil
   Pouch 2: Retrieval catheter, sheath introducer and dispenser coil

2. Inspect the pouches for any signs of damage to the sterile barrier.

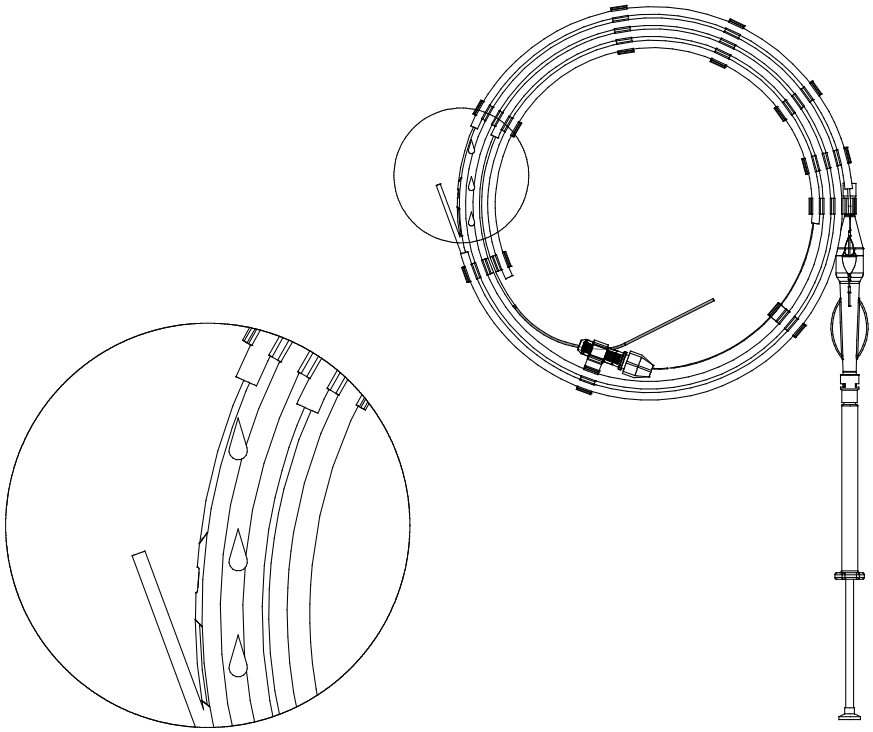
Warning: If it is suspected that the sterile barrier seal has been opened or compromised, do not use the Nanoparasol EPS and return to the manufacturer.

Delivery Device Preparation

1. Peel open pouch and remove the dispenser coil containing the EPD and delivery catheter.

2. Fill a 5-ml syringe with sterile heparinized saline solution. Remove air bubbles within the syringe. Attach the syringe to the luer lock on the EPD loading cover. While orienting the EPD loading cover and syringe vertically, inject into the EPD loading cover where the filter is located. Make sure all air bubbles from the filter are removed. Inject until saline is seen exiting the dispenser coil at where the wedge is located. See Figure Below.

   WARNING: Do not remove the filter from the loading cover during this step.



3. Unclip the torque device from the dispenser coil and ensure that the torque device is secured onto the capture delivery wire.

4. While securing the delivery catheter against the dispenser coil, pull on the torque device until the filter is withdrawn through the EPD loading cover and a hard stop is felt. Visually confirm that the distal tip of the delivery catheter has not migrated from within the proximal end of EPD loading cover and the EPD filter is fully loaded into the delivery catheter.

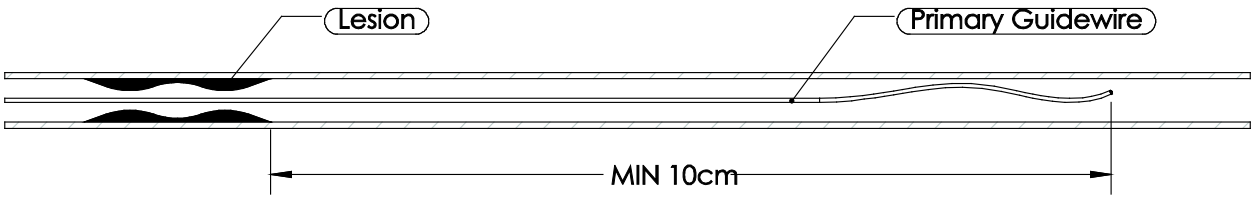
5. Remove the wedge from the dispenser coil.

6. Remove the EPD system from the dispenser coil.

EPD Deployment

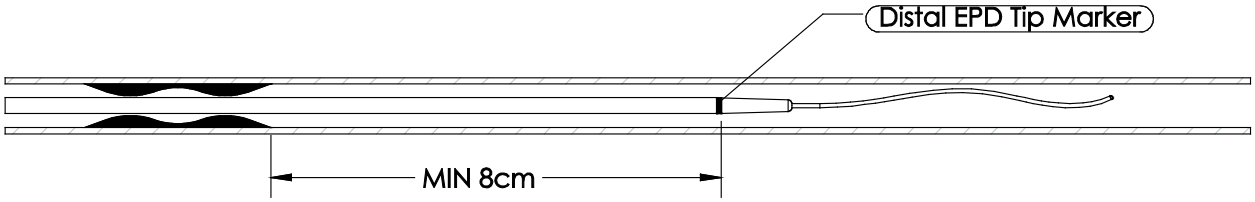
1. The Nanoparasol EPS can be used with either an introducer sheath or guide catheter. A RHV should be used with the guide catheter. The internal diameter of the introducer sheath or guide catheter should be at least .074” or greater.

2. Advance a primary .014” guidewire (not supplied with Nanoparasol EPS) beyond the target location to a minimum of 10 cm. Ensure adequate wire support is provided for the EPD system to advance to the target location. A wire introducer is included to pass a hemostasis valve within a sheath or RHV device to prevent damage to the guidewire. See Figure Below.



3. Load the EPD system over the .014” primary guidewire. Ensure the primary guidewire exits the proximal RX port of the delivery catheter. If the primary wire hits a stop or resistance is felt, withdraw the primary and re-attempt to have the primary guidewire exit the RX port, a slight rotation of the delivery catheter may be required.

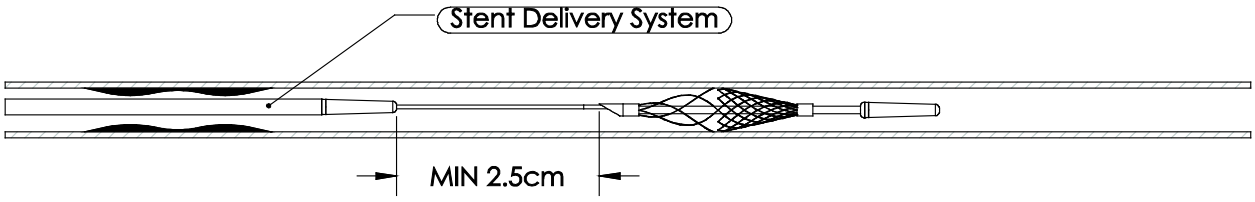
4. While maintaining position of the primary guidewire, advance the EPD and the delivery catheter slowly and deliberately beyond the lesion to a minimum of 8 cm. Perform device manipulation using fluoroscopic visualization. Do not advance any component of the Nanoparasol EPS against any resistance. Do not torque the delivery catheter during advancement. See Figure Below.



5. **Remove the primary .014” guidewire.**

6. Loosen the torque device and while holding the proximal delivery catheter end with the capture delivery wire, reposition the torque device against the RHV to ensure proper wire support for EPD deployment. Tighten the torque device onto the capture delivery wire.

7. Before deploying the EPD filter, identify the desired stent location and ensure that there is adequate distance between the proximal tip of the filter element and the most distal tip of the interventional device to be introduced over the filter delivery wire to avoid contact during the procedure. The appropriate distance should be 2.5cm between the distal tip of the interventional device and proximal end of the filter. See Figure below.



8. While maintaining position of the torque device, deploy the filter by pulling on the delivery catheter.

WARNING: Do not attempt to recapture or reposition the filter with the delivery catheter once the filter deployment has been initiated. If there is a need to change the position of filter, retrieve it using the retrieval catheter and use a new Nanoparasol system.

9. Verify that the filter is fully expanded and apposed to the vessel wall by visually confirming markers.

10. Completely remove the delivery catheter by continuing to withdraw the delivery catheter until the catheter is completely peeled through the torque device. Be sure to minimize EPD system movement.

    WARNING: A change in resistance may be felt when the Rapid exchange (Rx) port is peeled through the torque device. If the catheter begins to stretch or breaks while peeling, follow the steps below

    1. **Loosen the torque device and stabilize the EPD delivery capture wire**

    2. **Carefully remove the torque device and delivery catheter as one unit by sliding them over the delivery capture wire. Use caution to minimize EPD filter movement.**

11. Loosen the torque device and remove from the capture delivery wire before using any interventional devices.

EPD Retrieval

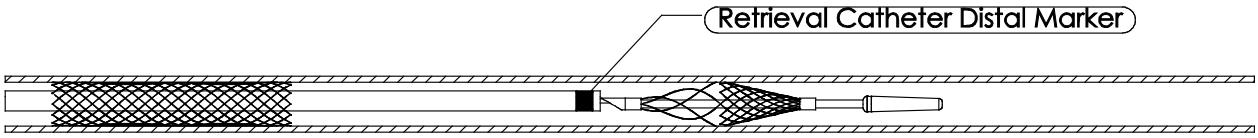
1. Peel the pouch and remove the dispenser coil containing the retrieval catheter.

2. Fill a 5ml syringe with saline ensuring no air emboli remains in the syringe.

3. Insert distal tip of the retrieval catheter into the syringe tip and seal with fingers.

4. Inject saline until saline drips out of the Rapid exchange (Rx) exit port.

5. Load the retrieval catheter over the EPD delivery capture wire and advance until the distal marker reaches the EPD filter. See Figure below.



6. While maintaining position of the retrieval catheter, pull on EPD capture delivery wire to withdraw the filter into the retrieval catheter. Withdraw until the EPD filter is fully captured or resistance is felt. Complete retrieval of the filter is achieved when the filter marker has been withdrawn proximal to the radiopaque retrieval catheter tip and a stop or resistance is felt.

7. Remove both the EPD and retrieval catheter simultaneously out of the access guide catheter or introducer sheath.

If an exceptionally large amount of embolic debris within the filter element prevents complete withdrawal of the filter element into the retrieval catheter tip or resistance is felt, the following steps of retrieval must be taken to retrieve the filter element.

1. Hold the retrieval catheter position steady by gripping the shaft close to the RHV.

2. Pull on the EPD capture delivery wire and filter into the retrieval catheter tip until resistance is felt. The proximal openings of the filter element are fully contained with the catheter tip once the radiopaque markers on the filter frame have been withdrawn into the radiopaque retrieval catheter tip. **Do not continue to retract the capture delivery wire against significant resistance.**

3. Withdraw both the capture delivery wire and retrieval catheter as one unit.

Warning: If the Nanoparasol device cannot be fully withdrawn as described above, the Nanoparasol device must be removed with the guide catheter or introducer sheath.

4. Retract the retrieval catheter and embolic protection device as one unit until the tip of the retrieval catheter is adjacent to the tip of the guide catheter or introducer sheath.

5. Withdraw the guide catheter or introducer sheath, retrieval catheter, and embolic protection device together as one unit and remove from the patient.

CLINICAL DATA

The CONFIDENCE study (IDE G140249) was a multicenter, single-arm, interventional study designed to evaluate the safety and effectiveness of the Roadsaver™ Carotid Artery Stent used in conjunction with the Nanoparasol™ EPS in patients at high risk for adverse events from carotid endarterectomy (CEA) who required carotid revascularization. All patients with qualifying carotid artery stenosis (n = 256) were treated with the devices. The primary endpoint was the Major Adverse Event (MAE) composite consisting of death, stroke, or MI within 30 days of the index procedure plus ipsilateral stroke between 31 days and 12 months. The secondary endpoints included procedure success and technical success of the Roadsaver™ Carotid Artery Stent and Nanoparasol™ EPS technical success. The results presented in this section is focused on the subject device, Nanoparasol™ EPS.

In the Intent-To-Treat (ITT) population, the mean (SD) age was 69.6 (6.8) years, and the majority of the subjects were male (65.2% [n=167]). 95.3% [n=244] of subjects were not of Hispanic or Latino; 4.7% of subjects identified themselves as Hispanic or Latino. 91% [n=233] of subjects were white; 4.3% (n=11) identified themselves as Black or African American. Overall, these demographic characteristics are consistent with a typical cohort of subjects with carotid artery stenosis at high operative risk for CEA.

The primary endpoint was MAE, a composite measure of death, stroke, or MI within 30 days of the index procedure plus ipsilateral stroke 31–365 days after the procedure In the ITT population, 15 patients (5.9% [95% exact binomial CI: 3.89, 10.69]; p=0.0014) experienced a MAE. In the ITT analysis using multiple imputations for subjects who discontinued prematurely, the MAE rate was 6.2% (16/256). The upper limit of the 95% exact binomial CI was 9.22%, which was below the PG of 13.9%. Thus, the primary endpoint of the study was met. Secondary endpoints include technical success and procedure success of the stent and embolic protection device technical success. Nanoparasol EPS technical success was achieved in 98.8% (253/256) of subjects.

Nanoparasol EPS Performance Analysis	**ITT Population N=256(%)**
EPS successfully inserted	255 (99.6%)
EPS successfully deployed in subject (Technical Success)	253 (98.8%)
EPS successfully retrieved	255 (99.6%)
Vessel dissection at EPS filter site	0

General safety results: With respect to the Nanoparasol EPS, one patient had an SAE most likely due to a strong relationship to the device. This SAE was a Nervous System Disorder (Cerebrovascular Accident).

HOW SUPPLIED

Sterile: This device is sterilized using Ethylene Oxide. Non-pyrogenic
Contents: One (1) Terumo Nanoparasol EPS
Storage: Store product in a cool and dry location.

WARRANTY DISCLAIMER

Terumo warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for particular purpose. Handling, storage, cleaning, and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure, and other matters beyond Terumo's control directly affect the device and the results obtained from its use. Terumo's obligation under this warranty is limited to the repair or replacement of this device through its expiration date. Terumo shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. Terumo neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Terumo assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Prices, specifications, and model availability are subject to change without notice.

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IFU100258 Rev. A
2024-10