



Cross-PilotTM
Laser Support Catheter

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Cross-Pilot™

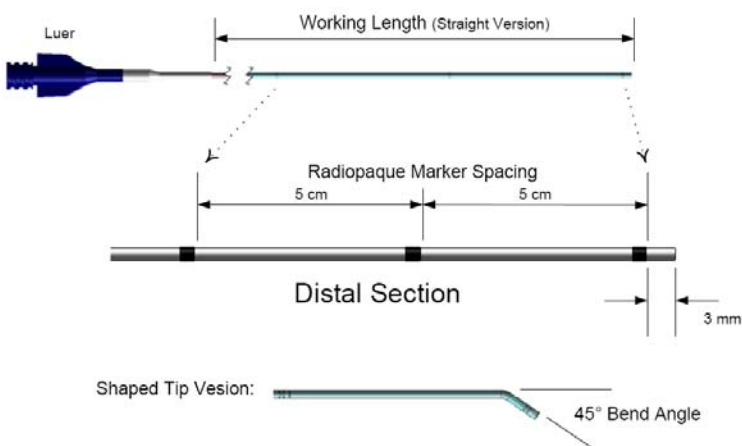
Turbo Elite® Support Catheter

Instructions for Use

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

Description

The Spectranetics Cross-Pilot™ Turbo Elite® Support Catheters are intravascular catheters. These catheters are available in a variety of lengths and tip configurations. All models have 3 radiopaque markers spaced equally along the distal shaft to aid in estimating geometry within the vascular system. The distal radiopaque marker is positioned within 3 mm of the distal catheter tip. A standard female luer is placed on the proximal end of each model. The catheter is coated with a lubricious, hydrophilic coating.



Indications for Use

Cross-Pilot Turbo Elite Support Catheters are intended to guide and support a Spectranetics 0.9 mm OTW Turbo Elite laser catheter during access of the vasculature and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Disclaimer

Spectranetics offers an exclusive limited warranty on this product. Spectranetics warrants that this product will perform as specified in the Instructions for Use for the period of time up to the product's "Use By" date.

Direction for Use

Note: Follow instructions for use for all equipment to be used with the Cross-Pilot Turbo Elite Support Catheters.

1. Preparation: Using sterile technique, open the sterile package. Gently remove the luer hub from the card and remove the catheter from the packaging. Fill a sterile standard luer-lock syringe with sterile saline and flush the lumen.
2. Insertion: Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the support catheter. Then, introduce the laser catheter through the Cross-Pilot catheter using standard technique.
3. Advancement: Use fluoroscopic guidance when advancing the catheter and laser catheter as a system to the desired location within the vasculature. Note: It is recommended to advance the system with the 0.9 mm OTW Turbo Elite laser catheter leading.
4. Removal: Gently withdraw the catheter and laser catheter using standard technique, being careful to maintain guidewire if the guidewire is to remain in place.
5. Infusion: To perform infusion, withdraw the guidewire and reference the specifications for maximum infusion pressure. Note: Do not exceed the recommended infusion pressures.

After use, dispose of all equipment in accordance with applicable requirements relating to hospital waste, and potentially bio-hazardous materials.

Warnings/Precautions

- Store in a cool, dry place. Protect from direct sunlight and high temperature (*greater than 55°C or 131°F*).
- Maximum Infusion Pressure: **500 psi**.
- The catheter is designed and intended for one time use only. **Do not re-sterilize and/or reuse.**
- Do not use if device or packaging is damaged.
- Use the catheter prior to the "Use By" date (Expiration date) specified on the package.
- The catheter should only be used by physicians qualified to perform percutaneous, vascular interventions.

Adverse Events

Vascular catheterization and/or vascular intervention may result in complications including but not limited to:

- Vessel dissection, perforation, rupture or total occlusion
- Infection
- Hematoma
- Unstable angina
- Embolism
- Hypo/hypertension
- Acute myocardial infarction
- Arrhythmia, including ventricular fibrillation
- Death

Specifications:

Model (Ref.)	Size	Max. (OD) Outer Diameter	Working Length	*Max Pressure psi (kPa)	Tip Shape
518-068	5 Fr	0.071" / 1.80 mm	100 cm	500 (3447)	Straight
518-070	5 Fr	0.071" / 1.80 mm	125 cm	500 (3447)	Straight
518-069	5 Fr	0.071" / 1.80 mm	100 cm	500 (3447)	Angled
518-071	5 Fr	0.071" / 1.80 mm	125 cm	500 (3447)	Angled
518-094	5 Fr	0.071" / 1.80 mm	135 cm	500 (3447)	Straight
518-095	5 Fr	0.071" / 1.80 mm	135 cm	500 (3447)	Angled

* 75/25 Optiray 320 Contrast Sterile Saline

