



Quick-Cross[®]
Support Catheter

Instructions for Use

Spectranetics[®]

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

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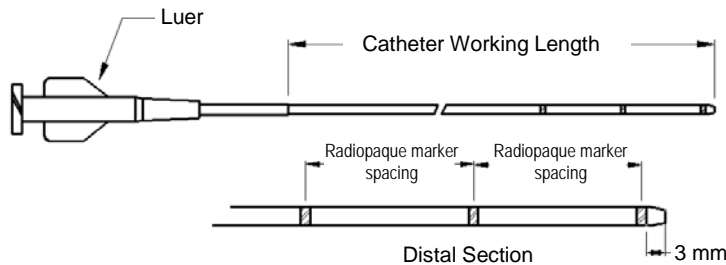
Description

The Spectranetics Quick-Cross® Support Catheters are intravascular catheters, available in 9 models. 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 distal 40 cm of each catheter model is coated with a lubricious, hydrophilic coating.

Model number 518-032 and 518-065 has a shaft of varying stiffness with a proximal shaft diameter of 3.0 Fr. tapering to a distal shaft diameter of 2.0 Fr and is compatible with a 0.014 inch or smaller guidewire.

Model numbers 518-033, 518-034, and 518-035 have a shaft of varying stiffness with a proximal shaft diameter of 3.4 Fr. tapering to a distal shaft diameter of 2.3 Fr and are compatible with a 0.018 inch or smaller guidewire.

Model numbers 518-036, 518-037, 518-038, and 518-066 have a shaft of varying stiffness with a proximal shaft diameter of 4.8 Fr. tapering to a distal shaft diameter of 3.8 Fr and are compatible with a 0.035 inch or smaller guidewire.



Specifications

	518-032	518-065	518-033	518-034	518-035	518-066	518-036	518-037	518-038
Maximum guidewire, inch	0.014	0.014	0.018	0.018	0.018	0.035	0.035	0.035	0.035
Catheter Working Length, cm	135	150	90	135	150	65	90	135	150
Minimum guidewire length, cm	180	180	150	180	180	150	150	180	180
Radiopaque marker spacing, mm	15	15	15	15	15	50	50	50	50
Proximal Shaft diameter, inch	0.039	0.039	0.044	0.044	0.044	0.063	0.063	0.063	0.063
Distal Shaft diameter, inch	0.026	0.026	0.030	0.030	0.030	0.050	0.050	0.050	0.050
Tip outside diameter, inch	0.020	0.020	0.023	0.023	0.023	0.041	0.041	0.041	0.041
Minimum Guide Catheter, Fr.	6	6	6	6	6	6	6	6	6
Minimum Introducer Sheath, Fr.	5	5	5	5	5	5	5	5	5

Notes

The Spectranetics Quick-Cross® Support Catheters are supplied **STERILE**. The devices are designated and designed for **SINGLE USE ONLY** and must not be resterilized and/or reused.

DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.

Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

Store in a cool, dry place. Protect from direct sunlight and high temperature (*greater than 60°C or 140°F*).

The sterility of the product is guaranteed only if the package is unopened and undamaged. Before use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised. Do not use catheter if its "Use Before Date," found on package labeling, has been passed.

Before use, examine carefully for defects, all of the equipment to be used. Do not use any equipment if it is damaged.

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

Indications for Use

The Spectranetics Quick-Cross® Support Catheters are guide wire exchange and infusion devices designed for use in the vascular system. The catheters are intended to support a guidewire during access of vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Directions for Use

Note: Follow instructions for use for all equipment to be used with the Quick-Cross® Support catheters. For example, guiding catheters, introducer sheaths, and guidewires.

1. Preparation: Using sterile technique, open the sterile package. Gently remove the protective hoop with the catheter from the pouch. Fill a sterile standard luer-lock syringe with sterile saline. Before removing the catheter from the hoop, connect the syringe to the catheter proximal luer fitting, flush the catheter and allow the saline to fill the hoop. Set catheter in hoop aside until ready for use.
2. Insertion: Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the catheter over an appropriate sized guidewire (see specifications) using standard technique.
3. Advancement: Use fluoroscopic guidance when advancing the catheter to the desired location within the vasculature.
4. Removal: Gently withdraw the catheter using standard technique, being careful to maintain guidewire position if the guidewire is to remain in place.
5. Infusion: To perform infusion, withdraw the guidewire and reference the chart below. Note: Do not exceed 300 psi inlet infusion pressure.

Quick-Cross® Infusion Flow Rates (ml/second) at 150 and 300 psi Injection Pressures for Saline and Contrast Solutions

Model	Size	Length	Sterile Saline		Contrast*	
			150 psi	300 psi	150 psi	300 psi
518-032	0.014	135	1.1	1.6	0.4	1.0
518-065	0.014	150	1.0	1.5	0.4	0.7
518-033	0.018	90	2.0	2.9	0.8	1.6
518-034	0.018	135	1.8	2.5	0.7	1.2
518-035	0.018	150	1.7	2.4	0.6	1.2
518-066	0.035	65	8.7	12.4	5.8	10.4
518-036	0.035	90	6.8	10.0	4.2	7.2
518-037	0.035	135	5.6	8.5	3.4	6.1
518-038	0.035	150	5.4	8.0	3.2	5.5

* 75/25 Optiray 320 contrast / Sterile Saline mix

Warnings/Precautions:

- Maximum infusion pressure is **300 psi**.
- The catheter is designed and intended for intravascular use only.

- This catheter is designed and intended for one time use only. **Do not re-sterilize and/or reuse.**
- Careful inspection before use should verify that the catheter has not been damaged in shipment and that its condition is suitable for the procedure.
- The catheter should not be advanced through an area of resistance unless the source of resistance is identified by fluoroscopy and appropriate steps are taken to reduce or remove the obstruction.
- Catheter manipulation should only occur under fluoroscopy.
- The catheter should not be advanced into a vessel having a diameter smaller than the catheter outer diameter.
- Only use guidewires of the recommended diameter and length.
- If the catheter is used for infusion, reference the table of flow rates and ensure infusion pressure does not exceed the recommendations.
- This catheter should only be used by physicians qualified to perform percutaneous, vascular interventions.
- Avoid introducing air or any other gas through the catheter into the vascular system.

Adverse Effects:

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

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

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 before" date.

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www.spectranetics.com



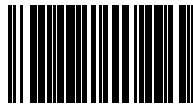
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P001256

Manufactured under one or more of the following patents:
5414075, 5637460, 6077698, 6278018B1,
6603040B1, 6706408B2
And other patents pending.

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