

Instruction for Use



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Quick-Cross® Support Catheter

Instructions for Use

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Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

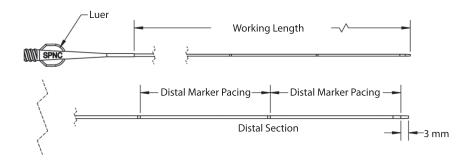
1. Description

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 quidewire.

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.



2. 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.

3. Specifications

	518-032	518-065	518-033	518-034	518-035	518-066	518-036	518-037	518-038
GW Compatibility, inch	0.014	0.014	0.018	0.018	0.018	0.035	0.035	0.035	0.035
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
Distal marker spacing, mm	15	15	15	15	15	50	50	50	50
Outer Diameter (0.D.), 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 Profile, inch	0.020	0.020	0.023	0.023	0.023	0.041	0.041	0.041	0.041
Minimum Guide Catheter, Fr.	5	5	5	5	5	6	6	6	6
Sheath Compatibility, Fr.	4	4	4	4	4	5	5	5	5

4. Contraindications

No known contraindications

5. Warnings

- This catheter should only be used by physicians qualified to perform percutaneous, vascular interventions.
- Catheter manipulation should only occur under fluoroscopy.
- 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.
- The catheter should not be advanced into a vessel having a diameter smaller than the catheter outer diameter

6. Precautions

- 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.
- · 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.
- Careful inspection before use should verify that the catheter has not been damaged in shipment and that its condition is suitable for the procedure.

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- 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.
- Avoid introducing air or any other gas through the catheter into the vascular system.

7. Adverse Events

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

8. How Supplied

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.

8.1 Sterilization

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.

8.2 Inspection Prior to Use

- Before use, examine carefully for defects, all of the equipment to be used. Do not use any equipment if it is damaged.
- Store in a cool, dry place. Protect from direct sunlight and high temperature (greater than 60°C or 140°F).

9. Compatibility

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

10. Directions for Use

Procedure Set-Up

· Follow the "Directions for Use" section below.

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.

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- 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

			Sterile Saline		Contrast*	
Model	Size	Length	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	4.7	7.8	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

11. Warranty Information

Manufacturer's Limited Warranty

Manufacturer warrants that the Quick-Cross catheter is free from defects in material and workmanship when used by the stated "Use By" date and when package is unopened and undamaged immediately before use. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective Quick-Cross catheter. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the Quick-Cross catheter. Damage to the Quick-Cross catheter caused by misuse, alteration, improper storage or handling, or any other failure to follow these Instructions for Use will void this limited warranty. THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. No person or entity, including any authorized representative or reseller of Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against Manufacturer.

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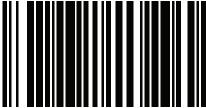
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