Quick-Cross™

Support Catheter

支撑导管

Instructions for Use

说明书

Spectranetics®

Instructions for Use - Sections by Language

English / English

Table of Contents

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

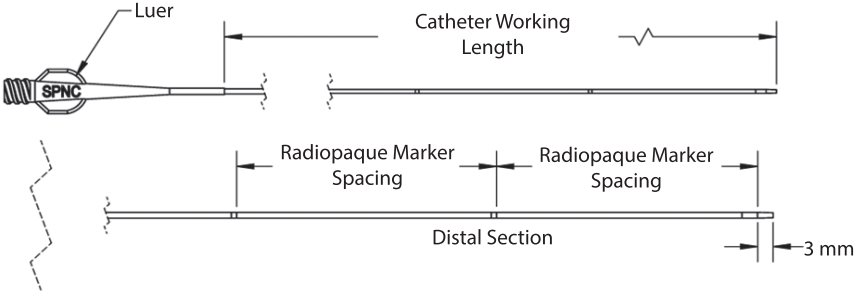
1. Description

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 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.



2. 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.	5	5	5	5	5	6	6	6	6
Minimum Introducer Sheath, Fr.	4	4	4	4	4	5	5	5	5

3. 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.

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.

4. 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.

5. Contraindications

No known contraindications

6. 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.

English / English

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

			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

7. 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.

8. 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

9. 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.

10. Non-Standard Symbols

Non-Pyrogenic	NON-PYROGENIC	**Tip Profile**	
GW Compatibility	GW Max OD	**Sheath Compatibility**	SC
Distal Marker Spacing		**Working Length**	
Outer Diameter (O.D.)		**Quantity**	QTY
Sterilized Using Radiation	STERILE R	**Do not use if package is damaged**	
Upper Limit of Temperature	60°C/140°F	**Consult Instructions for Use**	
Single Use		**Keep Dry**	
CAUTION: Federal law restricts this device to sale by or on the order of a physician.			Rx ONLY

目录

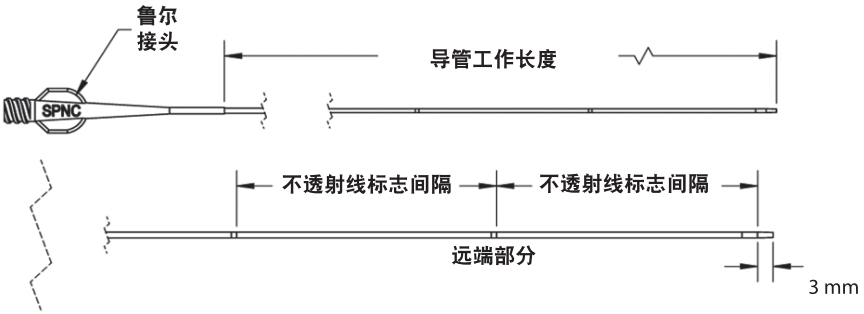
1. 说明

Spectranetics Quick-Cross支撑导管为血管内导管，共9种型号。所有型号都有3个不透射线标志沿远端轴均匀分布，以帮助预估血管系统的几何结构。远端不透射线标志位于导管末端3 mm处。每个型号的近端有一个标准的母鲁尔接头。每个导管型号的远端40 cm部分具有亲水润滑涂层。

型号518-032和518-065有一个硬度可变的轴，近端轴的直径是3.0 Fr.,远端逐渐变尖，直径为2.0 Fr,并且与0.014英寸或更小的导丝兼容。

型号518-033、518-034和518-035有一个硬度可变的轴，近端轴的直径是3.4 Fr.,远端逐渐变尖，直径为2.3 Fr,并且与0.018英寸或更小的导丝兼容。

型号518-036、518-037、518-038,和518-066有一个硬度可变的轴，近端轴的直径是4.8 Fr.,远端逐渐变尖，直径为3.8 Fr,并且与0.035英寸或更小的导丝兼容。



2. 规格

	518-032	518-065	518-033	518-034	518-035	518-066	518-036	518-037	518-038
最大导丝（inch）	0.014	0.014	0.018	0.018	0.018	0.035	0.035	0.035	0.035
导管工作长度（cm）	135	150	90	135	150	65	90	135	150
最大导丝长度（cm）	180	180	150	180	180	150	150	180	180
不透射线标志间隔（mm）	15	15	15	15	15	50	50	50	50
近端轴直径（inch）	0.039	0.039	0.044	0.044	0.044	0.063	0.063	0.063	0.063
远端轴直径（inch）	0.026	0.026	0.030	0.030	0.030	0.050	0.050	0.050	0.050
尖端外径（inch）	0.020	0.020	0.023	0.023	0.023	0.041	0.041	0.041	0.041
最小导引导管（Fr.）	5	5	5	5	5	6	6	6	6
最小导引鞘（Fr.）	4	4	4	4	4	5	5	5	5

3. 供货方式

Spectranetics Quick-Cross支撑导管属于**灭菌**产品。本器械**仅供一次性使用**，且不得重新灭菌和/或重复使用。

请勿对本器械进行重新灭菌或重复使用，因为不适当的再处理可能会损害器械的性能，或增加交叉感染的危险。重复使用这种一次性装置，可能会造成病人的严重伤亡，使得生产商的担保无效。

保存于干燥凉爽处。避免阳光直射和高温（超过60 摄氏度或140 华氏度）。

只有在包装未打开且未损坏的情况下，才能保证本产品的无菌性。使用之前，目视检查无菌包装，并确保其密封性未被破坏。如果包装的完整性被破坏，不要使用导管。如果已超过包装标签上注明的“使用截止日期”，则不要使用导管。

使用前，仔细检查所用的各种设备的缺陷。不要使用任何已损坏的设备。

用完之后，按照对医疗废弃物、潜在生物危害物的处理需求对所有设备进行处理。

4. 适应症

Spectranetics Quick-Cross支撑导管是为血管系统设计的导丝交换和输注器械。

本产品用于支撑导丝进入血管系统，允许导丝交换，并提供用于输入盐溶液或诊断造影剂的管道。

5. 禁忌症

无已知禁忌症

6. 使用说明

注意：遵守与Quick-Cross支撑导管配套使用的所有设备的使用说明。例如，导引导管、导引鞘和导丝。

1. 准备：运用灭菌技术，打开无菌包装。将小袋中导管的保护箍环小心移除。在无菌的标准鲁尔接头注射器中加入无菌盐水。从箍环上取下导管之前，将注射器与导管近端的鲁尔接口相连，冲洗导管，将盐水注入箍环中。将导管留在箍环中，直到使用时再取出。
2. 插入：通过以前插入的、大小合适的的导引导管或导引鞘，使用标准技术沿适当大小的导丝（见规格）插入导管。
3. 推进：在荧光透视引导下，将导管推进到血管内所需的位置。
4. 移除：使用标准技术轻轻撤回导管，如果要将导丝留在原位，注意保持导丝位置。

5. 输注：进行输注时，撤出导丝并参考下表。注意：不要超过300 psi的入口输注压。

当盐水和造影剂溶液的输注压为150和300 psi时，Quick-Cross的输注速率（毫升/秒）

			无菌盐水		造影剂*	
型号	尺寸	长度	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造影剂/无菌盐水混合液

7. 警告/注意事项

- 最大输注压是300 psi.
- 导管仅适用于血管内使用。
- 导管仅供一次性使用。请勿重新灭菌和/或重复使用。
- 使用前仔细检查以确保导管在运输过程中没有被损坏，并且其状况适合用于手术。
- 不应将导管推过存在阻力的部位，除非已通过荧光透视确定阻力来源，并采取了适当措施来减少或消除阻力。
- 仅可在荧光透视下操作导管。
- 导管不能推进直径小于导管外径的血管。
- 仅适用推荐直径和长度的导丝。
- 如果导管用于输注，请参考流速表，并确保输注压不超过推荐值。
- 本导管仅可由具有经皮血管介入术资质的医师使用。
- 在导管进入血管系统时，避免注入空气或其他气体。

8. 不良事件

血管插管术和/或血管介入术可能导致的并发症包括但不限于：

- 血管夹层、穿孔、破裂或完全闭塞
- 不稳定性心绞痛
- 栓塞
- 低/高血压
- 急性心肌梗塞
- 心律失常，包括心室颤动
- 死亡

9. 担保信息

生产商有限担保

生产商保证，如果在声明的“使用截止日期”之前使用，且在临近使用前包装未打开或破损，则Quick Cross在材料和工艺方面无缺陷。生产商在此担保下的责任限于更换有缺陷的Quick Cross导管或按购买价格退款。生产商不负责由于使用Quick Cross导管造成的任何偶然性、特殊性或结果性损坏。由于误用、改造、不当贮存或操作，或未按照本使用说明进行的其他操作而引起Quick Cross导管损坏，此时本有限担保将失效。**本有限担保明确替代所有其他明示或暗示的担保条款，其中包括对适销性和特定用途适用性的任何担保。**任何个人和实体，包括任何生产商授权的代表或零售商，都无权扩展或扩大本有限担保，任何声称扩大担保的行为对生产商均无强制力。

10. 非标准符号

Non-Pyrogenic 无热原	NON-PYROGENIC	**Tip Profile** 尖端外形	
GW Compatibility 导丝兼容性	GW Max OD	**Sheath Compatibility** 鞘管兼容性	SC
Distal Marker Spacing 远端标志间隔		**Working Length** 工作长度	
Outer Diameter (O.D.) 外径（O.D.）	∅	**Quantity** 数量	QTY
Sterilized Using Radiation 已使用辐射灭菌	STERILE R	**Do not use if package is damaged** 包装如有损坏，请勿使用	
Upper Limit of Temperature 温度上限	60°C/140°F	**Consult Instructions for Use** 参考使用说明	
Single Use 单次使用		**Keep Dry** 保持干燥	
CAUTION: Federal law restricts this device to sale by or on the order of a physician. 警告：联邦法律规定，本器械只能由医生直接销售或遵医嘱销售。			Rx ONLY

Spectranetics®

www.spectranetics.com

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代理人地址及联系方式：上海市静安区灵石路718号A1幢
电话：8008100038**中国**

P008275

说明书附页

产品名称:	支撑导管
型号、规格:	518-032, 518-033, 518-034 518-035, 518-036, 518-037 518-038, 518-065, 518-066
产品技术要求编号:	国械注进20203031531
医疗器械注册证编号:	国械注进20203031531
生产企业/注册人名称:	史派克公司Spectranetics Corporation
生产企业/注册人住所:	9965 Federal Drive Colorado Springs, Colorado 80921, USA
生产地址:	9965 Federal Drive Colorado Springs, Colorado 80921, USA
生产企业/注册人联系方式:	1-800-231-0978
代理人/售后服务单位名称:	飞利浦（中国）投资有限公司
代理人/售后服务单位住所:	上海市静安区灵石路718号A1幢
代理人/售后服务单位联系方式:	800 810 0038
生产日期:	见标签
使用期限/失效日期:	见标签