QuickCat™

Extraction Catheter

Instructions for Use

Spectranetics®

Instructions for Use - Sections by Language

Spectranetics®	QuickCat™ EXTRACTION CATHETER	INSTRUCTIONS FOR USE

English / English

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Read all instructions carefully prior to use. Observe all warnings and precautions, and keep in mind these instructions that run throughout this Instructions for Use. Failure to observe these warnings or precautions may lead to complications. All the suggestions made in these instructions are designed to serve general guidelines. They are not intended to replace an agreement in system or professional clinical judgment in terms of patient care.

WARNING: U.S. Federal Law restricts this device to sale to only internists or similar physicians.

1. DEVICE DESCRIPTION

QuickCat™ thrombus aspiration catheter is a disposable double-inner-cavity catheter that is designed to remove soft emboli and thrombosis in the vessels of arterial system. The end of the catheter is flexible, conical, and smooth, providing a channel into arterial system to prevent damages. The device is supplied sterile and for a single use.

2. DEVICE COMPONENTS

Catheter: The QuickCat™ thrombus aspiration catheter matches a 6F guiding catheter [I.D. ≥ 0.068 (1.73 mm)] and a 0.014" (0.36 mm) wire. The working length of the catheter is 145 cm, and its end is covered with a hydrophilic coating. There is a radiopaque mark at 1 mm of the tip.

Vacuum Assembly: Vacuum assembly comprises a 7.0 (177.8 mm) extension tube, a one-way hemostatic valve, and a 30 ml vacuum syringe with an adjustable locking piston. A 40 µm filter basket is used to assist in filtering blood and thrombotic substances for a visual or laboratory analysis.

3. INDICATIONS AND INTENDED USE

QuickCat™ thrombus aspiration catheter is used to remove the fresh and soft emboli and thrombosis in the vessels of arterial system.

The product can be used for one time only and should be operated by physicians trained and experienced in diagnostics and interventional procedures.

Standard techniques can be used to arrange vascular access sheathing canals, angiographic catheters and guidewires.

4. CONTRAINDICATIONS

- Use in blood vessel with a diameter < 1.5 mm
- Meridian system
- Removal of fibrous, adherent or calcified materials, such as chronic clots and atherosclerotic plaques

5. WARNINGS

- Do not use it if no guidewire is available, which may lead to a vascular injury.
- Do not try to advance or retract catheter in a resisting reverse direction until the origin of the resistance is determined by fluoroscopy or any other methods. An operation in a resisting reverse direction of the catheter may twist the catheter or cause a vascular injury.
- During the process of handling, if it is too loose or a guidewire loop is observed between guiding catheter and monorail portion of the QuickCat™ thrombus aspiration catheter, the guidewire may twist in the blood vessels when the catheter is advanced or retracted. Before the QuickCat™ catheter is advanced or retracted, remove any loose or looped guidewire to avoid a catheter damage and/or vascular injury.
- In the case of a flow into syringe or restriction, when the catheter is still in patient's body, do not try to flush the aspiration inner cavity of the QuickCat™ thrombus aspiration catheter. By doing so, it may cause a severe damage or death.

- Do not use curved, twisted or damaged catheter, because it may lead to a vascular injury and/or inability to advance or retract the catheter.
- Do not transfer or infuse any diagnostic, inserted, or therapeutic material into blood vessels.

6. PRECAUTIONS

- Prior to use, check if all connections between components are safe, and confirm that the system is completely prepared and whether the vacuum state is appropriate.
- Do not excessively tighten the hemostatic valve on the catheter shaft, or it may cause damage to catheter.
- Caution should be exercised when the QuickCat™ thrombus aspiration catheter is traversed or retracted to pass through the newly deployed drug coating site.
- Do not re-disinfect, reprocess or reuse the device.
- Do not re-disinfect or re-use this device, which may be harmful to the performance of the device, or increase the risk of cross-infection due to improper reprocessing.

  Reusing this disposable device may cause a serious patient injury or even death and void the manufacturer's warranty.
- Do not replace any system components with alternative components.

7. POTENTIAL ADVERSE REACTIONS

- Bleeding or hematoma of surgical site
- Damage of anastomosis
- Sudden closure or total occlusion of the treated site or blood vessels
- Pulmonary injury or limb ischemia due to peripheral embolism of fragments
- Local or systemic infection
- Arteriospasm
- Formation of arteriovenous fistula
- Drug reactions, adverse reactions to contrast agents
- Acute myocardial infarction
- Vascular anatomy, perforation, rupture or damage
- Emergency operation
- Death

8. DEVICE PREPARATION

1. Using an aseptic technique, open the bag and transfer the tray to a sterile area.
2. Remove the catheter from the protective ring, and check whether there is any bending or twisting.
3. Fill the 30 ml vacuum syringe with 5 ml – 10 ml of normal saline.
4. Connect the vacuum syringe to piston, connect the piston to extension tube, and connect the extension tube to the holder of the QuickCat™ thrombus aspiration catheter. Make sure all connections are secure.
5. Flush the system with normal saline to ensure complete filling.
6. Rotate the hemostatic valve to the Closed position.
7. Remove the 30 ml vacuum syringe and fill it with saturated saline solution.
8. Fit the 30 ml vacuum syringe onto the system assembly again.

9. PROCEDURE

1. Using a standard technique, insert the guidewire and the guiding catheter (I.D. ≥ 0.068 [1.73 mm]) with a hemostatic valve into the target vessel.
2. Load the QuickCat™ thrombus aspiration catheter on the guidewire.

WARNING: If any resistance is felt during the operation, the cause for the resistance must be determined before the catheter is advanced or retracted. Operating the catheter in a direction opposite to the resistance may lead to a vascular injury. If the catheter is twisted during use, carefully remove it from the patient body, and continue to use a new QuickCat™ thrombus aspiration catheter.

3. During fluoroscopy, push the QuickCat™ thrombus aspiration catheter to the target position.
4. Adequately tighten the hemostatic valve to prevent backflow, but do not tighten it too much to prevent the movement of catheter.
5. The piston is in the Closed position, and pull back the piston of the 30 ml syringe to a desired position for extraction. Turn the piston clockwise and lock the syringe in the desired vacuum position.
6. Determine the correct catheter location through fluoroscopy.
7. Turn the piston to the Open position to start aspiration. Slowly advance the QuickCat™ thrombus aspiration catheter to the target blood vessel. Blood will flow into the syringe until the space is filled up.

8. If no blood enters the syringe within 5 seconds, remove the catheter from the patient's body. Outside the patient's body, flush the catheter or replace it with a new catheter.

WARNING: In the case of a flow into the syringe or restriction, when the catheter is still in the patient's body, do not try to flush the aspiration inner cavity of the QuickCat™ thrombus aspiration catheter. By doing so, it may cause a severe damage or death. Remove the catheter from the patient's body and flush the aspiration inner cavity before reuse, or use a new QuickCat™ thrombus aspiration catheter.

9. Once the extraction process is completed, turn the piston to the Closed position, and remove the catheter from the patient's body. Use a filter basket with 40 µm tiny holes to filter the extracted blood and blood clots for a visual and/or laboratory analysis.

10. POST-OPERATIVE CARE

After operation, the sheath should be removed by following the care standards of hospital, and provide hemostasis to prevent major hemorrhage of the vascular access position.

11. HOW SUPPLIED

It is sterilized through radiation in the top plate, with a sealed tear-type opened package. It is for a single use; do not re-disinfect, reprocess or reuse it. If the package is unopened or intact, it will be sterile. If the package is suspected of having been opened, do not use the product again. After removing the package, thoroughly check the product to ensure that no damage, bending or twisting occurred during the course of loading.

12. STORAGE CONDITIONS

Store it in a cool and dry place. Avoid excessive exposure to sunlight.

Table 1: Non-standard graphical symbols for medical device labels

Wire Compatibility		**Working Length**	
Fast Exchange		**Vascular Diameter**	
Sheath Compatibility		**Guiding Catheter Compatibility**	
		Non-Pyrogenic	NON-PYROGENIC

13. WARRANTY INFORMATION

Manufacturer limited warranty

If the product is used before the specified "Use before this date" and the package is unopened and intact before use, the manufacturer will authorize the QuickCat™ catheter to be exempted from responsibilities for material defects and processes. Under this warranty, the manufacturer's responsibility is limited to replacing or partially refunding any defective QuickCat™ catheter based on the purchase price. The manufacturer is not responsible for any incidental, special or consequential damages caused by use of QuickCat™ catheter. Any QuickCat™ catheter damage due to misuse, modification, improper storage or operation, or any other failures to comply with these use rules is invalid under this limited warranty. **This limited warranty explicitly supersedes all other warranties, express or implied, including the default warranties of marketability or suitability for a particular purpose.** No individual or entity, including any authorized representative or reseller of the manufacturer, has the right to extend or develop this limited warranty and any purported attempt to do; to the manufacturer, these are non-enforceable.

Attachment to the Instructions for Use

[Product model] 60090-01

[Composition]

	Composition	
1	Aspiration catheter	Holder
		Pressure release band
		Proximal tube
		Middle tube
		Distal double-cavity tube
		Hydrophilic coating
		Radioactive label
2	Vacuum tube	
3	Filter mesh	
4	Vacuum syringe	
5	Rotating hemostatic valve	

[Sterilization method] Electron beam sterilization

[Length of validity] 3 years

[Manufacturer] Spectranetics Corporation

[Registered address] 9965 Federal Drive Colorado Springs Colorado 80921 USA

[Production address] 9965 Federal Drive Colorado Springs Colorado 80921 USA

[After-sale service institution] Philips (China) Investment Ltd. Co.

[Address] Building A1, #718 Lingshi Road, JingAn District, Shanghai

[Telephone No.] 8008100038

[Product standard number] 20163772416

[Medical device registration certificate number] 20163772416

QUICKCAT™血栓抽吸导管使用说明

在使用之前仔细阅读所有的说明书细则。遵守所有的警告和预防措施，记住贯穿说明书的这些指令。不能遵守警告和预防措施，可能会导致并发症。这些指令的任何建议都是设计用来服务于一般指南的。他们不打算代替制度上的协议或者关于病患照顾方面的专业的临床判断。

警告：美国联邦法律约束这款设备只能销售给内科医师或同类医师。

1. 设备描述

QuickCat™血栓抽吸导管是一次性使用的、用完即丢的双内腔导管，设计用来去除动脉系统的血管中的柔软的栓子和血栓。导管的末端是柔软的、锥形的和光滑的，提供一条进入动脉系统防止损伤的通道。设备供应的是无菌的，一次性使用。

2. 设备组件

导管： QuickCatTM血栓抽吸导管与6F引导导管 [I.D.≥0.068（1.73mm）]和0,014"（0.36mm）导线相匹配。导管的工作长度为145cm，它的末端位置是用亲水涂层覆盖的。尖端1mm处有一个不透射线标志。

真空装配： 真空装配包括7.0（177.8mm）的伸长管，单向止血阀和有可调节锁定活塞的30ml的真空注射器。40微米过滤篮用于协助过滤血液和血栓物质，以便进行可视化或实验室分析。

3. 适应症和预期用途

QuickCat™血栓抽吸导管用于移除动脉系统血管中的新鲜的、柔软的栓子和血栓。

产品只能用作一次性使用，由在诊断法和介入手术方面接受训练的和有经验的医师操作。

可以使用标准技术来布置血管通路鞘管、血管造影导管和导丝。

4. 禁忌症

- 在直径<1.5mm的血管中使用
- 经脉系统
- 除去纤维的、粘着的或钙化的材料（比如慢性的凝块，动脉粥样硬化斑块）

5. 警告

- 如果没有导丝，请不要使用，可能会导致血管损伤。
- 不要试图在阻力反方向前进或者缩回导管，直到阻力的起因是由荧光镜检查或其他方法决定的。对导管反阻力方向的操作可能导致导管扭结在一起或者血管损伤。
- 在处理过程中，如果过度松弛或者观察到引导导管和QuickCat™血栓抽吸导管单轨部分之间存在导线环，在导管前进或缩回期间，导线可能会扭结在血管内。在QuickCat™导管前进或缩回之前，移除松弛的或环状的导线，避免发生导管和/或血管损伤。
- 如果流入到注射器或者被限制，当导管还在患者体内时，不要试图用水冲洗QuickCat™血栓抽吸导管的抽吸内腔。可能会导致严重损害或者死亡。
- 不要使用弯曲的、扭结的或者被损坏的导管，由于这可能导致血管损伤和/或不能前进或返回导管。
- 不要往血管中传输或灌输诊断的、插入的或治疗的材料。

6. 预防措施

- 使用之前，检查组件之间所有的连接是否安全，并确定系统完全准备好或者真空状态是否合适。
- 不要过度绷紧导管轴上的止血阀，或者可能导致导管损伤。
- 当横越或缩回时，QuickCat™血栓抽吸导管穿过新近部署的药物涂层部位，要小心谨慎。
- 不要再消毒、再加工或者再利用设备。

- 不要进行重新消毒或者重新使用这套设备，这些行为可能会危害到设备性能或由于不适当的再加工而导致增加交叉感染的风险。

  再利用这个单次使用的设备可能会导致严重的患者伤害甚至死亡，且没有制造商的担保。
- 不要用交替的组件来替换系统组件。

7. 潜在的不良反应
   - 手术部位流血或血肿
   - 吻合的破坏
   - 治疗的部位或血管突然关闭或者全部闭塞
   - 碎片的末梢栓塞导致肺受伤或者肢体缺血
   - 局部或者全身感染
   - 动脉痉挛
   - 形成动静脉瘘
   - 药物反应，造影剂的不良反应
   - 急性心肌梗塞
   - 血管解剖，穿孔，破裂或者损害
   - 急诊手术
   - 死亡

8. 设备准备
   1. 使用无菌技术，打开袋子，将托盘转移到无菌区域。
   2. 从防护圈中移除导管，检查是否存在任何弯曲或扭结现象。
   3. 用5-10ml的生理盐水填充30ml的真空注射器。
   4. 连接真空注射器到活塞，连接活塞到伸长管，连接伸长管到QuickCat™血栓抽吸导管座。确保所有的连接都是安全的。
   5. 用生理盐水冲洗系统，保证完全填满。
   6. 转动止血阀到闭合位置。
   7. 移除30ml的真空注射器，并用饱和的盐溶液填充。
   8. 重新系上空的30ml真空注射器到系统装配上。

9. 程序
   1. 使用标准技术，将导丝和附有止血阀的引导导管（I.D.≥0.068[1.73mm]）插入目标血管。
   2. 在导丝上加载QuickCat™血栓抽吸导管。

警告：如果在操纵期间，感觉到任何阻力，导管前进或倒退之前必须判断阻力的形成原因。反阻力方向操纵导管可能导致导管或血管损伤。如果使用期间导管扭结在一起，小心地从患者体内移除，并继续使用一个新的QuickCat™血栓抽吸导管。

   3. 在荧光镜检查时，推进QuickCat™血栓抽吸导管到目标位置。
   4. 充分地绷紧止血阀以防止回流，但是不要太紧以至于阻碍导管运动。
   5. 活塞在闭合位置，拉回30ml注射器的活塞到想要的提取量位置。顺时针方向扭动活塞，在想要的真空位置锁住注射器。
   6. 确定正确的导管位置通过荧光镜检查。
   7. 扭转活塞到打开位置来开始抽吸。缓慢地前进QuickCat™血栓抽吸导管到目标血管。血液会流入到注射器直到空间被占满。
   8. 如果在5秒钟之内血液没有进入注射器，从患者体内移除导管。在患者体外冲洗导管或者替换一个新导管都可以。

警告：如果流入到注射器或者被限制，当导管还在患者体内时，不要试图用水冲洗QuickCatTM血栓抽吸导管的抽吸内腔。可能会导致严重损害或者死亡。将导管从患者体内移除，在重新使用之前冲洗抽吸内腔，或者使用一个新的QuickCat™血栓抽吸导管。

   9. 一旦提取过程完成了，转动活塞到闭合位置，并从患者体内移除导管。使用40微米的小孔过滤器篮子来过滤提取的血液和血栓，以便进行可视和/或实验室分析。

10. 手术后护理

手术后，应遵循医院的护理标准来移除护套，并提供止血来预防血管通路位置大出血。

11. 如何供应

在顶板内通过辐射消毒，密封的撕裂式开封包裹。用于单次使用；不能再消毒、再加工或者再利用。如果包裹是未打开的或者未损坏的，就是无菌的。如果怀疑包裹已经被打开过，请不要再使用产品。移除包裹后，彻底地检查产品，来确保装货过程中没有出现损伤、弯曲或者扭结现象。

12. 存储条件
存储在凉快的干燥的地方。避免过度暴露在阳光下。

表1.医疗设备标签的非标准图形符号

导线相容性		工作长度	
快速交换		血管直径	
护套相容性		引导导管相容性	
		非-高热的	NON-PYROGENIC

13. 保修信息
制造商有限质量保证

当在规定的"此日期前使用"之前使用和使用之前包裹是未打开且未损坏的，制造商授权QuickCat™导管免受材料缺陷和工艺的责任。根据本担保书，制造商的责任仅限于更换或者给任何有缺陷的QuickCat™导管按照进货价格进行部分退款。制造商不对由于使用QuickCat™导管而造成的任何偶然事件、特别的或者间接损害负责。由于误用、修改、不正确储存或操作、或任何其他未能遵守这些使用规则而造成的QuickCat™导管损害，对本分有限质量保证是无效的。这份有限质量保证清楚地替代所有其他担保，明示或默示，包含用于特殊目的的可销性或适合性的默认保证。个人或实体，包含任何经授权的代表或者制造商的转销商，都没有权利延伸或者发展这个有限质量保证和任何传说的尝试去做，这些对制造商来说都是不可实施的。

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电话：8008100038中国

P012405

说明书附页

【产品型号】60090-01

【结构组成】

	结构组成	
1	抽吸导管	座
		压力释放带
		近段管
		中段管
		远段双腔管
		亲水涂层
		放射性标记
2	抽真空管	
3	过滤网	
4	抽真空注射器	
5	旋转止血阀	

【灭菌方式】电子束灭菌

【有效期】3年

【生产商】Spectranetics Corporation 史派克公司

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【生产地址】9965 Federal Drive Colorado Springs Colorado 80921 USA

【售后服务机构】飞利浦(中国)投资有限公司

【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

【产品标准编号】国械注进20163772416

【医疗器械注册证书编号】国械注进20163772416