REFLOW MEDICAL

SPEX

SUPPORT CATHETER

Instructions for Use

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

Description

The speX 35 Support Catheters are single lumen catheters designed to access the vasculature. These catheters are available in a variety of lengths and offer a shapable tip. Each configuration has a braided support matrix and hydrophlilic coating on the distal segment of the catheter. The distal tip is clearly distinguished by a radiopaque marker. The speX Support Catheters will also allow for exchange of guidewires and other interventional devices, and provide a conduit for delivery of saline solutions or diagnostic contrast.

Indications for Use

SpeX 35 Support Catheters are intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. They may be used to facilitate placement and exchange of guidewires and other interventional devices, and provide a conduit for delivery of saline solutions or diagnostic/ therapeutics agents.

Contraindications

The speX 35 Support Catheter is contraindicated for use in the coronary and cerebral vasculature.

Warnings

Single Use only. Do not reuse/resterilize. Reusing the device could result in compromised device performance, cross-infection and other safety related hazards.
Do not use if device is open or packaging is damaged
Never advance, withdraw or rotate an intravascular device against resistance until the cause is determined by fluoroscopy.

Directions for Use

Note: Follow instructions for use on all equipment to be used with the speX Support Catheter

1. Preparation for Use:
   a. Using sterile technique, remove the speX catheter dispenser coil from its packaging and transfer it to the sterile field.
   b. Remove the speX catheter from the dispenser coil and inspect for any bends or kinks.
   c. If desired, insert the stylet provided and shape speX Catheter tip using standard technique. Do not reshape more than 3 times.
   d. Fill a sterile standard luer-lock syringe with sterile saline and flush the lumen.
   e. Prior to use, wet the distal 40cm of the speX catheter with Heparinized saline solution to activate the hydrophilic coating.
2. Insertion
   a. Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the distal end of the speX catheter over an appropriately sized guidewire (see specifications) using standard technique.
3. Advancement
   a. Use fluoroscopic guidance when advancing the speX catheter to the desired location within the vasculature.
   b. Never advance the speX catheter against strong resistance until the cause of the resistance is determined by fluoroscopy. If the cause cannot be determined, withdraw the catheter. Movement against resistance may result in damage to the vessel.
   c. In the case that a different guidewire is needed, retract the guidewire while holding the hub of the speX catheter in place. Once guidewire has been removed from the patient, a different guidewire can be introduced into the hub of the catheter and advanced to the distal tip.
4. Infusion
   a. To perform infusion, withdraw the guidewire and reference the specifications for maximum infusion pressure.
5. Removal
   a. Fix the guidewire using standard guidewire exchange techniques and carefully withdraw the speX Catheter
   b. After use, dispose of all equipment in accordance with applicable requirements relating to hospital waste, and potentially bio-hazardous materials.

Precautions

Store in a cool, dry place. Protect from direct sunlight and high temperature.
Use only appropriately sized ancillary device, as shown in the Specifications below.
Maximum Infusion Pressure: 360 psi (2482kpa)
Use the catheter prior to the "Use By" date specified on the package
The catheter should only be used by physicians qualified to perform percutaneous, vascular interventions.
Precautions to prevent or reduce clotting should be taken when any catheter is used in the vascular system. Use of systemic heparinization and heparinized saline solution should be considered.
Exercise care while handling the catheter during procedure to reduce the possibly of accidental damage, kinking or bending.
Manipulation of the catheter should only occur under fluoroscopy.

Complications

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
- If the catheter is damaged, this product may cut into a blood vessel wall. Extreme caution needs to be taken when removing a damaged device. In the case of complications resulting from the removal of the entire system, stop immediately the procedure, and perform appropriate treatment at the discretion of the physician.

Specifications

Model (Ref.)	Guide Compatibility	Guidewire Compatibility	Effective Length (cm)	Max Outer Diameter	Sheath Compatibility	Max Pressure psi(kpa)	Shapeable Tip Zone Length	Hydrophilic Coating Length
SPN35050US	MIN 6F (2mm)	.035" (.89mm)	50cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPN35090US	MIN 6F (2mm)	.035" (.89mm)	90cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPN35135US	MIN 6F (2mm)	.035" (.89mm)	135cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPN35150US	MIN 6F (2mm)	.035" (.89mm)	150cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm

Warranty and Limitation of Warranty

Manufacturer warrants that the speX Support 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 speX Support Catheter. Damage to the speX Support 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

Manufacturer: Reflow Medical
208 Avenida Fabricante #100
San Clemente, CA. 92672, USA

Standard Symbol Legend

LOT	Batch Code		Use By Date		Do not use if package is damaged		Do not reuse		Caution: See instructions for use	STERILE R	Sterilized using irradiation		Consult instructions for use
REF	Catalogue Number		Manufacturer	STERILE EO	Sterilized using ethylene oxide		Do not resterilize	RX ONLY	**Caution**: Federal (USA) law restricts this device to sale by or on the order of a physician	EC REP	Authorized representative in the European Community		Non-pyrogenic