Specifications

Model (Ref.)	Guide Compatibility	Guidewire Compatibility	Effective Length	Max Outer Diameter	Sheath Compatibility	Max Pressure psi(kpa)	Shapeable Tip Zone Length	Hydrophilic Coating Length (Distal)
SPX35050CE	MIN 6F (2mm)	.035" (.89mm)	50 cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPX35090CE	MIN 6F (2mm)	.035" (.89mm)	90cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPX35135CE	MIN 6F (2mm)	.035" (.89mm)	135cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPX35150CE	MIN 6F (2mm)	.035" (.89mm)	150cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPX18090CE	MIN 4F(1.3mm)	.018" (.46mm)	90cm	.038" (.97mm/2.9F)	MIN 4F (1.3mm)	360 (2482)	.25" (6mm)	40cm
SPX18135CE	MIN 4F(1.3mm)	.018" (.46mm)	135cm	.038" (.97mm/2.9F)	MIN 4F (1.3mm)	360 (2482)	.25" (6mm)	40cm
SPX18150CE	MIN 4F(1.3mm)	.018" (.46mm)	150cm	.038" (.97mm/2.9F)	MIN 4F (1.3mm)	360 (2482)	.25" (6mm)	40cm
SPX14090CE	MIN 4F(1.3mm)	.014" (.36mm)	90cm	.034" (.86mm/2.6F)	MIN 4F (1.3mm)	360 (2482)	.25" (6mm)	40cm
SPX14135CE	MIN 4F(1.3mm)	.014" (.36mm)	135cm	.034" (.86mm/2.6F)	MIN 4F (1.3mm)	360 (2482)	.25" (6mm)	40cm
SPX14150CE	MIN 4F(1.3mm)	.014" (.36mm)	150cm	.034" (.86mm/2.6F)	MIN 4F (1.3mm)	360 (2482)	.25" (6mm)	40cm
Spex LP								
SLP35090CE	MIN 5F (1.7mm)	.035" (.89mm)	90cm	.050" (1.27mm/3.8Fr)	Min 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP35135CE	MIN 5F (1.7mm)	.035" (.89mm)	135cm	.050" (1.27mm/3.8Fr)	Min 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP35150CE	MIN 5F (1.7mm)	.035" (.89mm)	150cm	.050" (1.27mm/3.8Fr)	Min 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP18090CE	MIN 5F (1.7mm)	.018" (.46mm)	90cm	.033" (.8mm/2.5F)	MIN 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP18135CE	MIN 5F (1.7mm)	.018" (.46mm)	135cm	.033" (.8mm/2.5F)	MIN 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP18150CE	MIN 5F (1.7mm)	.018" (.46mm)	150cm	.033" (.8mm/2.5F)	MIN 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP14090CE	MIN 5F (1.7mm)	.014" (.36mm)	90cm	.029" (.8mm/2.2F)	MIN 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP14135CE	MIN 5F (1.7mm)	.014" (.36mm)	135cm	.029" (.8mm/2.2F)	MIN 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
SLP14150CE	MIN 5F (1.7mm)	.014" (.36mm)	150cm	.029" (.8mm/2.2F)	MIN 4F (1.3mm)	360 (2482)	3.94" (100mm)	40cm
Spex SPN								
SPN35050CE	MIN 6F (2mm)	.035" (.89mm)	50cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPN35090CE	MIN 6F (2mm)	.035" (.89mm)	90cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPN35135CE	MIN 6F (2mm)	.035" (.89mm)	135cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm
SPN35150CE	MIN 6F (2mm)	.035" (.89mm)	150cm	.06" (1.5mm/4.6F)	MIN 5F (1.7mm)	360 (2482)	.75" (19mm)	40cm

Device Description

The Spex Shapeable Support Microcatheters (Spex or device) are single lumen, shapeable tip microcatheters designed to access the peripheral vasculature. The Spex allow for exchange of guidewires and other interventional devices and provide a conduit for delivery of saline solutions or diagnostic contrast. These catheters are available in a variety of lengths and diameters. Each configuration has a braided support matrix and hydrophilic coating on the distal segment of the microcatheter shaft. The distal tip of the Spex has one radiopaque marker, whereas the Spex LP has 3 radiopaque markers spaced equally along the distal shaft at 50mm increments, to aid in estimating geometry within the vascular system.

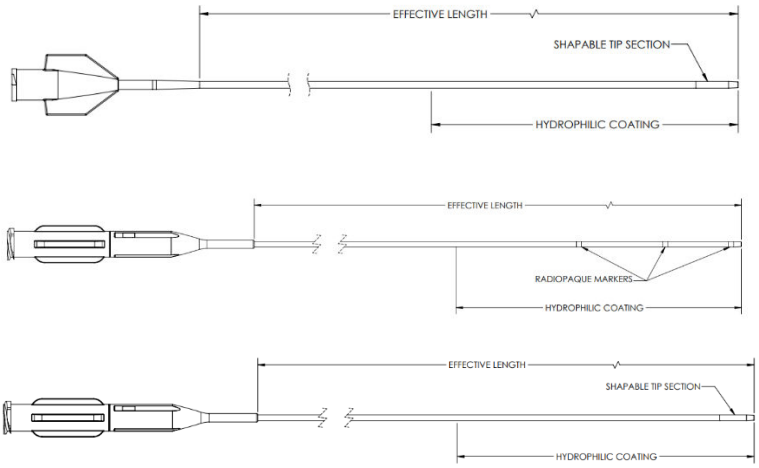

Figure 1. Spex (top), Spex LP (middle), SPN (bottom)

Intended Purpose

The Spex™ Shapeable Support Microcatheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the peripheral vasculature. To facilitate access in conjunction with a guidewire, it may be desired to shape the tip of the microcatheter. 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/ therapeutic agents.

Intended Use

The Spex Shapeable Support Microcatheter is intended to treat peripheral artery disease (PAD).

Intended User

The Spex Shapeable Support Microcatheter should only be used by physicians qualified to perform percutaneous vascular interventions.

Target Population

The device is intended for use in patients undergoing therapeutic or diagnostic peripheral endovascular procedures.

Contraindications

The Spex Shapeable Support Microcatheter 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 including patient injury.
- 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
- 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.

Precautions

- Store in a cool, dry, dark place. Storage of the device in extreme conditions may damage the device and/or affect device performance that could lead to patient injury.
- Use only appropriately sized ancillary device, as shown in the Specifications above.
- Maximum Injection 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 microcatheter during procedure to reduce the possibly of accidental damage, kinking or bending.
- Manipulation of the microcatheter should only occur under fluoroscopy.

Expected Clinical Benefit

The Spex™ Shapeable Support Microcatheters have a braid-enforced microcatheter body with a shapeable tip that provides improved vascular access and added support for the guidewire to cross the lesion. The Spex has a low profile to facilitate trackability and navigation through tortuous anatomy. Additionally, the Spex™ Shapeable Support Microcatheters facilitate guidewire exchange during the procedure.

Complications/Foreseeable events:

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

- Catheter related: Adverse reaction to device materials, device malfunction/ fracture, infection, distal embolization, vessel thrombosis/ clot formation, vascular damage/ dissection requiring surgical repair, incompatibility with accessories

Complications usually associated with endovascular procedures and percutaneous access including but not limited to:

- Unstable angina, Hypo/hypertension, Acute myocardial infarction, Hemorrhage at puncture site, False aneurysm formation, Renal dysfunction, Hematoma, Embolism, Arrhythmia, Death

How Supplied

The Spex, Spex SPN, and Spex LP are supplied sterile via ethylene oxide (EO) sterilization and are intended for single use (one patient) only.

Required Devices for the Spex Procedure

Contents: Spex Shapeable Support Microcatheter and stylet

The Spex Shapeable Support Microcatheters are intended to be used in conjunction with devices as shown in the Specification table.

Procedural Steps

Caution: Refer to the instructions for use for all equipment/devices to be used with the Spex and procedure.

1. Carefully inspect all packaging for damage or defects prior to use. Do not use the device if there is any sign of breach of sterile barrier, as this would indicate loss of sterility that could result in patient injury.
2. Preparation for Use:
   a. Using sterile technique, remove the Spex dispenser coil from its packaging and transfer it to the sterile field.
   b. Remove the Spex from the dispenser coil and inspect for any bends or kinks.
   c. If desired, insert the stylet provided and shape Spex 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 with Heparinized saline solution to activate thehydrophilic coating.
3. Insertion
   a. Through a previously inserted, appropriately sized guiding catheter or introducer sheath, introduce the distal end of the Spex over an appropriately sized guidewire (see specifications) using standard technique.
4. Advancement
   a. Use fluoroscopic guidance when advancing the Spex to the desired location within thevasculature.
   b. Never advance the Spex against strong resistance until the cause of the resistance is determinedby fluoroscopy. If the cause cannot be determined, withdraw the device. 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 in place. Once the guidewire has been removed from the patient, a different guidewire can be introduced into the hub of the microcatheter and advanced to the distal tip.
5. Injection

a. To perform injection, withdraw the guidewire and reference the specifications for maximum injection pressure.

6. Removal
   a. Fix the guidewire using standard guidewire exchange techniques and carefully withdraw the Spex device.
   b. If a device malfunction occurs or any defects are noted on the inspection, flush the guidewire lumen and clean the outer surface of the device with saline, store the device in a sealed biohazard plastic bag, and contact Reflow Medical, Inc. at complaints@reflowmedical.com for further instructions.
   c. After use this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices applicable laws and regulation.

Device Feedback and Return of Devices

If any device failure occurs prior to or during a procedure, discontinue use and contact your local representative and/or Reflow Medical, Inc. at complaints@reflowmedical.com or www.reflowmedical.com.

Additionally, for a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices): if, during the use of this device or as a result of its use, a serious incident has occurred, this must be reported to the EU member state.

Warranty: Manufacturer warrants that the Spex Shapeable Support Microcatheter 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 Shapeable Support Microcatheter. Damage to the Spex Shapeable Support Microcatheter 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 the Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against the Manufacturer.

Patents: This product is covered by U.S. Patent No. 10,799,255 and other pending applications, and foreign patents.

Basic UDI-DI: 856492005SupportCathKP

Electronic IFU: www.reflowmedical.com

Symbols:

LOT	Batch code		Non-pyrogenic
REF	Catalogue number		Keep dry
	Use by date		Keep away from sunlight
MD	Medical device		Consult instructions for use
	Manufacturer	1	Contains 1 unit (Contents: 1)
STERILE EO	Sterilized using ethylene oxide gas; single sterile barrier with protective packaging outside	UDI	Indicates a carrier that contains Unique Device Identifier information
	Single sterile barrier system with protective packaging outside	CE	Conformité Européenne
2 STERILIZE	Do not re-sterilize	EC REP	Authorized Representative in the European Community/European Union
2	Do not re-use	**UK RESPONSIBLE PERSON**:	Authorized Representative in the United Kingdom
	Do not use if package is damaged and consult instructions for use	CH REP	Authorized Representative in Switzerland
	Single sterile barrier system		Date of Manufacture

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