SURMODICS

INSTRUCTIONS FOR USE

Sublime™ 014|018|035 Microcatheter

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Explanation of possible symbols on product labeling:

Contents: One (1) Microcatheter

Sterilized Using EO

Ref Catalogue Number

Do Not Reuse

Non-pyrogenic

Caution, Consult Accompanying Documents

℞ only

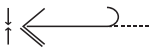
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Use by Date

Keep Dry

Do Not Use if Package is Damaged

Manufacturer



Maximum Guidewire Diameter

Keep Away From Sunlight/Heat

Lot Number

Working Length

Do Not Re-Sterilize

Date of Manufacture

Consult Instructions for Use

Maximum Injection Pressure

Angled Tip Configuration

Straight Tip Configuration

Medical Device

Single sterile barrier system with protective packaging inside

Country of Manufacture

Unique Device Identifier

SURMODICS™ SUBLIME™ MICROCATHETER INSTRUCTIONS FOR USE

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

The Surmodics™ Sublime™ Microcatheter is a single-use, over-the-wire microcatheter used to facilitate the placement and/or the exchange of guidewires in addition to providing a conduit for the delivery of saline solutions or diagnostic contrast agents into the peripheral vasculature.

The Sublime Microcatheter is a single lumen catheter shaft constructed of two layers of stainless steel braid encapsulated by two polymer layers. The proprietary braid technology is designed to offer maximum strength, kink-resistance, torque, and deliverability. The Sublime Microcatheter has a radiopaque marker located 2 mm from the distal tip to aid in placement and identification of the device under fluoroscopy. The distal 40 cm of the catheter is hydrophilic coated.

The Sublime Microcatheter is compatible with 0.014", 0.018" and 0.035" guidewire platforms and is available in working lengths of 65 cm, 90 cm, 135 cm, 150 cm and 200 cm. The working length and compatible guidewire diameter are indicated on the device hub/strain relief.

The Sublime Microcatheter is available in straight tip and angled tip configurations.

SPECIFICATIONS

Straight or **Angled** Tip Configuration

Model Number	Guidewire Compatibility (in)	Catheter Length (cm)	Catheter O.D. (mm)	Tip Configuration
SRA-MC14-STR065	.014	65	0.89	Straight
SRA-MC14-ANG065	.014	65	0.89	Angled
SRA-MC14-STR150	.014	150	0.89	Straight
SRA-MC14-ANG150	.014	150	0.89	Angled
SRA-MC14-STR200	.014	200	0.89	Straight
SRA-MC14-ANG200	.014	200	0.89	Angled

More model configurations continued on next page.

Model Number	Guidewire Compatibility (in)	Catheter Length (cm)	Catheter O.D. (mm)	Tip Configuration
SRA-MC18-STR065	.018	65	0.89	Straight
SRA-MC18-ANG065	.018	65	0.89	Angled
SRA-MC18-STR150	.018	150	0.89	Straight
SRA-MC18-ANG150	.018	150	0.89	Angled
SRA-MC18-STR200	.018	200	0.89	Straight
SRA-MC18-ANG200	.018	200	0.89	Angled
SRA-MC35-STR090	.035	90	1.40	Straight
SRA-MC35-ANG090	.035	90	1.40	Angled
SRA-MC35-STR135	.035	135	1.40	Straight
SRA-MC35-ANG135	.035	135	1.40	Angled
SRA-MC35-STR150	.035	150	1.40	Straight
SRA-MC35-ANG150	.035	150	1.40	Angled
SRA-MC35-STR200	.035	200	1.40	Straight
SRA-MC35-ANG200	.035	200	1.40	Angled

INDICATIONS FOR USE

The Sublime Microcatheter is intended to access the peripheral vasculature in order to facilitate the placement and/or the exchange of guidewires. The Sublime Microcatheter is also intended to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CONTRAINDICATIONS

None known.

WARNINGS

The catheter is provided sterile for single-use only; do not reuse.

Do not advance the catheter into a vessel with an effective diameter smaller than the diameter of the catheter.

Always advance the catheter over an already in-place guidewire. Do not use the catheter to cross a lesion ahead of the distal tip of the guidewire.

Do not advance, withdraw, or rotate device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, other device damage, or vessel injury.

Rotation of the catheter more than two (2) consecutive rotations without distal rotation may result in separation of the catheter, damage to the catheter, or vessel injury.

In the event of device failure, additional intervention may be necessary at the discretion of the operator.

Do not use the catheter in severely calcified or stenosed lesions.

PRECAUTIONS

Only use device in a sterile environment.

Inspect package seals for breaches in sterility, do not use the device if the packaging has been opened or damaged. An opened or damaged package could result in an unsterilized or damaged catheter.

Inspect the catheter prior to use for any damage, such as bends or kinks. Do not use a damaged catheter.

Do not perform high pressure injections exceeding the labeled maximum pressure.

Use the catheter by the expiration date specified on the device packaging.

Flush the catheter lumen with sterile, heparinized saline prior to use to remove all air from the catheter.

Utilize fluoroscopy when manipulating the catheter in the body.

This device has not been evaluated for use in the coronary or neurovasculature.

This device has not been evaluated for use with any pharmacological or therapeutic agents.

ADVERSE EVENTS

Potential adverse events that may be associated with the Sublime Microcatheter residual risks include, but are not limited to, the following:

- Systemic reaction/allergic reaction
- Infection
- Exposure to blood-borne pathogens
- Embolism
- Air Embolism
- Vessel Dissection
- Vessel Perforation
- Blood Loss
- Ischemia
- Patient Discomfort
- Delayed Procedure
- Vessel Spasm
- Death

CLINICAL PROCEDURE

The Sublime Microcatheter should be used by physicians trained on the procedures for which the device is intended. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient. All available data, including the patient's signs, symptoms and other diagnostic test results should be considered before determining a specific treatment plan.

PACKAGE CONTAINS

One (1) catheter per package.

ADDITIONAL ITEMS REQUIRED (NOT PROVIDED)

- Guide catheter or sheath with an inner diameter large enough to accommodate the outer diameter of the Sublime Microcatheter.
- Guidewire with a diameter appropriately sized to accommodate the Sublime Microcatheter (0.014", 0.018" 0.035").
- Sterile syringe (for flushing the microcatheter).
- Sterile heparinized saline (for flushing the microcatheter and lubricating the surface).

CATHETER PREPARATION

1. Carefully inspect the Sublime Microcatheter packaging for damage.
2. Utilizing aseptic technique, remove the Sublime Microcatheter from the packaging and transfer the catheter into the sterile field.
3. Using a sterile syringe, prepare the Sublime Microcatheter by injecting heparinized saline solution through the catheter.
4. Remove the Sublime Microcatheter from the hoop and inspect it for any damage, such as bends or kinks.
5. Soak the catheter prior to use in heparinized saline to lubricate the surface. Keep the surface of the catheter wet during use.

INSTRUCTIONS FOR USE

1. Backload the distal tip of the Sublime Microcatheter over the guidewire and into the hemostasis valve attached to the guiding catheter or sheath.
2. Carefully advance the Sublime Microcatheter to the target vessel under fluoroscopy.

   WARNING: Do not advance, withdraw, or rotate device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, other device damage, or vessel injury.

   WARNING: Rotation of the catheter more than two (2) consecutive rotations without distal rotation may result in separation of the catheter, damage to the catheter, or vessel injury.
3. If injection of contrast media is required, withdraw the guidewire and inject the contrast media from the catheter hub.

   PRECAUTION: Do not perform high pressure injections exceeding the labeled maximum pressure.

4. If a guidewire exchange is required, secure the microcatheter in place and exchange the guidewire with another of a compatible size.
5. The .014" and .018" Sublime Microcatheters are compatible for insertion through the .035" Sublime Microcatheter. If a smaller microcatheter is required, secure the guidewire and insert a second microcatheter through the .035" Sublime Microcatheter.

   PRECAUTION: The .014" and .018" Sublime Microcatheters have been designed to telescope through the .035" Sublime Microcatheter; however, device performance has not been evaluated in this configuration.
6. To remove the Sublime Microcatheter, secure the guidewire and withdraw the microcatheter.
7. Dispose the Sublime Microcatheter in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations.

REPORTING

Report any complications or device failures as soon as possible to the manufacturer, per the contact information provided on the device label.

STORAGE AND HANDLING

Store in a cool, dark, dry place. Avoid extended exposure to light and extreme temperatures. Upon removal from the packaging, inspect the product to ensure no damage has occurred.

WARRANTY INFORMATION

Surmodics hereby warrants to Buyer that the Products manufactured by Surmodics (i) are manufactured in accordance with good manufacturing practices, as required by the United States Food and Drug Administration; (ii) conform to manufacturer's specifications; (iii) are free from defects in materials and workmanship; and (iv) are not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act as amended. Surmodics' sole obligation in the event of a breach of the above warranties shall be, at Surmodics' option, to repair or replace such Product or to refund all payments made by Buyer to Surmodics for such Product.

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