SURMODICS

Sublime™ Radial Access

Surmodics™ Sublime™ Radial Access 018 RX PTA Dilatation Catheter

INSTRUCTIONS FOR USE

Sublime™ Radial Access 018 RX PTA Dilatation Catheter

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

Explanation of symbols on package labeling

Balloon Diameter

Balloon Length

Catalog number

Caution, consult the instructions for use for accompanying information

℞ only

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

Consult Instructions For Use

Contents: One (1) 018 Rx PTA Balloon Dilatation Catheter.

Date of Manufacture

Do not Exceed Rated Burst Pressure

Do Not Re-sterilize

Do Not ReUse

Do Not Use If Packaging Is Damaged

Effectlve Length

IP

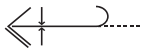
Inflation Pressure

Keep Dry

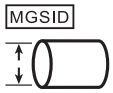
Keep Away From Heat

Lot Number

Manufacturer



Maximum Guidewire Diameter



Minimum Guide Sheath Inner Diameter

Nominal Pressure

Non-pyrogenic

Rated Burst Pressure

Sterilized Using EO

Use By Date

INSTRUCTIONS FOR USE

Sterile: Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque.

For single use only. Do not autoclave.

Carefully read all instructions prior to use, Failure to observe all warnings and precautions may result in complications.

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

1. Device Name

The device brand name is Surmodics™ Sublime™ Radial Access 018 RX PTA (Percutaneous Transluminal Angioplasty) Dilatation Catheter; the generic device name is .018" Rx PTA Balloon Dilatation Catheter.

2. Device Description

This device is a co-axial rapid exchange (Rx) catheter system designed for use with a 0.018" guidewire. The guidewire will pass through a lumen from an Rx access bond. The shaft of the Percutaneous Transluminal Angioplasty (PTA) balloon catheter contains a distal balloon and a luer hub on the proximal end. The balloon has two radiopaque markers that aid in the placement of the balloon within the stenosis. The clearance between the inner and outer catheter shaft acts as the passage for the inflation medium for balloon expansion. The balloon and catheter shaft are coated with a hydrophilic coating.

The proximal end of the RX catheter has a single standard luer hub connector for connection of an inflation device. The inflation device is used to inflate and deflate the balloon with a contrast medium. The 018 Rx PTA Balloon Catheter is to be provided sterile (via ethylene oxide, EtO) and is intended for single use only.

3. How Supplied

STERILE: This device is sterilized with ethylene oxide. Non-pyrogenic.

CONTENTS: One 018 Rx PTA Balloon Catheter.

STORAGE: Store in a dry, dark, cool place. Rotate inventory so that catheters are used prior to the expiration date on the package label.

4. Indications

The Sublime™ Radial Access 018 RX PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

5. Contraindications

No contraindications known for PTA procedure. The 018 Rx PTA Balloon Catheter is contraindicated for use in the coronary arteries and the neurovasculature.

6. Warnings

- This device is intended for single use only; do not reuse. Do not re-sterilize, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis in Percutaneous Transluminal Angioplasty (PTA).
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation.
- Do not advance or retract the device unless the balloon is fully deflated under vacuum.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure (RBP). Refer to the product label for device specific information. The RBP is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. To prevent over pressurization, use a pressure monitoring device.
- Inflation at a high rate may damage the balloon.
- Use only clinically recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Do not use with Lipiodol contrast media, or other such contrast media which incorporate the components of this agent.
- Do not use after the “Use by date” specified on the package.
- Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked; this may result in the shaft breaking. Instead prepare a new catheter.

7. Precautions

- A thorough understanding of the principles, clinical applications and risk associated with PTA is necessary before using this product.
- This device is not recommended for applications that may require inflation higher than those recommended for this catheter.
- Do not use if package is open or damaged.

- Prior to use, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- During the procedure, appropriate anti-coagulant therapy must be provided to the patient as needed. Anti-coagulant therapy should be continued for a period of time to be determined by the physician after the procedure.
- Consider the use of systemic heparinization. Flush all devices entering the vascular system with sterile heparinized saline or similar isotonic solution.
- The minimal acceptable sheath French size is indicated on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath than indicated on the label.
- Not intended for precise arterial blood pressure monitoring.
- Do not advance or withdraw the PTA catheter within the vasculature unless the catheter is pre-loaded onto a guide wire.
- Do not use for procedures other than those indicated in this Instructions for Use.

8. Adverse Events

Potential adverse events include but are not limited to:

- Thrombus
- Vessel dissection, perforation, rupture or spasm
- Death
- Abrupt closure
- Acute myocardial infarction
- Acute or subacute thrombosis
- Additional intervention required (major, moderate)
- Allergic reaction (device, contrast medium and medications)
- Amputation
- Angina
- Air embolization
- Aneurysm/Pseudoaneurysm
- Arteriovenous fistula
- Coma
- Embolization, which includes thromboembolization (arterial, pulmonary)

- Hematoma/Pseudoaneurysm at puncture site
- Hemorrhage, including bleeding at puncture site
- Hypotension/Hypertension
- Inflammation/Endarteritis
- Intimal tear
- Ischemia, including tissue ischemia, steal syndrome and necrosis
- Neurological events, including peripheral nerve injury and neuropathies
- Occlusion
- Organ failure (single, multiple)
- Paralysis
- Pyrogenic reaction
- Renal failure
- Seizures/Spasm
- Sepsis/Infection/Pyrogen reaction/Fever
- Shock
- Stroke
- Transient ischemic attack
- Weakness/Discomfort

9. Materials Required

- Introducer sheath(s) in the appropriate size and configuration for the selected vasculature. See product label for specific device compatibility.
- Guiding Catheter in the appropriate size and configuration to select the targeted artery (per 018 Rx PTA Catheter device Labeling) at the discretion of the physician.
- 2-3 syringes (10-20 cc)
- 0.018” (0.45mm) guide wire of appropriate length for the vasculature selected
- Contrast media diluted 1:1 with saline
- Inflation device with manometer
- Guidewire introducer
- Three-way stopcock
- Luer-lock syringe

10. Dilatation Catheter Preparation

a. Select the balloon catheter and confirm that the labelling matches the desired size, and the product use by date is not expired.

b. The catheter is packaged in a protective hoop; carefully remove the catheter from the package.

c. Remove the balloon protector (sheath) from the balloon and remove packaging mandrel from tip of catheter.

d. The balloon catheter in deflated position contains tiny air bubbles that should be purged prior to inserting the balloon catheter. To do this, connect a three-way stopcock to the inflation port fitting on the dilatation catheter. Connect a luer-lock syringe, partly filled with sterile normal saline and contrast medium, to the stopcock. Orient the dilatation catheter with the distal tip and the balloon pointing in a downward vertical position. Pull back the plunger and aspirate for 15 seconds until the air is completely evacuated. Close the three-way stopcock. Release the plunger. Disconnect the syringe and evacuate the collected air. Reconnect the syringe and repeat the operation a couple of times until the balloon is completely free of air bubbles.

e. Attach the flushing needle to a syringe filled with sterile saline. Carefully insert the flushing needle into the Rx port. Flush the wire lumen with sterile saline.

f. Prior to inserting the catheter, activate the coating by immersing the catheter in normal saline for approximately 30-60 seconds, or gently wiping down the catheter shaft with a gauze sponge saturated in normal saline.

CAUTION: Do not wipe down the catheter surface with dry gauze.

11. Inflation Device Connection to Catheter

a. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium.

b. With the stopcock in the closed position, disconnect the syringe used in preparation applying a slight positive pressure. A meniscus of contrast medium will appear in the stopcock port when the syringe is removed. Verify that a meniscus of contrast medium is evident in both the stopcock port (hub) and the inflation device connection. Couple the inflation device to the stopcock port of the balloon dilatation catheter.

12. Use of Balloon Angioplasty Catheter

a. Insert a guide wire through the hemostatic valve following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the introducer sheath. When complete, withdraw the guide wire introducer, if used.

b. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

c. Remove the torque device, wipe down the guide wire with saline using gauze, and back load the distal tip of the dilatation catheter onto the guidewire

NOTE: To avoid kinking, advance the dilatation catheter slowly, in small increments until the proximal end of the guidewire emerges from the catheter.

NOTE: To preserve the folded balloon shape during insertion and all catheter manipulation, maintain a vacuum on the inflation lumen.

d. Advance the catheter through the hemostatic valve slowly, while the balloon is fully deflated. It should be observed that the hemostatic valve is only closed as much to prevent blood return yet permitting easy movements of the dilatation catheter If resistance is encountered, do not advance the catheter through the adapter.

e. Under fluoroscopy, use the balloon radiopaque markers to position the balloon within the lesion to be dilated and inflate the balloon to the appropriate pressure (refer to balloon compliance table).

f. Repeat preparation and use of balloon catheter (maximum 10 times) until the desired result is achieved. Maintain negative pressure on the balloon between inflations.

g. Completely deflate the balloon catheter by applying negative pressure for a minimum of 120 seconds or until no contrast medium is visible in balloon or is emptying into inflation syringe. Withdraw the deflated dilatation catheter from the guiding catheter /introducer sheath, through the hemostatic valve and remove the balloon catheter.

CAUTION: If strong resistance is met during advancement or withdrawal of the catheter, discontinue movement and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, withdraw the entire system.

CAUTION: Do not exceed the rated burst pressure. Higher pressures may damage the balloon or catheter or over distend the selected vessel.

CAUTION: If the balloon cannot be withdrawn through the sheath, discontinue movement and determine the cause of resistance (with the aid of fluoroscopy) before proceeding. Ensure that you are using the correct sheath size and that the balloon is fully deflated.

13. References

The physician should consult current literature on current medical practice on balloon dilatation.

14. Warranty

CREAGH MEDICAL Ireland warrants that reasonable care has been used in the design and manufacture of this device. The 018 Rx PTA Catheter Balloon has been manufactured under carefully controlled conditions. As CREAGH MEDICAL Ireland has no control over the conditions under which this product is used, such as, device handling, patient diagnosis; this warranty is limited to the replacement of this instrument. For the avoidance of doubt CREAGH MEDICAL is not liable for any consequential loss arising from the manner in which the product is used.

This warranty is exclusive and in lieu of all other warranties either written, oral or implied. No other person may change any of the above or assume any additional liability in relation to this device.

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