



SLEEK® OTW

With SiLX²® coating

PTA Balloon Catheter Product Family

100000017142.1

Recommended Instructions for Use

Caution: This device should be used only by physicians trained in Percutaneous Transluminal Angioplasty (PTA).

This device is sterilized by Ethylene Oxide and intended for single patient use.

Manufactured By



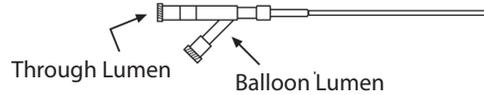
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I. **DESCRIPTION:**

- The **SLEEK® OTW** Percutaneous Transluminal Angioplasty (PTA) Peripheral Catheter Family are a non-reusable semi-compliant coaxial design catheter with a balloon mounted on its distal tip.
- The hub/"Y" connector consists of a through lumen, allowing the catheter to track over a guidewire, and a balloon port, used to inflate the balloon (See diagram below).



- The catheter shaft is small beneath the balloon to achieve low profile. The distal tip is further tapered to accept the appropriate guidewire.



- Platinum iridium marker bands allow the balloon to be located under fluoroscopy. There are two marker bands denoting the ends of the working surface on all sizes except the 1.25mm by 15mm and 1.5mm by 15mm balloons, where a single marker band is centered on the working surface
- A 0.014" (0.356 mm) guidewire is recommended for use with the **SLEEK® OTW** catheter.

Balloon Characteristics

- Please check the package label for the rated burst pressure. It is important that the balloon not be inflated beyond the rated burst pressure.

Compliance charts are provided with each product. Please note that balloon diameters may vary within manufacturing tolerances. All inflations should be viewed under fluoroscopy.

The **SLEEK® OTW** balloons reach their nominal diameter at 6 atm.

Pressures in excess of rated burst pressure may cause the balloon to burst.

II. **INDICATIONS:**

The **SLEEK® OTW** catheters are recommended for balloon dilatation of the femoral, popliteal and infra-popliteal arteries. Any use for procedures other than those indicated in these instructions is not recommended.

These catheters are not designed to be used in the coronary arteries.

III. **WARNINGS:**

- This device is intended for single patient use. Do NOT resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross-contamination.
- 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.
- **CAUTION:** Do not exceed the rated burst pressure. A syringe with pressure gauge is recommended to monitor pressure. Pressure in excess of the rated burst pressure can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath.
- Use a 20 ml or larger syringe for inflation.
- Use the catheter prior to the "Use By" date specified on the package.
- Do not advance the guidewire, balloon dilation catheter, or any component if resistance is met, without first determining the cause and taking remedial action.
- This catheter is not recommended for pressure measurement or fluid injection.

- In PTA, the dilated balloon should not markedly exceed the diameter of the vessel lying just proximal to the stenosis.
- This catheter is for one time use only. Do not reuse or resterilize.

IV. PRECAUTIONS:

- Dilation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- The sealed catheter container should be inspected prior to opening. If the seal is broken or the container has been damaged or wet, sterility cannot be assured.
- Careful attention must be paid to the maintenance of tight catheter connections to avoid the introduction of air into the system.
- If resistance is felt upon removal, then the balloon, guidewire and the sheath/guide catheter should be removed together as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath/guide catheter as a unit and withdrawing both together, using a gently twisting motion combined with traction.
- Before removing catheter from sheath/guide catheter it is very important that the balloon is completely deflated.
- Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.

V. ADVERSE EFFECTS:

Possible adverse effects include, but are not limited to, the following:

- Vessel perforation
- Vessel spasm
- Haemorrhage
- Haematoma
- Hypotension
- Pain and tenderness
- Arrhythmias
- Sepsis/infection
- Systemic embolization
- Endocarditis
- Short-term hemodynamic deterioration
- Death
- Vascular thrombosis
- Drug reactions, allergic reaction to contrast media.
- Pyrogenic reaction
- Arteriovenous fistula
- Thromboembolic episodes
- Vessel dissection
- Potential balloon separation following rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces.

NOTE: Published scientific literature has described the potential for general PTA balloons to burst circumferentially, possible due to tight focal strictures. In any instance of a balloon rupture while in use, it is recommended that a sheath be placed over the ruptured balloon prior to withdrawing through the entry site. For specific technique, refer to: Tegtmeier, Charles J., M.D. & Bexirdijan Diran R., M.D. "Removing the Stuck, Ruptured Angioplasty Balloon Catheter". Radiology, Volume 139, 231-232, April 1981.

VI. INSPECTION AND PREPARATION

NOTE: A 0.014" (0.356 mm) guidewire must be inserted in the SLEEK® OTW catheter across the balloon during any inflation of the balloon.

- Remove the balloon sleeve by first withdrawing the shipping mandrel slightly and then slowly removing the sleeve while holding the catheter as close to the balloon as possible.
- If any resistance is felt, or if any stretching of the catheter is observed while removing the balloon sleeve, the product should not be used.
- The catheter should then be inspected for bends, kinks or stretched portions.
- Prepare a mixture of contrast medium and normal saline as per normal procedure. (Recommended 25%/75%)
- Attach a stopcock and a 20 ml syringe half filled with the contrast solution to the balloon port.
- Point the syringe nozzle downward and aspirate until all air is removed from the balloon.
- Turn the stopcock off and maintain the vacuum in the balloon.
- Purge the catheter through lumen thoroughly.

VII. PROCEDURE:

Insertion Procedure:

Enter the vessel percutaneously using the standard Seldinger technique over the appropriate guidewire for the size catheter being used.

Advance the catheter across the lesion with fluoroscopic guidance using accepted percutaneous transluminal angioplasty technique. In most patients, the balloon should meet with minimal resistance to insertion.

NOTE: Do not inflate the balloon or advance the catheter unless the guidewire is in place.

VIII. Deflation and Withdrawal

- Deflate the balloon by drawing a vacuum with a 20 ml or larger syringe.
NOTE: The larger the syringe diameter, the greater the suction that is applied. For maximum deflation a 50 cc syringe is recommended.
- Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady, counterclockwise motion. If resistance is felt upon removal then the balloon and the sheath should be removed together as a unit under fluoroscopic guidance, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.
- Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

SYMBOLS:			
	USE BY		DO NOT REUSE
LOT	LOT NUMBER		SEE INSTRUCTIONS FOR USE
STERILE EO	STERILIZED BY ETHYLENE OXIDE GAS	 	DO NOT USE OPEN OR DAMAGED PACKAGES
	CONTENT: ONE (1)		NONPYROGENIC
	BALLOON DIAMETER		MANUFACTURER
	RECOMMENDED INTRODUCER		PRESCRIPTION ONLY
	PRESSURE NOMINAL: NOMINAL PRESSURE, RATED: RATED PRESSURE		STORE IN A COOL, DARK, DRY PLACE

IX. PRODUCT WARRANTY

We warrant that at the time of manufacture, these products were prepared and tested to verify that they are true to labelled claims. Due to biological differences in individuals, no product is 100% effective under all circumstances. In addition, because we have no control of the condition under which these products are used, diagnosis of the patient, the method of use or administration, and handling of the products after they leave our possession, we do not warrant for either a good effect or against ill effect following/during the use of the product. THE FOREGOING WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES EITHER WRITTEN, ORAL OR IMPLIED (INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PURPOSE). No representative of the company may change any of the foregoing and the buyer accepts the product subject to all terms hereof.

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