Skinny PTA Balloon Dilatation Catheter

SC OTW 0.018″

1.0 Device Description

The Skinny is an Over the Wire (OTW) peripheral balloon catheter, specially designed for Percutaneous Transluminal Angioplasty (PTA). It is a coaxial double lumen catheter with a balloon located near the distal tip. One lumen is used for inflation of the balloon and accessed via the side leg port. The second lumen, starting at the straight entry port, allows access to the distal tip of the catheter for guide wire insertion (max. 0.018″/0.46mm). The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. The balloon is dilated using the side leg port, at which the balloon material expands to a known diameter at specific pressure. The working pressure range for the balloon is between the nominal size pressure and the rated burst pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

- Device performance characteristics:
  Nominal Pressure (NP): 6 atm
  Rated Burst Pressure (RBP): 14 atm

2.0 Clinical benefit

The intended clinical benefit is to restore the patency of indicated vessel lumen.
The indicated vessels include iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and native or synthetic arteriovenous dialysis fistulae and post-stent dilation. The clinical benefits of treatment of symptomatic Peripheral Artery Disease are:
- to inhibit the progression of PAD
- to reduce cardiac and cerebrovascular events
- to reduce the risk of peripheral arterial events in an aneurysm
- to reduce pain
- to improve mobility/walking performance and quality of life

3.0 How supplied

- Contents:
  - One (1) Balloon Dilatation Catheter
  - One (1) Re-wrap Tool
- Sterile sterilized with ethylene oxide gas. Non-pyrogenic.
- Storage Store in a dry, dark, cool place

4.0 Intended use

The Skinny Balloon Dilatation Catheter is intended for dilatation of stenosis and post-deployed stent in the peripheral vasculature.

5.0 Indications

- The balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- This device is also indicated for stent dilatation post-deployment in the peripheral vasculature.

6.0 Intended Users

Intended users are the competent physicians who have the training of PTA Balloon catheter management.

7.0 Intended Patient Population

Patients with symptomatic ischemic peripheral artery disease needing PTA during treatment.

8.0 Contraindications

- None known for Percutaneous Transluminal Angioplasty (PTA).
- The Skinny PTA Catheter is contraindicated for use in the coronary arteries or the neurovasculature. It is also contraindicated when unable to cross the target lesion with a guidewire.

9.0 Warnings

- The Skinny PTA Dilatation Catheter is not intended for use in the coronary arteries
- This device should only be used by physicians who are experienced and have a thorough understanding of the clinical and technical aspects of PTA. For single patient, single procedure use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increase risk of inappropriate resterilization and cross contamination. Catheters and accessories should be discarded after one procedure. They are extremely difficult to clean adequately after being exposed to biological materials and may cause adverse patient reactions if reused. Cleaning these products may alter their structural properties. Accordingly,CNOVATE Medical will not be responsible for any direct, incidental or consequential damages resulting from reuse of the catheter.
- Do NOT use the catheter if its package has been opened or damaged
- 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
- 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 catheter 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. Use of a pressure-monitoring device is recommended to prevent over-pressurization.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked as this may result in the shaft breaking. Instead, prepare a new catheter.
- Use the catheter prior to the "Use by" date (Expiration Date) specified on the package

10.0 Precautions

- The catheter system should be used only by physicians trained in the performance of percutaneous transluminal angioplasty.
- Appropriate anticoagulation, antiplatelet and vasodilator therapy should be administered to the patient
- Do not use if inner package is damaged or opened.
- Use prior to the expiry date.
- Carefully inspect the catheter prior to use to verify that the catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used.
- Precautions to prevent or reduce clotting should be taken when any catheter is used.
- Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution via the guide-wire access port prior to use. Consider the use of systemic heparinization.
- When the system is introduced into the vascular system, it should be manipulated only under high quality fluoroscopy.
- The Skinny PTA Catheter must always be introduced, moved and or withdrawn over a guide wire (max. 0.018″/0.46mm).
- Never attempt to move the guide wire when the balloon is inflated.
- Do not advance the Skinny PTA Catheter against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
- The minimal acceptable guiding catheter or introducer sheath French size is printed on the package label. Do not attempt to pass the Skinny PTA Catheter through a smaller size guiding catheter or sheath introducer than indicated on the label.
- The size of the inflated balloon should be selected not to exceed the diameter of the artery immediately distal or proximal to the stenosis.
- Inflation in excess of the rated burst pressure may cause the balloon to rupture.
- Not intended for pressure monitoring or injection of contrast media or other fluids
- This product may become a biological hazard after use. Dispose and discard in accordance with accepted medical practice and applicable laws and regulations.

Caution: Larger models of Skinny PTA balloon catheter may exhibit slower deflation times particularly on long catheter shafts.

11.0 Adverse Events

Complications associated with the use of the Skinny PTA catheter are similar to those associated with standard PTA procedures. Possible adverse effects include, but are not limited to the following

Puncture related
- Local hematoma
- Local hemorrhage
- Local or distal thromboembolic episodes
- Thrombosis
- Arterio-venous fistula
- Pseudoaneurysm
- Local infections

Dilatation related
- Acute reocclusion necessitating surgical intervention
- Dissection in the dilated artery wall
- Perforation of the artery wall
- Prolonged spasms
- Restenosis of the dilated artery
- Total occlusion of the peripheral artery

Angiography related
- Allergic reaction to contrast medium
- Arrhythmias
- Death
- Drug reactions
- Endocarditis
- Hypotension
- Pain and tenderness
- Sepsis/infection
- Short-term hemodynamic deterioration
- Systemic embolization

Notice: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

12.0 Materials to be used in combination with a balloon catheter include:

- Guiding catheter(s) and / or introducer sheath(s) in the appropriate size and configuration for the selected vasculature (if applicable). See product label for specific device compatibility.
- Suitable guide wire, see product label for specific device compatibility.
- 20cc syringe for balloon preparation
- 10cc or smaller syringe for manual dye injections
- Appropriate inflation medium (e.g. 50:50 sterile mixture of a contrast medium and saline)
- Pressure-indicating inflation device
- Hemostasis valve

13.0 Preparation for Use

1. Select an appropriate balloon catheter for the target vessel
2. Remove the device from the sterile packaging
3. Prior to use, examine all devices carefully for defects. Examine the dilatation catheter for bends, kinks, or any other damage. Do NOT use any defective device.
4. Remove the protective balloon stylet and balloon protector
5. Balloon Purging, purge air from the catheter using a 20cc syringe filled with 2 to 3ml of the inflation medium with the balloon catheter pointing downward. Attach an inflation device to the balloon inflation port. Ensure that a meniscus of contrast medium is evident in both the catheter luer connector and the inflation device. Apply negative pressure with the inflation device. Do NOT attempt Pre-Inflation technique to purge the balloon lumen.

Caution: All air shall be removed from the balloon and displaced with contrast medium prior to inserting into the body. Otherwise complications may occur.

Instructions for Use

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14.0 Instruction for Use

- Insertion Technique
  - Place the guiding catheter or introducer sheath, with a hemostatic valve attached, in the orifice of the target artery
  - Advance the guide wire through the guiding catheter or introducer sheath to reach and cross the target lesion. Advance the distal tip of the balloon catheter over the proximal end of the guide wire. Ensure that the guide wire exits the balloon catheter through the guide wire exit location
  - The hemostasis valve should be gradually tightened to control back flow. Excessive valve tightening may affect balloon inflation/deflation time as well as movement of the guide wire.
  - Track the balloon catheter over the wire to cross the lesion using the radiopaque marker(s) to locate the balloon across the lesion
- Balloon Inflation
  - Inflate the balloon to dilate the lesion using standard PTA techniques
  - After each subsequent inflation, the distal blood flow should be assessed
  - If a significant stenosis persists, successive inflations may be required to resolve the stenosis. Do NOT exceed the rated burst pressure (see labeling)
  - Confirm the results with fluoroscopy
- Removing the Catheter
  - Apply negative pressure to the inflation device and confirm that the balloon is fully deflated
  - Withdraw the balloon catheter into the guiding catheter or introducer sheath while preserving guide wire position
  - After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile normal saline
  - Inspect the balloon catheter integrity
  - If reinserting the same balloon dilation catheter, flush the guide wire lumen of the balloon dilatation catheter using the flushing needle as described in the "Preparation for Use" section. Prior to reinsertion, the balloon dilatation catheter should be wiped clean with gauze soaked with sterile normal saline. The balloon may be refolded using the rewrap tool as described in the Re-Fold Tool as described in the "Re-Fold Tool" Section.
- Re-Fold Tool
  - This is an accessory component that allows the balloon to be rewrapped if required
    - Deflate the balloon by applying negative pressure to the inflation device and maintain under vacuum
    - Visually inspect the balloon to confirm that it is fully deflated
    - Remove the Re-fold Tool from Compliance Card
    - Load the non-flared end of the re-fold tool onto the stylet
    - Carefully load the stylet back through the distal tip of the catheter and past the proximal end of the balloon
    - While holding the catheter just proximal to the balloon, push the re-fold device over the balloon in a gentle twisting motion until the entire balloon is covered
    - Gently remove the re-fold device/stylet assembly
    - Inspect the balloon for any potential damage. Discard the balloon catheter if there is any visual damage present on the balloon.
- Disposal
  – After use, dispose and discard the product and packaging in accordance with hospital, administrative and/or local government policy.

15.0 Reference

Physicians should consult recent literature on current medical practice on balloon dilatation, such as published by American College of Cardiology/American Heart Association.

16.0 Disclaimer of Warranty

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Explanation of Symbols

Description	Symbol
Catalog Number	REF
Lot Number	LOT
Balloon Diameter	BALLOON
Balloon Length	BALLOON
Sterilized Using Ethylene Oxide	STERILE EO
Single Sterile Barrier System With Protective Packaging Inside	
Use-by date	
Do not re-use	
Caution	
Consult instructions for use or electronic instructions for use on company website	
Do Not Resterilize	
Guide wire (Maximum)	
Guiding Catheter (minimum)	
Introducer Sheath (minimum)	
Do not use if package damaged	
Contents (numeral represents quantity of units inside)	
Manufacturer	
CE Mark	CE 2797
Medical Device	MD
Unique Device Identifier	UDI
Date Of Manufacture	

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