Tiche PTA Balloon Dilatation Catheter OTW 0.035'' Instructions for Use ENGLISH

RX ONLY

Caution: Federal Law restricts this device to sale by or on the order of a physician.

1.0 Device Description

The Tiche is an Over the Wire (OTW) peripheral balloon catheter, specially designed for Percutaneous Transluminal Angioplasty (PTA). The device features a low-profile balloon and tip. The balloon is non- compliant. The balloon dilatation catheter features a dual lumen shaft ending in a Y-hub manifold with luer lock fittings. 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. 0.035"/0.89mm). The guide wire lumen is silicone coated from the tip to the entry port. 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.

Clinical benefit

The intended clinical benefit of the Tiche is to restore the patency of indicated vessel lumen. These indicated vessels include iliac, femoral, popliteal, tibial, peroneal, subclavian, renal arteries, and native or synthetic arteriovenous dialysis fistulae and post stent dilation. The clinical benefit of treatment of symptomatic Peripheral Artery Disease are:

- to inhibit the progression of Peripheral Artery Disease
- 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

Intended patient population

Patients with symptomatic ischemic peripheral artery disease.

Device performance characteristics

- The working lengths of the balloon catheter are 40cm, 75cm, 120cm, 135cm.
- Rated Burst Pressure is 24 atm (for Φ 3.0-5.0×20-200, Φ 6.0×20-100); 22atm (Φ 6.0×120-200); 20 atm (for Φ 7.0-8.0×20-100); 18 atm (for Φ 7.0-8.0×120-200, Φ 9.0×20-80); 14 atm (for Φ 10.0-12.0×20-80).
- Nominal pressure is 12 atm (for Φ 3.0-9.0) and 10 atm (for Φ10.0-12.0).
- The catheter is compatible with standard 0.035inch (0.89mm) guide wire.

2.0 How supplied

- Contents:
  - One (1) Balloon Dilatation Catheter
- Sterile sterilized with ethylene oxide gas. Non-pyrogenic.
- Storage Keep away from sunlight, keep dry, and store at room temperature.

3.0 Intended use

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

4.0 Indications

- The device is indicated for the treatment of obstructive lesions in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian 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.

5.0 Contraindications

- The Tiche PTA Catheter is contraindicated for use in the coronary arteries or the neuro vasculature. It is also contraindicated when unable to cross the target lesion with a guidewire.

6.0 Warnings

- The Tiche PTA Dilatation Catheter is not intended for use in the coronary arteries.
- Do NOT use the catheter if its sterile package has been opened or damaged.
- 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 resterilise and/or reuse it, as this can potentially result in compromised device performance and increase risk of inappropriate resterilisation 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, BrosMed Medical will not be responsible for any direct, incidental or consequential damages resulting from reuse of the catheter.
- 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.
- Do 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 appropriate 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 label.

7.0 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 sterile 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 Tiche PTA Catheter must always be introduced, moved and or withdrawn over a guide wire (max.0.035"/0.89 mm).
- Never attempt to move the guide wire when the balloon is inflated.
- Do not advance the Tiche 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 Tiche 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.
- The Tiche is not intended for pressure monitoring or injection of contrast media or other fluids.

8.0 Adverse Events

Complications associated with the use of the Tiche 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.

9.0 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.

10.0 Preparation for Use

- Select an appropriate balloon catheter for the target vessel.
- Remove the device from the sterile packaging.
- 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.
- Remove the protective balloon protector.
- 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.
- Prepare the wire lumen of the catheter by attaching a syringe to the wire port and flushing the lumen with approximately 5 ml sterile saline solution.

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

11.0 Instruction for Use

- Insertion Technique
  - Place the guiding catheter or introducer sheath, with a hemostasis 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 labelling).
  - 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 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.
- Disposal
  - After use, dispose and discard the product and packaging in accordance with hospital, administrative and/or local government policy.

12.0 Reference

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

13.0 Disclaimer of Warranty

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Explanation of Symbols

Description	Symbol
Catalogue Number	REF
Batch Code	LOT
Balloon Diameter	BALLOON ⌀
Balloon Length	BALLOON
Single Sterile Barrier System With Protective Packaging Inside	
Sterilized Using Ethylene Oxide	STERILE EO
Use-by Date	
Do Not Re-use	
Caution	
Consult instructions for use or consult electronic instructions for use on company website	
Do Not Resterilise	
Recommended Guide wire (Maximum)	GW R
Recommended Introducer Sheath (minimum)	IS R
Do not use if package damaged	
Contents (numeral represents quantity of units inside)	1
Date of Manufacture	
Manufacturer	
For Prescription Use Only	Rx ONLY
Medical Device	MD
Unique Device Identifier	UDI
Authorised representative in the European Community	EC REP
CE Mark	CE 2797
Keep away from sunlight	
Keep dry	

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