Boston Scientific

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Gladiator™

OVER-THE-WIRE

PTA Balloon Dilatation Catheter

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Gladiator Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is an over-the-wire (OTW), high performance balloon catheter for peripheral indications. The device features a low profile balloon and tip; the balloon is non-compliant. The catheter is compatible with 0.035 in (0.89 mm) guidewires.

The Gladiator PTA Balloon Dilatation Catheter features a dual lumen shaft ending in a Y-connector manifold with luer lock fittings. The manifold port marked "WIRE" is used to pass the catheter over 0.035 in (0.89 mm) guidewires. The second port marked "BALLOON" communicates with the balloon and is used to inflate and deflate the balloon during the procedure. Two radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the balloon. A lubricious coating is applied from the distal tip to just proximal of the balloon. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the inflation site. The working lengths of the balloon catheter are 40 cm and 75 cm.

Contents

1 Gladiator PTA Balloon Dilatation Catheter

INTENDED USE/INDICATIONS FOR USE

The Gladiator Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) 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.

The Gladiator Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

CONTRAINDICATIONS

None Known.

WARNINGS

To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length 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 felt during manipulation, determine the cause of the resistance before proceeding.

Do not exceed the rated balloon burst pressure. The rated burst pressure is based on *in vitro* testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure.

Use only the appropriate balloon inflation medium (typically a 50/50 mixture by volume of contrast medium and sterile saline). Never use air or any gaseous medium to inflate the balloon.

Never advance the dilatation catheter beyond the end of the guidewire or without the aid of a guidewire in order to avoid potential vessel trauma.

The Gladiator PTA balloon catheter is not for use in the coronary arteries. Any use for procedures other than those indicated in these instructions is not recommended.

PRECAUTIONS

Care should be taken to control the position of the introducer/guide sheath tip during manipulation of the balloon catheter.

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.

Use the catheter prior to the "Use By" date specified on the package.

The Gladiator PTA Balloon Dilatation Catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty.

The Gladiator PTA Balloon Dilatation Catheter should be used with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these inflation sites.

The Gladiator PTA Balloon Dilatation Catheters are not intended for injection of contrast medium.

To prevent over pressurization, use of a pressure monitoring device is recommended.

If resistance is felt during post procedure withdrawal of the catheter, it is recommended to extract the entire system with the introducer/guide sheath.

Precautions to prevent or reduce clotting should be taken when any catheter is used:

- Consider systemic anticoagulation.
- Flush or rinse all products with sterile saline or a similar solution prior to use.

To minimize the possible introduction of air into the system, it is imperative that prior to proceeding, careful attention is paid to the maintenance of tight catheter connections and thorough aspiration and flushing of the system.

Do not advance any portion of the dilatation catheter system against significant resistance. The cause of resistance should be determined via fluoroscopy before proceeding.

Do not pull the balloon protector proximally on to the catheter shaft.

ADVERSE EVENTS

The complications that may result from a balloon dilatation procedure include, but are not limited to:

- Allergic reaction (device, contrast medium and medications)
- Arteriovenous fistula
- Embolization (air, device, plaque, etc.)
- Hematoma
- Hemorrhage, including bleeding at puncture site
- Pseudoaneurysm
- Sepsis/infection
- Thromboembolic episodes
- Vessel injury, e.g. dissection, perforation, rupture
- Vessel occlusion
- Vessel spasm

HOW SUPPLIED

The Gladiator PTA Balloon Dilatation Catheters are supplied STERILE using an ethylene oxide (EO) process.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling & Storage

Store in a cool, dry, dark place.

Do not store catheters where they are directly exposed to organic solvents or ionizing radiation.

Rotate inventory so that the catheters and other dated products are used prior to the "Use By" date.

OPERATIONAL INSTRUCTIONS

Materials typically required for PTA with the Gladiator PTA Balloon Dilatation Catheter include:

- Guidewire(s) of appropriate diameter and length
- Appropriate introducer/guide sheath and dilator set
- Vial of contrast medium
- Vial of sterile saline solution
- Inflation device with manometer
- Luer-lock syringe
- Three-way stopcock

Note: Select guidewire and sheath as appropriate per product label.

Inspection Prior to Use

Prior to use, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged. Verify that the catheter size is suitable for the specific procedure for which it is intended. Do not use if sterile package is damaged.

Note: Do not continue to use the catheter if damage occurs or sterility is compromised.

Inflation Device Preparation

1. Prepare the inflation device according to the manufacturer's instructions.
2. Purge the system of air.

Balloon Catheter Preparation

1. Remove catheter from carrier tube. Use care when removing the catheter to avoid damage. Verify the balloon size and catheter length are suitable for the procedure.
2. Remove the balloon protector by holding the balloon catheter just proximal to the balloon. With the other hand, gently grasp the proximal section of the balloon protector and remove distally.

Caution: If unusual resistance is felt during removal of the balloon protector, do not use the catheter and replace with another. Follow the product returns procedure for unused product.

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3. Prepare the balloon catheter for purging. Select a syringe or inflation device with a 10 ml or larger capacity and fill approximately half of it with the appropriate balloon inflation medium (typically a 50/50 mixture by volume of contrast medium and sterile saline solution). Never use air or any gaseous medium to inflate the balloon.
4. Connect a three-way stopcock to the "BALLOON" port fitting on the balloon catheter. Connect the syringe to the stopcock. Flush through the stopcock.
5. Hold the syringe with the nozzle pointing downward and aspirate for 15-20 seconds. Release the plunger.
6. Remove the syringe and evacuate all air from the barrel.
7. To prevent the possibility of air embolization, repeat steps 5 and 6 two more times. If air bubbles persist, discard the device.
8. 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.
9. If device is not to be used immediately, remove syringe and immerse catheter in a sterile saline bath.

Inflation Device Connection to Catheter

1. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml of contrast medium.
2. Attach inflation device/syringe to stopcock; attach to inflation port.
3. Orient system vertically with tip down.
4. Open stopcock to balloon catheter; apply negative pressure for 15-20 seconds.
5. Close stopcock to balloon catheter; purge inflation device/syringe of all air.
6. Repeat steps 3-5 until all air is expelled. If bubbles persist, do not use device.
7. If a syringe was used, attach a prepared inflation device to stopcock.
8. Open stopcock to balloon catheter.

Use of the Gladiator™ PTA Balloon Dilatation Catheter

1. Backload the distal tip of the dilatation catheter over the pre-positioned guidewire ensuring the guidewire exits the "WIRE" port. When loading or exchanging the catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

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

2. Advance the dilatation catheter through the hemostatic valve slowly, while the balloon is fully deflated. If resistance is encountered, do not advance the dilatation catheter through the valve. If using a Touhy Borst type valve, care should be taken not to over-tighten the hemostatic valve around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.
3. Position the balloon relative to the site of inflation. If the desired site of inflation cannot be crossed with the desired dilatation catheter, use a smaller diameter balloon to cross and pre-dilate the site to facilitate passage of a more appropriately sized dilatation catheter. Inflate the balloon to the appropriate pressure (reference balloon compliance Table 1). If difficulty is experienced during balloon inflation, do not continue; remove the catheter. Repeat inflation of balloon (maximum 10 times) until the desired result is achieved. It is strongly recommended that negative pressure is maintained on the balloon between inflations.
4. Apply negative pressure to fully deflate the balloon. Confirm that the balloon is fully deflated under fluoroscopy.
5. Withdraw the balloon catheter until it is clear of the inflation site. Maintain guidewire position. Perform angiography to confirm dilatation.
6. While maintaining negative pressure, withdraw the deflated dilatation catheter from the introducer/guide sheath through the hemostatic valve. If resistance is felt during withdrawal of the dilatation catheter, it is recommended to extract the entire system with the introducer/guide sheath.

Note: If re-insertion of the deflated device is required, ensure all fluid has been evacuated from the balloon (apply vacuum again if necessary), ensure the stopcock is open and there is no syringe/inflation device attached to the catheter hub during re-insertion.
Caution: If resistance is encountered do not re-insert, select a new Gladiator product. On re-insertion use product as per "Use of the Gladiator PTA Balloon Dilatation Catheter" section herein.

Table 1. Typical Gladiator PTA Balloon Dilatation Catheter Compliance

	Balloon Diameter								
Pressure atm - kPa	**3 mm**	**4 mm**	**5 mm**	**6 mm**	**7 mm**	**8 mm**	**9 mm**	**10 mm**	**12 mm**
8 - 814							9.01*	9.97*	
10 - 1014	3.06*	3.98*	5.04*	6.03*	7.02*	8.05*	9.14	10.12	11.98*
12 - 1213	3.10	4.03	5.10	6.09	7.11	8.17	9.25	10.24	12.12
14 - 1420	3.13	4.08	5.13	6.16	7.18	8.25	9.34	10.34**	12.25**
16 - 1620	3.16	4.12	5.21	6.22	7.24	8.32	9.42		
18 - 1827	3.18	4.15	5.25	6.26	7.30	8.38	9.50**		
20 - 2027	3.21	4.18	5.29	6.31	7.32**	8.46**			
22 - 2227	3.23	4.21	5.32	6.35					
24 - 2434	3.25**	4.24**	5.36**	6.36**					

*Nominal pressure
**Rated Burst Pressure

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

EC REP EU Authorized Representative

Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

AUS Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
USA
USA Customer Service 888-272-1001

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Recyclable Package

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