PTA Balloon Dilatation Catheter

Gladiator™ Elite

OVER-THE-WIRE

**INTENDED USE/INDICATIONS**

The Gladiator Elite 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 Elite 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 over 0.035 in (0.89 mm) guidewires.

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

To prevent overpressurization, use of a pressure monitoring device is recommended. If resistance is felt during balloon inflation, it is recommended to extract the entire system with the introducer/guide sheath.

**PREREQUISITES**

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. The catheter prior to the “Use By” date specified on the package. The Gladiator Elite PTA Balloon Dilatation Catheter shall only be used by physicians trained in the procedure, including the catheter, to verify proper function.

**WARNING**

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, return the product to Boston Scientific.

For single use only. Do not re-use, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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 re-sterilization 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.

**CONTRAINDICATIONS**

None known.

**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 Elite PTA Balloon Dilatation Catheters are supplied STERILE using an ethylene oxide (EO) process. Do not store catheters where they are directly exposed to organic solvents or ionizing radiation.

**OPERATIONAL INSTRUCTIONS**

Materials typically required for PTA with the Gladiator Elite 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.
3. 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.
4. 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.
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. If resistance is maintained on the balloon between inflations, it is recommended to extract the entire system with the introducer/guide sheath through the hemostatic valve. If resistance is encountered, do not advance the dilatation catheter from the introducer/guide sheath.

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. Connect a three-way stopcock to the “BALLOON” port and flush the lumen with 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.

5. Withdraw the balloon catheter until it is clear of the inflation device connection to catheter.

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.

8. Open stopcock to balloon catheter.

9. If device is not to be used immediately, remove syringe and immerse catheter in a sterile saline bath.

Use of the Gladiator™ Elite PTA Balloon Dilatation Catheter

1. Backload the distal tip of the dilatation catheter over the 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.

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 dilation.

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.

Table 1. Typical Gladiator Elite PTA Balloon Dilatation Catheter Compliance

<table>
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<tr>
<th>Pressure atm - kPa</th>
<th>3 mm</th>
<th>4 mm</th>
<th>5 mm</th>
<th>6 mm</th>
<th>7 mm</th>
<th>8 mm</th>
<th>9 mm</th>
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<td>5.04*</td>
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<td>7.02*</td>
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*Nominal pressure
**Rated Burst Pressure

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.

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