PTA Balloon Dilatation Catheter

**DEVICE DESCRIPTION**

The Charger 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 Charger PTA Balloon Dilatation Catheter features a dual lumen shaft ending in a Y-connector manifold with luer lock fittings. The manifold 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, are used to inflate and deflate the balloon. A lubricious coating is applied from the distal tip to just proximal of the balloon. The cause of resistance should be determined before proceeding. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is felt during manipulation, do not advance or retract the catheter beyond the end of the guidewire or without the aid of a guidewire in order to avoid potential vessel trauma.

The Charger PTA balloon catheter is not for use in the coronary vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment 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.

**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.

**OPERATIONAL INSTRUCTIONS**

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. Purge the system of air. Carefully inspect the catheter prior to use to verify that the catheter and sterile packaging have not been damaged. 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.

**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
- Pseudaneursym
- Sepsis/infection
- Thromboembolic episodes
- Vessel injury, e.g. dissection, perforation, rupture
- Vessel occlusion
- Vessel spasm

**How Supplied**

The Charger 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.

**Precautions to prevent or reduce clotting should be taken when any device 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 imperatiave that the catheter be positioned so that 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.

**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 mixture (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 Charger 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.

**Use the catheter prior to the “Use By” date specified on the package.**

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**Preactuations**

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

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The Charger 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.
3. Prepare the balloon catheter for purging. Select a syringe or inflation device with a 50 ml or larger capacity and fill approximately half full 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 or 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 dilatation 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 Charger™ PTA Balloon Dilatation Catheter

1. Backload the distal tip of the dilatation catheter over the introducer/guide sheath.

2. Advance the dilatation catheter through the hemostatic valve. If resistance is encountered, do not 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 hemostatic valve any further.

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 the desired site. If resistance is encountered, do not re-insert, select a new Charger product. On re-insertion use product as per “Use of the Charger PTA Balloon Dilatation Catheter” section herein.

4. Confirm that the balloon is fully deflated under fluoroscopy. It is strongly recommended that negative pressure of balloon (maximum 10 times) until the desired result is achieved. 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.

5. Apply negative pressure to fully deflate the balloon. Confirm that the balloon is fully deflated under fluoroscopy.

6. Withdraw the balloon catheter until it is clear of the inflation site. Maintain guidewire position. Perform angiography to confirm dilation.

7. If a syringe was used, attach a prepared inflation device to stopcock.

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.

### 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.

### Table 1. Typical Charger PTA Balloon Dilatation Catheter Compliance

<table>
<thead>
<tr>
<th>Pressure atm</th>
<th>Pressure kPa</th>
<th>Diameter 3 mm</th>
<th>Diameter 4 mm</th>
<th>Diameter 5 mm</th>
<th>Diameter 6 mm</th>
<th>Diameter 8 mm</th>
<th>Diameter 10 mm</th>
<th>Diameter 12 mm</th>
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<tr>
<td>8 - 814</td>
<td>9.0*</td>
<td>10.0*</td>
<td>11.0*</td>
<td>12.0*</td>
<td>13.0*</td>
<td>14.0*</td>
<td>15.0*</td>
<td>16.0*</td>
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<tr>
<td>10 - 1014</td>
<td>3.1**</td>
<td>4.1**</td>
<td>5.1**</td>
<td>6.1**</td>
<td>7.1**</td>
<td>8.1**</td>
<td>9.1**</td>
<td>10.1**</td>
</tr>
<tr>
<td>12 - 1213</td>
<td>3.1</td>
<td>4.1</td>
<td>5.1</td>
<td>6.1</td>
<td>7.1</td>
<td>8.1</td>
<td>9.1</td>
<td>10.2</td>
</tr>
<tr>
<td>14 - 1420</td>
<td>3.1</td>
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<td>5.2</td>
<td>6.2</td>
<td>7.2</td>
<td>8.2</td>
<td>9.3</td>
<td>10.3**</td>
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<tr>
<td>16 - 1620</td>
<td>3.2</td>
<td>4.1</td>
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<td>6.2**</td>
<td>7.2**</td>
<td>8.3</td>
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</tr>
<tr>
<td>18 - 1827</td>
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<td>6.3**</td>
<td>7.3**</td>
<td>8.4**</td>
<td>9.4**</td>
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<tr>
<td>20 - 2027</td>
<td>3.2**</td>
<td>4.2**</td>
<td>5.3**</td>
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</tbody>
</table>

*Nominal pressure
**Rated Burst Pressure
* Balloon length (mm)

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**Balloon Diameter**

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<tr>
<th>Diameter</th>
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</tr>
</thead>
<tbody>
<tr>
<td>3 mm</td>
<td>8 - 814</td>
<td>9.0*</td>
</tr>
<tr>
<td>4 mm</td>
<td>10 - 1014</td>
<td>3.1**</td>
</tr>
<tr>
<td>5 mm</td>
<td>12 - 1213</td>
<td>3.1</td>
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<td>6 mm</td>
<td>14 - 1420</td>
<td>3.1</td>
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<tr>
<td>7 mm</td>
<td>16 - 1620</td>
<td>3.2</td>
</tr>
<tr>
<td>8 mm</td>
<td>18 - 1827</td>
<td>3.2</td>
</tr>
<tr>
<td>9 mm</td>
<td>20 - 2027</td>
<td>3.2**</td>
</tr>
</tbody>
</table>

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 Charger product. On re-insertion use product as per “Use of the Charger PTA Balloon Dilatation Catheter” section herein.

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