NC Emerge®
OVER-THE-WIRE
PTCA Dilatation Catheter

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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, death or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or lead to device failure which, in turn, may result in patient injury, death or death due to myocardial perfusion in patients with atherosclerosis.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION
Boston Scientific NC Emerge Over-The-Wire (OTW) Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter and NC Emerge Monorail (MR) PTCA Dilatation Catheter. The generic name of the device is Over-The-Wire Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter/Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

The NC Emerge OTW and NC Emerge MR PTCA Dilatation Catheters, from Boston Scientific, are OTW and rapid exchange catheters, respectively, with a low compliance balloon near the distal tip. The distal section of both catheters (and the proximal section of the OTW catheter) is dual-lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires >0.014 in (0.36 mm) to facilitate advancement of the catheter to and through the stenosis or stent to be dilated. The proximal section of the MR catheter is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The OTW catheter has a dual-luer port hub: one for inflation/deflation of the balloon, the other for guidewire lumen access. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the inner lumen to protect the patency of the catheter. The catheter’s tip is tapered to facilitate advancement of the catheter to and through the stenosis or stent. All shafts have Z®lite™ (hydrophilic) coating. For MR, the Z®lite is located from the guidewire port to just proximal of the proximal balloon waist. For OTW, the Z®lite is located from distal of the proximal marks to just proximal of the proximal balloon waist. All balloons have Xtra™ (hydrophilic) coating and some balloons have Z®lite applied from the distal tip to just proximal of the balloon, per Table 1.

<table>
<thead>
<tr>
<th>Balloon Diameter (mm)</th>
<th>Balloon Length (mm)</th>
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</thead>
<tbody>
<tr>
<td>2.00</td>
<td>Z®lite and Xtra</td>
</tr>
<tr>
<td>2.25</td>
<td></td>
</tr>
<tr>
<td>2.50</td>
<td></td>
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<tr>
<td>2.75</td>
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<td>3.75</td>
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<td>4.50</td>
<td></td>
</tr>
<tr>
<td>5.00</td>
<td></td>
</tr>
<tr>
<td>5.50</td>
<td></td>
</tr>
<tr>
<td>6.00</td>
<td></td>
</tr>
</tbody>
</table>

The effective length of the OTW is 142 cm and the MR catheter is 143 cm. Marks on the proximal portion of the catheter shaft indicate the end of the balloon catheter tip out of the guide catheter (for OTW, one at 90 cm and two at 100 cm; for MR, one at 90 cm and one at 100 cm). Radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the catheter’s balloon segment. A CLIPIT® Hypotube Clip is provided with the NC Emerge MR PTCA Dilatation Catheter to aid in handling the catheter.

Contents
One (1) NC Emerge (MR or OTW) PTCA Dilatation Catheter
One (1) CLIPIT Hypotube Clip (MR Catheter Only)

INTENDED USE/INDICATIONS FOR USE
The NC Emerge OTW and NC Emerge MR PTCA Dilatation Catheters (balloon models 2.00 mm 5.00 mm) are also indicated for the post-deployment expansion of balloon expandable stents (bare metal and drug-eluting).

Note: Bench testing was conducted with NC Emerge OTW and NC Emerge MR PTCA Dilatation Catheters and marketed Boston Scientific balloon expandable stents. Consideration should be taken when this device is used with different manufacturers’ stents due to differences in stent design. All stents should be deployed in accordance with the manufacturer’s indications and instructions for use.

CONTRAINDICATIONS
The NC Emerge PTCA Dilatation Catheter is contraindicated for use in:
- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS
General Warnings
- In patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
- Use extreme caution and careful judgment in patients for whom carotid occlusion is not indicated.
- Use extreme caution and careful judgment in patients who have severe reaction to contrast agents that cannot be adequately pre-mediated.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- 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.
- Use the balloon catheter prior to the “Use By” date specified on the package.

Catheter Handling
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Catheter Placement and Removal
- When the balloon 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 balloon rated burst pressure. The rated burst pressure is based on the results of 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 of a pressure monitoring device is recommended to prevent over or under pressurization.
- If difficulty is experienced during balloon inflation, do not continue; remove the catheter.
- Before withdrawing the balloon catheter, visually confirm complete balloon deflation by fluoroscopy.
- Balloon catheter retrieval methods (use of additional wires, snares, and/or forceps) may result in trauma to the treated vessel and/or the vascular access site. Complications can include but are not limited to bleeding, hematoma, or pseudoaneurysm.

PRECAUTIONS
General Precautions
- If the compatibility of the device has not been evaluated for the delivery of materials (e.g. alcohol or nitroglycerin, stem cells, etc.) through the guidewire lumen, other than those required for normal operation.
- The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.
- The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.
- Prior to angioplasty, the balloon catheter should be examined to verify functionality and to ensure that it is sized and shaped suitable for the specific procedure for which it is to be used.

The NC Emerge OTW and NC Emerge MR PTCA Dilatation Catheters (balloon models 2.00 mm 5.00 mm) are also indicated for the post-deployment expansion of balloon expandable stents (bare metal and drug-eluting).
• Femoral or brachial guide catheter(s) in the appropriate size and
• Guidewire(s) of appropriate size for advancement of guide catheter

Dilatation Catheter.

OPERATIONAL INSTRUCTIONS

Handling and Storage

• Store in a cool, dry, dark place.

Inflation Device Preparation

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

Catheter Selection

The inflation diameter of the balloon catheter should not exceed the diameter of the coronary artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired catheter, use a smaller diameter catheter to pre-dilate the stenosis to facilitate passage of a more appropriately-sized catheter.

Catheter Preparation

1. Remove the catheter from the protective hoop. Use care when removing the catheter to avoid damage (e.g., shaft kink).
2. Remove the balloon protector and mandrel by grasping the catheter just proximal to the balloon catheter (at the proximal balloon catheter bond site). With the other hand, gently grasp the balloon protector and remove distally. For NC Emerge OTW PTCA Dilatation Catheters, the mandrel shall slide off with the balloon catheter protector. For NC Emerge MR PTCA Dilatation Catheters, remove the mandrel distally after removing the balloon protector.

Care should be taken not to overtighten a hemostatic adapter to the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to inserting the catheter into the patient's body. Note: Care should be taken not to kink the shaft of the catheter upon application or removal of the CLIPIT Clip.

Catheter Exchange Procedure (NC Emerge OTW PTCA Dilatation Catheter)

1. Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.
2. Care should be taken to control the position of the guidewire tip during manipulation of the balloon catheter.
3. When loading or exchanging the balloon catheter; it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) that may be associated with the use of a PTCA Dilatation Catheter include, but are not limited to, the following:

• abrupt closure
• acute myocardial infarction
• angina or unstable angina
• arrhythmia, including ventricular fibrillation
• arteriovenous fistula
• cardiac tamponade/periocardial effusion
• cardiogenic shock
• coronary artery dissection/aneurysm
• coronary artery bypass graft surgery
• coronary artery spasm
• coronary artery thrombus
• coronary artery stenosis
• coronary artery dissection
• coronary artery bypass surgery
• cerebrovascular accident/stroke
• arrhythmia, including ventricular fibrillation

To, the following:

with the use of a PTCA Dilatation Catheter include, but are not limited to:

• In the case of simultaneous use of two NC Emerge® balloon catheters in one guide catheter, care should be taken when introducing the tergaping, and removing guide wires and balloon catheters to avoid entanglement.

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

Inflation Device Preparation

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

Catheter Selection

The inflation diameter of the balloon catheter should not exceed the diameter of the coronary artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired catheter, use a smaller diameter catheter to pre-dilate the stenosis to facilitate passage of a more appropriately-sized catheter.

Catheter Preparation

1. Remove the catheter from the protective hoop. Use care when removing the catheter to avoid damage (e.g., shaft kink).
2. Remove the balloon protector and mandrel by grasping the catheter just proximal to the balloon catheter (at the proximal balloon catheter bond site). With the other hand, gently grasp the balloon protector and remove distally. For NC Emerge OTW PTCA Dilatation Catheters, the mandrel shall slide off with the balloon catheter protector. For NC Emerge MR PTCA Dilatation Catheters, remove the mandrel distally after removing the balloon protector.

Care should be taken not to overtighten a hemostatic adapter to the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to inserting the catheter into the patient's body. Note: Care should be taken not to kink the shaft of the catheter upon application or removal of the CLIPIT Clip.

Catheter Exchange Procedure (NC Emerge OTW PTCA Dilatation Catheter)

1. Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.
2. Care should be taken to control the position of the guidewire tip during manipulation of the balloon catheter.
3. When loading or exchanging the balloon 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.

F. Roughly aspirate and flush the guidewire in preparation for introduction of the balloon catheter.

G. Carefully advance the catheter through the hemostatic adapter while the balloon is fully deflated. If unusual resistance is felt, do not advance the catheter through the adapter. Caution should be taken not to overtighten the hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

H. Connect the side port of the guide catheter hemostatic adapter to the proximal portion of the balloon catheter inflation line or manifold assembly, which permits proximal pressure recording or inflation through the guide catheter.

I. Advance the catheter over the guidewire under direct fluoroscopic visualization and position the balloon relative to the stenosis to be dilated. Use the radiopaque marker bands as a reference point. The outside edges of the marker bands indicate the balloon shell. Balloon inflation should not be undertaken if the balloon is not properly positioned within the stenosis or stent.

J. Simultaneous use of two balloon catheters in a guide catheter (Kissing Balloons): Bench and preclinical testing has shown that one 4.00 mm x 20 mm (or smaller) Monorail balloon catheter and one 3.25 mm x 20 mm (or smaller) Monorail balloon catheter can be inserted simultaneously into an 8F (minimum 0.090 in ID) guide catheter and one 4.00 mm x 30 mm (or smaller) Over-The-Wire balloon catheter and one 3.25 mm x 20 mm (or smaller) Over-The-Wire balloon catheter can be inserted into an 8F (minimum 0.088 in ID) guide catheter with acceptable compatibility. These tests did not account for all clinical situations and differing anatomy. Care should be used when attempting to use two balloon catheters simultaneously in a guide catheter; this technique was not clinically evaluated for safety and effectiveness in a clinical trial. Balloon catheters with a diameter greater than those mentioned have not been tested for simultaneous use in a single guide catheter.

3. Catheter Inflation

A. Inflate the balloon slowly to the appropriate pressure to perform dilation. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure. Refer to Table 2 for the balloon compliance chart. If difficulty is experienced during dilation, do not continue inflation; deflate and remove the catheter.

B. After completion of PTCA or post-dilation of a stent, deflate the balloon by pulling back on the inflation device on the inflation device during use. Do not exceed the rated balloon burst pressure. Refer to Table 2 for the balloon compliance chart. If difficulty is experienced during dilation, do not continue inflation; deflate and remove the catheter.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon inflation, do not continue inflation; deflate and remove the catheter.

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (NC Emerge OTW PTCA Dilatation Catheter) or step 6 – Catheter Exchange Procedure (NC Emerge MR PTCA Dilatation Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery is patent. Ensure balloon is fully deflated.

B. While withdrawing the deflated catheter and guidewire from the guide catheter through the hemostatic adapter, tighten the hemostatic adapter.

C. The NC Emerge MR PTCA Dilatation Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the hypotube should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to catheter exchange being inserted into the patient's body.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the CLIPIT Clip.

5. Catheter Exchange Procedure (NC Emerge OTW PTCA Dilatation Catheter)

B. After completion of PTCA or post-dilation of a stent, deflate the balloon by pulling back on the inflation device on the inflation device during use. Do not exceed the rated balloon burst pressure. Refer to Table 2 for the balloon compliance chart. If difficulty is experienced during dilation, do not continue inflation; deflate and remove the catheter.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon inflation, do not continue inflation; deflate and remove the catheter.

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (NC Emerge OTW PTCA Dilatation Catheter) or step 6 – Catheter Exchange Procedure (NC Emerge MR PTCA Dilatation Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery is patent. Ensure balloon is fully deflated.

B. While withdrawing the deflated catheter and guidewire from the guide catheter through the hemostatic adapter, tighten the hemostatic adapter.

C. The NC Emerge MR PTCA Dilatation Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only the hypotube should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the catheter. Remove the CLIPIT Clip prior to the catheter being inserted into the patient's body.

Note: Care should be taken not to kink or bend the shaft upon application or removal of the CLIPIT Clip.

5. Catheter Exchange Procedure (NC Emerge OTW PTCA Dilatation Catheter)
The NC Emerge® OTW PTCA Dilatation Catheter typically requires two operators to exchange. To perform a catheter exchange, execute the following steps:

**A.** Open the hemostatic adapter.
**B.** The primary operator holds the hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.
**C.** The secondary operator is positioned near the foot of the patient and should maintain the guidewire position in the coronary artery by holding the guidewire stationary and confirming guidewire position at all times under fluoroscopy while the primary operator begins pulling the catheter out of the guide catheter.
**D.** Withdraw the deflated catheter until the catheter tip exits the hemostatic adapter.
**E.** Close the hemostatic adapter and remove the catheter from the guidewire while maintaining guidewire position across the lesion.
**F.** Prepare the next device to be used as described in the Catheter Preparation section.
**G.** Back load the new catheter onto the guidewire as described in step 2 – Catheter Advancement and continue the procedure.

### Table 2. Typical NC Emerge PTCA Dilatation Catheter Balloon Compliance

<table>
<thead>
<tr>
<th>Balloon size (mm)</th>
<th>Pressure (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.00</td>
</tr>
<tr>
<td>3.0</td>
<td>204</td>
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<tr>
<td>4.0</td>
<td>405</td>
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<tr>
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<td>7.0</td>
<td>709</td>
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<td>9.0</td>
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</tr>
<tr>
<td>10.0</td>
<td>1013</td>
</tr>
<tr>
<td>11.0</td>
<td>1115</td>
</tr>
<tr>
<td>12.0</td>
<td>1216</td>
</tr>
</tbody>
</table>

**REFERENCES**

The physician should consult current medical text books on PTCA such as that published by the American College of Cardiology/American Heart Association.

### 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 expenses 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.

**Rated Burst Pressure and Stent Rated Burst Pressure. DO NOT EXCEED.**

**Back Load Pressure. DO NOT EXCEED.**

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Table 2. Typical NC Emerge PTCA Dilatation Catheter Balloon Compliance

<table>
<thead>
<tr>
<th>Pressure (atm)</th>
<th>Balloon size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.0</td>
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</tr>
<tr>
<td>13.0</td>
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<td>20.0</td>
<td>2.07</td>
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</table>

*Rated Burst Pressure and Stent Rated Burst Pressure. DO NOT EXCEED.*