Emerge™

OVER-THE-WIRE PTCA Dilatation Catheter

TABLE OF CONTENTS

WARNING ........................................................................................................ 1

DEVICE DESCRIPTION .................................................................................. 1

Table 1. Emerge Balloon Coatings ................................................................. 1

INTENDED USE/INDICATIONS FOR USE ................................................... 1

CONTRAINDICATIONS .................................................................................. 2

WARNINGS ........................................................................................................ 2

Catheter Handling ...................................................................................... 2

Catheter Placement and Removal ............................................................. 2

PRECAUTIONS ............................................................................................... 2

Catheter Handling ...................................................................................... 2

Catheter Placement .................................................................................... 2

ADVERSE EVENTS .......................................................................................... 2

OVERVIEW OF CLINICAL STUDY ................................................................ 2

EMERGE Clinical Study ................................................................................ 2

Study Purpose ............................................................................................. 2

Study Design ............................................................................................... 2

Demographics ............................................................................................ 2

Baseline Lesion Characteristics ................................................................. 2

Primary Endpoint (Device Procedural Success) ........................................... 2

Secondary Clinical Endpoint (Safety Events) ................................................ 2

Conclusion ................................................................................................... 3

HOW SUPPLIED ............................................................................................. 3

HANDLING AND STORAGE .......................................................................... 3

INSTRUCTIONS FOR USE ........................................................................... 3

Description .................................................................................................. 3

Inspection Prior to Use ................................................................................ 3

Inflation Device Preparation ....................................................................... 3

Catheter Selection ...................................................................................... 3

Catheter Preparation .................................................................................. 3

Insertion Procedure .................................................................................... 3

REFERENCES ................................................................................................ 4

Table 4. Typical Emerge PTCA Dilatation Catheter Balloon Compliance ....... 4

WARRANTY ..................................................................................................... 4

Table 1. Emerge Balloon Coatings

<table>
<thead>
<tr>
<th>Balloon Diameter</th>
<th>Balloon Length</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8 mm</td>
</tr>
<tr>
<td>1.20 mm Push</td>
<td>1.20 mm</td>
</tr>
<tr>
<td>1.50 mm Push</td>
<td>1.50 mm</td>
</tr>
<tr>
<td>2.00 mm</td>
<td>2.00 mm</td>
</tr>
<tr>
<td>2.25 mm</td>
<td>2.25 mm</td>
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<tr>
<td>2.50 mm</td>
<td>2.50 mm</td>
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<tr>
<td>2.75 mm</td>
<td>2.75 mm</td>
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<tr>
<td>3.00 mm</td>
<td>3.00 mm</td>
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<tr>
<td>3.25 mm</td>
<td>3.25 mm</td>
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<td>3.50 mm</td>
<td>3.50 mm</td>
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<tr>
<td>3.75 mm</td>
<td>3.75 mm</td>
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<tr>
<td>4.00 mm</td>
<td>4.00 mm</td>
</tr>
</tbody>
</table>

The effect length of the OTW is 143 cm and the rapid exchange catheter is 144 cm. Marks on the proximal portion of the catheter indicate the exit of the balloon catheter tip out of the guide catheter (one at 90 cm and two at 100 cm). Radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the catheter’s balloon segment. The 1.20 mm and 1.50 mm models have one radiopaque marker band, while all other models have two radiopaque marker bands. A CLIPIT® Hypotube Clip is provided with the Emerge Monorail PTCA Catheter to aid in handling of the catheter.

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.

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 diseases 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.

Table 1. Emerge Balloon Coatings

- Coronary artery spasm in the absence of a significant stenosis.
- Unprotected left main coronary artery.
- Coronary artery spasm.

Note: Bench testing was conducted with Emerge Over-The-Wire and Emerge Monorail 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.
catheters in a guide catheter.

- Use extreme caution and careful judgment in patients who have severe reaction to contrast agents that cannot be adequately pre-medicated.
- 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, or be less than, the diameter of the vessel just proximal and distal to the stenosis.

**Catheter Handling**

- Use 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% of the balloons (with a 95% confidence interval) will not burst at or below their rated burst pressure.
  - Use of a pressure monitoring device is recommended to prevent over 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.

**Precautions**

- **General Precautions**
  - The compatibility of the device has not been evaluated for the delivery of materials (e.g., drugs, alcohol, or stem cells) through the guidewire lumen, other than those required for normal use.
  - The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty techniques.

**Catheter Handling**

- Prior to angioplasty, the balloon catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.

- **Catheter Placement**
  - Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.

- **Catheter Placement and Removal**
  - When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guidewire clean for better catheter movement on the guidewire.

- Do not expand the balloon if it is not properly positioned in the vessel.

**Study Design**

The EMERGE study was a prospective, open-label, multi-center, single arm, observational study designed to evaluate the safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter in subjects with stenotic coronary arteries or bypass grafts during their index procedure. As illustrated in Table 2, 98.3% (59/60) of subjects and 98.5% (66/67) of lesions achieved device procedural success, including successful delivery, inflation, deflation and withdrawal of the Emerge 1.20 mm PTCA Dilatation Catheter. Device procedural failure was observed in 1.7% (1/60) of subjects and 1.5% (1/67) of lesions and was related to unsuccessful delivery (i.e., failure to cross a lesion) of the study device. No procedural complications were observed in the intent-to-treat subject population. This included no vessel perforation, no flow-limiting distention, and no reduction in TIMI flow from baseline. Furthermore, 100% (60/60) of subjects and 100% (67/67) of lesions had a final TIMI flow grade of 3 at the conclusion of the PCI procedure.

Table 2. Primary Endpoint Outcomes

<table>
<thead>
<tr>
<th>Device Procedural Success</th>
<th>EMERGE Subjects (N=60)</th>
<th>EMERGE Lesions (N=67)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Procedural Failure</td>
<td>1.7% (1/60)</td>
<td>1.5% (1/67)</td>
</tr>
<tr>
<td>Failure of delivery, inflation/deflation and withdrawal</td>
<td>1.7% (1/60)</td>
<td>1.5% (1/67)</td>
</tr>
<tr>
<td>Vessel perforation, flow limiting distention or reduction in TIMI flow</td>
<td>0.0% (0/60)</td>
<td>0.0% (0/67)</td>
</tr>
<tr>
<td>Failure of final TIMI flow</td>
<td>0.0% (0/60)</td>
<td>0.0% (0/67)</td>
</tr>
</tbody>
</table>

Secondary Clinical Endpoint (Safety Events)

As illustrated in Table 3, the in-hospital major adverse cardiac events were observed in 6.1% (4/60) of the subjects. The non-Q-wave MI rate was 6.7% (4/60), characterized by elevation of post-procedure creatine kinase-myoglobin band (CK-MB) levels to 3 to 8 times upper limit of normal (ULN). The Q-wave MI rate was 0% (0/60). The all-cause death and TVR rates were 0% (0/60). The in-hospital stent thrombosis rate, per Academic Research Consortium (ARC), was 0% (0/60). No clinically significant aneurysms requiring intervention were observed in this study.
**Table 3. Secondary Endpoint Outcomes**

<table>
<thead>
<tr>
<th>Event</th>
<th>EMERGE Subjects (N=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital MACE</td>
<td>6.7% (4/60)</td>
</tr>
<tr>
<td>All Death or MI</td>
<td>6.7% (4/60)</td>
</tr>
<tr>
<td>MI</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>Q-Wave MI</td>
<td>6.7% (4/60)</td>
</tr>
<tr>
<td>Non-Q-Wave MI</td>
<td>6.7% (4/60)</td>
</tr>
<tr>
<td>TVR, Overall</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>TVR, PCI</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>TVR, CABG</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>TLR, Overall</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>TLR, PCI</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>TVR Remote, Overall</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>TVR Remote, PCI</td>
<td>0.0% (0/60)</td>
</tr>
<tr>
<td>TVR Remote, CABG</td>
<td>0.0% (0/60)</td>
</tr>
</tbody>
</table>

**Conclusion**

The results of the EMERGE™ study support the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter and its intended use as a pre-dilatation catheter in the stenotic portion of a coronary artery or bypass graft stenosis (>70% stenosis).

**HOW SUPPLIED**

Non-proprietary.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

**HANDLING AND STORAGE**

Store in a cool, dry, dark place.

**INSTRUCTIONS FOR USE**

One or more of each of the following materials are required for PTCA with the Emerge Over-The-Wire or Emerge Monorail® PTCA Dilatation Catheter.

- Guidewire(s) of appropriate size for advancement of guide catheter
- Atrial sheath and dilator set (for femoral approach only)
- Femoral or brachial guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.014 in (0.36 mm) (Emerge Over-The-Wire PTCA Catheter)
- Femoral or brachial guide catheter(s) in the appropriate size and configuration to select the coronary artery; minimum I.D. of guide catheter = 0.014 in (0.36 mm) (Emerge Over-The-Wire PTCA Catheter)
- Guide catheter with acceptable compatibility. These tests should be used to confirm the CEC-Clinical Arrythmias

- Sterile saline or heparinized normal sterile saline
- Inflation device with manometer
- Emerge Over-The-Wire PTCA Dilatation Catheter(s)
- Emerge Monorail PTCA Dilatation Catheter(s)
- ≥0.014 in (0.36 mm) x 300 cm guidewire(s) (Emerge Over-The-Wire PTCA Catheter)
- ≥0.014 in (0.36 mm) x 185 cm guidewire(s) (Emerge Monorail PTCA Catheter)
- 16, 12 or 20 ml (cc) luer-lock syringe
- Hemostatic adapter
- Three-way stopcock
- CLIPIT® Clip (Emerge Monorail PTCA Catheter only)
- Torque device

**Inspection Prior to Use**

Prior to angioplasty, 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 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 must 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 Emerge Over-The-Wire PTCA Catheters, the mandrel will slide off with the balloon catheter protector. For Emerge Monorail PTCA Catheters, remove the mandrel distally after removing the balloon protector.

**Caution:** If unusual resistance is felt during removal of the balloon protector or mandrel, do not use the catheter and replace with another.

3. The Emerge Monorail PTCA Catheter may be coiled once and secured using the CLIPIT Clip provided in the catheter package. Only 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.

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

4. Prepare the catheter for purging. Fill a luer lock syringe or inflation device with appropriate balloon catheter inflation medium (e.g., the equivalent of a 50/50 mixture of contrast medium and sterile saline). Do not use air or any gaseous medium to inflate the balloon catheter.

5. Connect a three-way stopcock to the port fitting on the catheter. Flush the stopcock.

6. Hold the syringe or inflation device with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger or open stopcock to air.

7. Remove the syringe or inflation device and evacuate all air from the barrel.

8. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If bubbles persist, check luer connections. If bubbles still persist, inflate the balloon to verify that there are no leaks present prior to insertion. Do not use the balloon catheter if there are any leaks.

9. To remove any air lodged in the distal lumen fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium while holding the inflation device pointed upwards.

10. Disconnect the syringe used in preparation. Verify that a meniscus of contrast medium is evident in both the balloon catheter port and the inflation device connection to ensure a fluid to fluid connection. Adding a drop of inflation medium to the port may be necessary. Securely couple the inflation device to the balloon catheter port of the catheter.

11. Open the stopcock to the catheter and leave on neutral.

**Insertion Procedure**

1. Guidewire Lumen Flush.

A. For Emerge Monorail PTCA Catheters, flush the guidewire lumen of the catheter with sterile saline through the distal tip of the catheter.

B. For Emerge Over-The-Wire PTCA Catheters, flush the guidewire lumen of the catheter with sterile saline through the guidewire port of the catheter hub.

C. Check for bends, kinks and other damage. Do not use if any defects are noted.

2. Catheter Advancement

A. Prepare the vascular access site according to standard practice.

B. Maintain neutral pressure on the inflation device attached to the catheter.

C. Insert a guidewire through the hemostatic adapter following the manufacturer’s instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.

D. Attach a torque device to the guidewire, if desired. Under fluoroscopy, advance the guidewire to the desired vessel, then across the stenosis or stent.

E. Backload the distal tip of the catheter onto the guidewire ensuring that the guidewire exits the midsection opening in the Emerge Monorail PTCA Catheter or the wire port of the Emerge Over-The-Wire PTCA Catheter manifold. When loading or exchanging the catheter, it is recommended to thoroughly wet 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. Thoroughly aspirate and flush the guidewire in preparation for introduction of the 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.

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

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

I. Advancing the catheter over the guidewire under direct fluoroscopic visualization and position the balloon relative to the stenosis or stent to be dilated. Use the radiopaque marker band or bands as a reference point. The outside edges of the marker bands indicate the balloon shoulders on the 2.00-4.00 mm models; the 1.20-1.50 mm models have a single central marker band. 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. Bench and preclinical testing has shown that one 4.00 x 30 mm (or smaller) Monorail balloon catheter and one 3.25 x 20 mm (or smaller) Monorail balloon catheter can be inserted simultaneously into a 6F (minimum 0.070” ID) guide catheter and two 4.00 x 30 mm (or smaller) Over-The-Wire balloon catheters can be inserted into an 8F (minimum 0.088” 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 study. Balloon catheters with a diameter greater than those mentioned should not be used for simultaneous use in a single guide catheter.

3. Catheter Inflation

A. Inflate the balloon slowly to the appropriate pressure to perform PTCA or post-dilation of a stent. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure.
4. Catheter Removal

5. Catheter Exchange Procedure (Emerge Over-The-Wire PTCA Catheter)

D. If catheter exchange is necessary, proceed to step 5 – Catheter Exchange Procedure (Emerge™ Over-The-Wire PTCA Catheter) or step 6 – Catheter Exchange Procedure (Emerge Monorail® PTCA Catheter). Otherwise, proceed to step 4 – Catheter Removal.

4. Catheter Removal

A. Confirm with angiography that the lumen of the dilated artery has not abruptly occluded. Ensure balloon is fully deflated.

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

C. The Emerge Monorail PTCA 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 in the patient’s body.

D. Withdraw the deflated catheter until the catheter tip exits the hemostatic adapter.

E. Close the knurled knob on the hemostatic adapter and remove the catheter from the guidewire while maintaining guidewire position across the stenosis or stent.

F. Prepare the next catheter to be used as described in the Catheter Preparation section.

G. Back load the new catheter onto the guidewire as described under step 2 – Catheter Advancement – and continue the procedure.

5. Catheter Exchange Procedure (Emerge Over-The-Wire PTCA Catheter)

The Emerge Over-The-Wire PTCA Catheters require two operators to exchange. To perform a catheter exchange, execute the following steps:

A. Loosen the knurled knob on the hemostatic adapter.

B. While withdrawing the deflated catheter and guidewire, tighten the knurled knob on the hemostatic adapter, and remove the catheter from the guidewire while maintaining guidewire position across the stenosis or stent.

C. The operator should consult current medical practice literature on PTCA, such as that published by the American College of Cardiology/American Heart Association.

REFERENCES

Table 4. Typical Emerge PTCA Dilatation Catheter Balloon Compliance

<table>
<thead>
<tr>
<th>Balloon Size</th>
<th>Pressure (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.20 mm</td>
<td>1.39 - 1.96</td>
</tr>
<tr>
<td>1.50 mm</td>
<td>2.06 - 2.53</td>
</tr>
<tr>
<td>2.00 mm</td>
<td>2.28 - 2.76</td>
</tr>
<tr>
<td>2.25 mm</td>
<td>2.85 - 3.10</td>
</tr>
<tr>
<td>2.50 mm</td>
<td>3.10 - 3.58</td>
</tr>
<tr>
<td>2.75 mm</td>
<td>3.58 - 3.80</td>
</tr>
<tr>
<td>3.00 mm</td>
<td>3.80 - 4.25</td>
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<tr>
<td>3.25 mm</td>
<td>4.25 - 4.75</td>
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<tr>
<td>3.50 mm</td>
<td>4.75 - 5.25</td>
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<tr>
<td>3.75 mm</td>
<td>5.25 - 5.75</td>
</tr>
<tr>
<td>4.00 mm</td>
<td>5.75 - 6.25</td>
</tr>
</tbody>
</table>

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

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.