Boston Scientific

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Emerge™

MONORAIL®

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, 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.

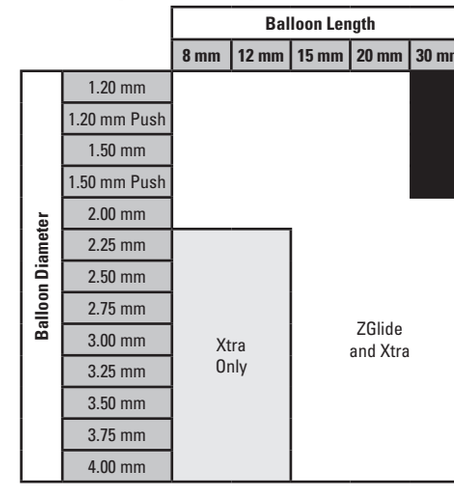
After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

Boston Scientific Emerge Over-The-Wire PTCA Dilatation Catheter and Emerge Monorail 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 Emerge Over-The-Wire (OTW) and Emerge Monorail (MR) Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheters, from Boston Scientific, are Over-The-Wire and rapid exchange catheters, respectively, with a semi-compliant 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 rapid exchange 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. In addition to the standard design, the 1.20 mm and 1.50 mm catheters are offered in "Push" models that provide different performance characteristics. All shafts have ZGlide™ (hydrophilic) coating. For MR, the ZGlide is located from the guidewire port to just proximal of the proximal balloon waist. For OTW, the ZGlide is located from distal of the proximal marks to just proximal of the proximal balloon waist. All balloons have Xtra™ (hydrophobic) coating and some balloons have ZGlide applied from the distal tip to just proximal of the balloon, per Table 1.

Table 1. Emerge Balloon Coatings



The effective length of the OTW is 143 cm and the rapid exchange catheter is 144 cm. Marks on the proximal portion of the catheter shaft 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

Quantity	Material
1	Emerge (Monorail or Over-The-Wire) PTCA Dilatation Catheter
1	CLIPIT Hypotube Clip (Monorail Catheter only)

INTENDED USE/INDICATIONS FOR USE

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis).

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-4.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

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.

CONTRAINDICATIONS

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

WARNINGS

General Warnings

PTCA 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 anticoagulation is not indicated.

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.

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 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 additional trauma to the vascular access site. Complications can include but are not limited to bleeding, hematoma, or pseudoaneurysm.

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.

The safety and effectiveness of this PTCA balloon catheter for the treatment of in-stent restenosis (ISR) has not been established.

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.

Caution should be taken not to overtighten a hemostatic adapter around the catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

Catheter Placement

Before insertion of the balloon catheter, administer appropriate anticoagulant and coronary vasodilator therapy.

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

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.

Models not specified within step J of the Insertion Procedure have not been evaluated for simultaneous use of two balloon catheters in a guide catheter.

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

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/pericardial effusion
- cardiogenic shock
- cerebrovascular accident/stroke
- coronary aneurysm
- coronary artery bypass graft surgery
- coronary artery spasm
- coronary vessel dissection, perforation, rupture or injury
- death
- drug reactions, allergic reaction to contrast medium
- embolism
- hemodynamic compromise
- hemorrhage or hematoma
- hypo/hypertension
- infection
- minor vessel trauma
- myocardial ischemia
- percutaneous re-intervention
- pseudoaneurysm (at site of catheter insertion)
- pyrogenic reaction
- renal failure
- respiratory insufficiency
- restenosis of the dilated vessel
- side branch occlusion
- slow flow/no reflow
- thrombosis
- total occlusion of the coronary artery or bypass graft
- transient ischemic attack
- vasovagal reactions
- ventricular irritability/dysfunction
- vessel trauma requiring surgical repair or intervention
- volume overload

OVERVIEW OF CLINICAL STUDY

EMERGE Clinical Study

Study Purpose

The objective of the EMERGE study was to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter when used to initially treat the stenotic portion of coronary arteries or bypass grafts.

Study Design

The EMERGE study was a prospective, open label, multi-center, single arm, observational study designed to evaluate the acute safety and device procedural success of the Emerge 1.20 mm PTCA Dilatation Catheter in subjects with stenotic coronary arteries or bypass grafts during percutaneous coronary intervention (PCI).

Sixty (60) subjects were treated at 3 US sites with the Emerge 1.20 mm PTCA Dilatation Catheter to pre-dilate coronary arteries or bypass grafts during their index procedure. All subjects were to be screened according to the protocol inclusion and exclusion criteria and were followed through hospital discharge.

The primary endpoint was device procedural success consisting of successful delivery, inflation, deflation and withdrawal of the study balloon; no evidence of vessel perforation, flow limiting dissection (grade C or higher) or reduction in TIMI flow from baseline related to the study balloon; final TIMI flow grade of 3 at the conclusion of the PCI procedure.

The secondary clinical endpoints measured through hospital discharge included in-hospital MACE (cardiac and non-cardiac death, MI and TVR); in-hospital stent thrombosis within the target vessel; clinically significant arrhythmias requiring intervention.

Subjects were followed through hospital discharge.

Demographics

A total of 60 subjects with 67 target lesions were enrolled in the study at 3 US sites. The subject population was predominantly male (71.7%) and Caucasian (95.0%) with an average age of 61 years. Most subjects had a history of medically treated hyperlipidemia (85.0%) and hypertension (93.3%) with a history of PCI (61.7%), myocardial infarction (23.3%) and coronary bypass surgery (18.3%). Medically-treated diabetic subjects accounted for 35% of the subject population, of which 16.7% were insulin-requiring.

Baseline Lesion Characteristics

A total of 67 target lesions were treated in the study, of which 97% (65/67) were located in native coronary arteries and 3.0% (2/67) in bypass graft. The average reference vessel diameter was 2.6 ± 0.5 mm, average minimum lumen diameter was 0.7 ± 0.4 mm, average diameter stenosis was 73.0% ± 12.6%, and average lesion length was 15.5 ± 14.7 mm. Total occlusion was observed in 10.4% (7/67) of target lesions.

Very severe stenosis was the primary lesion characteristic in 40.0% (4/10) of all Push devices used in the trial. Pushability was the primary physician preference in 60.0% (6/10) of all Push devices used in the trial. Preference of the Standard model was given mainly for tortuosity 20.4% (11/54), calcification 20.4% (11/54) and very severe stenosis 27.8% (15/54) lesion characteristics. Deliverability was the primary physician preference in 51.9% (28/54) followed by Pushability in 27.8% (15/54) of all Standard devices used in the trial.

Primary Endpoint (Device Procedural Success)

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 dissection, 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

	EMERGE Subjects (N=60)	EMERGE Lesions (N=67)
Device Procedural Success	98.3% (59/60)	98.5% (66/67)
Device Procedural Failure	1.7% (1/60)	1.5% (1/67)
Failure of delivery, inflation/deflation and withdrawal	1.7% (1/60)	1.5% (1/67)
Vessel perforation, flow limiting disection or reduction in TIMI flow	0.0% (0/60)	0.0% (0/67)
Failure of final TIMI flow	0.0% (0/60)	0.0% (0/67)

Numbers are % (Count/Sample Size), and based on number of subjects and lesions with site reported data.

Secondary Clinical Endpoint (Safety Events)

As illustrated in **Table 3**, the in-hospital major adverse cardiac events were observed in 6.7% (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 >3.0 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 arrhythmias requiring intervention were observed in this study.

Table 3. Secondary Endpoint Outcomes

	EMERGE Subjects (N=60)
In-hospital MACE	6.7% (4/60)
All Death or MI	6.7% (4/60)
All Death	0.0% (0/60)
MI	6.7% (4/60)
Q-Wave MI	0.0% (0/60)
Non-Q-Wave MI	6.7% (4/60)
TVR, Overall	0.0% (0/60)
TVR, PCI	0.0% (0/60)
TVR, CABG	0.0% (0/60)
TLR, Overall	0.0% (0/60)
TLR, PCI	0.0% (0/60)
TLR, CABG	0.0% (0/60)
TVR Remote, Overall	0.0% (0/60)
TVR Remote, PCI	0.0% (0/60)
TVR Remote, CABG	0.0% (0/60)
In-hospital ARC Stent Thrombosis	0.0% (0/60)
In-hospital Clinical Significant Arrhythmias	0.0% (0/60)

Numbers are % (Count/Sample Size), and based on number of subjects with site reported and CEC adjudicated data.

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-pyrogenic.

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.

Description

- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial 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 = 0.066 in (1.68 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 = 0.056 in (1.42 mm) (Emerge Monorail PTCA Catheter)
- Vial of contrast medium
- 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)
- 10, 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.

   Note: 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 through the stopcock. Connect syringe or inflation device to stopcock. Assure luer connections are properly aligned to avoid stripping the luer thread causing subsequent leakage and use care when connecting the catheter to avoid damage (e.g., shaft kink).
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 luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium while holding the inflation device pointing 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 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. Thoroughly aspirate and flush the guide catheter 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 over tighten 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. Advance 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 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 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 PTCA or post-dilatation of a stent. Maintain negative pressure on the balloon between inflations. Do not exceed the rated balloon burst pressure. Refer to

Table 2 or to the balloon compliance chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the catheter.

B. After completion of PTCA or post-dilatation of a stent, deflate the balloon by pulling negative pressure on the inflation device until the balloon is fully deflated. Bench testing has demonstrated that, on average, the deflation times range from 2 to 18 seconds, dependent upon balloon volume.

C. Confirm angiographic results using standard angiographic techniques. Fluoroscopic visualization during balloon expansion should be used to properly judge the optimum expanded balloon diameter as compared to the proximal and distal coronary artery diameter(s). Repeat inflation of balloon until the desired result is achieved.

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.

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

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

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

A. Loosen the knurled knob on 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 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.

6. Catheter Exchange Procedure (Emerge Monorail PTCA Catheter)

The Emerge Monorail PTCA Catheters have been specifically designed for rapid, single operator catheter exchanges. To perform a catheter exchange, execute the following steps:

A. Loosen the knurled knob on the hemostatic adapter.

B. Hold the guidewire and hemostatic adapter in one hand, while grasping the catheter shaft in the opposite hand.

C. Maintain the guidewire position in the coronary artery by holding the guidewire stationary. Begin pulling the catheter out of the guide catheter while monitoring the guidewire position under fluoroscopy.

D. Withdraw the deflated catheter until the opening in the guidewire lumen is reached (approximately 25 cm proximal to the balloon catheter tip).

E. Carefully slide the flexible, distal portion of the catheter out of the hemostatic adapter, and tighten the knurled knob onto the guidewire to hold it securely in place. Completely remove the catheter from the guidewire while maintaining guidewire position across the stenosis.

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.

REFERENCES

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

Table 4. Typical Emerge PTCA Dilatation Catheter Balloon Compliance

	Balloon Size										
Pressure atm (kPa)	**1.20 mm**	**1.50 mm**	**2.00 mm**	**2.25 mm**	**2.50 mm**	**2.75 mm**	**3.00 mm**	**3.25 mm**	**3.50 mm**	**3.75 mm**	**4.00 mm**
3.0 (304)	1.09	1.39	1.86	2.06	2.28	2.53	2.76	3.01	3.19	3.45	3.66
4.0 (405)	1.13	1.45	1.93	2.14	2.37	2.61	2.85	3.10	3.30	3.58	3.80
5.0 (507)	1.16	1.48	1.99	2.20	2.44	2.68	2.93	3.18	3.39	3.67	3.88
6.0 (608) Nominal	1.20	1.52	2.03	2.26	2.50	2.75	3.00	3.26	3.46	3.75	3.96
7.0 (709)	1.23	1.55	2.07	2.31	2.55	2.81	3.06	3.33	3.52	3.81	4.04
8.0 (811)	1.26	1.58	2.10	2.34	2.59	2.85	3.11	3.37	3.57	3.86	4.09
9.0 (912)	1.28	1.60	2.13	2.38	2.62	2.88	3.15	3.41	3.61	3.90	4.14
10.0 (1013)	1.31	1.62	2.15	2.40	2.65	2.91	3.18	3.45	3.64	3.95	4.18
11.0 (1115)	1.33	1.64	2.18	2.42	2.67	2.94	3.21	3.48	3.68	3.98	4.22
12.0 (1216)	1.35	1.65	2.19	2.44	2.69	2.96	3.23	3.51	3.72**	4.02**	4.25**
13.0 (1317)	1.37	1.66	2.21	2.46	2.72	2.99	3.26	3.54	-	-	-
14.0 (1419)	1.39	1.68*	2.23**	2.48**	2.74**	3.02**	3.28**	3.57**	-	-	-
15.0 (1520)	1.41	-	-	-	-	-	-	-	-	-	-
16.0 (1621)	1.42	-	-	-	-	-	-	-	-	-	-
17 (1723)	1.43	-	-	-	-	-	-	-	-	-	-
18.0 (1824)	1.45*	-	-	-	-	-	-	-	-	-	-
19.0 (1925)	1.46	-	-	-	-	-	-	-	-	-	-
20.0 (2027)	1.48	-	-	-	-	-	-	-	-	-	-

* Rated Burst Pressure. Do not exceed.
** Rated Burst Pressure and Stent Rated Burst Pressure. Do not exceed.

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.**

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Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

BRA **Brazil Local Contact**

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