Contents

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GC R Recommended Guide Catheter

GW R Recommended Guidewire

CL Includes CLIPIT™ Hypotube Clip

EC REP

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Wolverine™ Coronary Cutting Balloon™

MONORAIL™

Microsurgical Dilatation Device

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

REUSE 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.

Carefully review all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

The Wolverine Monorail (MR) Coronary Cutting Balloon Microsurgical Dilatation Device consists of a balloon with 3 or 4 atherotomes (microsurgical blades) mounted longitudinally on its outer surface. 2.00 mm – 3.25 mm balloon diameter models contain 3 atherotomes and 3.50 mm – 4.00 mm balloon diameter models contain 4 atherotomes. When the device is inflated, the atherotomes score the plaque, creating initiation sites for crack propagation. This process, referred to as atherotomy, allows dilation of the target lesion with less pressure.

The distal section 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 device to and through the stenosis to be dilated. The proximal section is a single-lumen, stainless steel hypotube with a single luer port hub for inflation/deflation of the balloon. The balloon with atherotomes 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 device. The device's tip is tapered to facilitate advancement of the device to and through the stenosis. All shafts have ZGlide (hydrophilic) lubricious coating. The ZGlide is located from the guidewire port to the distal tip of the device.

The effective catheter length of the Wolverine MR Cutting Balloon Device is 143 cm. Marks on the proximal portion of the device shaft, one at 90 cm and one at 100 cm, indicate the exit of the balloon device tip out of the guide catheter.

The device is provided in 6 mm, 10 mm, and 15 mm balloon lengths. The functional atherotome length is the distance between the radiopaque marker bands. These radiopaque marker bands, in conjunction with fluoroscopy, aid in the placement of the cutting balloon segment. A CLIPIT Hypotube Clip is provided with the Wolverine MR Cutting Balloon Device to aid in handling the device.

Contents

Quantity	Material
One (1)	Wolverine MR Cutting Balloon Device
One (1)	CLIPIT Hypotube Clip

Operating Principle

During the atherotomy procedure, access to the vasculature is gained through a small opening in the femoral or radial artery. While the balloon is deflated, the Wolverine MR Cutting Balloon Device is inserted over a guidewire through a guide catheter and advanced to the narrowed coronary artery. Once positioned inside the narrowed artery, the balloon is inflated and the atherotomes score the plaque, creating initiation sites for crack propagation. The inner lumen of the artery is enlarged so that blood can flow more easily. The balloon is then deflated, and the catheter is removed.

Materials

The Wolverine MR Cutting Balloon Device is comprised of a proximal stainless steel hypotube and a polymer distal outer shaft. The distal portion of the catheter has a polymer inner component and two platinum iridium marker bands for radiopacity.

The Wolverine MR Cutting Balloon Device has a polymer balloon. The stainless steel atherotomes are cast in a urethane acrylate adhesive to form the blade pads. A hydrophilic coating is applied from the guidewire port to the distal tip to reduce friction when tracking the catheter through tortuous vasculature.

Contains cobalt: The stainless steel hypotube is a metal alloy that contains cobalt (CAS No. 7440-48-4; EC No. 231-158-0, which is defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight). Current scientific evidence supports that metal alloys containing cobalt used in medical devices do not cause an increased risk of cancer or adverse reproductive effects.

Non-pyrogenic

This device meets pyrogen limit specifications.

User Information

The device should be used only by physicians experienced in the performance of Percutaneous Transluminal Coronary Angioplasty (PTCA).

INTENDED USE / INDICATIONS FOR USE

The Wolverine Cutting Balloon Device is indicated for dilation of stenoses in coronary arteries for the purpose of improving myocardial perfusion in those circumstances where a balloon resistant lesion is encountered. In addition, the target lesion should possess the following characteristics:

- Discrete (≤ 15 mm in length), or tubular (10 mm to 20 mm in length)
- Reference vessel diameter (RVD) of 2.00 mm to 4.00 mm
- Readily accessible to the device
- Light to moderate tortuosity of proximal vessel segment
- Nonangulated lesion segment (< 45°)
- Smooth angiographic contour
- Absence of angiographically visible thrombus

CLINICAL BENEFIT STATEMENT

The Wolverine Coronary Cutting Balloon is a minimally invasive medical device used for the purpose of dilating coronary artery stenoses to improve myocardial perfusion in patients with stenotic coronary lesions.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European Database on Medical Devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed).

CONTRAINDICATIONS

The Wolverine Cutting Balloon Device is contraindicated for use in:

- Delivery through the side cell of a previously placed stent as the deflated Cutting Balloon could become entangled in the stent.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

- Exercise extreme care when treating a lesion distal to a stent. If the guidewire has passed through a stent cell rather than down the lumen of the stent, the deflated device could become entangled in the stent. When treating lesions at a bifurcation, the device can be used prior to placing a stent, but should not be taken through the side cell of a stent to treat the side branch of a lesion at a bifurcation.
- The atherotomy process, because of its mechanism of action, may pose a greater risk of perforation than that observed with conventional PTCA. Over sizing increases the risk of perforation. To reduce the potential for vessel damage, the inflated diameter of the device should approximate a 1.1:1 ratio of the diameter of the vessel just proximal and distal to the stenosis.
- The atherotomy process in patients who are not acceptable candidates for coronary artery bypass surgery requires careful consideration, including possible hemodynamic support during the atherotomy process, as treatment of this patient population carries special risk.
- When the device is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the device unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9% of the balloons (with 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure-monitoring device is recommended to prevent over pressurization.
- When performing percutaneous atherotomy, the availability of on-site surgical backup should be included as a clinical consideration.
- During preparation and positioning of the device, it is important that all air and fluid are excluded from the inflation lumen of the device until the balloon is in position at the lesion site.
- Use only the recommended balloon inflation medium (e.g. contrast medium). Never use air or any gaseous medium to inflate the balloon.
- If resistance is encountered when withdrawing the device through the guide, consider removing the guide and the device as a complete unit.

PRECAUTIONS

- Prior to performing the procedure, the device should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The device should be used only by physicians experienced in the performance of PTCA.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy should be provided to the patient. Anticoagulant therapy should be continued for a period of time after the procedure as determined by the physician.
- The device is not designed for, and therefore, cannot be used to monitor in vivo arterial pressures.
- After removal from the guide catheter, system integrity should be verified prior to reinsertion.
- Use the device prior to the "Use By" date specified on the package.
- If difficulty is experienced during balloon inflation, do not continue; remove the device and do not attempt to use it. Select another device.
- Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.
- Prior to an angioplasty, the device 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.
- Excessive handling can cause catheter damage such as delivery system kinking, shaft rupture or separation, which may necessitate additional procedures. Do not bend or kink the device during removal from packaging.
- Infusion of any medium through the guidewire lumen other than heparinized saline may compromise device performance.
- Do not attempt to reposition a partially inflated balloon. Attempted repositioning of a partially inflated balloon may result in severe vessel damage.
- Do not use a guidewire having a diameter greater than 0.014 in (0.36 mm).
- Used devices may pose a biohazard risk and must be handled and disposed of properly.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following:

- *Abrupt closure, slow flow/no reflow*
- *Additional intervention including surgery*
- *Arrhythmia, including ventricular fibrillation or heart block*
- *Bleeding, hemorrhage or hematoma*
- *Cardiac tamponade/pericardial effusion*
- *Cerebrovascular accident (stroke or transient ischemic attack)*
- *Death*

BSC (MB IFU Template 16.5354 x 11.6929 A3, 92310061) IFU, MB, Wolverine, MR, en, 51328366-01A

- *Drug reactions including allergy*
- *Embolism (air, tissue, device fragments, plaque)*
- *Hemodynamic compromise including vasovagal reaction*
- *Infection*
- *Myocardial ischemia or infarction*
- *Radiation injury*
- *Renal failure/insufficiency*
- *Respiratory failure/insufficiency*
- *Thrombosis*
- *Vasospasm*
- *Vessel occlusion*
- *Vessel injury (perforation, dissection, rupture, aneurysm, pseudoaneurysm, arteriovenous fistula) possibly requiring surgical intervention*

Table 1. Wolverine Cutting Balloon Device Compliance

Pressure ATM (kPa)	Model Diameter (mm) x Ave. Balloon Diameter (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)	1.90	2.14	2.38	2.62	2.88	3.11	3.28	3.55	3.80
4.0 (405)	1.95	2.18	2.43	2.69	2.94	3.17	3.35	3.62	3.89
5.0 (507)	1.98	2.22	2.48	2.73	2.99	3.22	3.41	3.69	3.96
6.0 (608) NOM	2.02	2.26	2.52	2.78	3.06	3.28	3.48	3.77	4.04
7.0 (709)	2.05	2.30	2.56	2.83	3.10	3.33	3.55	3.84	4.11
8.0 (811)	2.08	2.33	2.60	2.88	3.15	3.38	3.61	3.90	4.17
9.0 (912)	2.11	2.36	2.64	2.91	3.18	3.41	3.65	3.95	4.22
10.0 (1013)	2.13	2.39	2.67	2.95	3.22	3.45	3.70	3.99	4.26
11.0 (1115)	2.15	2.41	2.69	2.97	3.25	3.48	3.74	4.04	4.31
12.0 (1216) RBP	2.17	2.44	2.71	3.00	3.28	3.51	3.78	4.07	4.34

HOW SUPPLIED

- Contents supplied STERILE using an ethylene oxide (EO) process
- Non-pyrogenic

Device Details

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

If damage is found, call your Boston Scientific representative.

Handling and Storage

This product has no special handling or storage requirements.

OPERATIONAL INSTRUCTIONS

Additional Items for Safe Use

In addition to the Wolverine MR Cutting Balloon Device, the following supplies should be prepared for use:

- Guidewire(s) of appropriate size for advancement of guide catheter
- Arterial sheath and dilator set
- ≤ 0.014 in (0.36 mm) x 185 cm guidewire(s)
- Femoral or radial guide catheter(s) in the appropriate size and configuration to select the coronary artery
  - Minimum I.D. of 6 FR guide catheter = 0.066 in (1.68 mm) (Wolverine MR Cutting Balloon Device with 3.50 mm-4.00 mm balloon diameters)
  - Minimum I.D. of 5 FR guide catheter = 0.056 in (1.42 mm) (Wolverine MR Cutting Balloon Device with 2.00 mm-3.25 mm balloon diameters)
- Sterile saline or heparinized sterile saline
- Radiopaque contrast medium
- Three-way stopcock or infusion manifold/apparatus
- Inflation device with manometer
- 10 ml, 12 ml, or 20 ml (cc) luer-lock syringe
- Hemostasis valve
- Guidewire torque device
- Other supplies and medications per local protocols

Inspection Prior to Use

All equipment to be used for the procedure, including the Wolverine Cutting Balloon Device, should be examined carefully to verify functionality. Inspection prior to use should verify that the device and sterile packaging have not been damaged in shipment and that it is ready to be used. Do not use if sterile package is damaged. The device should be prepared and tested following the directions provided below prior to insertion in the body.

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

Wolverine Cutting Balloon Device - Preparation

Caution: This is a wet negative prep procedure. Customary balloon preparation methods do not apply. These steps must be followed exactly.

1. Sizing the device to the reference artery is extremely important for a successful dilation. Over sizing the balloon increases the risk of perforation. To reduce the potential for vessel damage, the inflated diameter of the device should approximate a ratio of 1.1:1 in relation to the average diameter of the reference coronary artery.
2. Using sterile technique, remove the device in its protective hoop from its package and place onto a sterile field. Do not remove the device from its protective hoop. Do not remove the balloon protector from the device tip.
3. Connect a three-way stopcock to the balloon port. Turn stopcock lever OFF to the balloon. Prepare an inflation device with 5 cc of contrast solution (mixture must be at least 50:50 contrast medium and sterile saline).
4. Attach the 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 device to avoid damage (e.g., shaft kink). Purge stopcock by flushing 1 cc-2 cc of contrast medium through the middle port.
5. Turn the stopcock lever towards the middle port or open to the balloon and immediately withdraw inflation device plunger to full negative and place the inflation device in a locked position. This will maintain a constant vacuum on the device.

   Do not allow fluid into the balloon until inflation. This will maintain the folding integrity of the balloon and protect the atherotomes. If fluid has prematurely been introduced into the balloon, do not use the device. If air has been introduced into the balloon, do not use the device.
6. When the device is ready to be inserted into the body, remove the device from its protective hoop. Use care when removing the device to avoid damage (e.g., shaft kink).
7. Using straight force (not a twisting motion), pull the balloon protector distally from the device tip. 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 device and replace with another.

8. The device may be coiled once and secured using the CLIPIT Clip provided in the device package. Only the proximal shaft should be inserted into the CLIPIT Clip; the clip is not intended for the distal end of the device. Remove the CLIPIT Clip prior to inserting the device into the patient's body.

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

9. Flush the guidewire lumen of the device with heparinized saline through the distal tip of the device.

Caution: When handling device, ensure the balloon and blades are not damaged during flushing of the wire lumen. Do not use if any defects are noted. Discard the protective hoop and the balloon protector.

10. Maintain device on a sterile table until ready for use.

Procedure

Wolverine Cutting Balloon Device – Positioning

1. Prepare the vascular access site according to standard practice.
2. Insert a guidewire through the hemostasis valve following the manufacturer's instructions or standard practice. Advance the guidewire carefully into the guide catheter. When complete, withdraw the guidewire introducer, if used.
3. Under fluoroscopy, advance the guidewire to the desired vessel, then position the distal wire in the desired location.
4. Confirm the device is fully deflated and under vacuum. Back load the device distal tip onto the guidewire ensuring that the guidewire exits the midsection opening. When loading or exchanging the device, it is recommended to thoroughly wipe the guidewire clean for better device movement on the guidewire. Guidewire position in the distal portion of the artery must be maintained while loading the balloon onto the guidewire.

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

5. Thoroughly aspirate and flush the guide catheter in preparation for introduction of the cutting balloon device.
6. Carefully load the device onto the guidewire and advance through the hemostasis valve using fluoroscopic guidance to the tip of the guide catheter.

Caution: Holding the balloon/blade subassembly too tightly or not opening the hemostasis valve enough may result in blade induced damage to the balloon material. If unusual resistance is felt, do not advance the device through the valve. Care should be taken not to over tighten the hemostasis valve around the device shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

7. Under fluoroscopy, while maintaining guidewire position, advance the device out of the guide catheter and into the selected coronary artery. Marks on the proximal portion of the catheter shaft indicate the exit of the balloon catheter tip out of the guide catheter, and may also be used as guidance. Advance the device and position within the lesion by centering the two radiopaque markers on either end of the lesion. The cutting edge of the atherotomes are located between the radiopaque markers. Confirm that the device is centrally located within the lesion segment before proceeding with the dilation.

Wolverine Cutting Balloon Device – Inflation

1. Under fluoroscopy, slowly inflate the device (1 atm/5 sec) to 6 atm (nominal size). Do not inflate the device above 12 atm (rated burst pressure). Refer to Table 1 or the balloon compliance chart. If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the device.
2. When using the device on long lesion segments (those lesions in which the targeted area of dilation exceeds the length of the Wolverine Cutting Balloon), the distal portion of the target lesion should be treated first. Then, dilation of the proximal lesion segment may be performed. Repeat coronary arteriography after each use to evaluate results. Perform repeat dilation if needed.

Wolverine Cutting Balloon Device – Removal

1. Deflate the device by dialing down on the inflation/deflation device, then pull a negative vacuum. Maintain vacuum on the device and verify full deflation under fluoroscopy.
2. Repeat coronary arteriography to confirm successful result.
3. Withdraw the device into the guiding catheter. While withdrawing the deflated device and guidewire from the guide catheter through the hemostasis valve, tighten the hemostasis valve.

Disposal

Dispose of the entire device. For Single Use Only.

To minimize the risk of infection or microbial hazards after use, dispose of device and packaging as follows: After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

INFORMATION TO BRIEF THE PATIENT

The following sections/clauses in the IFU contain information that may be useful for briefing the patient prior to use of this device:

- Clinical Benefit Statement
- Adverse Events statements with potential relevance to the patient are in italics
- Patients should be informed on post-procedure medications.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at

www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document.

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