Boston Scientific
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WOLVERINE™
Cutting Balloon™ Dilatation Device

General Specifications	
Indication	The WOLVERINE Cutting Balloon Device is indicated for dilatation of stenoses in coronary arteries for the purpose of improving myocardial perfusion in those circumstances where a balloon resistant lesion is encountered.
Mechanism of action	When the device is inflated, the atherotomes modify the plaque, creating initiation sites for crack propagation. This process, referred to as atherotomy, allows dilatation of the lesion with less pressure.
Balloon platform	NC EMERGE™ PTCA Dilatation Catheter
Device delivery platform	Monorail™ (143 cm)
Available balloon diameters	Monorail: 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
Available balloon lengths	6 mm, 10 mm, 15 mm
Rated burst pressure	12 ATM (1216 kPa)
Nominal pressure	6 ATM (608 kPa)
Guide catheter inner diameter	2.00–3.25 ≥ 0.056" (1.42 mm), 5F compatible 3.50–4.00 ≥ 0.066" (1.68 mm), 6F compatible
Crossing profile	0.037" (0.93 mm)
Tip lesion entry profile	0.017" (0.43 mm)

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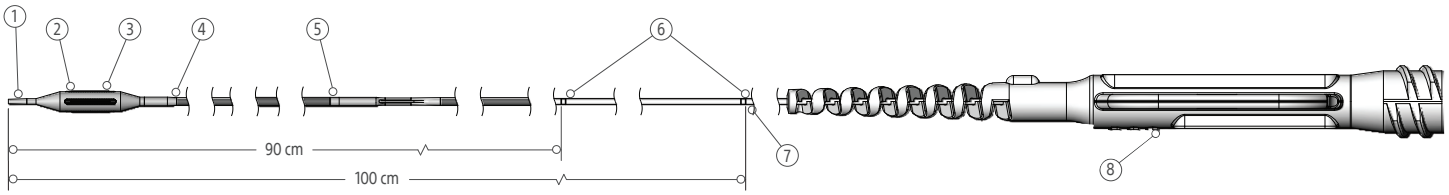

1. Bumper Tip
2. Acrylated Urethane Atherotome Adhesive
3. Atherotomes
4. Z-Glide™ Hydrophilic Coating
5. Midshaft
6. Proximal Marks
7. Hypotube/Corewire Assembly
8. Manifold

Product Information

MONORAIL™

Balloon Diameter (mm)	Order Number (GTIN)	Ref/Catalog Number
	6 mm Length	
2.00	08714729888130	H749 **3940106200** 0
2.25	08714729888147	H749 **3940106225** 0
2.50	08714729888154	H749 **3940106250** 0
2.75	08714729888161	H749 **3940106275** 0
3.00	08714729888178	H749 **3940106300** 0
3.25	08714729888185	H749 **3940106325** 0
3.50	08714729888192	H749 **3940106350** 0
3.75	08714729888208	H749 **3940106375** 0
4.00	08714729888215	H749 **3940106400** 0
	10 mm Length	
2.00	08714729888222	H74939 **40110200** 0
2.25	08714729888239	H74939 **40110225** 0
2.50	08714729888246	H74939 **40110250** 0
2.75	08714729888253	H74939 **40110275** 0
3.00	08714729888260	H74939 **40110300** 0
3.25	08714729888277	H74939 **40110325** 0
3.50	08714729888284	H74939 **40110350** 0
3.75	08714729888291	H74939 **40110375** 0
4.00	08714729888307	H74939 **40110400** 0

Balloon Diameter (mm)	Order Number (GTIN)	Ref/Catalog Number
	15 mm Length	
2.00	08714729888314	H74939 **40115200** 0
2.25	08714729888321	H74939 **40115225** 0
2.50	08714729888338	H74939 **40115250** 0
2.75	08714729888345	H74939 **40115275** 0
3.00	08714729888352	H74939 **40115300** 0
3.25	08714729888369	H74939 **40115325** 0
3.50	08714729888376	H74939 **40115350** 0
3.75	08714729888383	H74939 **40115375** 0
4.00	08714729888390	H74939 **40115400** 0

WOLVERINE Coronary Cutting Balloon
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. **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. 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. To reduce the potential for vessel damage, the inflated diameter of the device should approximate a 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. • Balloon pressure should not exceed the rated burst pressure. • When performing percutaneous atherotomy, the availability of on-site surgical backup should be included as a clinical consideration. **Precautions:** • The device should be used only by physicians experienced in the performance of PTCA • If difficulty is experienced during balloon inflation, do not continue; remove the device and do not attempt to use it • 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. • 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 • 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. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
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