Boston Scientific
Advancing science for life™

WOLVERINE™
Cutting Balloon™ Dilatation Device

Proven On Calcium.

Effective. Safe. Versatile.

NC EMERGE™
Balloon Platform

With calcium, the right tools make a difference

The **WOLVERINE** advantage:

Superior Mechanism of Action[3]

Atherotomes anchor to calcium and produce controlled, longitudinal fractures.

Strategic Atherotome Placement

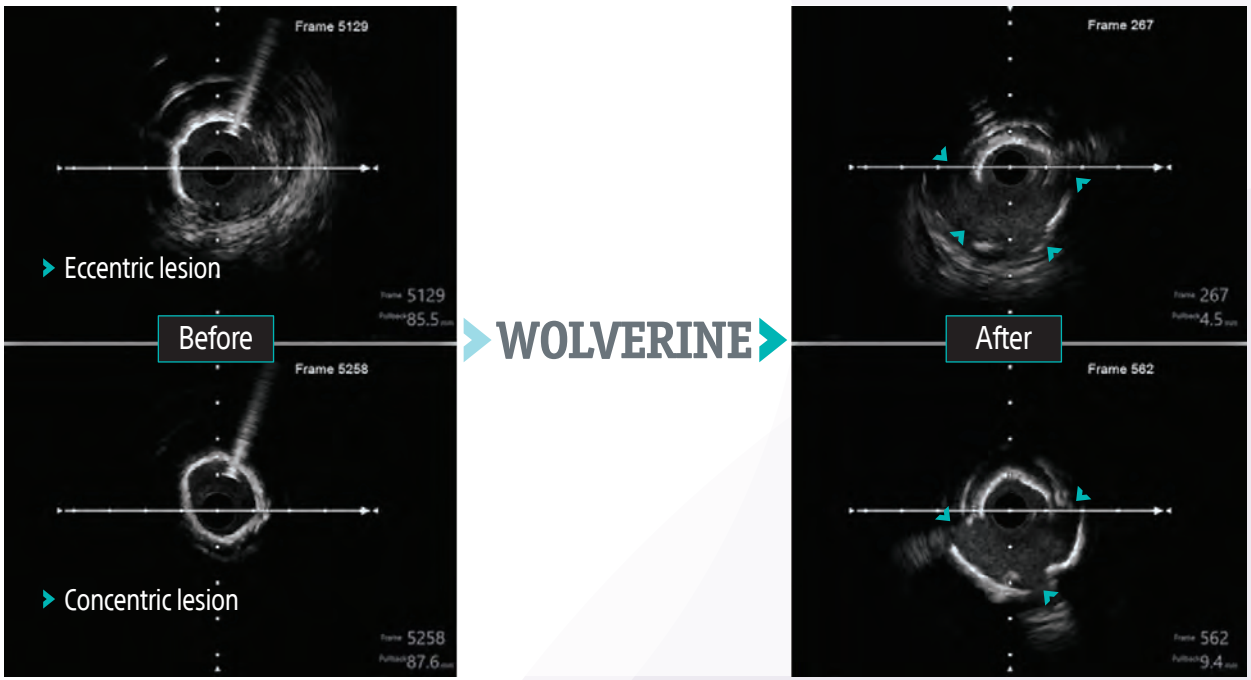
Enables up to 4 points of contact with calcium, improving the probability of modification with a single balloon.

Focused Force to Amplify Impact

Forces amplified 3x at atherotomes, precisely fracturing calcium at lower balloon inflation pressures

Seeing is believing

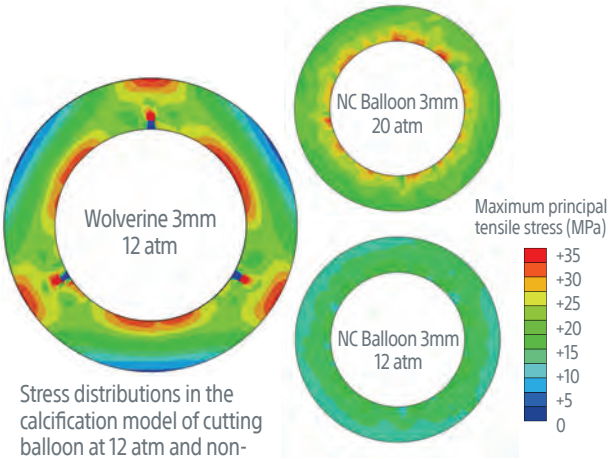
With clinically demonstrated efficacy in cases ranging from **0° to 360° calcification**[4], eccentric calcium has finally met its match with **WOLVERINE**.



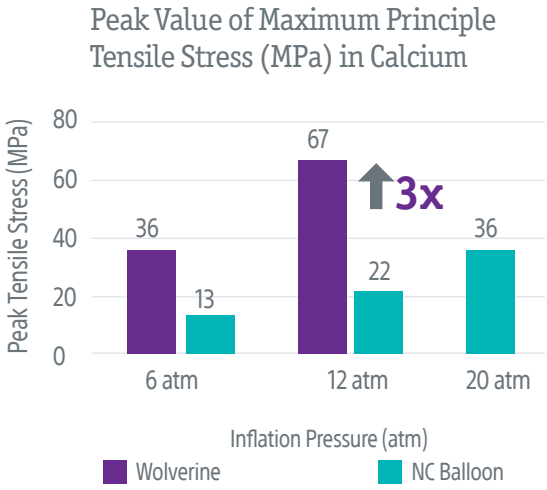
1. X Xhu, K Iwasaki, Circ Rep 2021; 3: 1-8.
2. Am J Physiol Heart Circ Physiol 289: H2048–H2058, 2005
3. Cardiovascular Intervention and Therapeutics (2019) 34:325–334
4. Cardiovascular Intervention and Therapeutics (2021) 36:198–207

Maximum impact at lower pressure

Secured atherotomes amplify force in calcium up to **3x**[1] so lesions can be modified at lower pressures than possible with POBA or scoring balloons



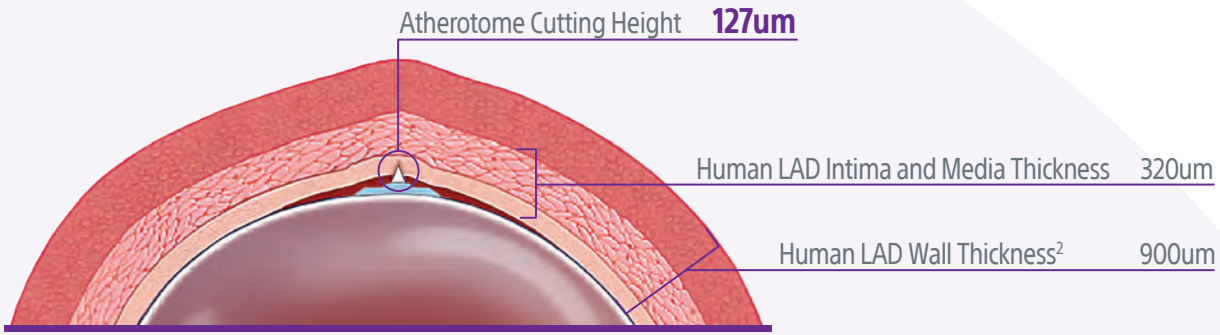
Stress distributions in the calcification model of cutting balloon at 12 atm and non-compliant at 12 atm and 20 atm.



WOLVERINE is tough on calcium and safe for healthy tissue

WOLVERINE's atherotomes anchor into the plaque and amplify pressures to safely fracture calcium at lower pressures. These controlled, microsurgical incisions are no thicker than a strand of hair.

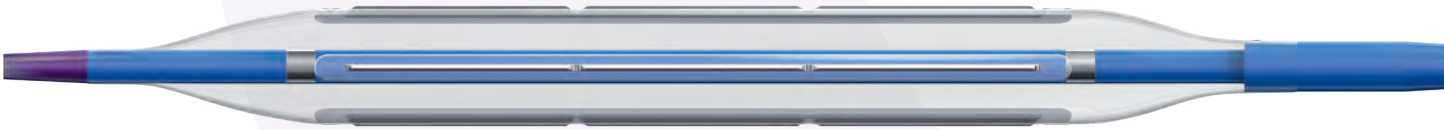
WOLVERINE's precision: Combined with appropriate balloon sizing, enables better luminal gain at a lower pressure while reducing the risk of barotrauma in resistant lesions.[3]



WOLVERINE™
Cutting Balloon™ Dilatation Device

WOLVERINE Cutting Balloon is a versatile, non-compliant balloon:

- Modifies resistant, fibrotic lesions
- Novel mechanism of action
- Recommended to achieve optimal lumen gain at lower pressures



- 5F & 6F compatible
- 6, 10, & 15mm working lengths
- Treats small vessels, coronary ostium, bifurcations, ISRs & fibrotic and calcific lesions

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 Percutaneous Transluminal Coronary Angioplasty (PTCA). 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. • 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 trained 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. • 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). **Potential ADVERSE EVENTS** Potential adverse events include, but are not limited to, the following: • Abrupt closure • Acute myocardial infarction • Angina or unstable angina • Arrhythmias, 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, possibly requiring surgical repair or intervention • Death • Drug reactions, including allergic reaction to contrast medium • Embolism • Hemodynamic compromise • Hemorrhage or hematoma • Hypo/hypertension • Infection • Minor vessel trauma • Myocardial ischemia • Percutaneous re-intervention • Pseudoaneurysm (at vascular access site) • 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 reaction • Ventricular irritability/dysfunction • Vessel trauma requiring surgical repair or intervention • Volume overload **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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
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IC-1304703-AA