

WOLVERINECutting Balloon Dilatation Device

for the Hospital Purchasing Committee

MASTER THE COMPLEX



PRODUCT OVERVIEW

WHAT IS A CUTTING BALLOON?

Coronary cutting balloon is intended for opening coronary arteries in those circumstances where a resistant lesion is encountered and unable to be opened with traditional balloon angioplasty.

WHAT MAKES THIS PRODUCT UNIQUE?

Treating complex lesions with traditional balloon angioplasty can result in complications like vessel dissection, poor luminal gain, lesion recoil, balloon slippage, and poor stent apposition.

The unique design of the WOLVERINE Cutting Balloon combines a proprietary atherotome and low pressure balloon design to directly address each of these complications.

TECHNOLOGY OVERVIEW

WOLVERINE Cutting Balloon delivers industry-leading performance with:

- Improved crossability and deliverability
- Precise, controlled cutting
- A proven mechanism of action

The result is optimal lumen gain with thorough vessel preparation.

Improved Inner and Outer Flexibility

Improved Tip Flexibility and Visibility

Reduced Lesion Entry Profile

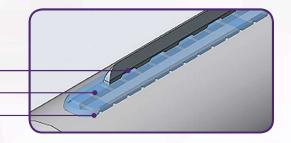
Reduced Crossing Profile

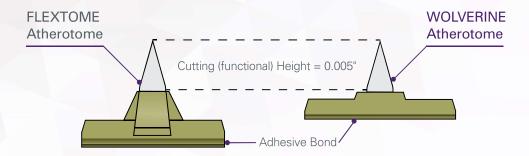
TECHNOLOGY OVERVIEW

ATHEROTOME COMPARISON

A smaller profile is achieved through the reduction in the T-Slot height.

- T-Slot -
- Cast Pad -
- Adhesive Bond

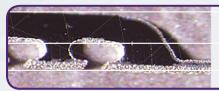


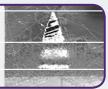


T-SLOT BLADE DIMENSION CHANGES

- T-Slot (non-functional) height reduced by 57%
- Elongated T-Slot shape to ensure strong blade to adhesive cure

FLEXTOME





Functional Height 0.005"

T-Slot Height 0.0059"

WOLVERINE

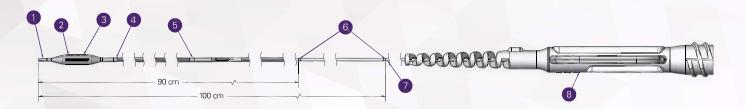




Functional Height 0.005"

T-Slot Height 0.0025"

GENERAL SPECIFICATIONS



- 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

Indication	The WOLVERINE Cutting Balloon is indicated for use in patients with coronary vessel disease who are acceptable candidates for coronary artery bypass graft surgery, should it be urgently needed, for the purpose of improving myocardial perfusion. See page 5 for additional information.
Mechanism of Action	When the device is inflated, the atherotomes score 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 Di l atation Catheter
Device Delivery Platform	Monorail™ (143 cm) and Over-the-Wire (142 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
	Over-the-Wire: 2.00 mm, 2.50 mm, 3.00 mm, 3.50 mm, 4.00 mm
Available Balloon/Blade Lengths	6 mm, 10 mm, 15 mm
Rated Burst Pressure	12 ATM (1216 kPa)
Nominal Pressure	6 ATM (608 kPa)
Guide Catheter Inner Diameter	$2.00-3.25 \ge 0.056$ " (1.42 mm) $3.50-4.00 \ge 0.066$ " (1.68 mm)
Crossing Profile	0.036" (0.91 mm)
Tip Lesion Entry Profile	0.017" (0.43 mm)

MASTER THE COMPLEX

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