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#### 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.

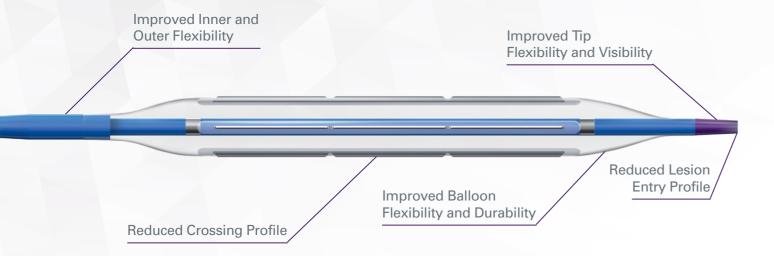
## TECHNOLOGY OVERVIEW

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#### WOLVERINE Cutting Balloon delivers industry-leading performance with:

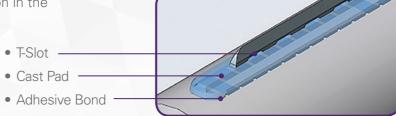
- Improved crossability and deliverability
- Precise, controlled cutting
- A proven mechanism of action

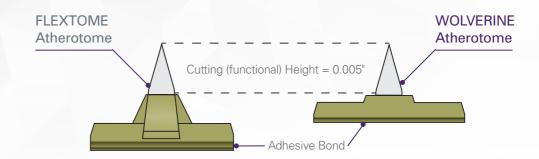
The result is optimal lumen gain with thorough vessel preparation.



#### ATHEROTOME COMPARISON

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





#### 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**



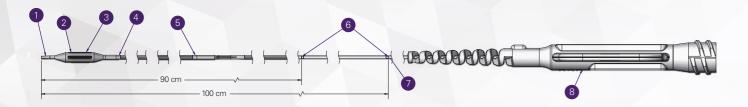


Functional Height 0.005"

T-Slot Height 0.0025"

## GENERAL SPECIFICATIONS

# ORDERING INFORMATION



| 1 Bumper 11p                             |
|--|
| 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 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/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)<br>$3.50-4.00 \ge 0.066$ " (1.68 mm)  |
| Crossing Profile                | 0.036" (0.91 mm)  |
| Tip Lesion Entry Profile        | 0.017" (0.43 mm)  |

| Manufacturer   | Boston Scientific   |  |  |  |
|--|---|--|--|--|
| Will this product replace or supplement a current in-house product?  | This product can replace or supplement existing cutting balloons.                                       |  |  |  |
| Ship unit  | 1 each per box  |  |  |  |
| Minimum order quantity?  | No  |  |  |  |
| What are the dimensions of the shipping carton container?  | The carton for the single disposable is 11 $14" \times 9 34" \times 12"$                                |  |  |  |
| What is the list price per each unit or unit of utilization?   | Please speak to your Boston Scientific sales representative for the price per each unit.                |  |  |  |
| Method of purchase   | Please speak to your Boston Scientific sales representative regarding sales programs for this purchase. |  |  |  |
| Workstation storage considerations   | Per the DFU, store at room temperature, in a dry, dark place.   |  |  |  |
| Is this a dated product?   | Yes, with a 2-year shelf life.  |  |  |  |
| Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space? | No, however a brief in-service by a Boston Scientific sales representative is suggested prior to use.   |  |  |  |
| Does this item and its packaging contain latex?  | There is no detectable latex in this product.   |  |  |  |

### ORDERING INFORMATION

| GTIN           | REF/CATALOG NUMBER       | MATERIAL DESCRIPTION |
|----------------|--------------------------|----------------------|
| 08714729888406 | H749 <b>3940306200</b> 0 | (MR) 6 mm × 2.00 mm  |
| 08714729888413 | H749 <b>3940306225</b> 0 | (MR) 6 mm × 2.25 mm  |
| 08714729888420 | H749 <b>3940306250</b> 0 | (MR) 6 mm × 2.50 mm  |
| 08714729888437 | H749 <b>3940306275</b> 0 | (MR) 6 mm × 2.75 mm  |
| 08714729888444 | H749 <b>3940306300</b> 0 | (MR) 6 mm × 3.00 mm  |
| 08714729888451 | H749 <b>3940306325</b> 0 | (MR) 6 mm × 3.25 mm  |
| 08714729888468 | H749 <b>3940306350</b> 0 | (MR) 6 mm × 3.50 mm  |
| 08714729888475 | H749 <b>3940306375</b> 0 | (MR) 6 mm × 3.75 mm  |
| 08714729888482 | H749 <b>3940306400</b> 0 | (MR) 6 mm × 4.00 mm  |
| 08714729888499 | H749 <b>3940310200</b> 0 | (MR) 10 mm × 2.00 mm |
| 08714729888505 | H749 <b>3940310225</b> 0 | (MR) 10 mm × 2.25 mm |
| 08714729888512 | H749 <b>3940310250</b> 0 | (MR) 10 mm × 2.50 mm |
| 08714729888529 | H749 <b>3940310275</b> 0 | (MR) 10 mm × 2.75 mm |

| 08714729888536 | H749 <b>3940310300</b> 0 | (MR) 10 mm × 3.00 mm |
|----------------|--------------------------|----------------------|
| 08714729888543 | H749 <b>3940310325</b> 0 | (MR) 10 mm × 3.25 mm |
| 08714729888550 | H749 <b>3940310350</b> 0 | (MR) 10 mm × 3.50 mm |
| 08714729888567 | H749 <b>3940310375</b> 0 | (MR) 10 mm × 3.75 mm |
| 08714729888574 | H749 <b>3940310400</b> 0 | (MR) 10 mm × 4.00 mm |
| 08714729888581 | H749 <b>3940315200</b> 0 | (MR) 15 mm × 2.00 mm |
| 08714729888598 | H749 <b>3940315225</b> 0 | (MR) 15 mm × 2.25 mm |
| 08714729888604 | H749 <b>3940315250</b> 0 | (MR) 15 mm × 2.50 mm |
| 08714729888611 | H749 <b>3940315275</b> 0 | (MR) 15 mm × 2.75 mm |
| 08714729888628 | H749 <b>3940315300</b> 0 | (MR) 15 mm × 3.00 mm |
| 08714729888635 | H749 <b>3940315325</b> 0 | (MR) 15 mm × 3.25 mm |
| 08714729888642 | H749 <b>3940315350</b> 0 | (MR) 15 mm × 3.50 mm |
| 08714729888659 | H749 <b>3940315375</b> 0 | (MR) 15 mm × 3.75 mm |
| 08714729888666 | H749 <b>3940315400</b> 0 | (MR) 15 mm × 4.00 mm |

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