Effect of Wolverine™ Cutting Balloon on Lesion Preparation for Calcified Lesions

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Disclosure

- Notihing to disclosure

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WOLVERINE™

Cutting Balloon™ Dilatation Device

In-Service Presentation

Contents

WOLVERINE™
Cutting Balloon™ Dilatation Device

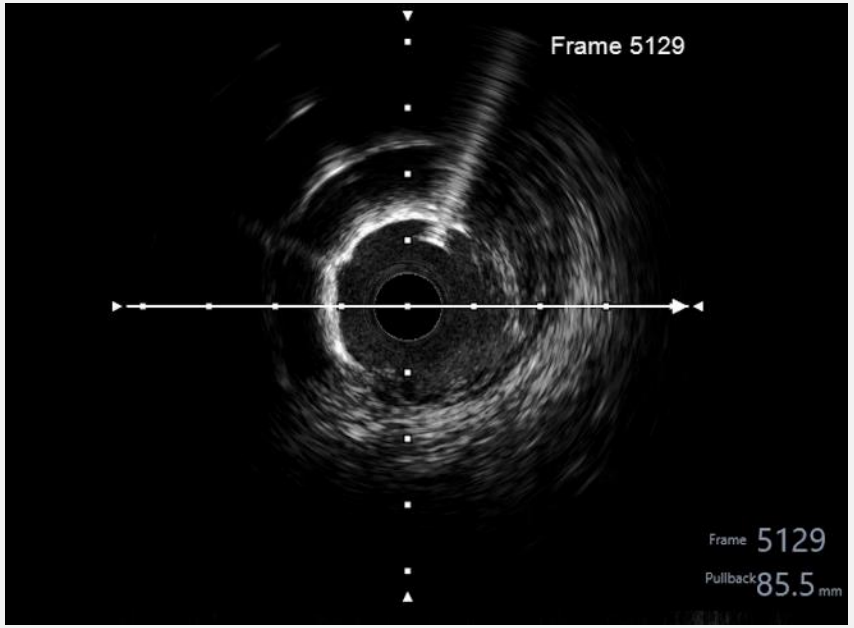
Product Information

Indications and Intended Use

The WOLVERINE™ Cutting Balloon Device 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.

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



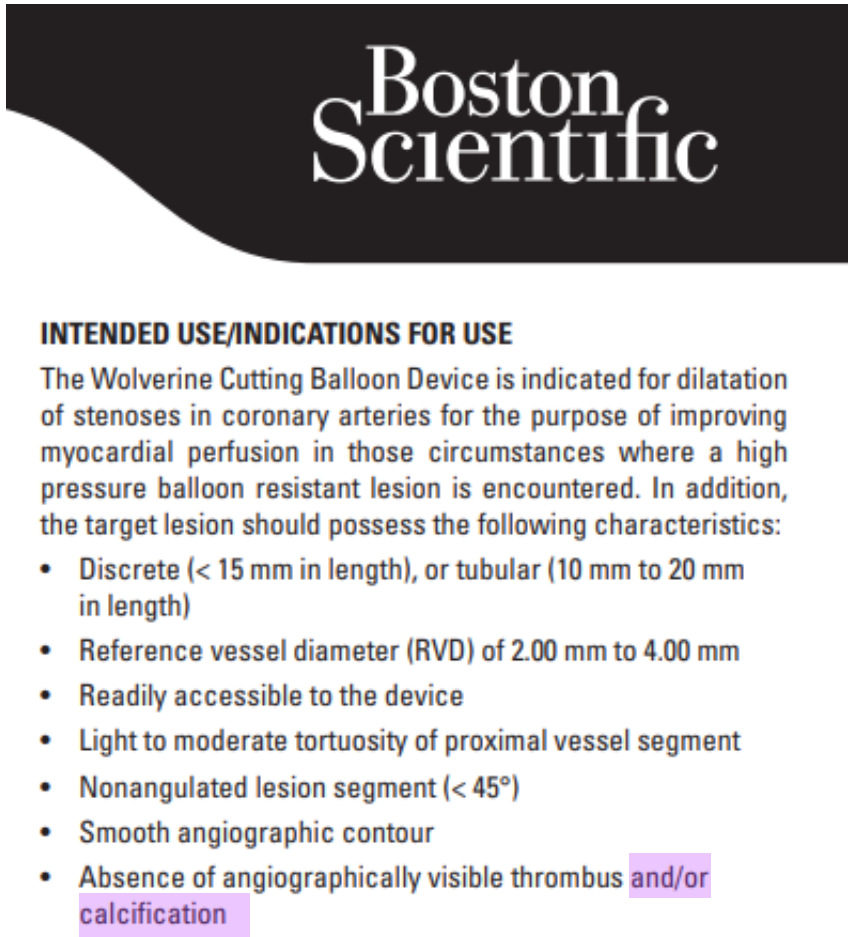
Cutting Balloon 급여기준

Cutting balloon 에 대한 급여기준 고시문([2007-46] 경피적관상동맥확장술(PTCA)시 사용한 cutting balloon catheter의 인정기준)의 내용에 따라 사용하시면 되기에 Cutting Balloon은 PTCA Balloon 개수 제한에 포함되지 않음.

Category	Cutting Balloon Catheter
중분류	CUTTING PTCA BALLOON CATHETER
급여 상한금액	1,344,420 원
제품명	WOLVERINE FLEXTOME
급여 기준	Cutting Balloon Catheter는 스텐트내의 재협착(Instent Restenosis)에 경피적 관상동맥확장술시 사용한 경우에 인정함.(고시 제2007-46호. 2007.6.1 시행)

WOLVERINE™ FDA US IFU Updates

November 2021



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INTENDED USE/INDICATIONS FOR USE

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 high pressure 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 and/or calcification

Changes

- Removed "and/or calcification" in target lesion characteristics bullet points
- Emergency surgical backup now a clinical consideration
- Additional cleanup and formatting for clarity

Rationale

- Align Instruction for Use with modern product usage
  - Cutting Balloon was first introduced before stents were approved for coronary use
  - Modern use of cutting balloon has since changed
- Supported by extensive literature, clinical data and real-world experience
- FDA approved changes in Nov 2021

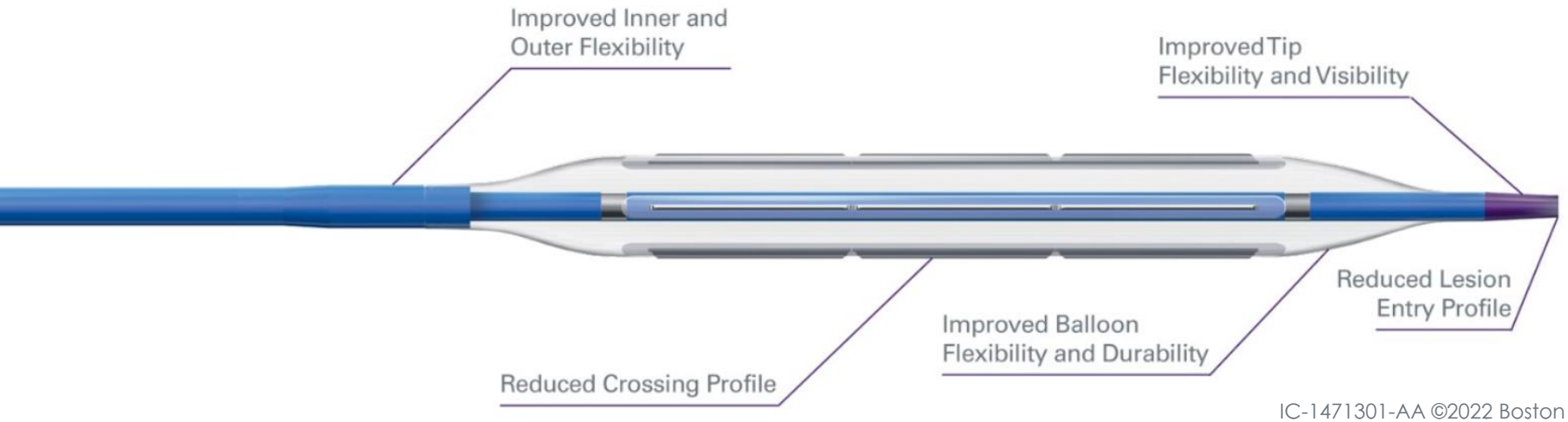
Product Design

Traditional balloon angioplasty can result in complications like:

VESSEL DISSECTION | **POOR LUMINAL GAIN** | **LESION RECOIL** | **BALLOON SLIPPAGE** | **POOR STENT APPOSITION**

The WOLVERINE™ Advantage

The unique design of the WOLVERINE Cutting Balloon is designed with **proprietary atherotomes** on a **low pressure non-compliant balloon** to directly address each of these complications



NC EMERGE™ Balloon Platform

Balloon Matrix and Inflation Pressures

Monorail Balloon Catheter with working lengths of 6, 10 and 15 mm
For vessels with reference diameter of 2.0 – 4.0 mm

BALLOON DIAMETER (mm)			BALLOON BODY LENGTH 6 mm	10 mm	15 mm
	2.00	3 Atherotomes			
	2.25				
	2.50				
	2.75				
	3.00				
	3.25				
	3.50	4 Atherotomes			
	3.75				
	4.00				

5F Compatible
GUIDEZILLA II 6F

6F Compatible
GUIDEZILLA II 7F

INFLATION PRESSURE RATING

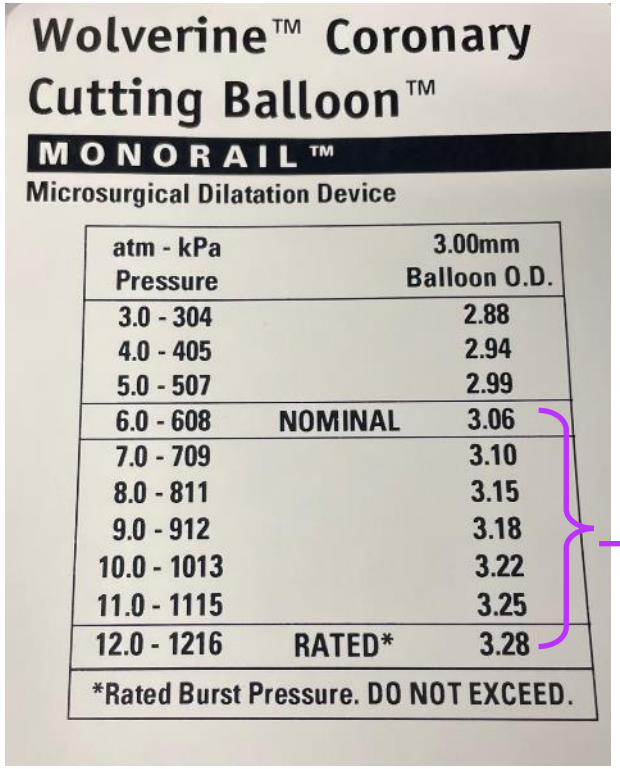
Nominal = 6 ATM

Rated Burst = 12 ATM

Sizing Considerations

WOLVERINE™ utilizes the NC EMERGE™ Catheter Platform, yet the balloon was designed to have a lower nominal pressure resulting in a different compliance

Growth Chart Example (3.0 mm)



Wolverine™ Coronary Cutting Balloon™

MONORAIL™

Microsurgical Dilatation Device

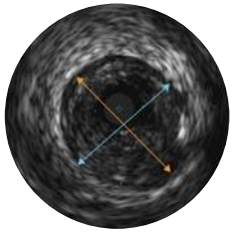
atm - kPa Pressure		3.00mm Balloon O.D.
3.0 - 304		2.88
4.0 - 405		2.94
5.0 - 507		2.99
6.0 - 608	NOMINAL	3.06
7.0 - 709		3.10
8.0 - 811		3.15
9.0 - 912		3.18
10.0 - 1013		3.22
11.0 - 1115		3.25
12.0 - 1216	RATED*	3.28

*Rated Burst Pressure. DO NOT EXCEED.

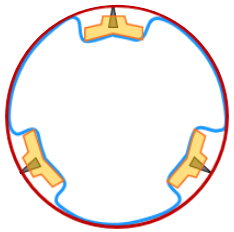
Sizing Considerations:

WOLVERINE grows roughly a quarter size when going from nominal (6 ATM) to rated burst pressure (12 ATM)

Physician consensus is to measure the normal distal reference with IVUS and then downsize WOLVERINE a half size from that measurement



Oversizing at nominal pressure will cause atherotomes to be "pillowed" by the balloon and may not provide adequate forces to modify calcium



Oversizing Example
Blue = Balloon
Red = Vessel

Oversizing at rated burst pressure may lead to vessel stretching and trauma due to balloon growth (not atherotomes)

Device Preparation and Use Instructions

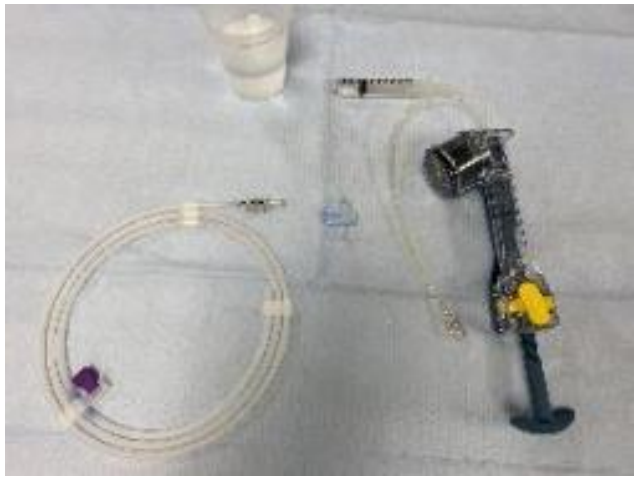
Device Preparation

Important: WOLVERINE™ preparation uses a wet negative prep procedure. Customary balloon preparation methods do not apply!

1

Sizing

- The Wolverine IFU states that the inflated diameter of the device should approximate a ratio of 1.1:1 in relation to the average diameter of the reference vessel. Oversizing increases risk of perforation. **As stated earlier, sizing a quarter to half size down may be needed if using higher inflation pressures.**



2

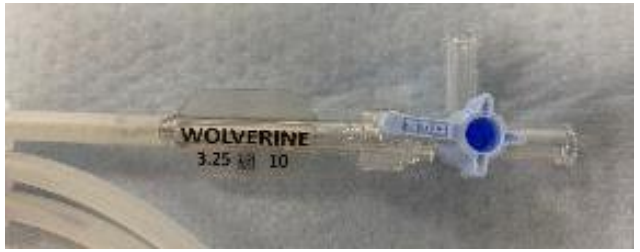
Unpacking

- 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

Attach Stopcock & Prepare Inflation Device

- 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).



Device Preparation

4

Attach Inflation Device & Purge

- 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 1-2 cc of contrast medium through the middle port.

5

Pull Full Negative

- 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.

6

Remove Device from Hoop

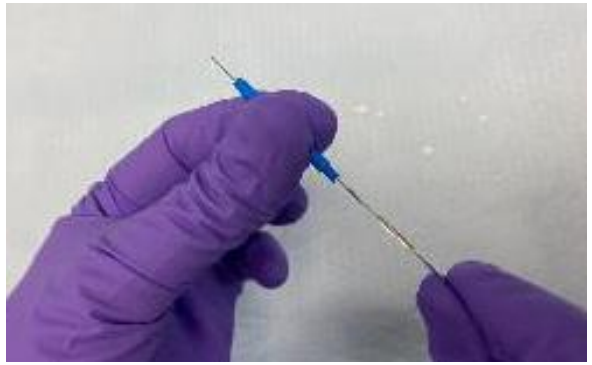
- When the device is ready to be inserted into the body, remove the device from its protective hoop. Use care when removing the device to avoid damage (e.g., shaft kink).

Device Preparation

7

Remove Balloon Protector

- Using straight force (not a twisting motion), pull the balloon protector distally from the device tip. For WOLVERINE MR Cutting Balloon Devices, 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

Coiling & Securing with CLIPIT Clip

- The WOLVERINE MR Cutting Balloon 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.

9

Flush Guidewire Lumen

- Flush the guidewire lumen of the device with heparinized saline. For WOLVERINE MR Cutting Balloon Device flush through the distal tip of the device.

10

Sterility

- Maintain device on a sterile table until ready to use.

Inflation & Removal Instructions

Inflation

1. **Go Slow**
   - 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).
     - If difficulty is experienced during balloon inflation, do not continue inflation; deflate and remove the device.
2. **Treat Distal then Proximal**
   - When using the device on long lesion segments, treat distal portion first and then proximal lesion segment second. Repeat coronary arteriography after each use to evaluate results.

Tips and Tricks

Prior to advancing the catheter, it may help to increase pressure to 1 atm and then pull negative to aid in loosening the packaged balloon crimp and provide added flexibility

Removal

1. **Deflate & Pull Negative**
   - 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. **Confirm Successful Result**
   - Repeat coronary arteriography to confirm successful result.
3. **Withdraw**
   - 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.

Tips and Tricks

Deflating slowly by dialing down pressure methodically to optimize balloon re-wrap

WOLVERINE™
Cutting Balloon™ Dilatation Device

Clinical Use Scenarios

WOLVERINE™

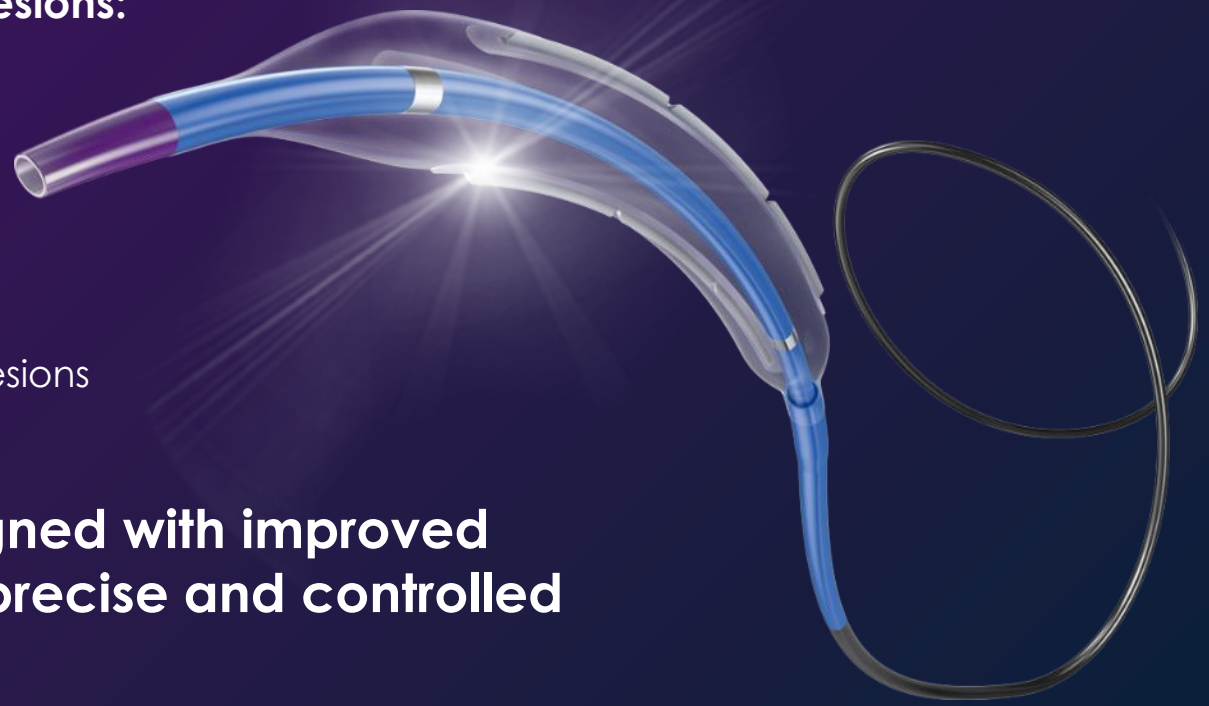
The right tool for vessel preparation device

Boston Scientific

Proper Solution to Help Prepare Lesions Prior to Stenting

WOLVERINE is right tool at helping treat a wide range of lesions:

- Cuts fibrotic plaque to limit recoil
- Cracks thin concentric and eccentric calcium
- Prepare small vessels prior to Drug Coated Balloon
- **Address In-Stent Restenosis**
- Limit balloon slippage in coronary ostium and bifurcation lesions



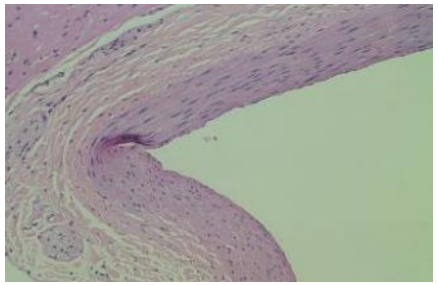
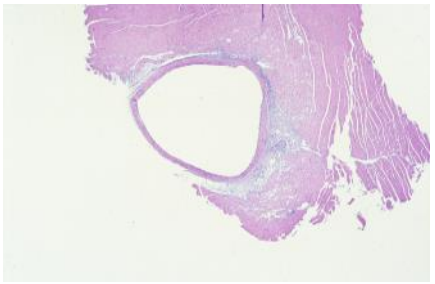
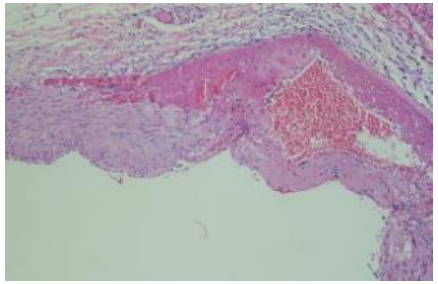
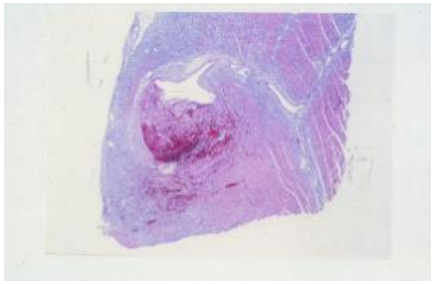
Cutting balloon angioplasty device designed with improved crossability and deliverability, to deliver precise and controlled cutting action

Clinical Use Scenarios

	Small Vessel Lesions REDUCE RESTENOSIS	Ostial and Bifurcation Lesions AVOID PLAQUE SHIFT	Fibrotic Lesions CHANGE LESION COMPLIANCE	Calcified Lesions CRACK CALCIUM TO ALLOW EXPANSION
LESION CHALLENGES	• High rates of restenosis • Tendency to dissect • Abrupt closure[1]	• Recoil • Plaque Shift • Side Branch Compromise	• High concentration of elastin and muscle fibers • High risk of vessel recoil	• Calcium deposits in plaque that prevent lumen gain • Varying degrees of burden and arcs
CUTTING BALLOON OBJECTIVES	• Use as stand-alone therapy • DCB or Stent?	• Dilates while reducing elastic recoil[2] • More plaque compression • Minimal plaque shift • Less vessel stretching[3]	• Atherotomes score through fibrotic plaque[4] • Reduce hoop strain and limit recoil • Lumen Gain	• Use as stand-alone therapy in eccentric and thin concentric calcium • Possible additive therapy with atherectomy • Lumen Gain

WOLVERINE™ Mechanism of Action

Porcine Artery Models

	ACUTE	14-DAY
CUTTING BALLOON		
POBA		

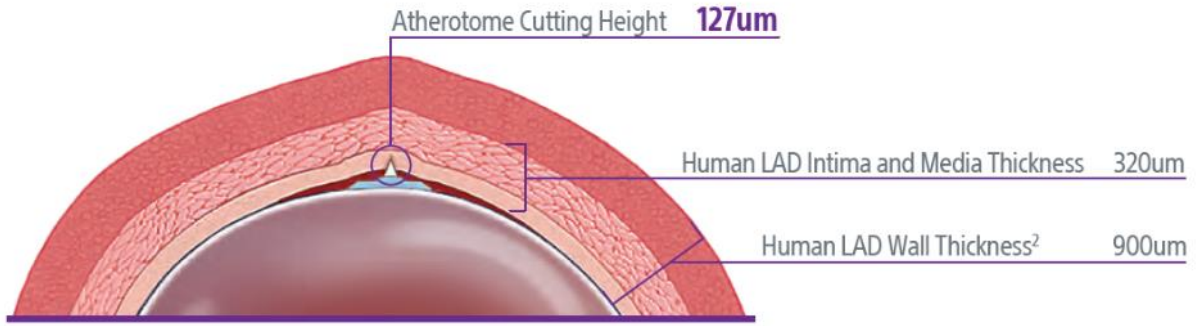
Acutely there is **over stretch*** and visible trauma to the vessel wall with POBA

At 14-days the vessel has **recoiled with POBA** and stayed open with cutting balloon

*This level of over-stretch was done for investigational purposes only

Reliable Option

- **25+ Year Track Record:** WOLVERINE has been used for over 25 years, and has a long track record of safety with real-world patients and clinical trials
- **Atherotome Height:** Approximately the same height as 1st generation stents or a human hair
- **Penetration Depth:** Even when placed in healthy tissue, WOLVERINE's atherotomes typically only penetrate partially into the media



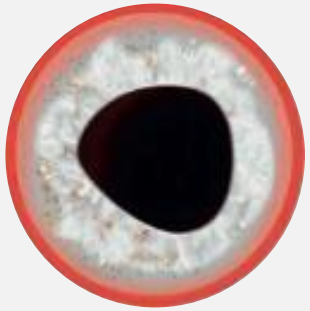
Data on file. Photos taken by Boston Scientific. Results of pre-clinical studies are not predictive of clinical performance. Clinical results may vary.

WOLVERINE™
Cutting Balloon™ Dilatation Device

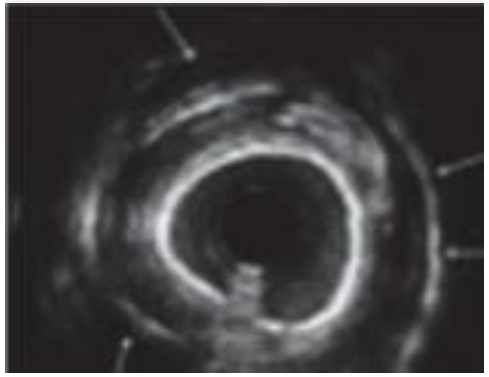
Calcium Modification

Calcium Morphology

CONCENTRIC

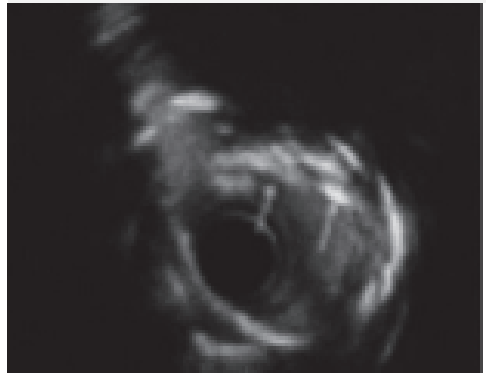


360˚Calcium Arc
Smooth Surface

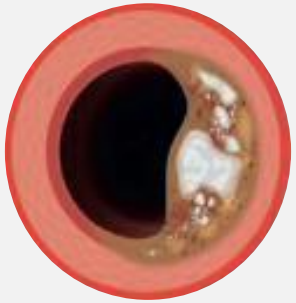


ECCENTRIC

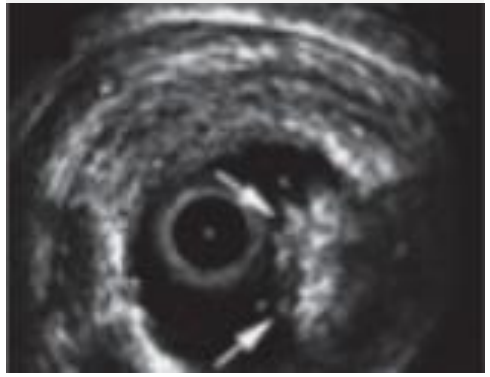
180 – 270˚ Calcium Arc
Irregular Surface



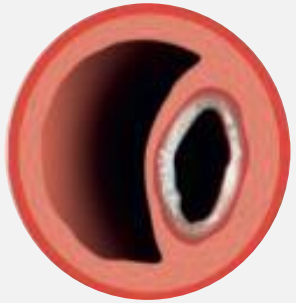
NODULE



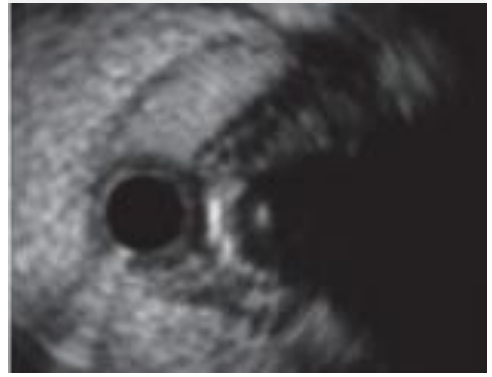
90 – 180˚ Calcium Arc
Luminal protrusion and
irregular leading edge



PSEUDO-NODULE



Extra-plaque
during CTO-PCI



Adapted from Dr. Anja Oksnes, School of Rock#5 Boston Scientific, Dec 14th 2021
Oksnes et al. J Intv Cardiol. 2021; 1, Article ID 9958035, 6 pages

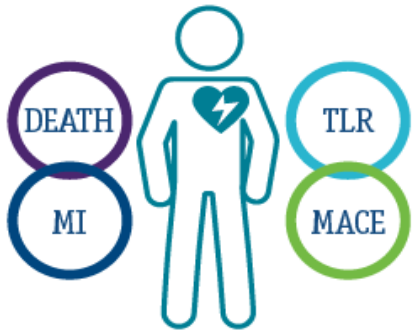
Calcium Needs to be Properly Treated

Calcium is a growing problem that can negatively impact PCIs if left untreated

Calcium is prevalent in patients undergoing PCI

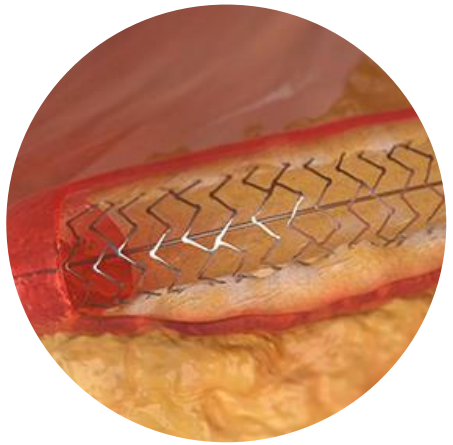
Over **30%** of all US PCI patients present with calcium.[1]

Calcium leads to worse clinical outcomes



Moderate to severe calcium creates a significantly higher chance of complications [2]

Calcium can inhibit optimal stenting



1. As reported to NHLBI Dynamic Registry. Bortnick, et. al. Am J Cardiol 2 014;113:573-579
2. Généreux, P. et al. J Am Coll Cardiol 2014 May;63(18):1845-1854

The Right Tools Make a Difference

Controlled Mechanism of Action

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

Pressure at atherotomes amplified to precisely fracture calcium at lower balloon inflation pressures

Calcific Lesion Modification Strategy

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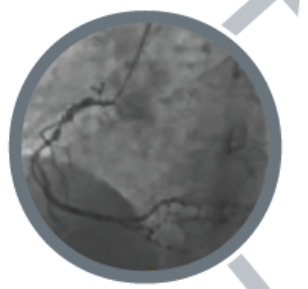
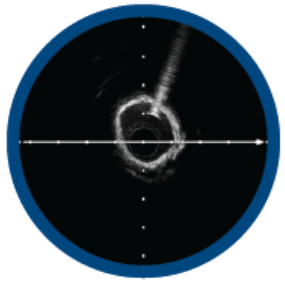
IVUS > Assess > Modify



Calcific disease

Device passes or undilatable (1:1 size)

Device won't pass



Measure arc (< 270° vs. > 270°)

Extent of disease (focal vs. diffuse)

Lesion location (ostial)

Size MLD (< 2 mm vs. > 2 mm)

Larger MLD device delivers eccentric arc < 180°

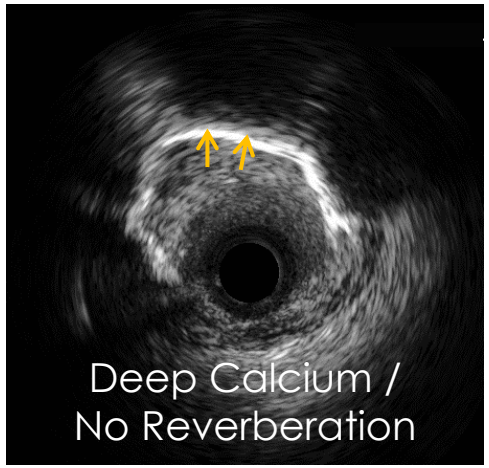
Smaller MLD ostial/ diffuse concentric arc preferred > 270°

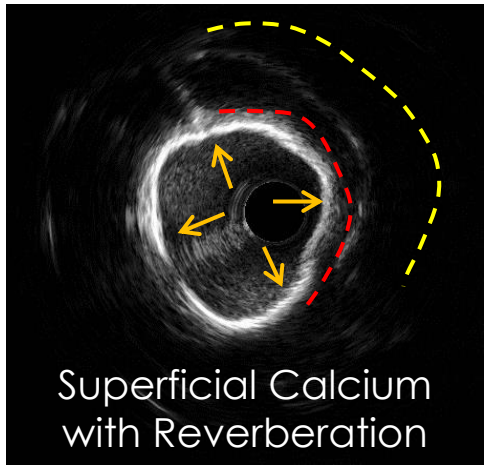
Larger MLD ostial/ focal concentric arc preferred > 270°

IVUS 123 ESSENTIALS

Assess Calcium FIRST with IVUS

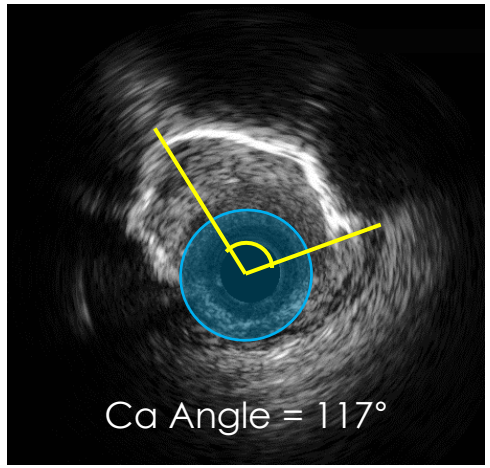
Thickness





Reverberation
Surface of calcium

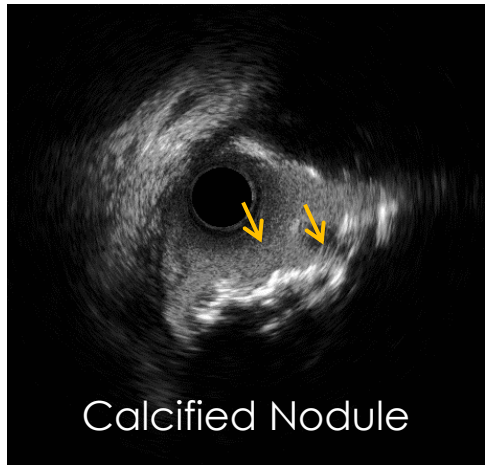
Angle

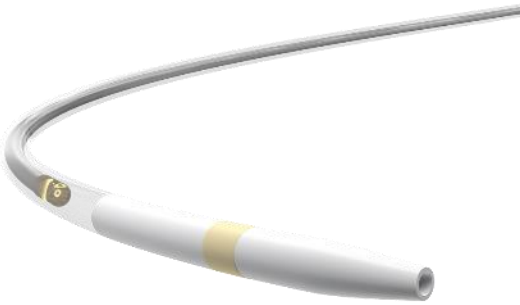


Length

LONGITUDINAL VIEW

Nodule





Adapted from A. Mahaera TCT 2020

Proven Mechanism of Action

Effective. Safe. Versatile.

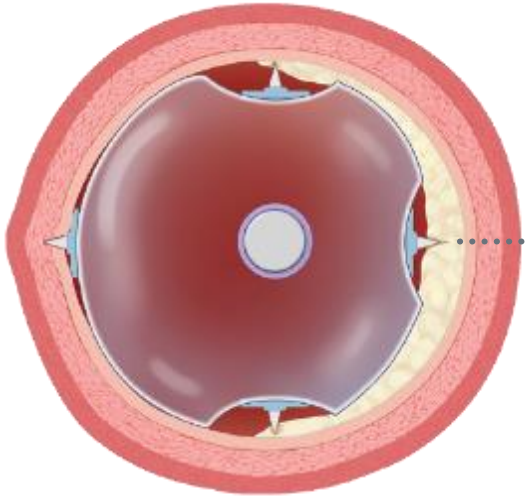
Wolverine's innovative design safely and efficiently cracks calcium[3]

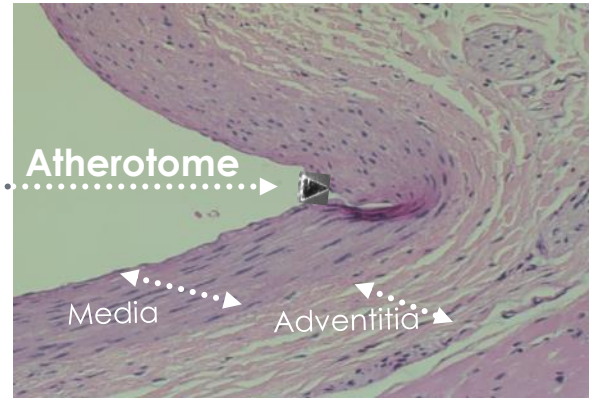
1 **Atherotome Amplified Force.[1]**

The atherotomes anchor into the plaque and amplify pressures generated by the balloon. This creates controlled, longitudinal cracks in the calcium.[1]

2 **Safely Cracks Calcium.**

Due to its unique design, Wolverine can modify calcium at lower pressures than POBA.[3] Atherotomes penetrate a small distance into the vessel wall, even in healthy tissue.[4]





Pre-clinical Swine Coronary artery post Cutting Balloon[1]

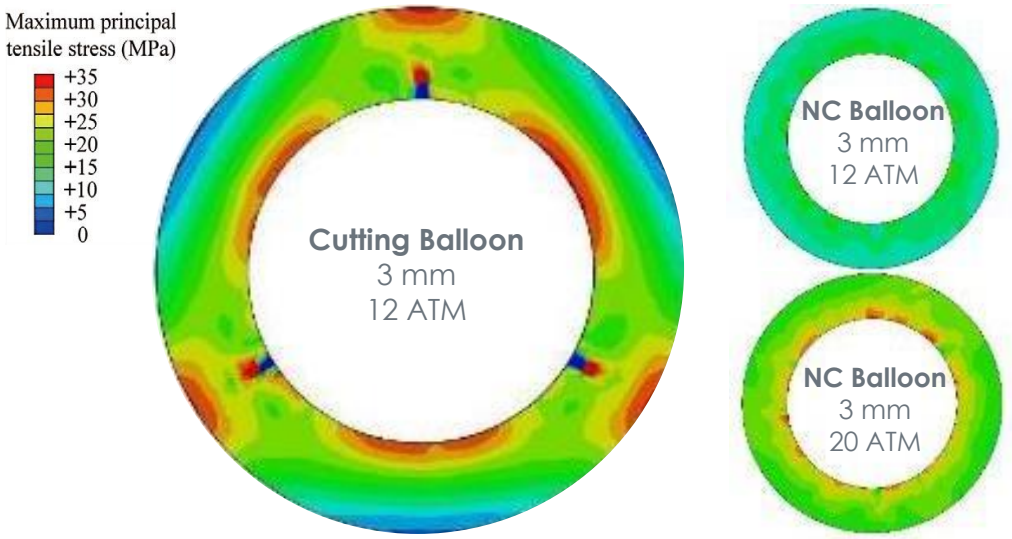
Atherotome Cutting Height	127 µm
Human LAD Media Thickness[2]	320 µm
Human LAD Wall Thickness[2]	900 µm

1 Xiaodong Zhu et al.;Circ Rep 2021; 3: 1 – 8 doi: 10.1253/circrep.CR-20-0070. Results of computer models are not predictive of clinical performance. Clinical results may vary.
2 Bonan, J InvasivCardiol, 1999; 11: 230
3 Mangieri, A. Cutting Balloon to Optimize Predilatation for Stent Implantation: The COPS Randomized Trial, TCT 2022
4 Data on file. Photos taken by Boston Scientific. Results of internal bench studies are not representative of clinical performance. Clinical results may vary.

Treating Calcium with WOLVERINE™

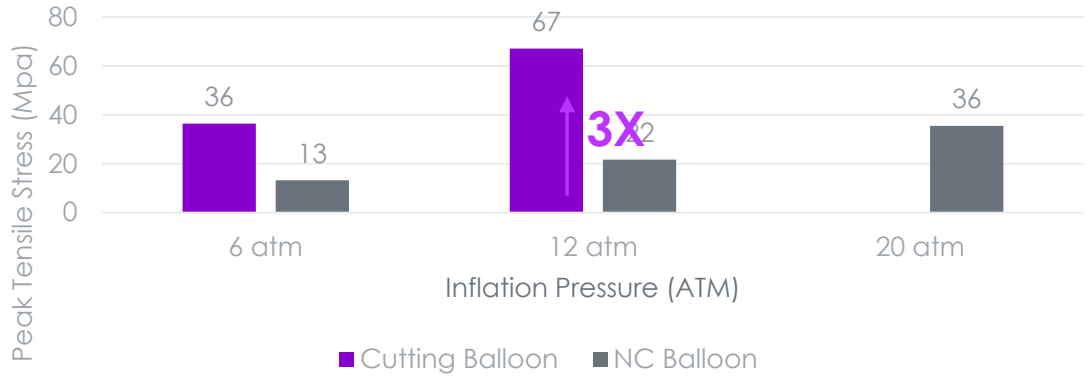
Boston Scientific

Calcification Model Stress Distributions

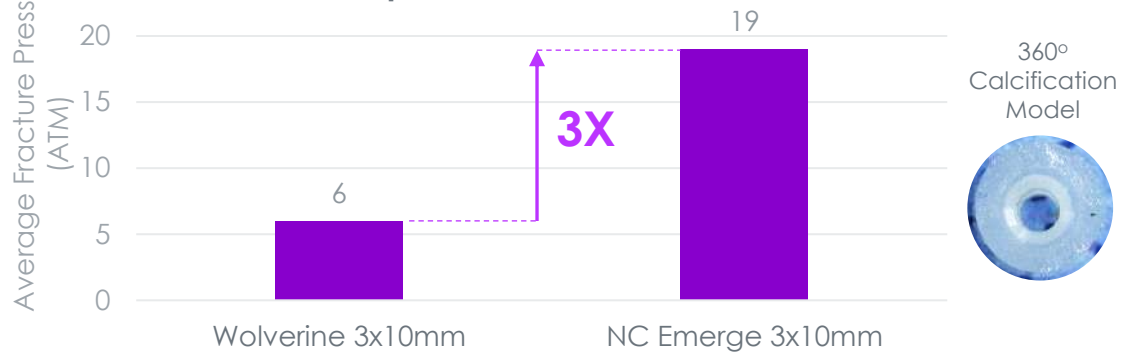


- WOLVERINE™ atherotomes **amplified balloon peak tensile strength 3X** vs NC Balloon
- Force is focused at atherotomes for controlled even calcium cracking
- **Balloon dilation force is enhanced** between the anchored atherotomes

Peak Value of Maximum Principle Tensile Stress (MPa)



Average Fracture Pressure (ATM) 400 µm 360° Lesion

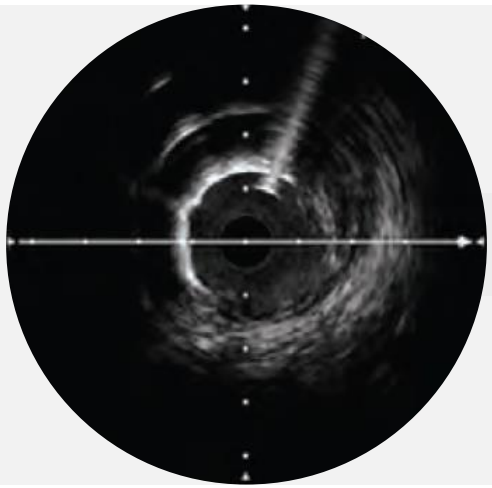
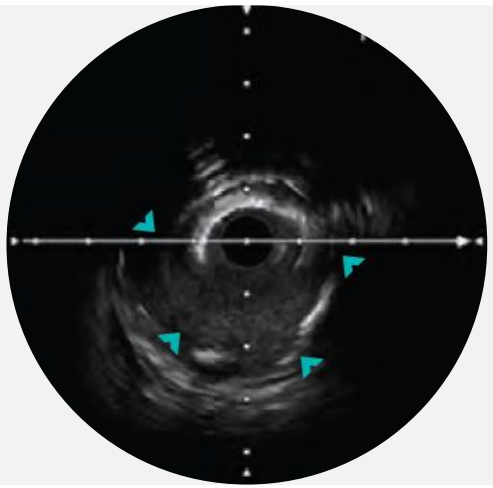
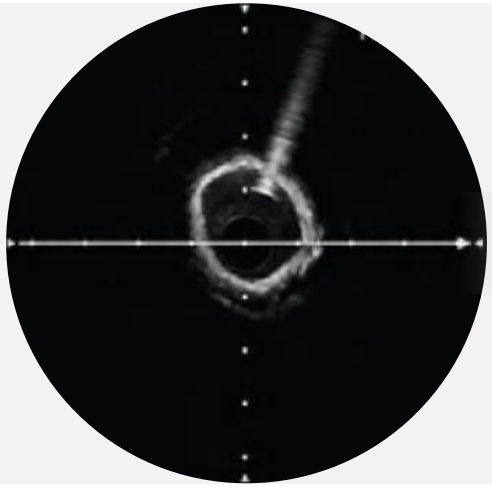
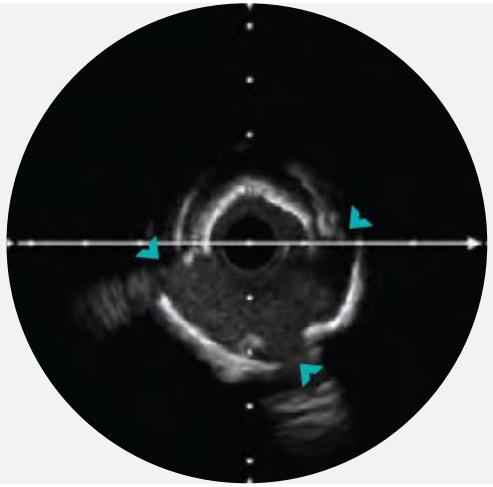


Kiyotaka IWASAKI. Euro PCR 2019; Influences of thickness and circumferential angles of calcification on the capability of fracturing calcification of the cutting balloon: an experimental investigation. Inflated up to 20 ATM until calcification model cracked in 37C water bath.
Results of bench models are not predictive of clinical performance. Clinical results may vary.

Xiaodong Zhu et al.;Circ Rep 2021; 3: 1 – 8 doi: 10.1253/circrep.CR-20-0070.
Results of computer models are not predictive of clinical performance. Clinical results may vary.

Demonstrated Efficacy in both Concentric and Eccentric Calcium

Boston Scientific

	BEFORE	AFTER
ECCENTRIC LESION		
CONCENTRIC LESION		

WOLVERINE™ has clinically demonstrated effectiveness in calcium ranging from 0° to 360° with a proven mechanism of action.[1]

Images courtesy of Dr. Simon Walsh, Royal Victoria Hospital, Belfast, Ireland; AUG 2020.

1. Ishihara et al.; Cardio. Intervention and Therapeutics (2021) 36:198-207

The COPS Trial

Cutting balloon to Optimize Predilatation for Stenting

Primary Investigators

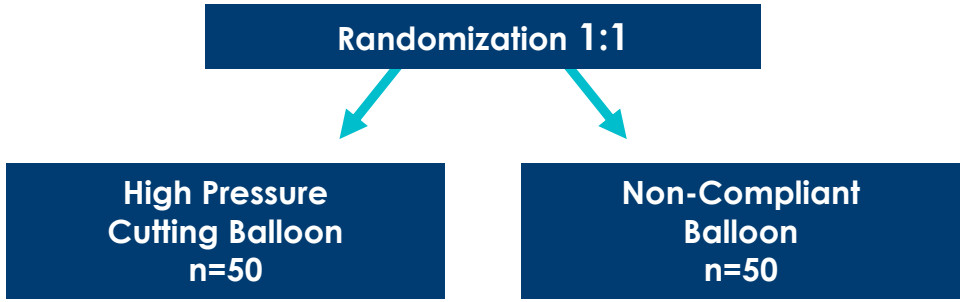
Dr. Antonio Mangieri, Dr. Antonio Columbo

Three hospitals in Italy

Maria Cecilia Hospital, Humanitas Rozzano, Clinica Mediterranea

Study Design

- Prospective, randomized, multicenter open-label trial which enrolled 100 patients with significant calcified lesions evaluated at IVUS



Primary Endpoint

- Minimal Stent Area (MSA) at Calcium Site

Secondary Endpoint

- Eccentricity Index : (LD max – LD min) / LD max
- MSA
- Device Failure
- Safety: Procedural Complications & One-Year MACE

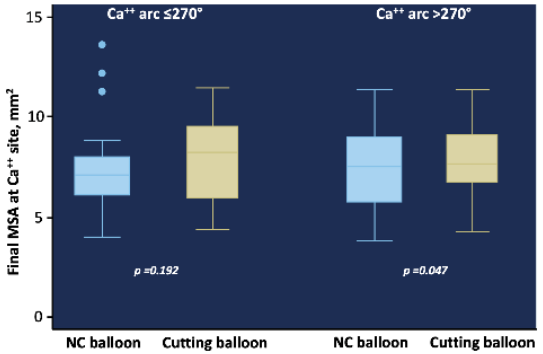
The COPS Trial: Results

Study contained a range calcium 100 – 360° and 29.4% avg of deep calcium

	Overall	CB (n=44)	NCB (n=43)	P value
Lesion Type				
Type B1	25 (28.7)	14 (32.5)	11 (25)	
Type B2/C	62 (71.2)	29 (67.4)	33 (75)	
Calcium distribution				0.482
Mixed Calcium	34 (40)	15 (34.8)	19 (45.2)	
Deep Calcium	25 (29.4)	15 (34.8)	10 (23.8)	
Superficial Calcium	26 (30.5)	13 (30.2)	13 (30.9)	
Arch of calcium (degrees)	266±84	274±84	258±85	0.373
Calcium length (mm)	12±6.6	11.9±7.3	12.5±6	0.667
Lesion length (mm)	24.3±9.7	23.5±9.6	25.1±9.8	0.442
Minimal lumen area (mm^2)	3.2±0.9	3.4±1.1	3±0.7	0.02
QCA evaluation				
Reference vessel diameter (mm)	3.4±0.4	3.51±0.3	3.39±0.4	0.112
Percentage of stenosis (%)	81.2±8.1	79.4±7.6	82.7±8.3	0.97

WOLVERINE is clinically proven to provide superior MSA at the calcium site compared to POBA

	CB (n=44)	NCB (n=43)	P value
Final MSA (mm^2)	7.1±1.7	6.5±2.1	0.116
Minimal Stent Diameter	2.7±0.4	2.5±0.4	0.064
Maximal Stent Diameter	3.2±0.4	3.1±0.4	0.189
Final MSA at calcium site	8.1±2	7.3±2.1	0.035
Minimal stent diameter at calcium site	2.9±0.7	2.7±0.4	0.016
Maximal stent diameter at calcium site	3.5±0.5	3.3±0.4	0.132
Eccentricity index at calcium site	0.84±0.7	0.8±0.8	0.013



The benefit was magnified in presence of severe calcifications

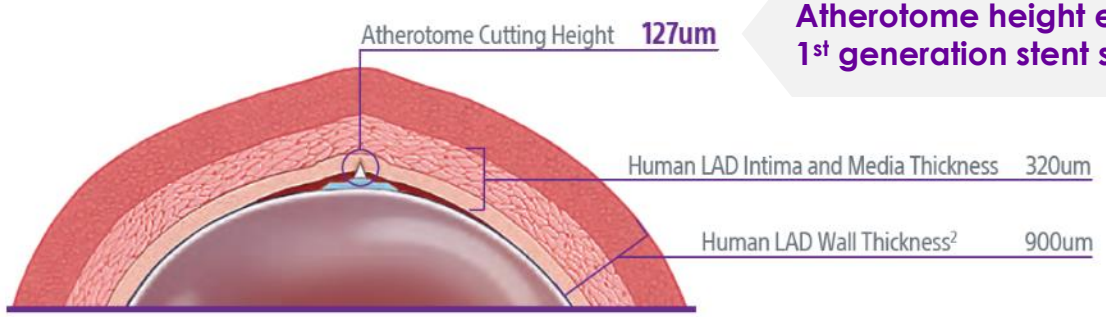
The COPS Trial: Safety

WOLVERINE™ use in calcium is safe, with no significant differences in procedural complications and 1-year MACE

	Overall	CB (n=44)	NCB (n=43)	P value
Device failure	3 (3.4)	3 (6.8)	0 (0)	0.517
Additional use of rotational atherectomy	1 (1.1)	1 (2.2)	0 (0)	0.79
Ellis type 1 vessel rupture	2 (2.2)	2 (4.4)	0 (0)	0.189
Implantation of a covered stent	1 (1.1)	1 (2.2)	0 (0)	0.65
Final TIMI flow >3	87 (100)	44 (100)	43 (100)	0.854
One year Follow-up				
Deaths	3 (3.4)	1 (1.1)	2 (4.6)	0.342
Cardiac deaths	1 (1.1)	0 (0)	1 (2.3)	0.887
Stroke	0 (0)	0 (0)	0 (0)	0.91
MI	0 (0)	0 (0)	0 (0)	0.96
TLR	3 (3.4)	1 (1.1)	2 (4.6)	0.49

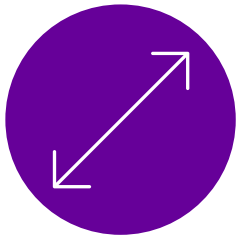
WOLVERINE provided excellent procedural success with limited need for atherectomy (n=1) despite a high rate of severe calcium in the study

WOLVERINE is both a safe and effective option for modifying severely calcified lesions



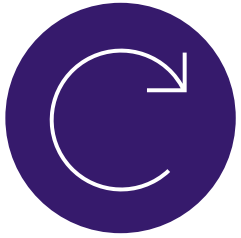
Atherotome height equivalent to 1st generation stent strut thickness

The COPS Trial: Key Learnings



WOLVERINE™ resulted in a **significantly larger minimal stent area** at the calcified segment.

This difference was especially apparent in cases with **severe calcification**.



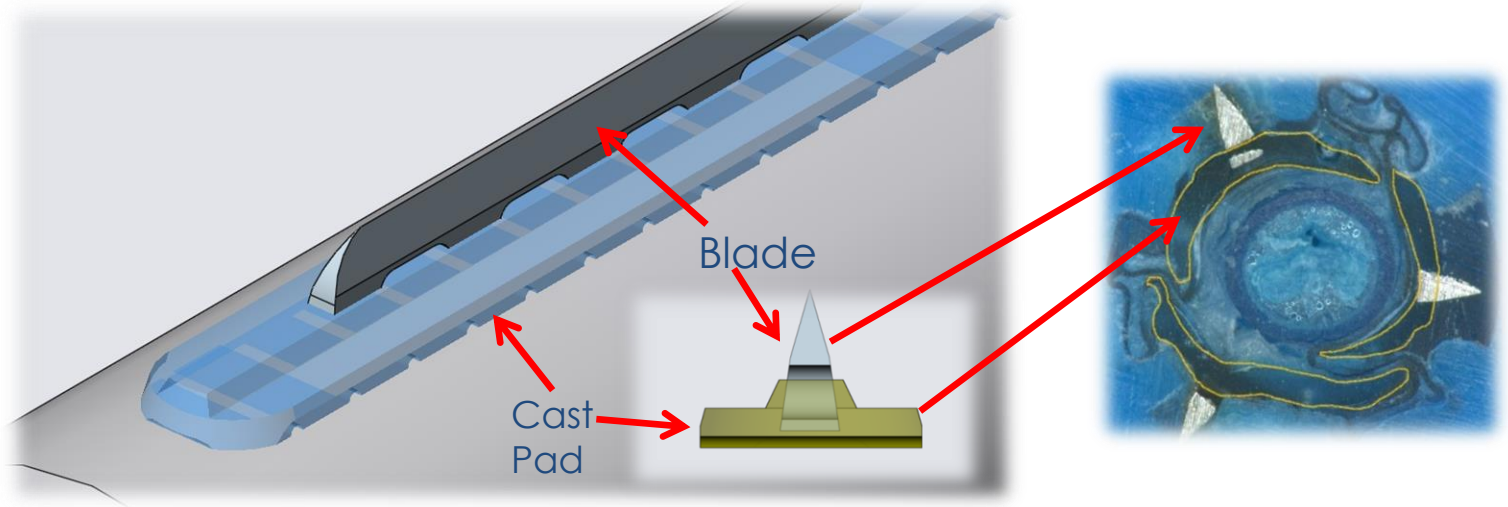
Stents had significantly **more uniform expansion** after vessel preparation with WOLVERINE.

WOLVERINE is safe for calcium treatment, even when inflated past rated burst pressure.

Competitive Product Comparisons

Wolverine VS Flextome

- Reduce non-functional blade height (portion in the cast pad) to improve profile
- Reduce cast pad height and width to improve profile



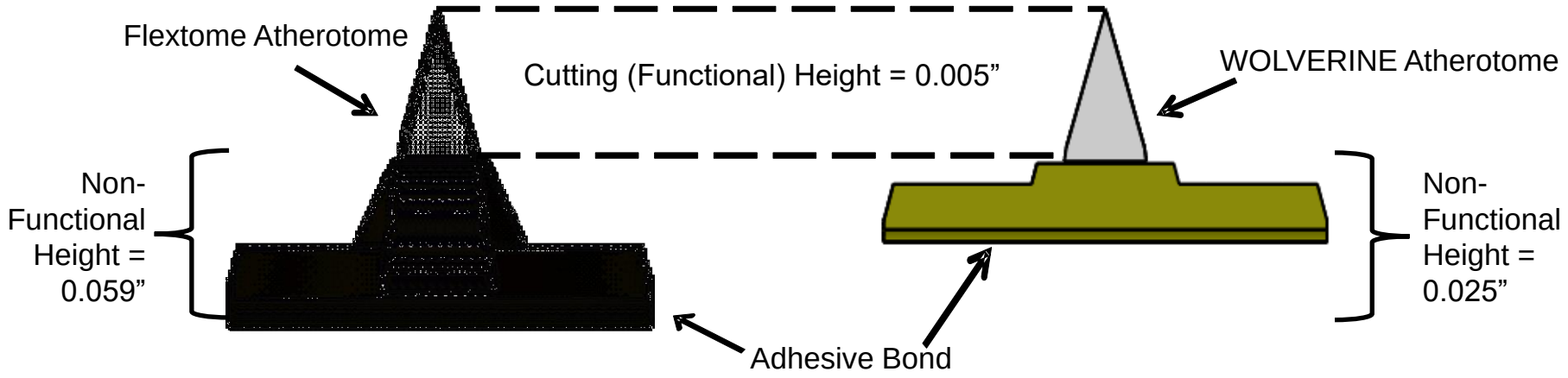


Figure 4: Cross Section of WOLVERINE and Flextome Atherotome

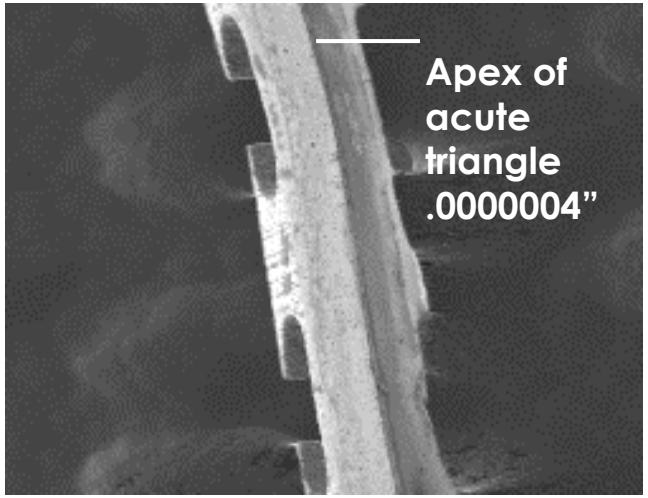
Competitive Specifications

WOLVERINE™ is compatible with smaller guide catheter and offer the broad size matrix to treat according to the type of lesions

	WOLVERINE™	Product A	Product B	Product C
Guide Cath Compatibility	**5F, 6F**	**5F**	**6F**	**5F**
Size Matrix: Diameter (mm)	2, 2.25, 2.5, 2.75, 3, 3.25, 3.5, 3.75, 4	2, 2.5, 3, 3.5	2, 2.25, 2.5, 2.75, 3, 3.25, 3.5, 4	2, 2.5, 3, 3.5, 4
Size Matrix: Length (mm)	6, 10, 15	6, 10, 15, 20	13	10, 15, 20
Pressures (ATM)	NOM: **6** RBP: **12**	NOM: **8-10** RBP: **16**	NOM: **6** RBP: **14**	NOM: **12** RBP: **20**
Catheter Length (cm)	143	139	142	139
Balloon Compliance	Non-Compliant	Semi-Compliant	Semi-Compliant	Non-Compliant
Plaque Mod Method	**3 or 4** evenly spaced atherotomes	Wire wrapped balloon	3 scoring elements	Single scoring wire

The Atherotome Advantage

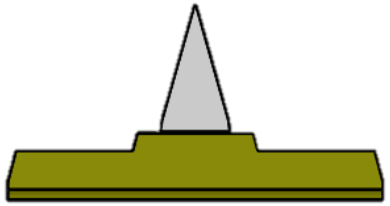
WOLVERINE™ Cutting Balloon™ Device
Atherotome



WOLVERINE Atherotome Advantage:

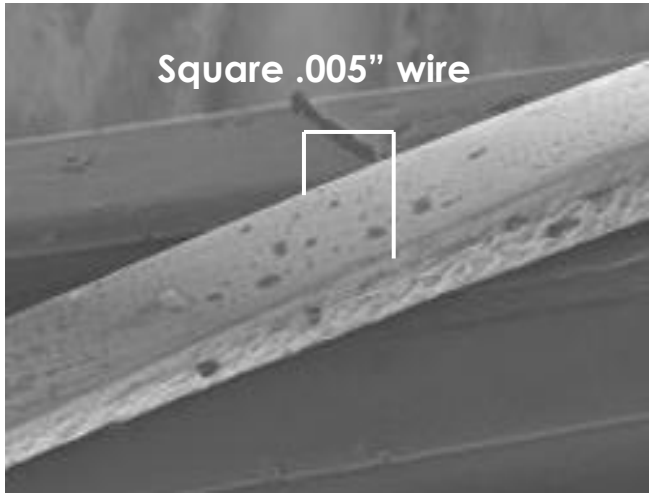
- Amplify balloon inflation pressures in calcium
- Create **microsurgical incisions** in fibrotic plaque

These two applications help to prepare vessels and limit recoil.



CUTTING BALLOON
CROSS SECTION

Product A
Nitinol Wire



Scoring Balloon Design:

- **Flat scoring design** provides a **blunt force** spread over a greater area.
- May explain why published data shows other scoring balloons to not generate **as high of acute gain** than cutting balloon.

Matsukawa, et al, Cardiovascular Intervention and Therapeutics (2019) 34:325 - 334

SCORING BALLOON
CROSS SECTION

Photographs taken by Boston Scientific at 100X magnification

Clinical Study: Cutting Balloon vs. Scoring Balloon in Severely Calcified Patients

Plaque modification using a cutting balloon is more effective for stenting of heavily calcified lesion than other scoring balloons

Primary Investigator

- Ryuichi Matsukawa, Fukuoka Red Cross Hospital, Fukuoka, Japan

Study Design

- Retrospective analysis of 156 patients treated for calcified coronary artery disease with either Cutting Balloon (n=30), NSE Scoring Balloon (n=39) or Scoreflex Scoring Balloon (n=87) from April 2015 – December 2017

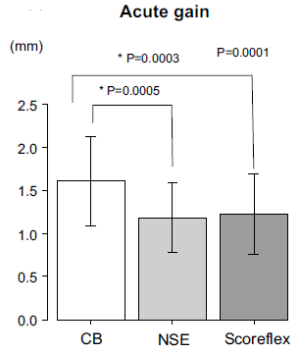
Notable Patient Characteristics

- Patients in all groups had similar characteristics including age, gender, lesion location, Minimum Lumen Diameter, reference vessel diameter and balloon to artery ratio
- However, the cutting balloon patients had a significantly higher rate of severe calcification (83.3%) than NSE (59%) or Scoreflex (44.8%)

Summary of Key Results

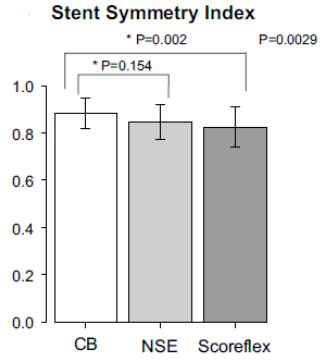
30% HIGHER ACUTE GAIN

Despite a significantly higher percentage of severe calcium, cutting balloon resulted in a statistically significant higher acute gain than scoring balloon.



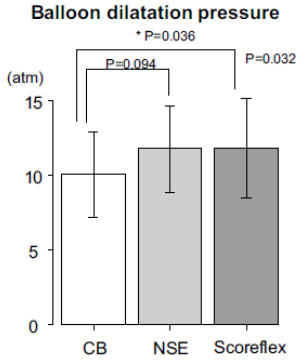
BETTER LUMEN SYMMETRY

Cutting balloon also had a superior effect on stent symmetry index, meaning that the stent lumen was more symmetrical than with scoring balloon.



ACHIEVED AT LOWER PRESSURES

This 30% higher acute gain was achieved with cutting balloon despite using a statistically significant lower inflation pressure than scoring balloon.



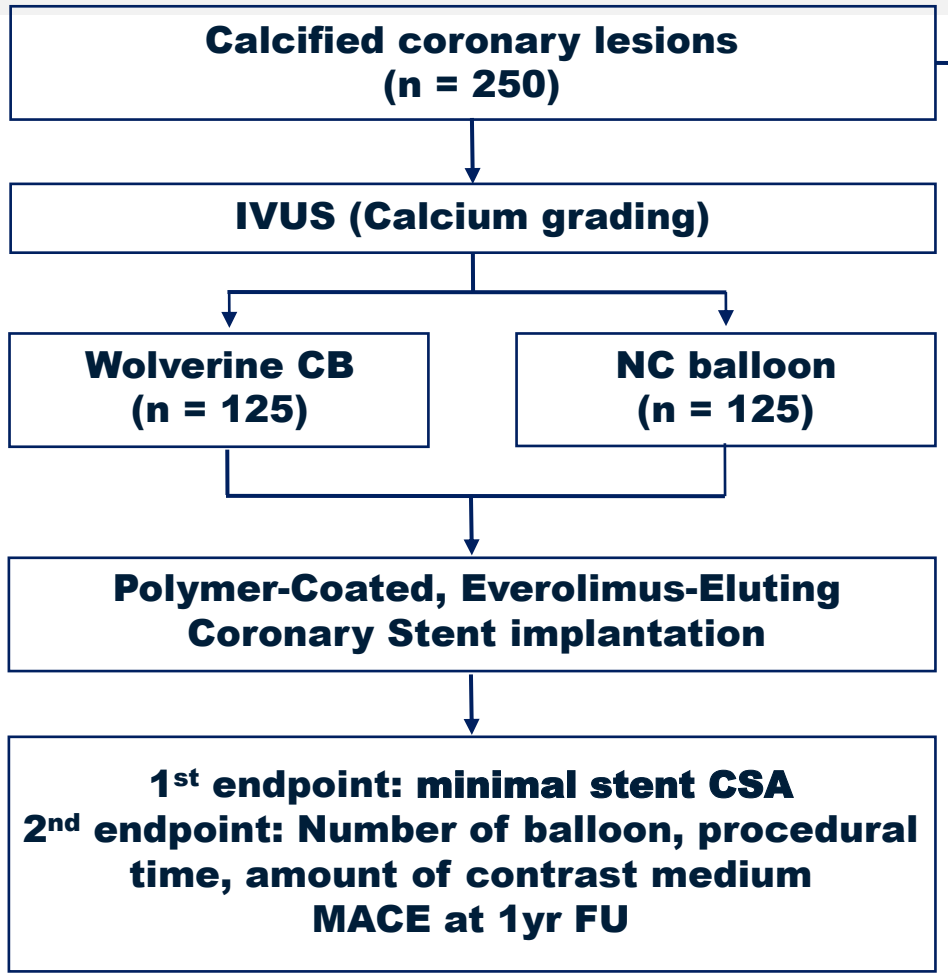
Matsukawa, et al, Cardiovascular Intervention and Therapeutics (2019) 34:325 - 334

WOLVERINE™
Cutting Balloon™ Dilatation Device

CUPID Trial

Assessment of Cutting-Balloon Angioplasty with Novel Bioabsorbable Polymer-Coated Everolimus-Eluting Stent in Treating Calcified Coronary Lesions Guided by Intravascular Ultrasound (CUPID trial): Study Design and Protocol

Novel cutting balloon prospective, randomized, open-label, multi-center study



Inclusion criteria

(1) Coronary artery disease including ISR or de novo lesion with a stenosis of ≥ 70%
(2) Target lesion calcification was confirmed by imaging studies (an arch of calcium at least 100 degrees)
(3) A reference vessel diameter between 2.0 and 4.0mm and deemed suitable for PCI

Exclusion criteria

(1) Extremely tortuous or angulated lesions
(2) Lesions with dissection before balloon pre-dilatation
(3) Lesions within the vein graft
(4) Extremely narrow lesions in which IVUS cannot pass through the lesion even after pre-dilatation
(5) STEMI
(6) Comorbidities which preclude the achievement of one year follow up

The CUPID Trial: Key points

- Expand the indications of the cutting balloon for the treatment of mild-to-severe coronary calcified lesions by conducting a comparative study of NC and cutting balloons in the treatment of calcified lesions.

- Investigate the clinical benefits of intraprocedural and periprocedural outcomes and operator convenience, including the number of total balloons used, procedure time, and amount of contrast.

- Confirm the mid- to long-term clinical benefits of aggressive modification of calcified lesions by cutting balloons

- The scope of insurance coverage for cutting balloons remains limited in some countries; therefore, this study also aims to provide evidence for extending insurance coverage to the treatment of de novo calcified lesions and ISR lesions

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 26, 2023

ClinicalTrials.gov ID: NCT06177808

Study Identification

Unique Protocol ID:	JSuh
Brief Title:	Assessment of Cutting-Balloon Angioplasty With Everolimus-Eluting Stent(EES) in the Treatment of Coronary Calcified Lesion(CCL) Guided by Intravascular Ultrasonography(IVUS)
Official Title:	Assessment of Cutting-Balloon Angioplasty With Novel Bioabsorbable Polymer-Coated, Everolimus-Eluting Stent in the Treatment of Calcified Coronary Lesions Guided by Intravascular Ultrasound
Secondary IDs:	

Study Status

Record Verification:	December 2023
Overall Status:	Recruiting
Study Start:	January 1, 2024 [Anticipated]
Primary Completion:	December 31, 2024 [Anticipated]
Study Completion:	December 31, 2025 [Anticipated]

Sponsor/Collaborators

Sponsor:	Soonchunhyang University Hospital
Responsible Party:	Principal Investigator Investigator: Jon Suh [jsuh] Official Title: Jon Suh, MD/PhD, Principal investigator Affiliation: Soonchunhyang University Hospital
Collaborators:	Boston Scientific Corporation Soonchunhyang University Hospital Eulji University The Catholic University of Korea Hanil General Hospital, Korea

WOLVERINE™
Cutting Balloon™ Dilatation Device

Brief Summary

WOLVERINE™ Brief Summary

The Wolverine Cutting Balloon Device 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. 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**
- **Calcified lesions**

+ Waiting for the results of CUPD trials

Disclaimers

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.