

WOLVERINE™

Coronary Cutting Balloon | The ShortCUT Trial

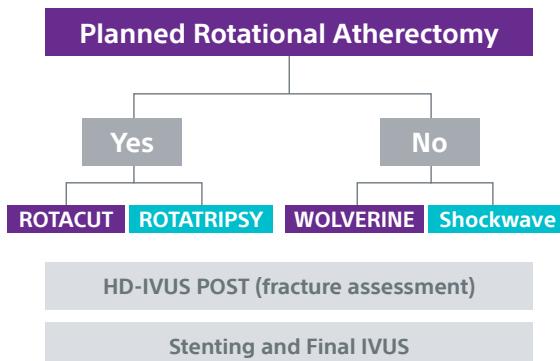


The ShortCUT Trial demonstrated WOLVERINE Cutting Balloon is non-inferior to Shockwave IVL with regard to MSA at the site of maximum calcium in moderate-severe calcified coronary lesions within the total study population.

Presented by Dr. Suzanne Baron, TCT 2025

ShortCUT Study Design

Randomized, non-inferiority trial of N=413 patients at 21 US sites with moderate-severe calcified lesions



Primary Endpoint (non-inferiority):
MSA at site of max calcification

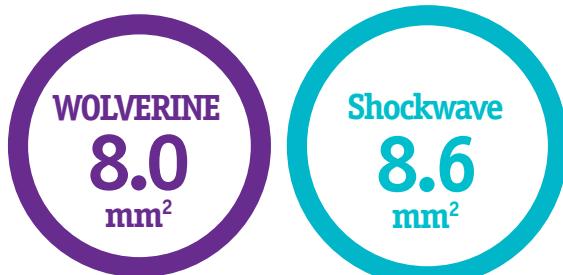
Key Secondary Endpoint (superiority):
Total procedural cost

Key Lesion Characteristics

	WOLVERINE N=212	Shockwave N=218
Reference Vessel Diameter	3.4 mm	3.5 mm
Target Lesion Stenosis	89%	87%
Median Max Calcium Arc	338°	347°
Nodular Calcium	25%	25%
CTO	13.5%	12.5%

WOLVERINE demonstrated non-inferiority to Shockwave in regards to MSA as site of max calcium. The ShortCUT Trial showed no differences in stent expansion and presence of calcium fractures in the total patient cohort.

MSA at site of max calcium
in total cohort



Secondary Endpoints

Stent Expansion at site of maximum calcium

WOLVERINE **Shockwave**
97.7% **97.7%**

P-value = 0.99

Calcium Fracture

WOLVERINE **Shockwave**
78.9% **77.4%**

P-value = 0.72

Cost

Total procedural costs were significantly lower with WOLVERINE, showing it is a cost-effective strategy for IVUS guided PCI procedures.

Total Procedural Cost

WOLVERINE	\$9,409	Total procedural cost was \$3,642 less with WOLVERINE
Shockwave	\$13,051	

Difference in total procedural cost was mainly driven by cost of randomized device

Safety

There were no significant differences in complication associated with randomized device, intraprocedural adverse events or MACCE through 30 days, validating WOLVERINE's comparable safety to Shockwave.

Endpoint	WOLVERINE N=206 Patients	Shockwave N=207 Patients	P-Value
Complication associated with randomized device	5.5%	4.0%	0.34
In-Hospital MACCE	1.0%	1.0%	1.00
30-Day MACCE	2.9%	2.9%	1.00
Intraprocedural adverse events	1.0%	1.0%	1.00

- ▶ ShortCUT trial protocol called for WOLVERINE Cutting Balloon to be sized 0.5mm smaller than reference vessel diameter and inflated to high pressures (16-20 atm). Average pressure used for WOLVERINE based on protocol was 17 atm.
- ▶ HD-IVUS was strongly recommended prior to randomization and mandatory after randomized device use (pre-stent implantation) & at procedure completion.

Ordering Information

Balloon Diameter (mm)	6 mm Blade length	10 mm Blade Length	15 mm Blade Length
2.00	H749 3940106200 0	H74939 40110200 0	H74939 40115200 0
2.25	H749 3940106225 0	H74939 40110225 0	H74939 40115225 0
2.50	H749 3940106250 0	H74939 40110250 0	H74939 40115250 0
2.75	H749 3940106275 0	H74939 40110275 0	H74939 40115275 0
3.00	H749 3940106300 0	H74939 40110300 0	H74939 40115300 0
3.25	H749 3940106325 0	H74939 40110325 0	H74939 40115325 0
3.50	H749 3940106350 0	H74939 40110350 0	H74939 40115350 0
3.75	H749 3940106375 0	H74939 40110375 0	H74939 40115375 0
4.00	H749 3940106400 0	H74939 40110400 0	H74939 40115400 0

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ShortCUT trial presented at TCT 2025 by Dr. Suzanne Baron.



**WOLVERINE™ Cutting Balloon™ Dilatation Device
Indications, Safety, and Warnings**

Interventional Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001

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