PHILIPS

AngioSculpt Evo

Maximize gain. Minimize risk.

With the most deliverable specialty balloon[1,2,3]

1. Costa JR, Mintz GS, Carlier SG, et al. Nonrandomized comparison of coronary stenting under intravascular ultrasound guidance of direct stenting without predilation versus conventional predilation with a semi-compliant balloon versus predilation with a new scoring balloon. Am J Cardiol. 2007;100:812-817.
2. Marketing Claims Report (most deliverable) 3. CER, D050055

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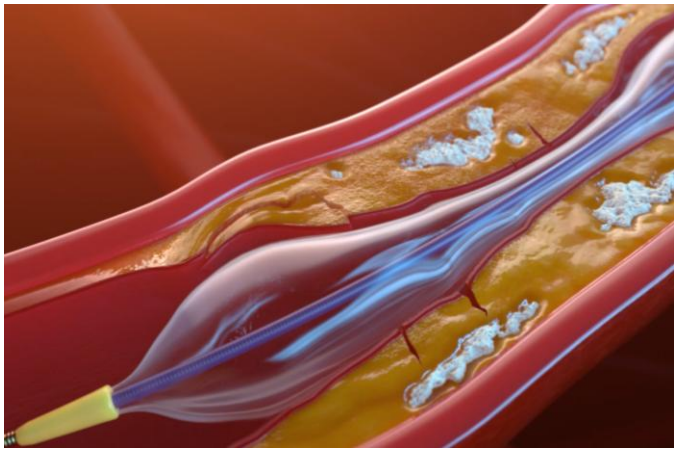
Maximize acute gain with AngioSculpt Evo[1]

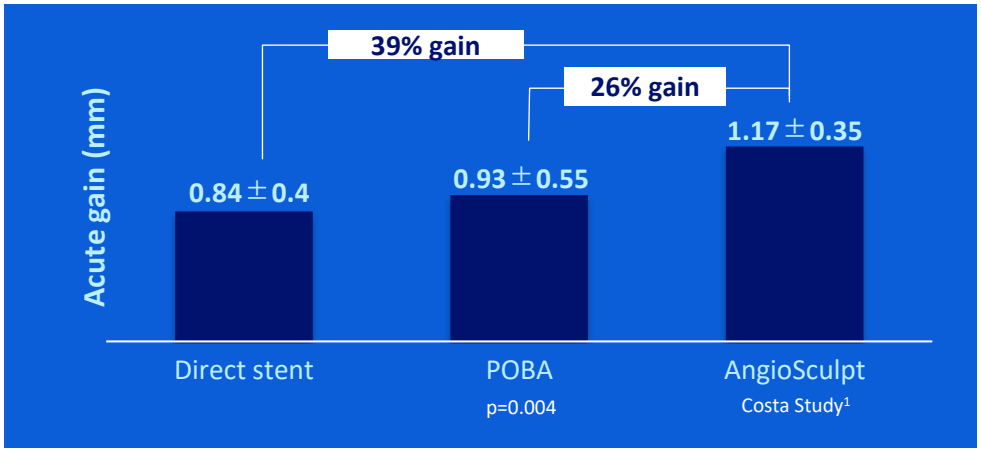
Limitations of POBA

- Power
- Dog boning
- Dissection rates

Benefits of AngioSculpt Evo

- Achieve greater luminal gain vs direct stenting and POBAs
- Minimize slippage
- Low dissection rates





Based on AngioSculpt PTCA clinical data

1. Costa JR, Mintz GS, Carlier SG et al. Nonrandomized Comparison of Coronary Stenting Under IVUS Guidance of Direct Stenting Without Predilation Versus Conventional Predilation With a Semi-Compliant Balloon Versus Predilation With a New Scoring Balloon. *Am J Cardiol*, 2007; 100:812-817.

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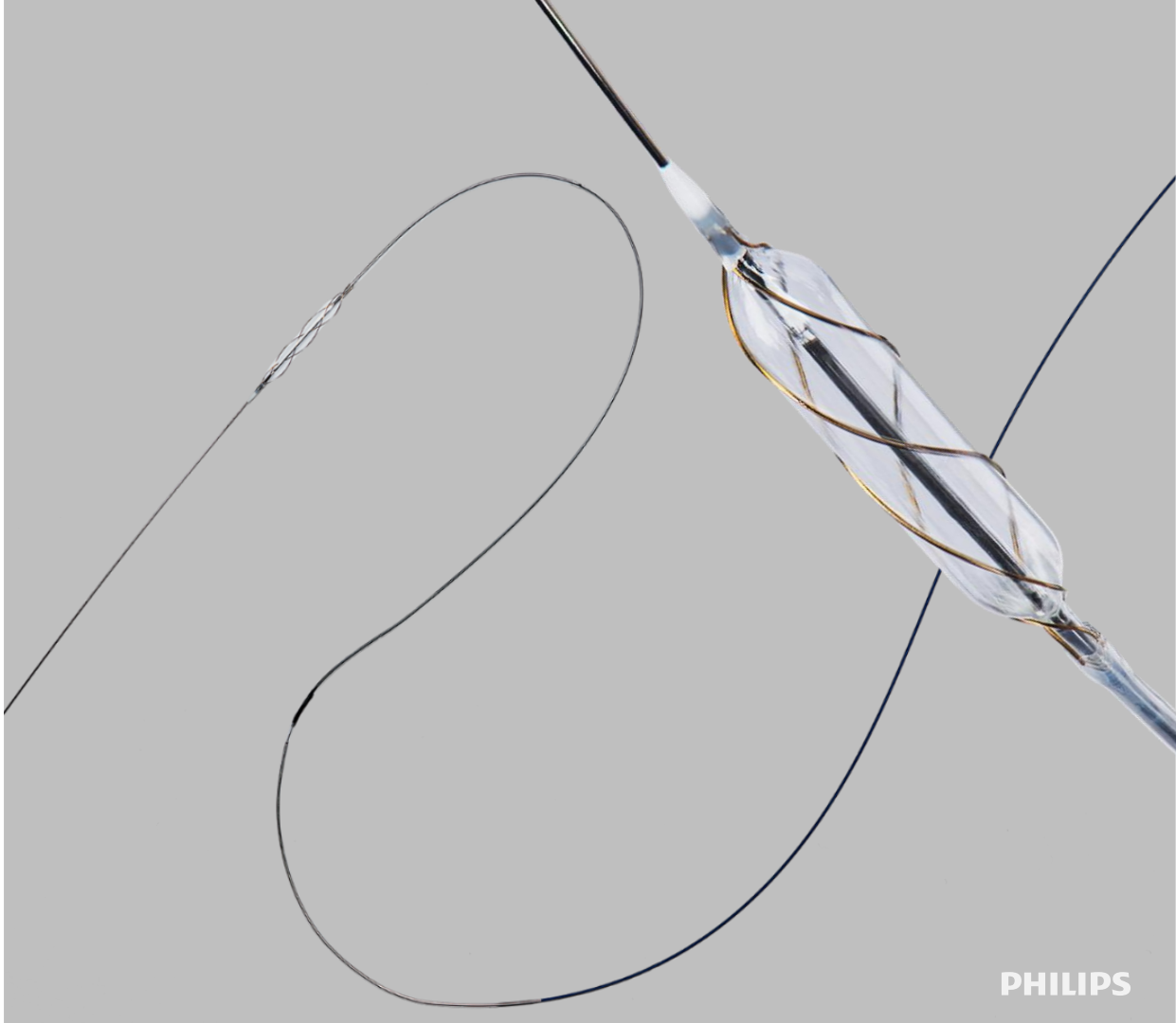
No compromise with AngioSculpt Evo

AngioSculpt Evo is designed to be a highly deliverable scoring balloon, with the power to safely dilate resistant lesions.[1,2,3]

- Circumferential scoring
- Controlled power
- Strong safety profile



Based on AngioSculpt PTCA clinical data

1. D051336 AngioSculpt Evo Marketing Claims Report.
2. Costa JR, Mintz GS, Carlier SG, et al. Nonrandomized comparison of coronary stenting under intravascular ultrasound guidance of direct stenting without predilation versus conventional predilation with a semi-compliant balloon versus predilation with a new scoring balloon. *Am J Cardiol.* 2007;100:812-817.
3. Costa RA, Mooney MR, Teirstein PS, et al. Final results from the multi-center trial of the angiosculpt scoring balloon catheter for the treatment of complex coronary artery lesions Cardiovascular Revascularization Medicine 7 (2006)81–126

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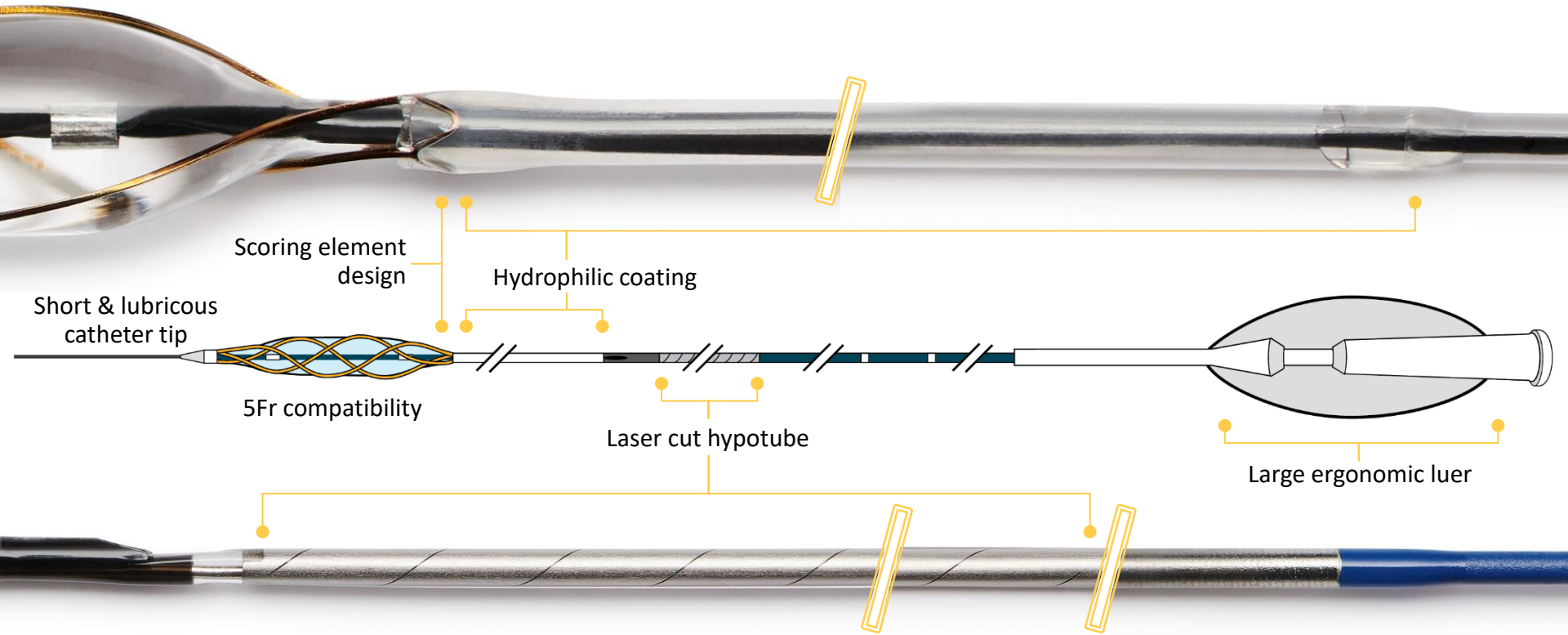
AngioSculpt Evo—key designs



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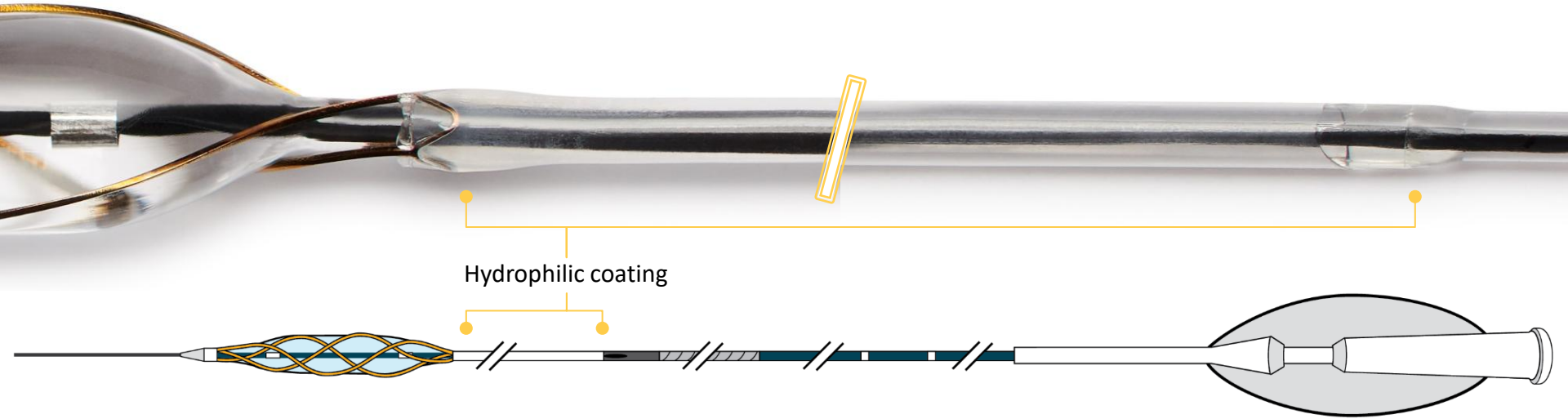
Superior deliverability and a small crossing profile[1]

AngioSculpt Evo is 5Fr guide compatible with a 43% smaller crossing profile than Wolverine
Hydrophilic coating applied to the catheter reduces required push force

44% less push force than Wolverine



1. D051336 AngioSculpt Evo Marketing Claims Report.

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AngioSculpt Evo deliverability[1]

Hydrophilic coating, laser-cut hypotube, and a small tip allows AngioSculpt Evo greater deliverability with:

44% less push force than Wolverine

37% less push force than AngioSculpt

1. D051336 AngioSculpt Evo Marketing Claims Report.

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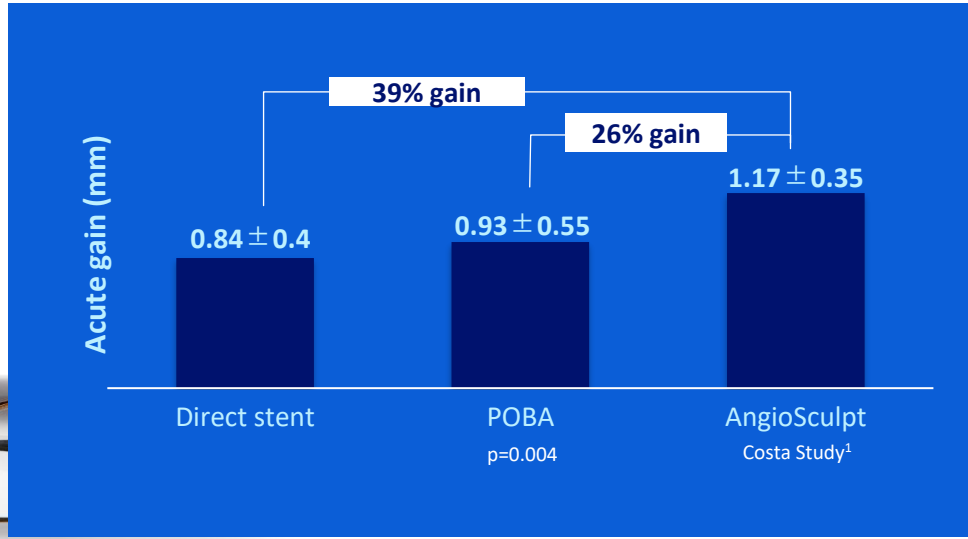
AngioSculpt Evo delivers up to 26% more luminal gain than balloon angioplasty

Controlled power

- Tested for 20 dilatations[1]
- Up to 25x the power of conventional balloons[2]
- Dilation forces concentrate along rectangular scoring elements in a controlled manner for uniformed scoring[2]



AngioSculpt Evo delivers greater power to achieve more luminal gain

Based on AngioSculpt PTCA clinical data

1. D051336 AngioSculpt Evo Marketing Claims Report.
2. AngioSculpt Test Report SR-1571.A (2008)
3. Costa JR, Mintz GS, Carlier SG et al. Nonrandomized Comparison of Coronary Stenting Under IVUS Guidance of Direct Stenting Without Predilation Versus Conventional Predilation With a Semi-Compliant Balloon Versus Predilation With a New Scoring Balloon. *Am J Cardio.* 2007; 100:812-817.

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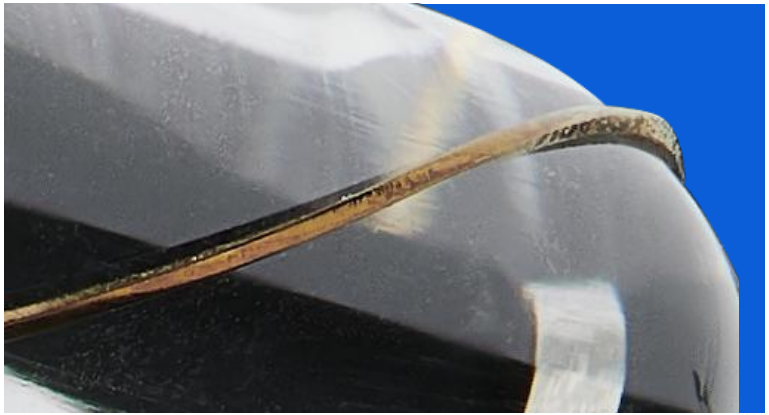
Controlled power improves vessel compliance during expansion

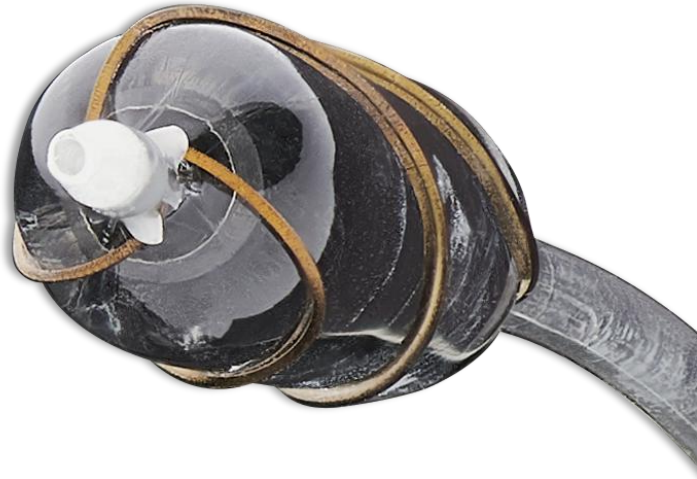
Controlled Power

- Helical nitinol scoring elements lock AngioSculpt Evo into the lesion[1]
- Circumferential dilatation across the lesion minimizing slippage[1]
- Achieved 39% acute gain vs Direct Stenting and 26% acute gain vs POBAs[2]



Nitinol scoring element strut height 0.005” – 0.007”

Edges “lock” in



Based on AngioSculpt PTCA clinical data

1. D051336-01 Report, AngioSculpt EVO Marketing Claims Report
2. Costa JR, Mintz GS, Carlier SG et al. Nonrandomized Comparison of Coronary Stenting Under IVUS Guidance of Direct Stenting Without Predilation Versus Conventional Predilation With a Semi-Compliant Balloon Versus Predilation With a New Scoring Balloon. Am J Cardiol, 2007; 100:812-817.

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AngioSculpt Evo strong safety profile

ISR

- Indicated for ISR[1,2]
- Designed to resist slipping[3,4]
- Optimize luminal gain[5,6]

Calcium/Fibrotic

- Designed for highly resistant lesions[5,6]
- Up to 25x the force of POBA[7]
- Used as adjunct to other atherectomy devices

Small vessels & side branches

- Designed to resist slipping[3,4]
- Low dissection rates compared to conventional therapy*[4,5,8]
- 93% angiographic success, AGILITY Study[9]

*Based on AngioSculpt PTCA clinical data

1. AngioSculpt Evo IFU P015608-B.
2. Data on file at Philips IGTD: D050055_Clinical Evaluation Report AngioSculpt EVO and PTCA Scoring Balloon Catheter.
3. D051336-01 Report, AngioSculpt EVO Marketing Claims Report
4. Costa, R. A., Mooney, M. R., Teirstein, P. S., Moses, J. W., Turco, M., Reisman, M., … Leon, M. B. (2006). Final results from the multi-center trial of the angiosculpt scoring balloon catheter for the treatment of complex coronary artery lesions. Cardiovascular Revascularization Medicine, 7(2), 112. https://doi.org/10.1016/j.carrev.2006.03.068
5. Costa JR, Mintz GS, Carlier SG, et al. Nonrandomized comparison of coronary stenting under intravascular ultrasound guidance of direct stenting without predilation versus conventional predilation with a semi-compliant balloon versus predilation with a new scoring balloon. *Am J Cardiol*. 2007;100:812-817.
6. AngioSculpt Evo IFU P015608
7. AngioSculpt Test Plan SR-1571.A (2008)
8. Fonseca A, Costa JR, Abizaid A, et al. Intravascular ultrasound assessment of the novel AngioSculpt Scoring Balloon Catheter for the treatment of complex coronary lesions. J Invasive Cardiol. 2008; 20:1
9. Weisz, G., Metzger, D. C., Liberman, H. A., O'Shaughnessy, C. D., Douglas, J. S., Jr, Turco, M. A., Mehran, R., Gershony, G., Leon, M. B., & Moses, J. W. (2013). A provisional strategy for treating true bifurcation lesions employing a scoring balloon for the side branch: final results of the AGILITY trial. Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions, 82(3), 352–359. https://doi.org/10.1002/ccd.24630

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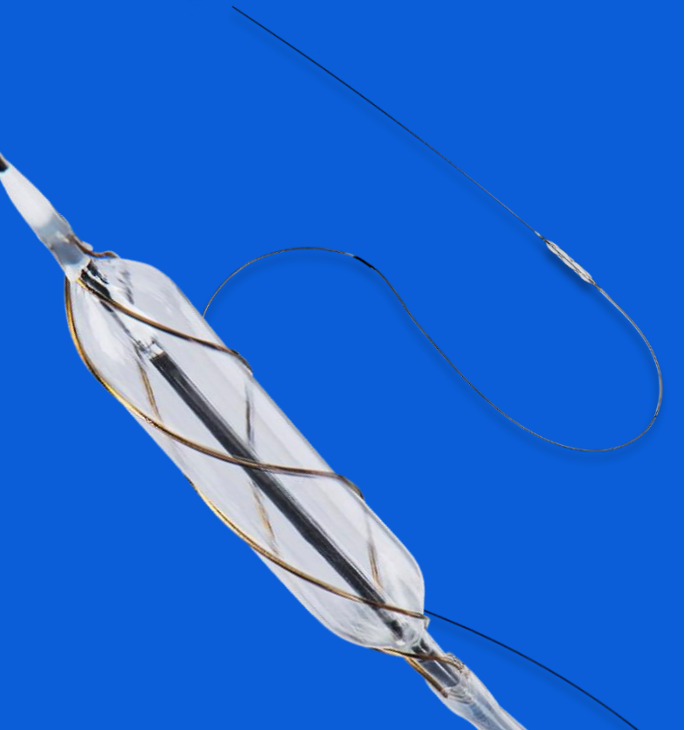
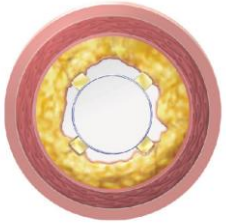
AngioSculpt Evo Summary



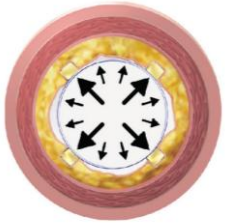
AngioSculpt Evo address' the three clinical needs of any balloon deliverability, crossability, and dilatation power—all in a safe balloon design



Precision

Minimal slippage

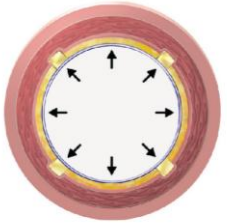
As the device expands, the rectangular scoring elements are designed to lock it in place in challenging lesions, minimizing slippage and geographic miss.[1]



Power

More dilatation force

AngioSculpt Evo delivers focal forces up to 25x greater than a conventional balloon. The helical design of the nitinol scoring elements applies circumferential dilation force against the lesion regardless of device orientation.[1,2]



Safety

Low dissection rate

AngioSculpt Evo provides the largest effective scoring area of any specialty balloon and has lower dissection rates compared to conventional therapies.[2,3,4,5]

*Based on AngioSculpt PTCA clinical data

1. D051336 AngioSculpt Evo Marketing Claims Report.
2. AngioSculpt Test Report SR-1571 (2008)
3. Costa JR, Mintz GS, Carlier SG, et al. Nonrandomized comparison of coronary stenting under intravascular ultrasound guidance of direct stenting without predilation versus conventional predilation with a semi-compliant balloon versus predilation with a new scoring balloon. Am J Cardiol. 2007;100:812-817.
4. Costa RA, Mooney MR, Teirstein PS, et al. Final results from the multi-center trial of the angiosculpt scoring balloon catheter for the treatment of complex coronary artery lesions Cardiovascular Revascularization Medicine 7 (2006)81–126.
5. Fonseca A, Costa JR, Abizaid A, et al. Intravascular ultrasound assessment of the novel AngioSculpt Scoring Balloon Catheter for the treatment of complex coronary lesions. *J Invasive Cardiol*. 2008; 20:1.

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Broadest specialty balloon applications

The AngioSculpt Evo scoring balloon catheter is 5Fr guide compatible and indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including:

AngioSculpt Evo scoring balloon compared to Wolverine cutting balloon

Indications for use	**AngioSculpt Evo[1,2]**	**Wolverine[3]**
In-stent restenosis (ISR)	✓	✗
ACC/AHA lesion specific classification Type B2 and C	✓	✗
Total occlusions – traversable by guidewire	✓	✗
Moderately and severely calcified	✓	✗
Eccentric lesions	✓	✗
Ostial lesions	✓	✗
Long lesions > 20 mm diffuse disease	✓	✗

*Based on AngioSculpt PTCA clinical data

1. AngioSculpt Evo IFU P015608-B.
2. Data on file at Philips IGTD: D050055_Clinical Evaluation Report AngioSculpt EVO and PTCA Scoring Balloon Catheter.
3. Boston Scientific. (n.d.). Wolverine coronary cutting balloon. Boston Scientific. Retrieved December 11, 2025 https://www.bostonscientific.com/us/en/healthcare-professionals/products/balloons-catheters-and-guidewires/cutting-balloons/wolverine-coronary-cutting-balloon/fp00000353/indications-safety-and-warnings.html

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Advantages of Circumferential Scoring

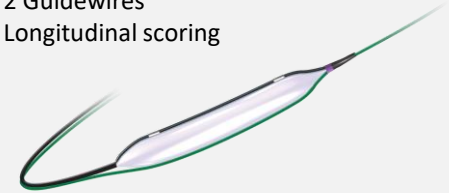
AngioSculpt Evo
Helical scoring elements
Circumferential scoring

Precision: AngioSculpt Evo modifies plaque in a controlled manner for uniform scoring[1]

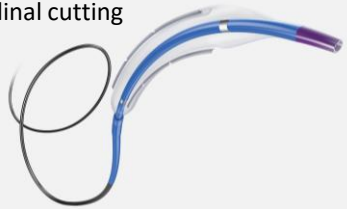
Power: The nitinol scoring element wraps the entire balloon to concentrate focal forces up to 25x the force of conventional balloons[1]

Safety: Reduced risk of dissection – A U.S. pivotal study reported only 1% Type D-F flow-limiting dissections post-AngioSculpt, underscoring its safety*[2]

Scoreflex[3]
2 Guidewires
Longitudinal scoring



Wolverine[4]
3-4 Atherotomes
Longitudinal cutting



*Based on AngioSculpt PTCA clinical data

1. Data on file, SR-1571.A
2. AngioSculpt Evo IFU P015608-B.
3. Abbott. (n.d.). Scoreflex NC scoring balloon. Abbott. Retrieved December 11, 2025, from https://www.cardiovascular.abbott/us/en/hcp/products/percutaneous-coronary-intervention/coronary-dilatation-catheters/scoreflex-nc-scoring-balloon.html
4. Boston Scientific. (n.d.). Wolverine coronary cutting balloon. Boston Scientific. Retrieved December 11, 2025 https://www.bostonscientific.com/us/en/healthcare-professionals/products/balloons-catheters-and-guidewires/cutting-balloons/wolverine-coronary-cutting-balloon/fp00000353/indications-safety-and-warnings.html

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AngioSculpt Evo Ordering Information and Compliance Chart

Number	Balloon diameter (mm)	Balloon length (mm)	Catheter length	Guidewire compatibility	Guide catheter compatibility
2200-2006-B	2.0	6	139	0.014”	5Fr
2200-2010-B	2.0	10	139	0.014”	5Fr
2200-2015-B	2.0	15	139	0.014”	5Fr
2200-2020-B	2.0	20	139	0.014”	5Fr
2200-2506-B	2.5	6	139	0.014”	5Fr
2200-2510-B	2.5	10	139	0.014”	5Fr
2200-2515-B	2.5	15	139	0.014”	5Fr
2200-2520-B	2.5	20	139	0.014”	5Fr
2200-3006-B	3.0	6	139	0.014”	5Fr
2200-3010-B	3.0	10	139	0.014”	5Fr
2200-3015-B	3.0	15	139	0.014”	5Fr
2200-3020-B	3.0	20	139	0.014”	5Fr
2200-3506-B	3.5	6	139	0.014”	5Fr
2200-3510-B	3.5	10	139	0.014”	5Fr
2200-3515-B	3.5	15	139	0.014”	5Fr
2200-3520-B	3.5	20	139	0.014”	5Fr

Evo	Balloon Diameter (mm)				
Pressure (atm)	2	2.5	3	3.5	
2	1.69	2.04	2.42	2.87	
4	1.8	2.15	2.54	3.03	
6	1.86	2.25	2.68	3.19	
8	1.93	2.36	2.83	3.35	Nominal Pressure
10	2.01	2.46	2.96	3.46	
12	2.09	2.54	3.06	3.54	
14	2.16	2.61	3.14	3.61	Rated Burst Pressure
16	2.24	2.69	3.22	3.67	
18	2.33	2.76	3.31	3.73	

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AngioSculpt Evo Important Safety Information

The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis and complex type C lesions, for the purpose of improving myocardial perfusion.

The AngioSculpt catheter should not be used for coronary artery lesions unsuitable for treatment by percutaneous revascularization, and coronary artery spasm in the absence of a significant stenosis.

Possible adverse effects include, but are not limited to: death; heart attack (acute myocardial infarction); embolism, total occlusion of the treated coronary artery; coronary artery dissection, perforation, rupture, or injury; pericardial tamponade; no/slow reflow of treated vessel; emergency coronary artery bypass (CABG); emergency percutaneous coronary intervention; CVA/stroke/embolic stroke; pseudoaneurysm; restenosis of the dilated vessel; unstable angina; thromboembolism or retained device components; irregular heart rhythm (arrhythmias, including life-threatening ventricular arrhythmias); severe low (hypotension)/high (hypertension) blood pressure; coronary artery spasm; hemorrhage or hematoma; need for blood transfusion; surgical repair of vascular access site; creation of a pathway for blood flow between the artery and the vein in the groin (arteriovenous fistula); drug reactions, allergic reactions to x-ray dye (contrast medium); and infection.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

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