PHILIPS

RX PTCA Scoring Balloon Catheter

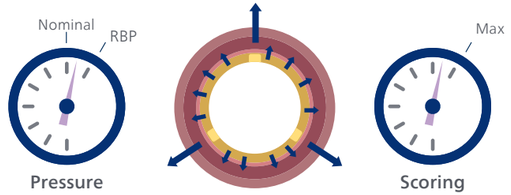
AngioSculpt Evo

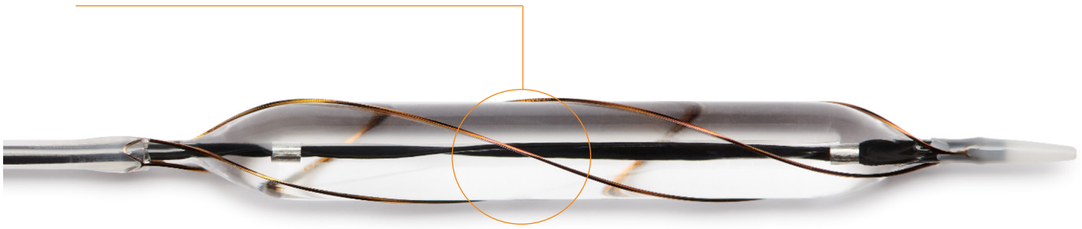
Designed for superior performance

Maximize gain. Minimize risk.

The Philips Scoring Balloon Catheter – AngioSculpt Evo – is an effective solution to efficiently modify plaque, prepare vessels for optimal stent placement and treat a wide variety of lesion complexities.

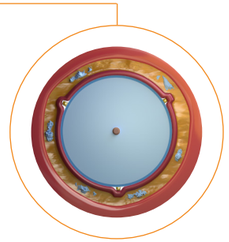
Evo is built on semi-compliant balloon, allowing it to be tailored precisely to the vessel diameter. The helical design of the nitinol scoring elements applies circumferential dilation force against the lesion regardless of device orientation.





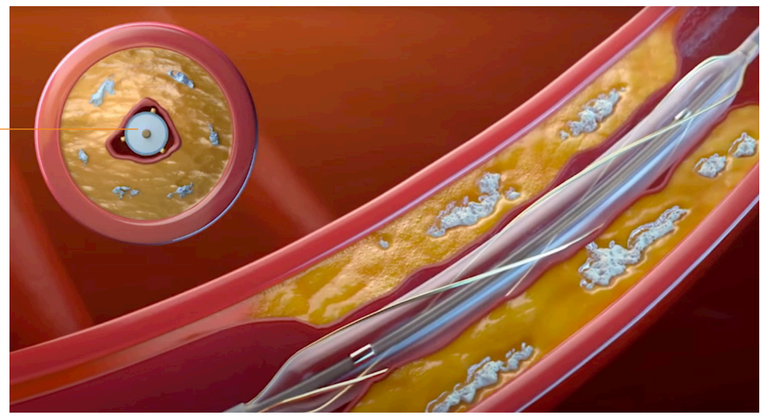
Dilation forces concentrate along rectangular scoring elements – delivering up to **25x** more force than conventional balloons in a controlled manner for uniformed scoring.[1]

25x



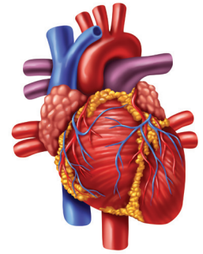
As the device expands the rectangular scoring elements lock device in place, minimizing slippage or geographic miss.
Evo provides the power and precision to safely dilate plaque and achieve maximum luminal gain.

Edges lock in devices



Example of Philips AngioSculpt Evo scoring balloon catheter

When selecting a balloon for complex PCI cases, deliverability, crossability and dilation power are key.



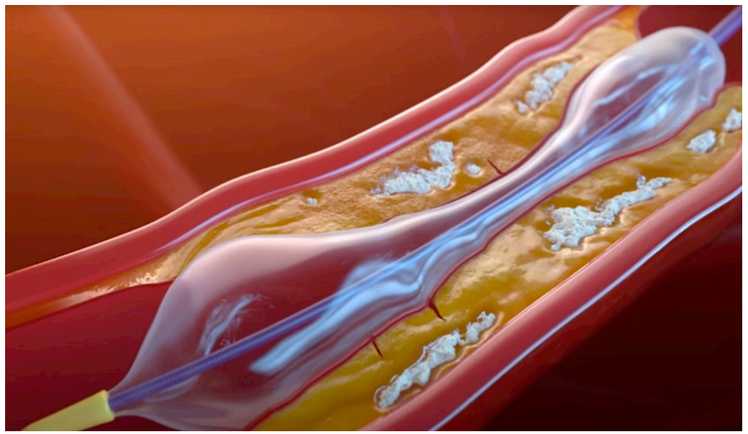
AngioSculpt Evo is designed for exceptional performance in all three factors.

Limitations of Plain Old Balloon Angioplasty (POBA)

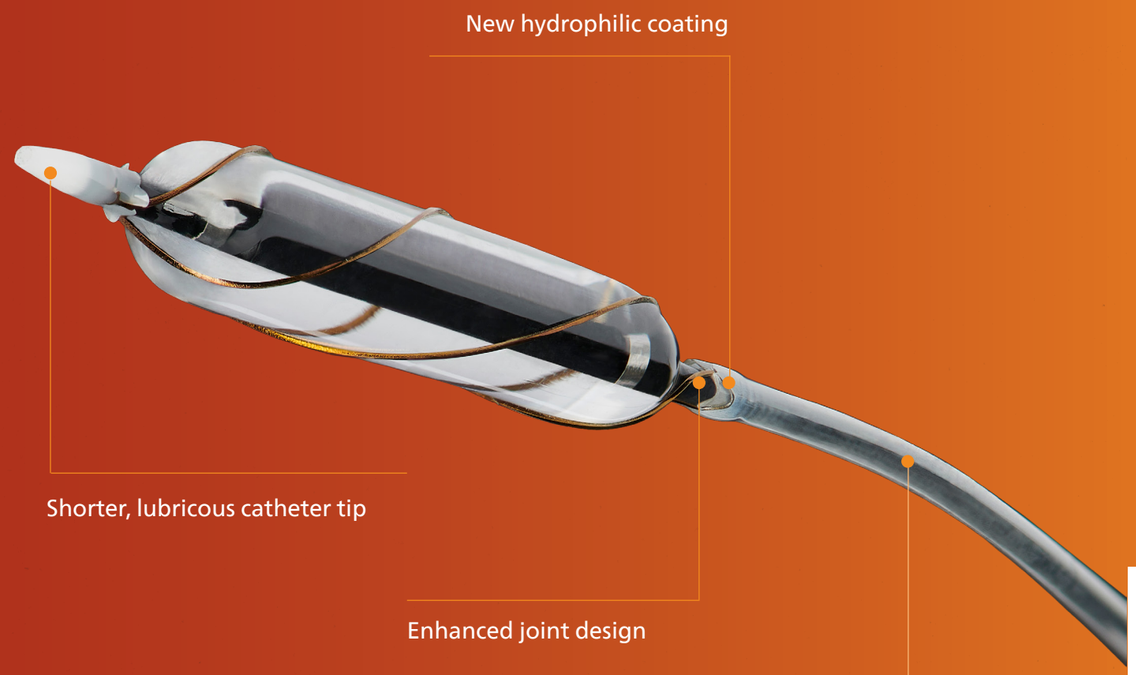
- Power
- Dog boning
- Higher dissection rates

Limitations of cutting balloons

- Localized cutting versus 360 scoring
- Deliverability
- Limited re-wrap



Example of POBA



AngioSculpt Evo delivers greater power to achieve more luminal gain[2]*

*Based on AngioSculpt PTCA clinical data.

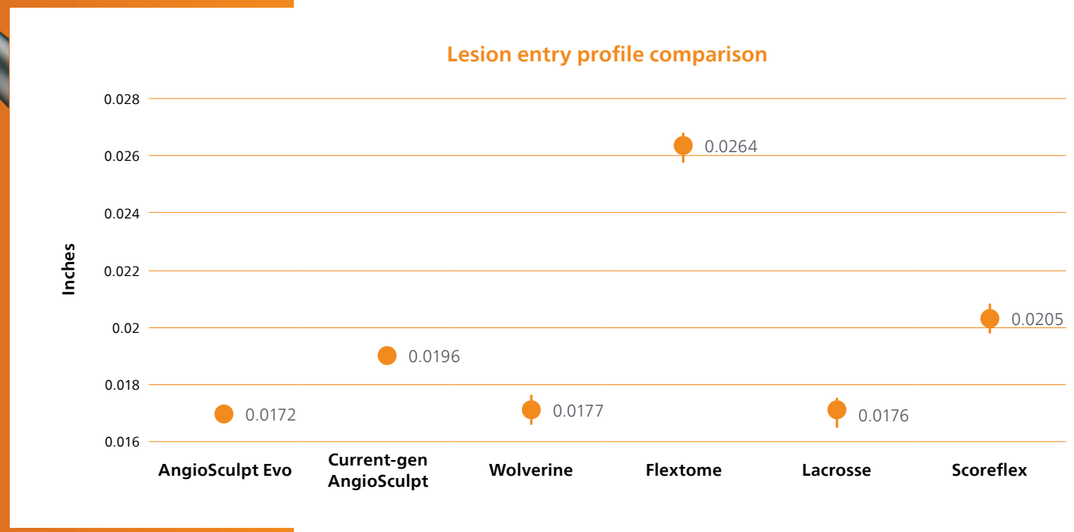
Superior deliverability

Designed to be the most deliverable scoring balloon – AngioSculpt Evo has the power to safely dilate resistant lesions.[3,4,5]*

Deliverability performs better than other speciality balloons: Lower profile[3], hydrophilic coating and laser cut hypotube facilitate access to more lesions.

44%
more deliverable then the Wolverine balloon[3]

37%
more deliverable than the original AngioSculpt PTCA[3]



Graph: D045801-00 Protocol Marketing Claims Testing-2019 (Bench testing 'n' of 5)

Strong safety profile

The only balloon in its class indicated for type-C lesions, including ISR, ostial lesions, moderate or severe calcification and excessive tortuosity.[6]

Low dissection rates compared to conventional therapy *[4,5,7]

Lesion type use cases	AngioSculpt Evo
Type A lesion: ACC/AHA lesion classification[8]	Indicated
Type B1, B2[9], C lesion: ACC/AHA lesion classification[8]	Indicated
In-stent restenosis (ISR)	Indicated
Wired chronic total occlusion (CTO)	Indicated
Calcium (moderate or severe)	Indicated
Ostial lesions	Indicated
Bifurcation	Clinical trial validated[10]
Excessive tortuosity	Indicated
Eccentric lesions	Indicated
Presence of thrombus	Indicated
Degenerated vein grafts	Indicated
Diffuse (>20mm)	Indicated
Irregular contour	Indicated

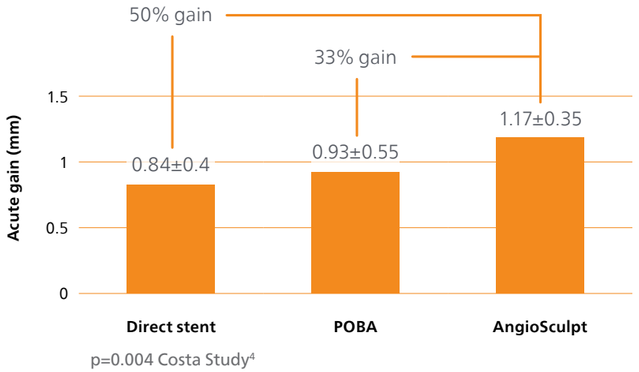
Lesion type	Clinical challenge	AngioSculpt Evo advantage
Calcified	Conventional balloons may deliver sub-optimal vessel preparation and stent expansion	• 25x force of conventional balloons[1] • Large effective scoring area • Minimize balloon slippage
ISR	A mix of mechanical, technical and physiological issues may limit conventional balloons ability to maximize luminal gain	• 25x force of non-conventional balloon[1] • Greater luminal gain • Minimize balloon slippage
Side branches	Balloon slippage and dissections in small side branch vessels may complicate definitive treatment	• Circumferential scoring • Low dissection rates* • Minimize balloon slippage

*Based on AngioSculpt PTCA clinical data.

Controlled power improves vessel dynamics during expansion[4]

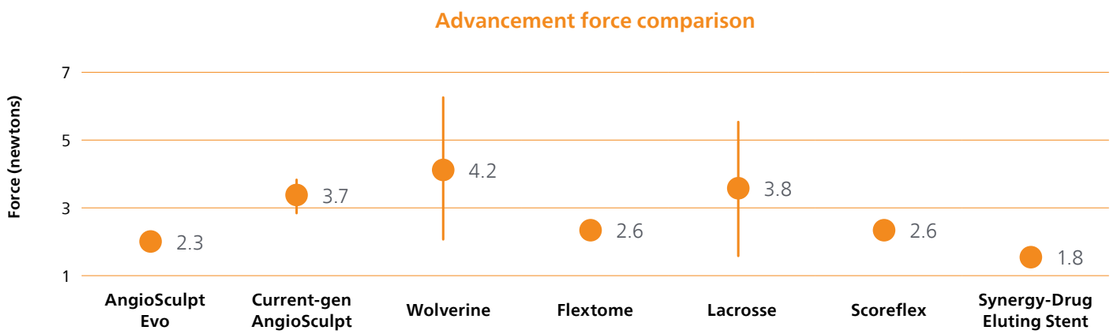
- Controlled focal forces deliver up to 25x the force of non-compliant balloons[1]
- Provides the largest effective scoring area of any specialty balloon[1]
- Delivers significantly more luminal gain than a direct stent or conventional pre-dilation strategy.[4*]

AngioSculpt Evo deliverables up to 33% more luminal gain than POBA[1]



p=0.004 Costa Study[4]

- Tested for 20 dilations[1]
- Treat multiple lesions across multiple vessels
- Overcome resistant lesions with greater expantion



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Summary of safety and effectiveness–PTCA catheter

AngioSculpt Evo PTCA important safety information

The AngioSculpt Evo 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 Evo 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.

Caution: Federal law restricts this device to sale by or on the order of a physician

References:

1. Internal AngioSculpt Test Report SR-1571.A (2008)
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. D051336 AngioSculpt Evo Marketing Claims Report.
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5. 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.
6. AngioSculpt Evo IFU P015608
7. 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
8. Ryan TJ, Faxon DP, Gunnar RM, Kennedy JW, King SB III, Loop FD,Peterson KL, Reeves TJ, Williams DO, Winters WL Jr, et al. Guidelines for ercutaneous transluminal coronary angioplasty. A report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Percutaneous Transluminal Coronary Angioplasty). Circulation 1988;78:486–502.
9. Ellis S, Vandormael M, Cowley M, et al. Coronary Morphologic and Clinical Determinants of Procedural Outcome with Angioplasty for Multivessel Coronary Disease. Circulation. 1990;82 (4) 1193-1202.
10. AGILITY study. 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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