Balloons proven non-inferior to IVL and Orbital Atherectomy

Why Waste Time and Money?

PHILIPS

What the Latest Trials Reveal

Short-CUT Trial[1]

- The Short-CUT trial aimed to evaluate the safety, efficacy and procedural cost of specialty balloons compared with IVL in PCI for patients with moderate-to-severe calcification.
- A total of 413 patients were randomized across 21 sites in the United States, 207 were randomized to IVL and 206 to cutting balloons.
- The primary endpoint, mean post-procedural MSA, was 8.6 ± 2.5 mm^2 in the IVL group and 8.0 ± 2.4 mm^2 in the specialty balloon group, demonstrating that specialty balloons were non-inferior (p=0.007).
- The trial showed a significant difference in total procedural cost difference of $3,632 in favor of specialty balloons (p<0.001).

Victory Trial[2]

- The VICTORY trial sought to assess whether lesion preparation using the super high-pressure OPN NCB is non-inferior to a strategy involving IVL, in terms of the completeness of final stent expansion (SE), measured as a percentage (%) by imaging in patients with heavily calcified coronary lesions.
- A total of 278 patients were enrolled in the trial and were randomized 1:1 to each study arm.
- The primary outcome was final stent expansion measured by imaging, which was 85.0% with OPN and 84.0% with IVL. OPN NCB did not demonstrate superiority over IVL for this outcome (p=0.570)
- The procedure time was numerically higher in the IVL arm (mean 79 vs 70 minutes; p=0.06).

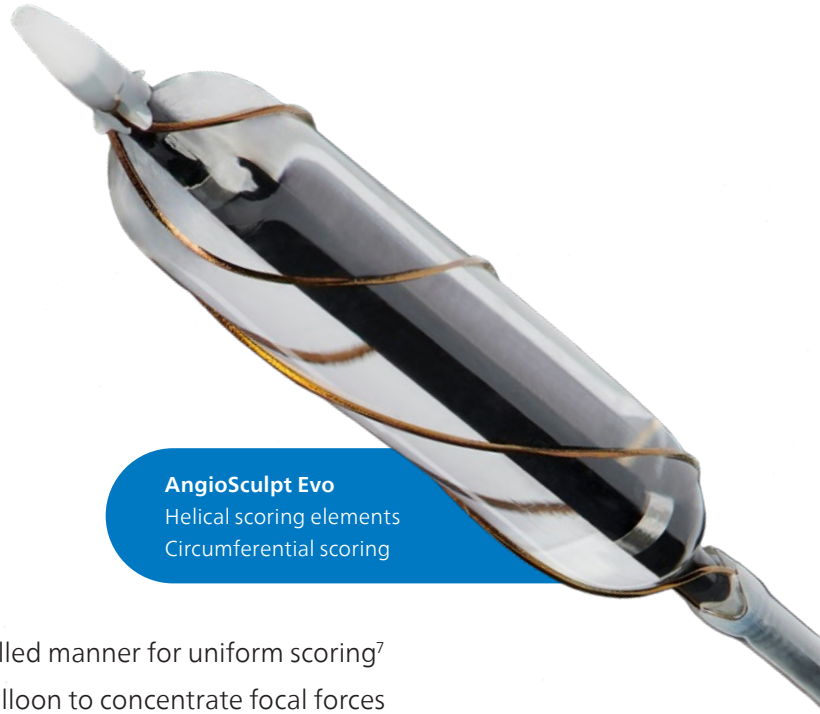
ECLIPSE Trial[3]

- The study enrolled 2,005 patients (2,492 lesions across 104 sites in the U.S. between March 2017 and April 2023. Patients were randomized into either the orbital atherectomy group (1,008 patients) or conventional balloon angioplasty group (997 patients).
- Among patients with severely calcified coronary lesions, the ECLIPSE trial failed to show that routine use of orbital atherectomy prior to DES implantation is superior to conventional PCI without orbital atherectomy.
- Mean MSA at the maximum calcium site defined by imaging (555 patients): OA vs. conventional balloon angioplasty (7.67 vs. 7.42 mm^2) (p=0.08)
- TVF rates at 1-year: OA vs. conventional balloon angioplasty (11.5% and 10.0%) (p=0.28)

AngioSculpt Evo

Maximize gain. Minimize risk.

- AngioSculpt Evo has the power to safely dilate resistant lesions[4,5,6]
- Provides the largest effective scoring area of any specialty balloon[7]
- AngioSculpt Evo is 43% smaller and 44% more deliverable than Wolverine[4]
- AngioSculpt Evo is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) and complex type C lesions[8,9]



Advantages of Circumferential Scoring

- **Precision:** AngioSculpt Evo modifies plaque in a controlled manner for uniform scoring[7]
- **Power:** The nitinol scoring element wraps the entire balloon to concentrate focal forces up to 25x the force of conventional balloons[7]
- **Safety:** Reduced risk of dissection – A U.S. pivotal study reported only 1% Type D-F flow-limiting dissections post-AngioSculpt, underscoring its safety*[8]

*Based on AngioSculpt PTCA clinical data

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. Cader, Aaysha. "Randomised Comparison of Intravascular Lithotripsy vs. Cutting Balloon Treatment in Calcified Coronary Artery Disease – the Short-CUT Trial." Pcronline.com, 27 Oct. 2025, www.pcronline.com/News/Whats-new-on-PCRonline/2025/TCT/Short-CUT-intravascular-lithotripsy-vs.-cutting-balloon-angioplasty-in-calcified-CAD. 2. Alasnag, Mirvat. "A Randomised, Multicenter, Non-Inferiority Comparison of Intravascular Lithotripsy and Super-High-Pressure Non-Compliant Balloons for Treatment of Calcified and Refractory Coronary Lesions - the VICTORY Trial." Pcronline.com, 27 Oct. 2025, www.pcronline.com/News/Whats-new-on-PCRonline/2025/TCT/VICTORY-Intravascular-lithotripsy-vs.-super-high-pressure-PTCA-in-calcified-and-refractory-coronary-lesions. 3. Kirtane, A. J., et al. (2025). Orbital atherectomy versus balloon angioplasty before drug-eluting stent implantation in severely calcified lesions eligible for both treatment strategies (ECLIPSE): a multicentre, open-label, randomised trial. Lancet (London, England), 405(10486), 1240–1251. https://doi.org/10.1016/S0140-6736(25)00450-7 4. D051336 AngioSculpt Evo Marketing Claims Report. 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. 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. 7. Data on file, SR-1571. 8. AngioSculpt Evo IFU P015608-B. 9. Data on file at Philips IGTD: D050055_Clinical Evaluation Report AngioSculpt EVO and PTCA Scoring Balloon Catheter.

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