PHILIPS

RX PTCA Scoring Balloon Catheter

AngioSculpt Evo

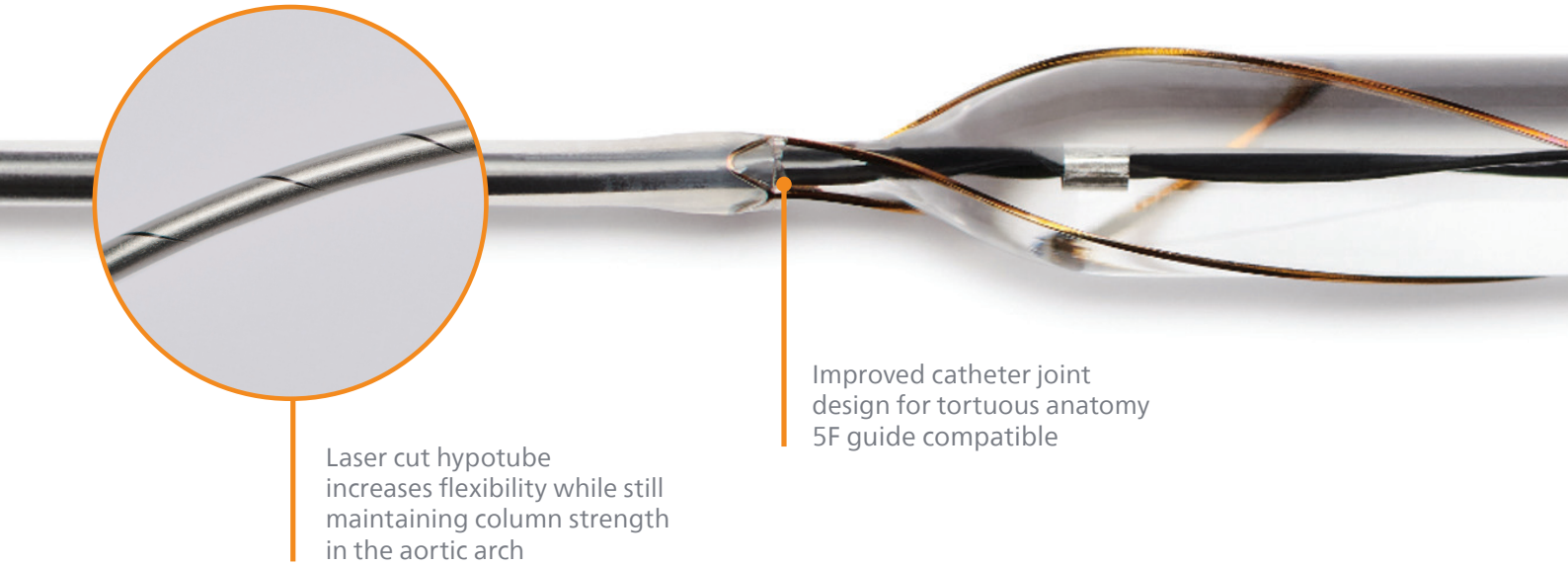
Maximize gain. Minimize risk.

Philips' most deliverable specialty balloon[1]

Tip to tail

Combine power and safety with greater deliverability

Deliverability, crossability, and dilatation power are key factors when selecting a balloon. The Philips Scoring Balloon Catheter – AngioSculpt Evo – is designed for exceptional performance in all three factors.



Superb deliverability

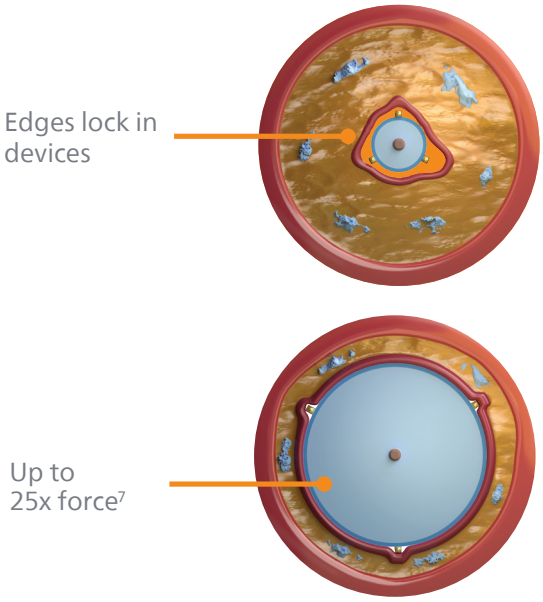
Reduced push force by 38% compared to previous-gen AngioSculpt with new hydrophilic coating[1]

83% of physicians rated AngioSculpt Evo as deliverable as, or more deliverable than, a NC Balloon[5]

Strong safety profile*

ISR, calcific and fibrotic lesions, bifurcations and ostial lesions

- 1% dissections (Type D-F flow limiting) from US pivotal study post-AngioSculpt[6*]
- Minimize slippage[2*]
- Greater force with less pressure, up to 25x non-compliant balloons[3]
- Bifurcations, 93.5% angiographic success in AGILITY Study[4*]



Controlled power

AngioSculpt Evo delivers greater power to achieve more luminal gain[7]

- Tested for 20 dilatations
- Treat multiple lesions across multiple vessels
- Achieved 26-40% acute gain vs. direct stenting or POBA[2]

Philips Scoring Balloon Catheter – AngioSculpt Evo

Ordering information

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

Compliance chart

Pressure (atm)	Pressure (kPa)	Balloon diameter (mm)			
		2.0	2.5	3.0	3.5
2	203	1.69	2.04	2.42	2.87
4	405	1.80	2.15	2.54	3.03
6	608	1.86	2.25	2.68	3.19
8	811	1.93	2.36	2.83	3.35
10	1013	2.01	2.46	2.96	3.46
12	1216	2.09	2.54	3.06	3.54
14	1419	2.16	2.61	3.14	3.61
16	1621	2.24	2.69	3.22	3.67
18	1824	2.33	2.76	3.31	3.73

6, 10, 15, 20 mm length balloons

Nominal pressure **Rated burst pressure**

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.

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.

*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. AngioSculpt Test Report SR-1571.A (2012)
4. 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.
5. D059995 Customer Preference Study Report: 85 respondents out of 102 rated AngioSculpt Evo as deliverable as, or more deliverable than, a NC Balloon
6. AngioSculpt Evo IFU 300009200321
7. AngioSculpt Test Plan ST-1197 (2008), on file at AngioScore, Inc.

Always read the label and follow the directions for use.
Products subject to country availability. Please contact your local sales representative.

Approved for external use. D2021070901B * SEPT2024

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