PHILIPS

RX PTCA Scoring Balloon Catheter

AngioSculpt Evo

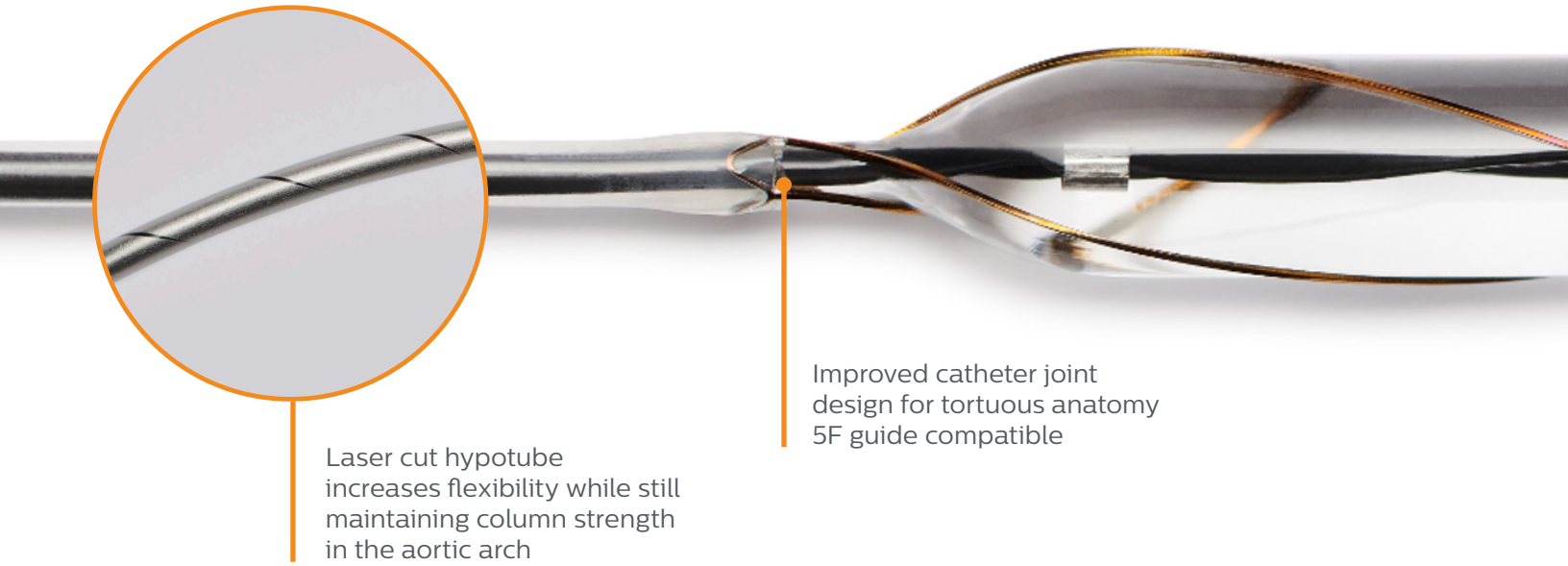
# Maximize gain. Minimize risk.

Philips' most deliverable specialty balloon[1]

# Tip to tail

## Newly designed AngioSculpt Evo combines 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.




## Superior deliverability

### AngioSculpt Evo is more deliverable than the leading scoring/cutting balloon[6]

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

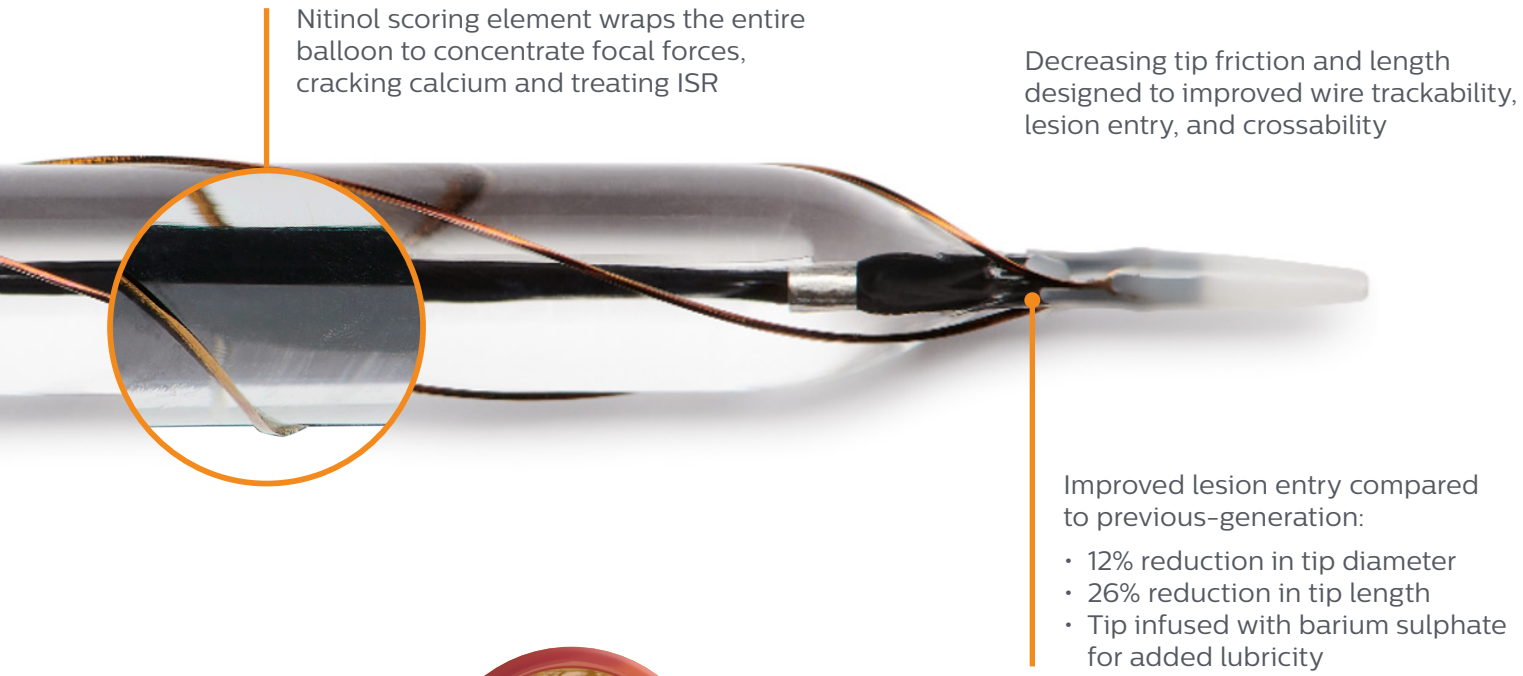
83% of physicians rated AngioSculpt Evo as deliverable as, or more deliverable than, a NC Balloon[5]

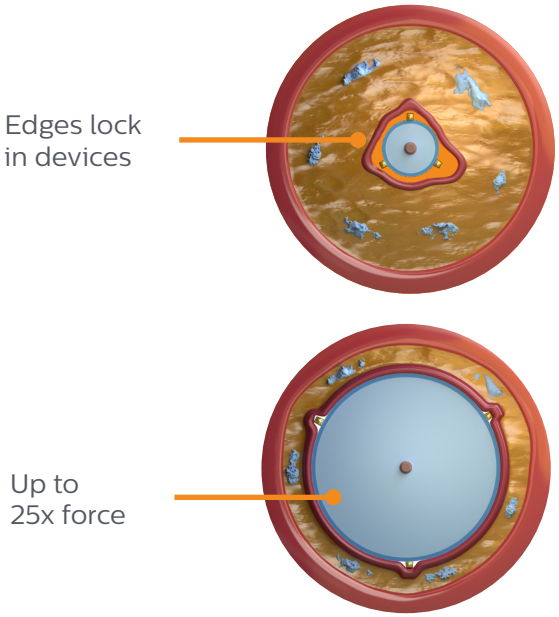
# Strong safety profile*

## ISR, calcific and fibrotic lesions, bifurcations and ostial lesions

- 1% dissections (Type D-F flow limiting) from US pivotal study post-AngioSculpt[7*]
- Minimize slippage[2*]
- Greater force with less pressure, up to 25x non-compliant balloons[3]
- Bifurcations, 93.5% angiographic success in AGILITY Study[4*]
- The only balloon in its class indicated for type C lesions, ISR, eccentric and calcified lesions[7]

91% of physicians rated AngioSculpt Evo overall performance better than Wolverine[6]




# Controlled power

## AngioSculpt Evo delivers greater power to achieve more luminal gain

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

## Ordering information

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

Contact your local Philips sales representative for more information.

## 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.

*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 (2008).
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 Evo Claims validated by clinician feedback on clinical cases performed with AngioSculpt EVO, with a sample size of 39 physicians using AngioSculpt EVO on 105 cases. Clinicians participating in the survey compared AngioSculpt EVO's deliverability against the deliverability of their most used non-compliant balloon.
6. D059995 Customer Preference Study Report Evo Claims validated by clinician feedback on clinical cases performed with AngioSculpt EVO, with a sample size of 39 physicians using AngioSculpt EVO on 105 cases. Clinicians participating in the survey reported primarily using Wolverine as their current scoring/cutting balloon.
7. AngioSculpt Evo IFU P015608.



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