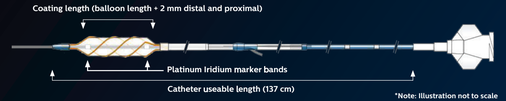


*Note: Illustration not to scale

Ordering information

Catalogue number	Balloon diameter (mm)	Balloon length (mm)	Nominal pressure (atm)	Rated burst pressure (atm)
2322-2010	2.0	10	8	20
2322-2015	2.0	15	8	20
2322-2020	2.0	20	8	20
2322-2510	2.5	10	8	20
2322-2515	2.5	15	8	20
2322-2520	2.5	20	8	20
2322-3010	3.0	10	8	18
2322-3015	3.0	15	8	18
2322-3020	3.0	20	8	18
2322-3510	3.5	10	10	16
2322-3515	3.5	15	10	16
2322-3520	3.5	20	10	16

Compliance data

Technical data

Drug	Paclitaxel
Dose	3 µg/mm^2
Excipient	NDGA
Catheter usable length	137 cm
Guidewire compatibility	0.014"
Guide catheter compatibility	6 F
Number of nitinol scoring elements	3
Nitinol scoring element thickness	0.005"
Brachial marker location	90 cm
Femoral marker location	100 cm
Shaft design	Rapid exchange

Important safety information
AngioSculptX Drug-Coated PTCA Scoring Balloon Catheter is a standard PTCA catheter with a scoring balloon near the distal tip. The distal end of the catheter has a conventional nylon-blend balloon and a nitinol scoring element with three spiral struts that wrap around the balloon. The struts create focal concentrations of dilating force, which minimize balloon slippage and assist in the luminal expansion of stenotic arteries. The scoring balloon is coated with a specialized formulation that includes the anti-proliferative drug, paclitaxel. The drug-coated scoring balloon is designed to expand to a specified diameter and length at a specified pressure. Conventional radiopaque markers aid in positioning the balloon in the stenosis.

Indications
The AngioSculptX Drug-Coated PTCA Scoring Balloon is indicated for the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis, for the purpose of improving myocardial perfusion.

Contraindications
The AngioSculptX catheter should not be used for the following:
- Coronary artery lesions unsuitable for treatment by percutaneous revascularization.
- Coronary artery spasm in the absence of a significant stenosis.
- Patients with known hypersensitivity to paclitaxel or paclitaxel related compounds.
- Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy.
- Women who are breastfeeding, pregnant, or are intending to become pregnant or men intending to father children.

Warnings
To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Do not exceed the rated burst pressure (RBP) during balloon inflation. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with 95% confidence) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potential cardiovascular injury or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Proceed cautiously when using the AngioSculptX catheter in a freshly deployed stent. The AngioSculptX catheter has not been tested for post-dilatation of stents or lesions distal to freshly deployed stents in clinical studies.
- Use the device prior to the expiration date specified on the package.

Precautions
- Do not immerse the AngioSculptX catheter in a saline bath. Contact with fluids prior to insertion may compromise therapeutic drug delivery. In order to ensure therapeutic drug delivery, replace any device where the balloon has come into contact with fluids prior to use.
- The AngioSculptX catheter should be handled with dry sterile gloves whenever possible prior to use. Care should be taken to minimize contact with the coated balloon portion of the
- AngioSculptX catheter during preparation and insertion.
- To ensure therapeutic drug delivery:
  – Never inflate the AngioSculptX catheter prior to reaching the target lesion.
  – The AngioSculptX catheter should be advanced to the target site in an efficient manner (i.e. ≤ 3 minutes) and immediately inflated.
- Maintain balloon inflation for a minimum of 30 seconds.
- Predilatation of the lesion with an uncoated standard PTCA balloon should be performed.
- Always advance and retrieve the AngioSculptX catheter under negative pressure. Whenever possible, the AngioSculptX catheter should be the final treatment of the vessel.
- The AngioSculptX catheter is intended to treat a single lesion in a single patient; do not re-use the AngioSculptX catheter to dilate additional lesions.
- Prior to angioplasty, examine the catheter to verify functionality, catheter integrity and to ensure that its size and length are suitable for the specific lesion for which it is to be used.
- Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the AngioSculptX catheter.
- Appropriate dual antiplatelet, anticoagulant and coronary vasodilator therapy should be administered before, during, and after treatment with the AngioSculptX catheter. Antiplatelet therapy for less than 3 months following treatment with the AngioSculptX catheter has not been studied and patients in the first-in-human study were administered dual antiplatelet therapy consisting of aspirin plus either clopidogrel or ticlopidine for a minimum of 3 months following treatment with the AngioSculptX catheter.
- Do not rotate the catheter shaft in excess of 180 degrees when the tip is constrained.
- Do not rotate the catheter luer hub in excess of five (5) turns during use.
- Do not advance or retract the AngioSculptX catheter over the floppy portion of the guide wire.
- Catheter manipulation, including advancement and retraction, should be performed by grasping the hypotube shaft.
- If unusual resistance is felt when the catheter is being manipulated or if it is suspected that the guide wire has become kinked, carefully remove the entire catheter system (AngioSculptX catheter and steerable guide wire) as a unit.
- If fluoroscopic guidance indicates that the AngioSculptX catheter has advanced beyond the end of the guide wire, withdraw the catheter and reload the wire before advancing again.
- It is not recommended that the AngioSculptX catheter be used in conjunction with other drug coated balloons or drug eluting stents to treat the same lesion in the same procedure or within 90 days. The safety of combinations of different drug-device products has not been assessed.
- DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross contamination due to inappropriate reprocessing.
- Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

References

1. Fonseca AG, Abizaid AS, Abizaid A et al. A Novel Scoring Balloon (AngioSculpt) for the Treatment of Complex Coronary Lesions. An Intravascular Ultrasound Study. *Am J Cardiol* October 2006; Vol. 98, Issue 8, Supplement: 190M
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. Herz I, Kraikover R, Grenadier E et al. Final Results from the Israeli Multi-Center Registry of the AngioSculpt Scoring Balloon Catheter for the Treatment of Complex Coronary Artery Lesions. American Journal of Cardiology, October 2006; Vol. 98, Issue 8, Supplement: 121M.
4. Mooney M, Teirstein P, Moses J et al. Final Results from the U.S. Multi-Center Trial of the AngioSculpt Scoring Balloon Catheter for the Treatment of Complex Coronary Artery Lesions. American Journal of Cardiology, October 2006; Vol. 98, Issue 8, Supplement: 121M.
5. Takano M, Yamamoto M, Murakami D et al. Optical Coherence Tomography After New Scoring Balloon Angioplasty for In-Stent Restenosis and De Novo Coronary Lesions. Int J Cardiol. 2008; 11: 154
6. Weinz G, Metzger DC, Liberman HA, O'Shaughnessy CD, Douglas JS, Turco MA, Mehran R, Gershony G, Leon MB, Moses JW. 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 2013;82(3):352–359
7. Cremers B, Schmitmeier S, Clever YP, Gershony G, Speck U, Scheller B. Inhibition of neo-intimal hyperplasia in porcine coronary arteries utilizing a novel paclitaxel–coated scoring balloon catheter. Catheter Cardiovasc Interv. 2014 Dec 1;84(7):1089–98.
8. Scheller B, Fontaine T, Manginer N, et al. A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis: Results From the Nulti-Center Randomized Controlled PATENT-C First-In Human Trial. Cath and Cardiovasc Interv. 2016; 88:51–59.
9. Scheller et al. "A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis Two-Year Results from the PATENT-C First-in-Human Trial," TCT 2015

Spectranetics International BV Plesmanstraat 6
3833 LA Leusden
The Netherlands
ve_vewebl@philips.com

PHILIPS

AngioSculptX

Drug-coated PTCA scoring balloon catheter

Designed for enhanced **drug delivery**

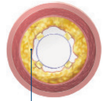
One device. Two technologies.

AngioSculptX is a unique combination of the trusted antirestenotic action of Paclitaxel and proven capabilities of its scoring platform for:

1 An optimized balloon inflation

The AngioSculptX catheter is based on the same innovative AngioSculpt platform that has earned the trust of physicians with more than 400,000 procedures performed worldwide (PTCA + PTA).*

Precision

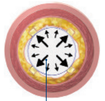


Edges lock in

Minimize geographical-miss

Helical scoring elements lock the device in place, stabilizing inflation[1,2] during drug delivery.

Power



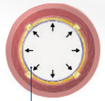
~15 – 25x scoring force

Optimize balloon to vessel contact

Uniform luminal enlargement

Nitinol elements deliver 15–25 times the force of a conventional balloon[3].

Safety



~1x force post scoring

Low rate of adjunctive stenting

Low dissection** rate and minimal perforations[1,2], no flow-limiting dissections[5,6]

* Data on file at Spectranetics

** +9% to 13.6% dissection rate with AngioSculpt vs. +30% for conventional POBA

2 Potential for better drug uptake

The unique scoring mechanism of the AngioSculptX catheter is designed for lumen gain improvement through controlled dissection with enhanced drug delivery.

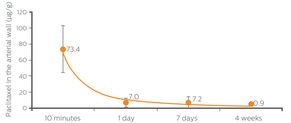
Proprietary anti-restenotic formulation

- 3 µg/mm² Paclitaxel
- NDGA excipient to facilitate drug transfer to tissue*

Targeted drug delivery by scoring

- Minimizes balloon slippage to enable accurate balloon positioning[1,3,4]
- Stable inflation prevents inadvertent movement when coating is in contact with vessel[1,3,4]

Pharmacokinetics*



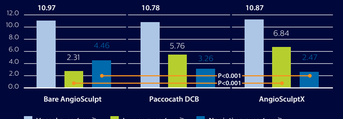
- Demonstrated desired drug tissue transfer
- Efficacious tissue drug dose through 28 days
- Proven transfer of paclitaxel from the balloon to the artery wall
- NDGA rapidly metabolized by body and not detected at any time points in tissue

* animal pK Study

Improving acute and long term outcomes while leaving nothing behind

Predictable acute results through stable, no-slip dilatation and large lumen gain. Sustained antirestenotic effect by enhanced drug delivery.

Pre-clinical testing: AngioSculptX catheter vs. bare AngioSculpt vs. competitive DCB[7]



The AngioSculptX catheter significantly increases lumen area, decreases neointimal area vs. bare AngioSculpt without vessel overstretching and shows potential for similar benefit vs. DCB in an animal model.

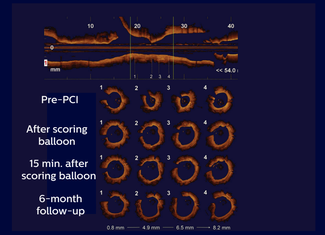
PATENT-C: Proven long-term performance through randomized controlled trial[8]

PATENT-C study design

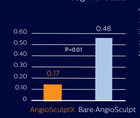
- Randomized controlled trial of AngioSculptX catheter vs. bare AngioSculpt catheter for the treatment of bare metal stent ISR (61 pts)
- Multi-center: 4 sites, Germany (3) and Brazil (1)
- Independent QCA corelab
- Independent clinical event adjudication by Clinical Event Committee
- Primary endpoint: angiographic in-segment late lumen loss (LLL)
- Secondary endpoints: clinically driven TLR, composite MACE, stent thrombosis and other variables

PATENT-C trial results demonstrated a significant improvement in late lumen loss (LLL) target lesion revascularization (TLR) and major adverse cardiac events (MACE) at 6-months and 24-months in the treatment of in-stent restenosis (ISR).[8,9]

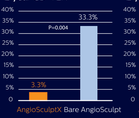
PATENT-C: Acute and sustained luminal gain in ISR



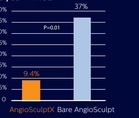
6-month in-segment LLL[8]



2 year CD-TLR[9]



2 year MACE[9]



At 2 years, significant reduction in clinically-driven TLR and MACE rates