

Changing the landscape of balloon angioplasty for coronary artery disease



 **AngioSculpt[®] PTCA**

Scoring Balloon Catheter

CORONARY APPROVAL INCLUDES TYPE C LESIONS

The AngioSculpt Scoring Balloon Catheter

COMPLIANCE CHARACTERISTICS

Pressure (atm)	Balloon Diameter (mm)			
	2.0	2.5	3.0	3.5
2	1.88	2.28	2.73	3.19
4	1.91	2.35	2.79	3.26
6	1.95	2.40	2.88	3.37
Nominal Pressure 8	2.01	2.49	3.01	3.51
10	2.08	2.59	3.16	3.65
12	2.15	2.69	3.27	3.73
14	2.22	2.77	3.36	3.81
16	2.28	2.85	3.43	3.86
18	2.32	2.89	3.50	3.91
Rated Burst Pressure 20	2.37	2.95	3.57	3.97
22	2.39	2.99	3.63	—

ORDERING INFORMATION

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)	Guidewire Compatibility	Guide Catheter Compatibility	Catheter Length (cm)
2027-2010	2.0	10	0.014"	6F	137
2027-2015	2.0	15	0.014"	6F	137
2027-2020	2.0	20	0.014"	6F	137
2027-2510	2.5	10	0.014"	6F	137
2027-2515	2.5	15	0.014"	6F	137
2027-2520	2.5	20	0.014"	6F	137
2027-3010	3.0	10	0.014"	6F	137
2027-3015	3.0	15	0.014"	6F	137
2027-3020	3.0	20	0.014"	6F	137
2027-3510	3.5	10	0.014"	6F	137
2027-3515	3.5	15	0.014"	6F	137
2027-3520	3.5	20	0.014"	6F	137

SAFETY SUMMARY

INDICATIONS: The AngioSculpt 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.

CONTRAINDICATIONS: The AngioSculpt 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.

WARNINGS: Administer appropriate antiplatelet, anticoagulant and coronary vasodilator therapy, consistent with institutional practice for coronary stent procedures, during and after the procedure. This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate reesterilization and cross contamination. For use in de novo or in-stent restenosis (ISR) lesions, the inflated diameter size of the balloon should approximate the vessel diameter size just proximal and distal to the stenosis, in order to reduce potential vessel damage. When used to pre-dilate the lesion prior to pre-planned stenting, the catheter should be one size smaller than the estimated vessel diameter (e.g., a 2.5 mm diameter device should be used in a vessel estimated to have a 3.0 mm diameter). 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. Use the device prior to the expiration date specified on the package.

PRECAUTIONS: Take extra care when using the AngioSculpt catheter to treat a lesion distal to a freshly deployed stent. This precaution is particularly applicable to a drug-eluting stent so as to minimize the risk of damage to the stent coating. Prior to angioplasty, examine the catheter to verify functionality, catheter integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used. Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the AngioSculpt 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 AngioSculpt catheter over the floppy portion of the guide wire. Catheter manipulation, including advancement and retraction, should be performed by grasping the 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 (AngioSculpt catheter and steerable guide wire) as a unit. If fluoroscopic guidance indicates that the AngioSculpt catheter has advanced beyond the end of the guide wire, withdraw the catheter and reload the wire before advancing again.

POSSIBLE ADVERSE EFFECTS: Death; Heart Attack (acute myocardial infarction); 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; 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); Infection.

REFERENCES: 1. Costa JR, Leon MB, Mintz GS, et al. Impact of different pre-dilatation strategies on stent expansion: an intravascular ultrasound study. *Circulation*. 2006;114(suppl II):732. 2. 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. *Am J Cardiol*. 2006;98(8 suppl):121M. 3. Holmes DR Jr, Mathew V, eds. *Atlas of Interventional Cardiology*. 2nd ed. Philadelphia, Pa: Current Medicine Group; 2003. 4. AngioSculpt Study Report: AngioSculpt efficacy and safety study in a porcine model of coronary artery in-stent restenosis (ISR). March 23, 2003. 5. Vlietstra RE, Holmes DR Jr, eds. *Coronary Balloon Angioplasty*. Boston, Mass: Blackwell Scientific Publications; 1994:399-451. 6. Sonoda S, Morino Y, Aki J, et al. Impact of final stent dimensions on long-term results following sirolimus-eluting stent implantation: serial intravascular ultrasound analysis from the SIRIUS trial. *J Am Coll Cardiol*. 2004;43:1959-1963.

To learn more about the clinical advantages of the AngioSculpt Scoring Balloon Catheter, please contact your AngioScore representative today.



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CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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Innovation by design

TECHNOLOGY THAT SETS A NEW STANDARD

- Flexible nitinol scoring element with three rectangular spiral struts works in tandem with a semi-compliant balloon to score the target lesion
- Balloon inflation focuses uniform radial forces along the edges of the nitinol element, scoring the plaque and resulting in a more precise and predictable outcome
- Low crossing profile (~2.7F), 0.014" OTW system compatible with 6F guiding catheters
- Semi-compliant balloon material allows the physician to tailor the device size to the vessel (2–16 atm)
- Two radiopaque markers indicate the working ends of the scoring balloon
- Nitinol-enhanced balloon deflation for excellent rewrap and recross capabilities



Electropolished struts provide a margin of safety, resulting in zero perforations and no slippage.

The AngioSculpt Scoring Balloon Catheter: A new dimension in patient outcomes

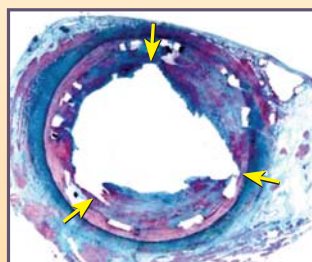
The AngioSculpt Scoring Balloon Catheter transforms the landscape of treating coronary artery disease. It is an essential new tool in the treatment of simple to complex lesions, including in-stent restenosis (ISR) and type C lesions. When used for pre-dilatation prior to stenting, AngioSculpt has been proven to yield a 33%–50% greater luminal gain than either direct stenting or pre-dilatation with a conventional angioplasty balloon catheter.¹

The innovative nitinol scoring element scores the plaque circumferentially, providing a precise and predictable solution to even the most difficult lesion challenges. As demonstrated in clinical studies, AngioSculpt was used successfully in treating fibro-calcific, bifurcation and ostial lesions. AngioSculpt provides the versatility and effectiveness required of a new technology together with the simplicity and deliverability of a high-performance balloon catheter.

REDUCED DISSECTION RATES



Severe dissection post-POBA
of human coronary artery³



Post-AngioSculpt scoring
of porcine ISR⁴

A NEW MEASURE OF SUCCESS

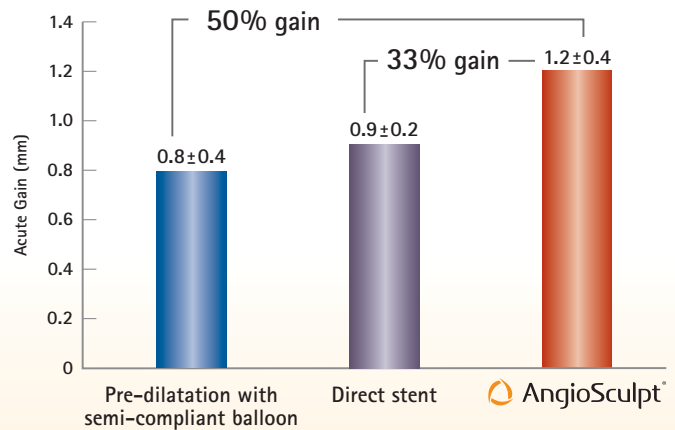
- Procedural success rate of 98.5%, with 76% of lesions being types B2/C²
- Freedom from major adverse cardiac events 97.5%²
- Only coronary balloon catheter with specific indication for treating type C lesions
- Proven effective in complex calcified (35%), bifurcation (29%) and ostial (13%) lesions²
- Significantly low dissection rate of 13.6%² versus ~30% for POBA⁵
- No device slippage (even in ISR) for more accurate placement and no "geographic miss"²
- Zero perforations as confirmed by an independent core laboratory²

A new dimension in lesion preparation

BETTER FINAL POST-STENT DIMENSIONS

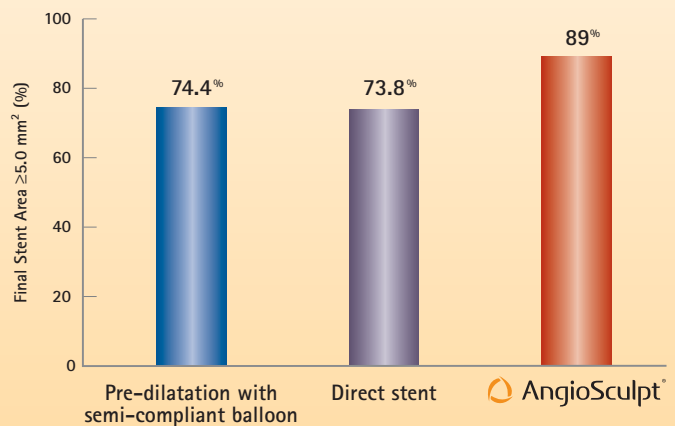
- Clinical studies show that final stent luminal dimensions are an important predictor of better long-term results⁶
- Pre-dilatation with AngioSculpt yields a 33%–50% greater luminal gain than direct stenting or pre-dilatation with a conventional angioplasty balloon catheter ($p < 0.001$)¹
- Pre-dilatation with AngioSculpt resulted in a post-stent luminal area $\geq 5.0 \text{ mm}^2$ 89% of the time, compared to only 74% with direct stenting or pre-dilatation with a conventional angioplasty balloon catheter ($p < 0.001$)¹
- AngioSculpt achieved larger post-stent luminal dimensions than direct stenting or pre-dilatation with a conventional balloon regardless of the type of lesion plaque morphology (i.e., soft, fibrotic, calcific or mixed plaque)¹

MORE LUMINAL GAIN ($p < 0.001$)¹

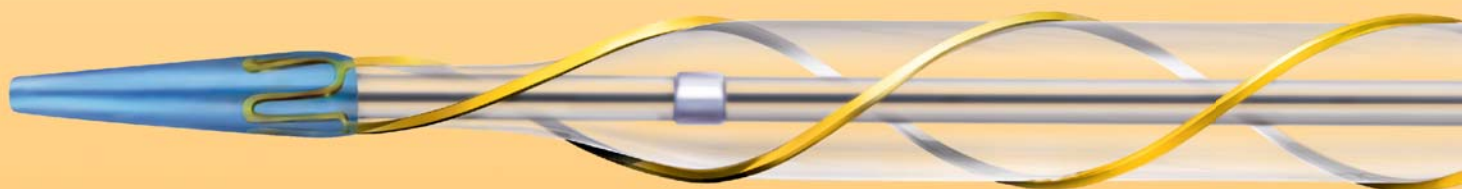


Note: There was no statistically significant difference between the results for pre-dilatation with a conventional angioplasty balloon and direct stenting.

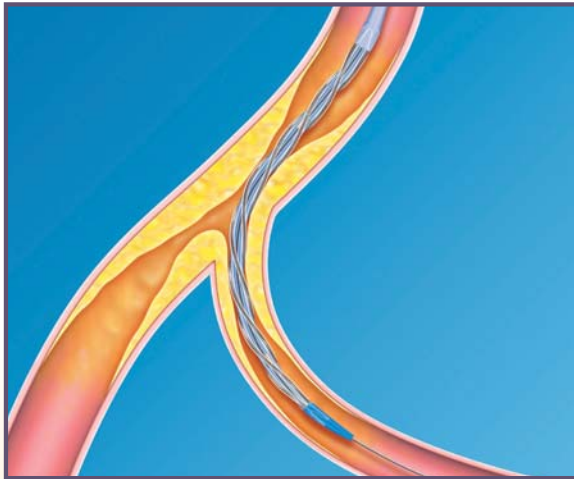
BETTER FINAL LUMINAL DIMENSIONS ($p < 0.001$)¹



Note: There was no statistically significant difference between the results for pre-dilatation with a conventional angioplasty balloon and direct stenting.



A versatile tool for treating bifurcation lesions



Pre-treatment: AngioSculpt placed at side branch in bifurcation lesion



Post-treatment: AngioSculpt used as stand-alone treatment in side branch and pre-dilatation tool in main branch

The clinical challenges common in bifurcation lesions—dissection, slippage and plaque shifting—can make a lengthy procedure even longer. AngioSculpt offers physicians an effective, time-saving tool for treating the unique challenges of bifurcation lesions.

- No device slippage² for precise and predictable treatment of the target lesion
- Uniform, radial, scoring forces beneficial for treating elastin-rich ostial lesions
- Low dissection rates² may lead to reduced need for "bail-out" stenting
- Electropolished nitinol edges provide a margin of safety in complex anatomy
- Better final luminal dimensions in the main branch post-stenting¹



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