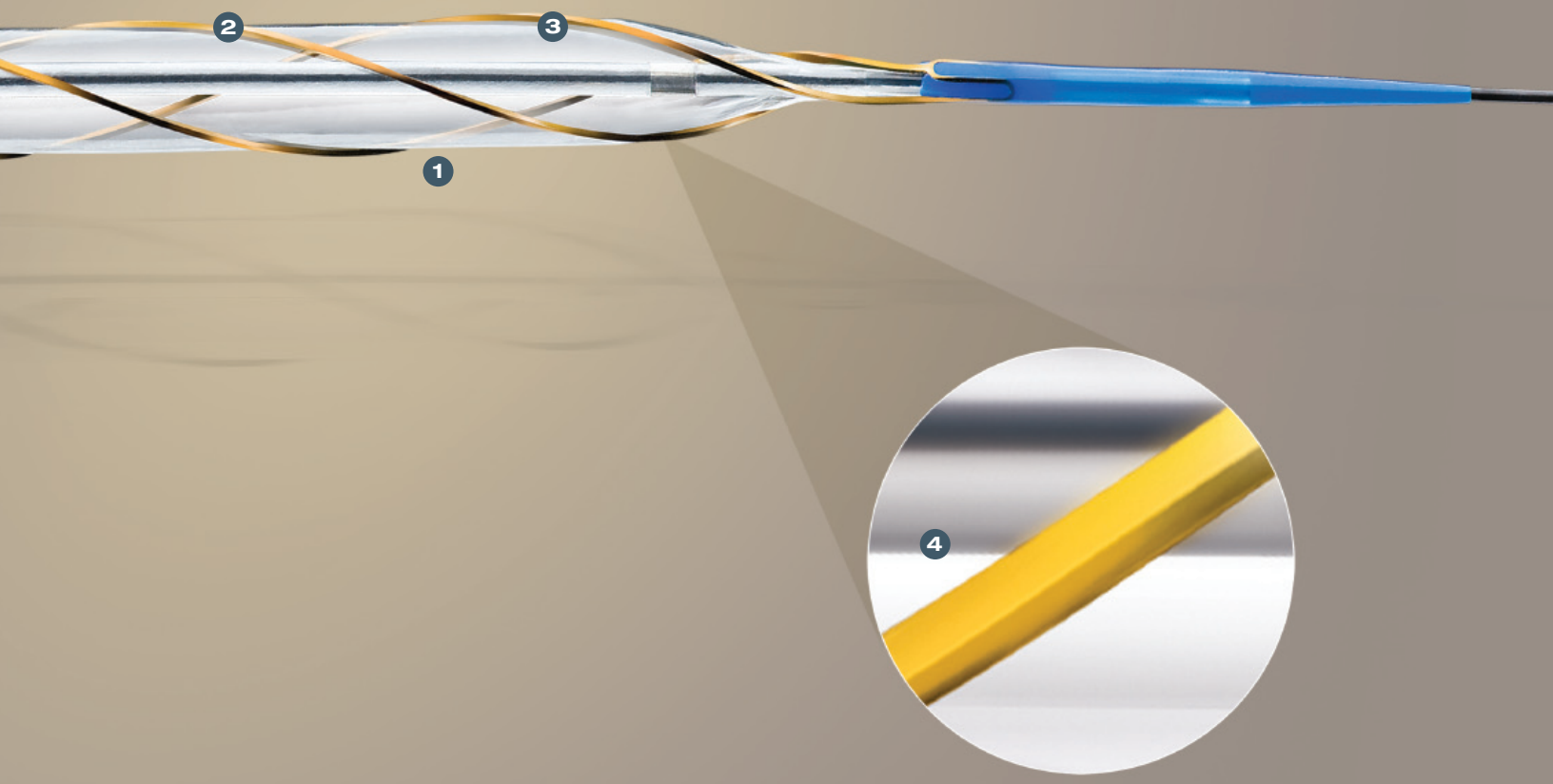
Changing the Landscape

Just Got Easy.

AngioSculpt® EX

PTCA Scoring Balloon Catheter

The Benefits of Advanced Technology



1. Large working range (2–up to 20 atm) allows physician to tailor device to vessel size*
2. Nitinol-enhanced balloon deflation for excellent rewrap and recross capabilities
3. Electropolished, helical scoring element safely scores lesion circumferentially[4]
4. Rectangular edges provide a predictable dilatation resulting in zero perforations and no slippage[1]

*Please refer to AngioSculpt EX product labeling, including the instructions for use, to select the appropriate device size.

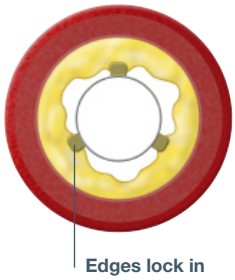
The AngioSculpt® Advantage

The Benefits of Advanced Technology

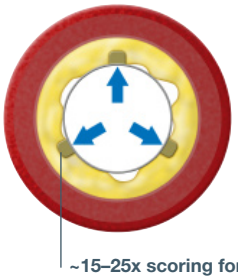
The AngioSculpt® Easy Exchange (EX) PTCA Scoring Balloon Catheter delivers all of the advantages of the AngioSculpt system in a new rapid-exchange design. It's an essential tool in the treatment of a wide range of lesions, including in-stent restenosis (ISR) and type C lesions. In fact, it's the only device of its kind with a specific indication for treating type C lesions.

One Unique Device—Three Distinct Benefits

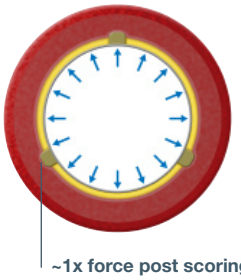
Precision



Predictable Power



Safety



Proper Placement

– Rectangular scoring edges lock the device in place

– No device slippage or "watermelon seeding," even in ISR[1]

Enhanced Mechanical Leverage

– The leading edges are designed to drive outward expansion with up to ~15–25 times the force of conventional balloons[2]

– Helical nitinol scoring element creates a uniform initial luminal enlargement

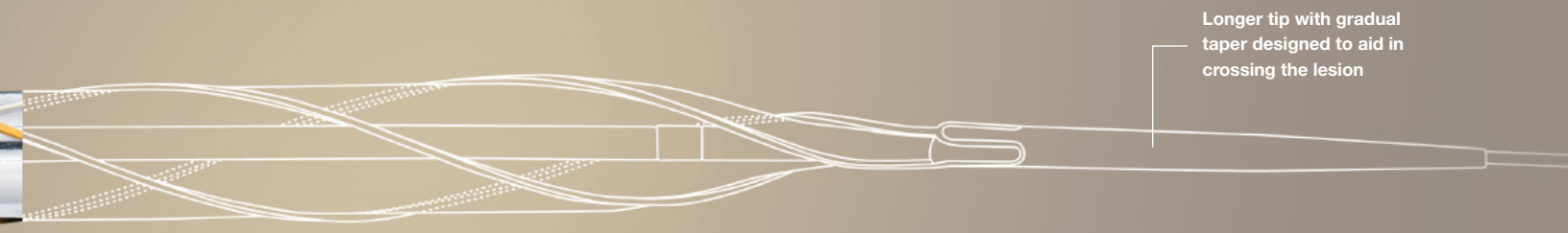
Predictable Results

– Post scoring, outward forces are designed to be equivalent to that of a conventional balloon

– Significantly low dissection rate of 13.6%[1] vs. ~30% of POBA[3]

– Zero perforations[1]

Nothing's More Rapid



Than Easy

Easy Exchange

The AngioSculpt EX features a new rapid-exchange design that enhances ease of use without compromising on procedural results.

- Single-operator system
- Rapid deployment
- Reinforced catheter shaft for enhanced pushability
- Same familiar procedure as other rapid exchange systems[5]

Easy Procedure... Same Remarkable Results

Procedural success rate of 98.5%, with 76% of lesions being types B2/C[1]

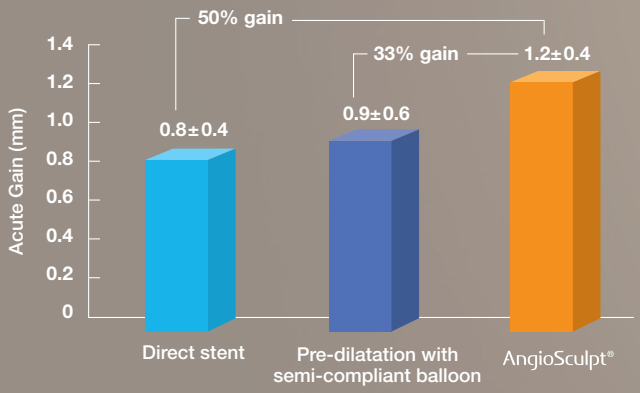
- Demonstrated effective in a wide range of lesion types: complex, calcified and ostial[1]
- Only coronary balloon catheter with specific indication for treating type C lesions

Larger Luminal Gain = The Measure of Success

Clinical studies have shown that final stent luminal dimensions are an important predictor of better long-term results.[6]

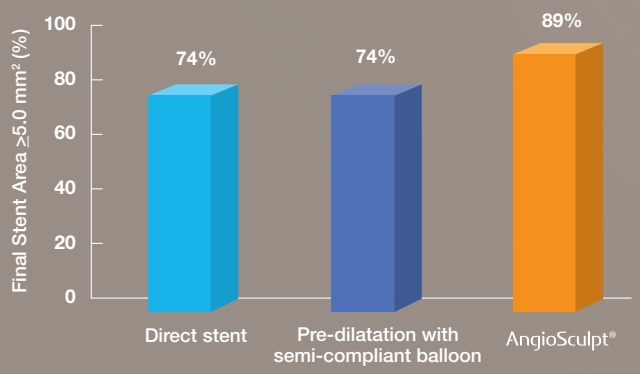
For pre-dilating prior to stenting, AngioSculpt has been proven to yield a 33%–50% greater luminal gain than either direct stenting or pre-dilatation with a market-leading conventional angioplasty balloon (p=0.004).[7]

More Luminal Gain (p=0.004)[7]



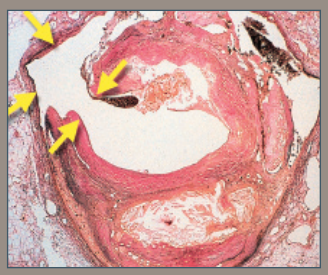
Note: There was no statistically significant difference between the results for pre-dilatation with a conventional angioplasty balloon and direct stenting.

Better Final Luminal Dimensions (p<0.001)[7]

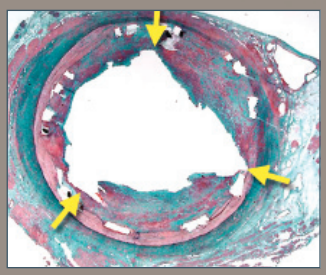


Note: There was no statistically significant difference between the results for pre-dilatation with a conventional angioplasty balloon and direct stenting.

Reduced Dissection Rates



Severe dissection post-POBA of human coronary artery[8]



Post-AngioSculpt scoring of porcine ISR[4]

AngioSculpt® EX
PTCA Scoring Balloon Catheter

The AngioSculpt® EX PTCA Scoring Balloon Catheter

Ordering Information					
Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)	Guidewire Compatibility	Guide Catheter Compatibility	Catheter Length (cm)
2034-2010	2.0	10	0.014″	6F	139
2034-2015	2.0	15	0.014″	6F	139
2034-2510	2.5	10	0.014″	6F	139
2034-2515	2.5	15	0.014″	6F	139
2034-3010	3.0	10	0.014″	6F	139
2034-3015	3.0	15	0.014″	6F	139
2034-3510	3.5	10	0.014″	6F	139
2034-3515	3.5	15	0.014″	6F	139

Compliance Chart					
	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
	20	2.37	2.95	3.57	3.97
Rated Burst Pressure	22	2.39	2.99	3.63	-

SUMMARY OF SAFETY AND EFFECTIVENESS – PTCA CATHETER

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 resterilization 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 catheter 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. 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(suppl 8):121M. **2.** AngioSculpt Report ST-1197 (2008), on file at AngioScore, Inc. **3.** Vlietstra RE, Holmes DR Jr, eds. *Coronary Balloon Angioplasty*. Boston, MA: Blackwell Scientific Publications; 1994:399-451. **4.** Scheinert D, Peeters P, Bosiers M, O'Sullivan G, Sultan S, Gershony G. Results of the multicenter first-in-man study of a novel scoring balloon catheter for the treatment of infra-popliteal peripheral arterial disease. *Catheter Cardiovasc Interv.* 2007;70:1034-1039. **5.** AngioSculpt Study Report: SR-1109 (2008), on file at AngioScore. **6.** Sonoda S, Morino Y, Ako 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. **7.** 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. **8.** Holmes DR Jr, Mathew V, eds. *Atlas of Interventional Cardiology.* 2nd ed. Philadelphia, PA: Current Medicine Group; 2003.

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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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