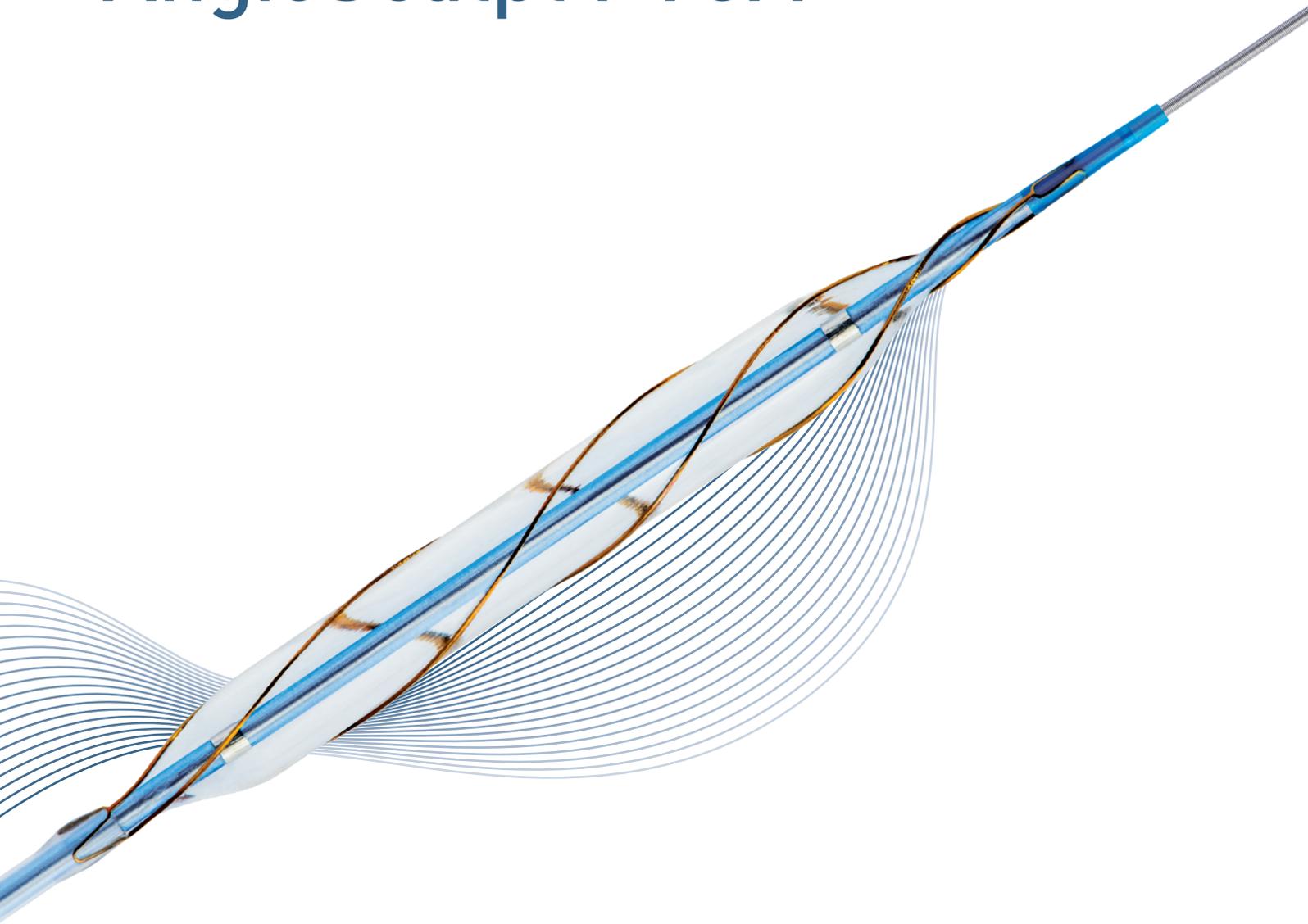


Vascular Intervention // Coronary
Scoring Balloon Catheter

AngioSculpt PTCA



Advanced scoring balloon technology



Precision, power and predictable results



Larger luminal gain

AngioSculpt PTCA

Advanced technology delivering precision, power and predictable results in plaque modification.

Advanced scoring balloon technology

Electropolished, helical scoring element safely scores lesion circumferentially.¹

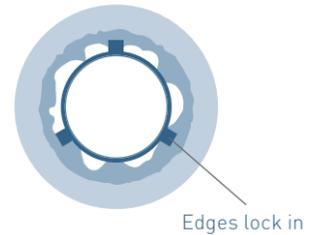
Rectangular edges provide a predictable dilatation resulting in low dissection rates and minimal device slippage.²

Nitinol-enhanced balloon deflation for excellent rewrap and recross capabilities.

Large working range (2–20 atm) allows device to be tailored to vessel size.

Precision, power and predictable results

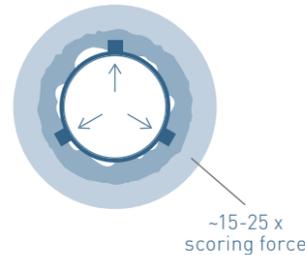
Precision



Proper placement

- Rectangular scoring edges lock the device in place.
- No significant device slippage or 'watermelon seeding', even in ISR.²

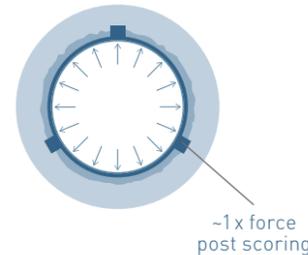
Predictable power



Enhanced mechanical advantage

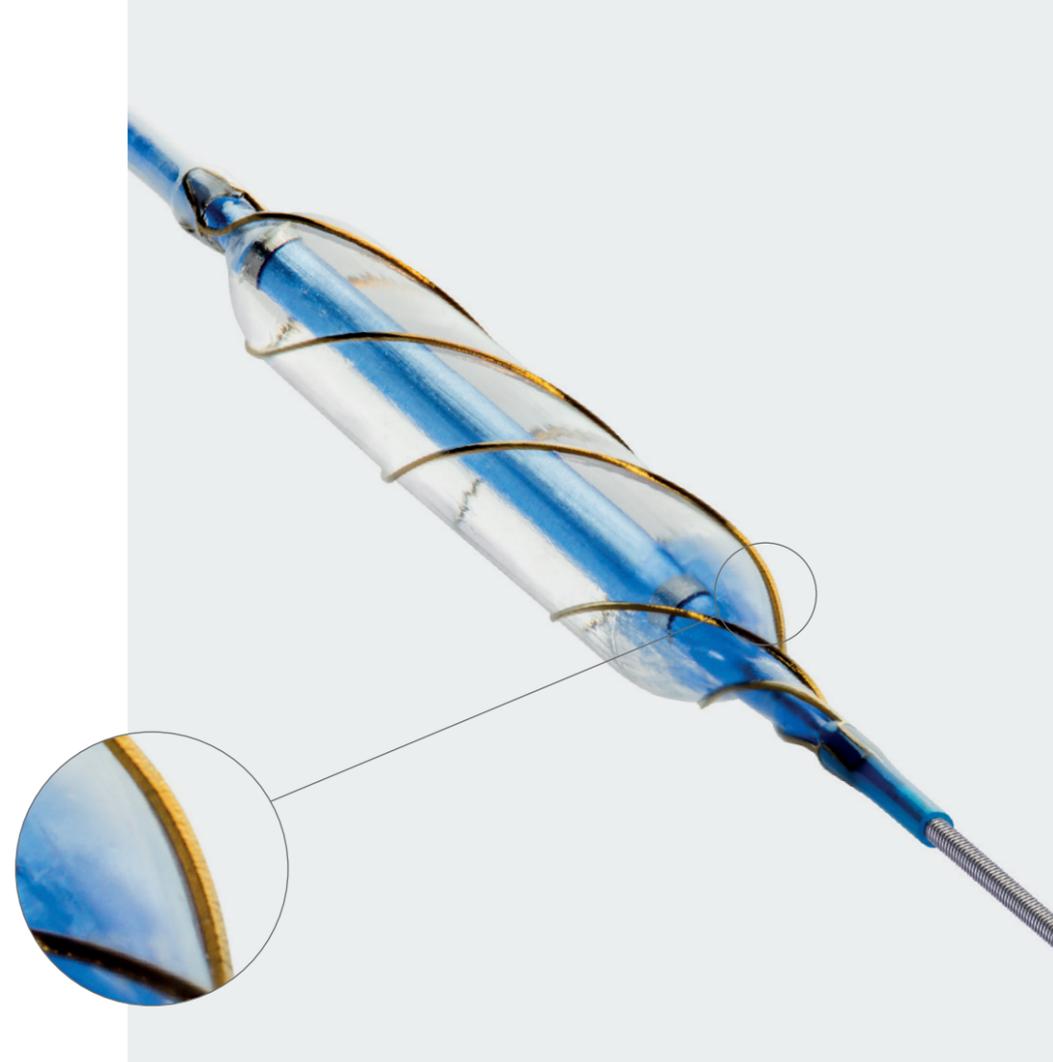
- The leading edges are designed to drive outward expansion with up to ~15–25 times the force of conventional balloons.³
- Helical nitinol scoring element creates a large initial luminal expansion for stent implantation.⁴

Safety



Predictable results

- Post scoring, outward forces are designed to be equivalent to that of a conventional balloon.
- Low dissection rate of 13.6%.²

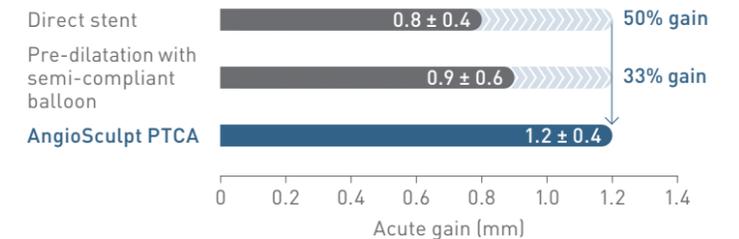


Larger luminal gain

Post-stent luminal area is an important predictor of long-term outcome. Studies have shown that greater acute luminal gain is associated with better long-term results.⁵

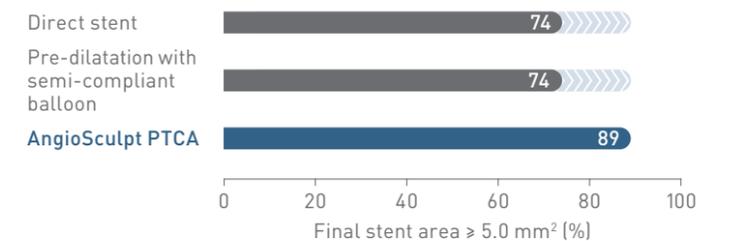
The AngioSculpt group exhibited greater stent expansion than both POBA and direct stent groups, regardless of lesion type or plaque morphology (e.g. soft, fibrotic, calcific or mixed plaque).⁴

More luminal gain (p = 0.004)⁴



Pre-dilatation with AngioSculpt yielded 33% - 50% greater luminal gain than direct stenting or pre-dilatation with a conventional angioplasty balloon.⁴

Better final luminal dimensions (p < 0.001)⁴



89% of the vessels predilated with AngioSculpt had final stent area ≥ 5.0 mm² compared to 74% for direct stenting or pre-dilatation with a conventional angioplasty balloon.⁴

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



AngioSculpt PTCA

Indicated for the treatment of a hemodynamically significant coronary artery stenosis, including in-stent restenosis, for the purpose of improving myocardial perfusion.

Technical Data	Balloon catheter
Catheter type	Rx
Recommended guide wire	0.014"
Usable length	137 cm
Balloon coating	Uncoated for non-slip
Balloon markers	2 markers
Nitinol scoring elements	3 ea.
Profile of scoring elements	~0.005"
Guiding catheter	6F (0.068"/1.73 mm)
Crossing profile	~2.7F

Compliance Chart		Balloon diameter x length (mm)			
		ø 2.0 x 10-20	ø 2.5 x 10-20	ø 3.0 x 10-20	ø 3.5 x 10-20
Nominal Pressure (NP)	atm*	8	8	8	8
	ø (mm)	2.01	2.49	3.01	3.51
Rated Burst Pressure (RBP)	atm*	20	20	18	16
	ø (mm)	2.37	2.95	3.50	3.86

*1 atm = 1.013 bar

Ordering Information	Balloon ø (mm)	Catheter length 137 cm (balloon length mm)		
		10	15	20
6F	2.0	360217	360218	360220
	2.5	360221	360222	360225
	3.0	360227	360228	360229
	3.5	360230	360231	360233

1. Fonseca A, Costa JR, Abizaid A, et al. Intravascular ultrasound assessment of the novel AngioSculpt Scoring Balloon Catheter for the treatment of complex coronary lesions. *J Invasive Cardiol.* 2008; 20: 21- 27; 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[suppl 8]: 121M; 3. AngioSculpt Test Plan ST-1197 (2008), on file at Spectranetics Corp.; 4. 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; 5. 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 Cardio.* 2004; 43: 1959-1963.

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