

**PHILIPS**

PTCA Scoring  
Balloon Catheter

AngioSculpt

# Advanced technology delivers big results

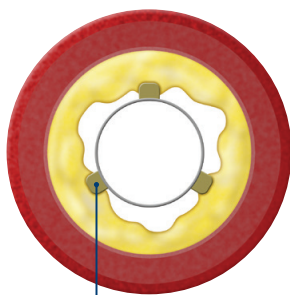


# Your prescription for complex lesions

The AngioSculpt RX PTCA scoring balloon catheter delivers the proven advantages of the AngioSculpt system combined with a new, tapered tip design that enhances deliverability. The result is an essential tool in the treatment of a wide range of coronary lesions, including in-stent restenosis (ISR) and type C lesions.

## Discover the benefits

### Precision

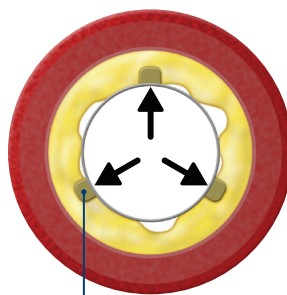


Edges lock in

#### Proper placement

- Rectangular scoring edges lock the device in place
- Minimal device slippage or "watermelon seeding," even in ISR<sup>1</sup>

### Power

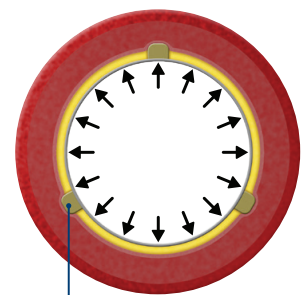


~15–25x scoring force

#### Enhanced mechanical advantage

- The leading edges are designed to drive outward expansion with up to 15–25 times the force of conventional balloons<sup>2</sup>
- Helical nitinol scoring element creates a large luminal expansion for stent implantation<sup>3</sup>

### Safety



~1x force post-scoring

#### Predictable results

- Post-scoring, outward forces are designed to be equivalent to that of a conventional balloon
- Low dissection rate of 13.6% (majority were non-flow limiting)<sup>1</sup>

# Advanced technology delivers big results

- 1 Large working range (2 atm 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<sup>4</sup>
- 4 Rectangular edges provide a predictable dilatation resulting in low dissection rates and minimal device slippage<sup>1</sup>

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

## Larger luminal gain

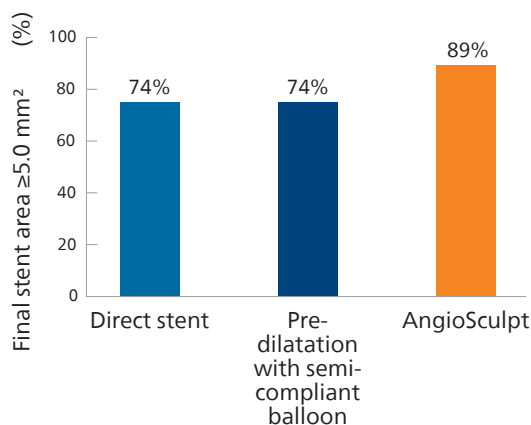
### A new dimension in plaque modification

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.<sup>5</sup>

- Pre-dilatation with AngioSculpt yielded 33% to 50% greater luminal gain than direct stenting or pre-dilatation with a conventional angioplasty balloon.<sup>3</sup>
- 89% of the vessels predilated with AngioSculpt had final stent area  $\geq 5.0 \text{ mm}^2$  compared to 74% for direct stenting or pre-dilatation with a conventional balloon.<sup>3</sup>
- 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).<sup>3</sup>

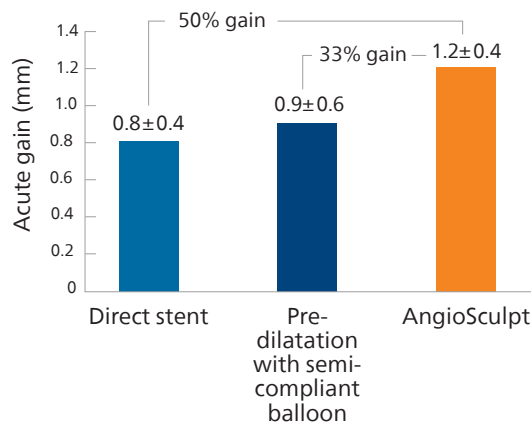
### Better final luminal dimensions

( $P < 0.001$ )<sup>3</sup>

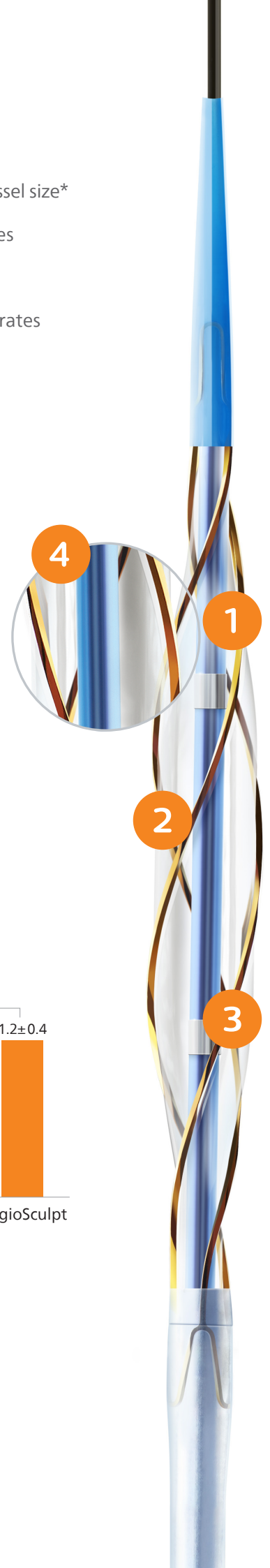


### More luminal gain

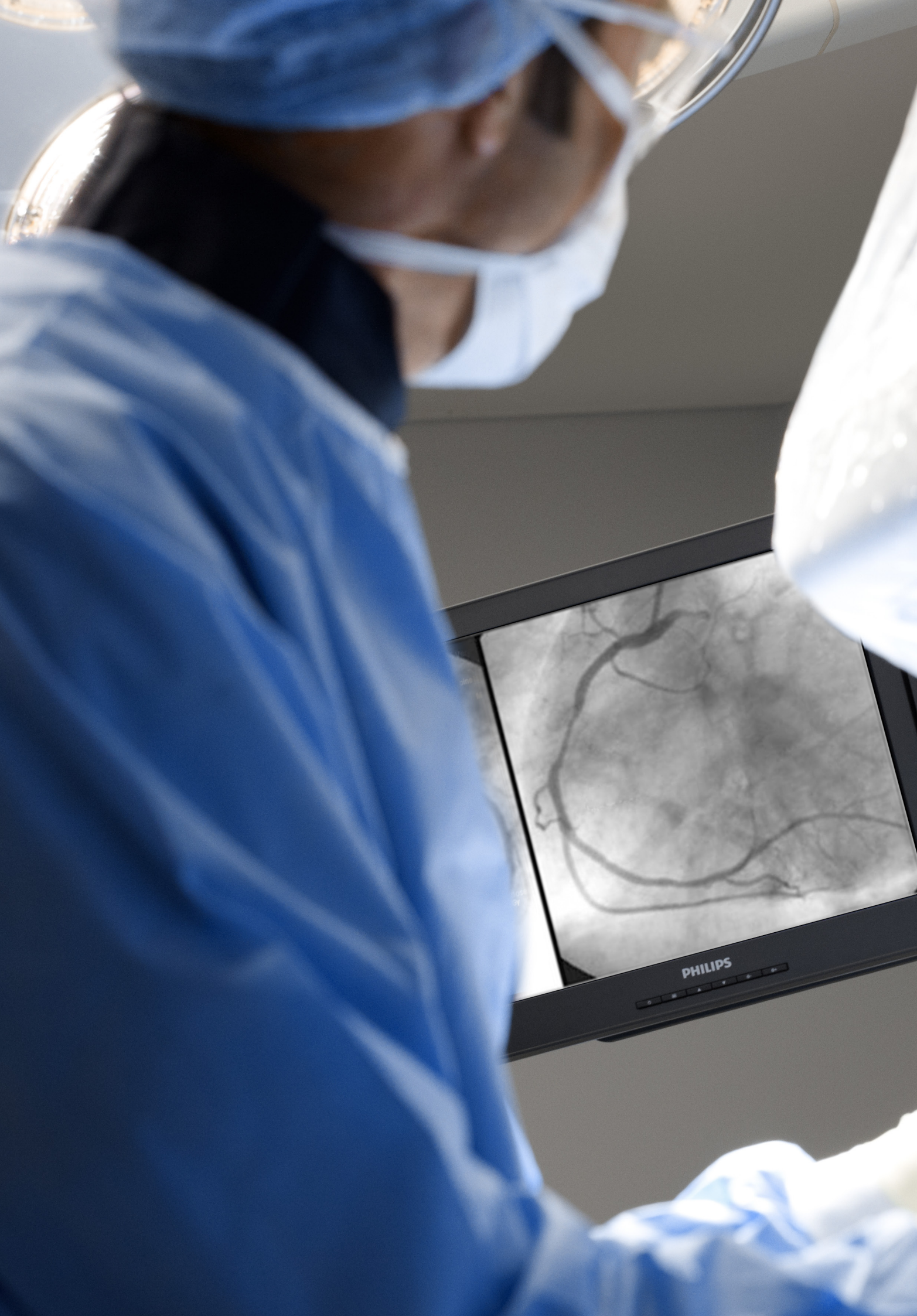
( $P = 0.004$ )<sup>3</sup>



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









New tip designed for improved delivery

## You can trust the delivery

The new Philips AngioSculpt RX PTCA scoring balloon catheter features an advanced molded, tapered tip that facilitates reliable catheter delivery.

- Smooth transitions throughout the distal end of the catheter for improved crossing
- The most agile and nimble AngioSculpt design ever
- Elevates procedural confidence

Compliance chart

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

Nominal pressure

Rated burst pressure

## Ordering information

Number	Balloon diameter (mm)	Balloon length (mm)	Catheter length	Guidewire compatibility	Guide catheter compatibility
2200-2006	2.0	6	137	0.014"	6F
2200-2010	2.0	10	137	0.014"	6F
2200-2015	2.0	15	137	0.014"	6F
2200-2506	2.5	6	137	0.014"	6F
2200-2510	2.5	10	137	0.014"	6F
2200-2515	2.5	15	137	0.014"	6F
2200-3006	3.0	6	137	0.014"	6F
2200-3010	3.0	10	137	0.014"	6F
2200-3015	3.0	15	137	0.014"	6F
2200-3506	3.5	6	137	0.014"	6F
2200-3510	3.5	10	137	0.014"	6F
2200-3515	3.5	15	137	0.014"	6F

## 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.

### 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.

## 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 Test Plan ST-1197 (2008), on file at AngioScore, Inc.
3. 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.
4. 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.
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.

### 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 guidewire. 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 guidewire has become kinked, carefully remove the entire catheter system (AngioSculpt catheter and steerable guidewire) as a unit. If fluoroscopic guidance indicates that the AngioSculpt catheter has advanced beyond the end of the guidewire, withdraw the catheter and reload the wire before advancing again.

### Possible adverse effects

Possible adverse effects include, but are not limited to, the following: 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.

### Product subject to country availability.

Please check with your local sales representative.

Always read the label and follow the directions for use.

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