

PHILIPS

Image Guided Therapy

Coronary Vascular

A clear treatment
strategy for ISR



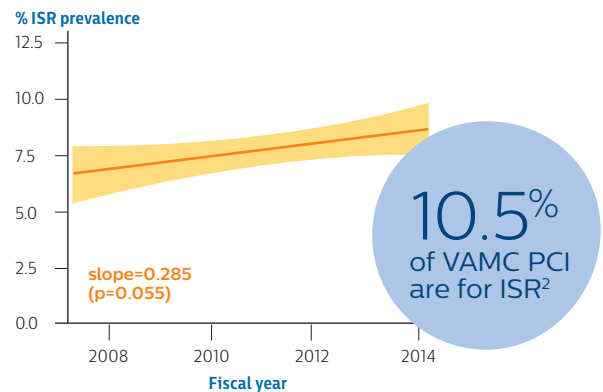
In-stent restenosis (ISR) accounts for 12% of PCI¹

ISR cases are one of the most complex challenges, often resulting in costly and lengthy procedures, that require a high degree of personalization.

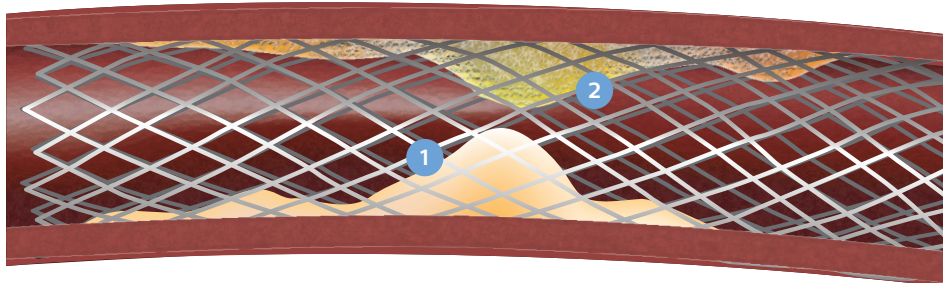
As ISR cases increase², a clear treatment strategy is needed

- Clear procedural guidance with imaging is recommended to determine the extent and mechanism of restenosis.
- Optimize vessel preparation with products that are designed and indicated for addressing the morphology differences of ISR.

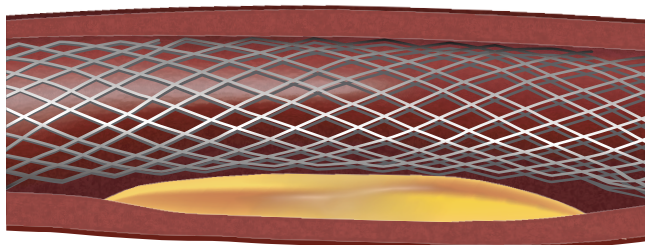
% PCI sessions treating in-stent restenosis



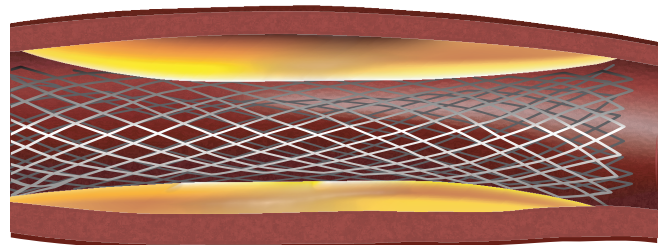
Common causes of in-stent restenosis



- 1 Neointimal hyperplasia**
Mainly smooth muscle cell proliferation
- 2 Neo-atherosclerosis**
Newly formed atherosclerotic changes within the neo-intima



Stent malapposition



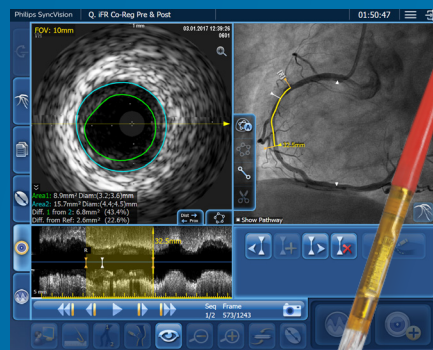
Stent underexpansion

Our approach to ISR

Clear procedural guidance and optimal vessel preparation may help you succeed in ISR cases.

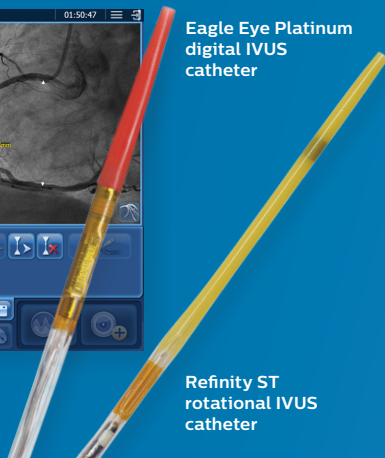
See clearly

- **Help determine** the mechanism of stent restenosis or stent thrombosis
- **Allow optimization** for treatment strategy and device utilization
- **Help confirm** pre and post therapy results



IVUS
Co-registration

Eagle Eye Platinum
digital IVUS
catheter



Refinity ST
rotational IVUS
catheter

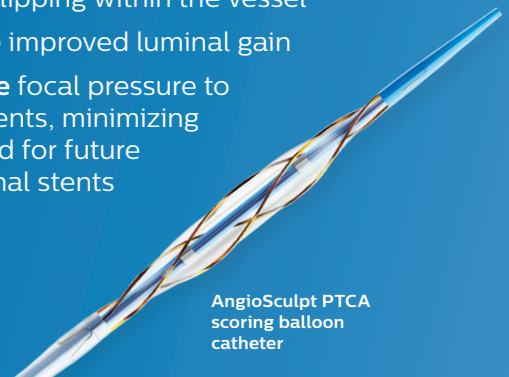
Treat optimally

- **Modify** plaque, even behind struts, leading to better stent apposition
- **Ablate** lesion material
- **Maximize** lumen for additional stent expansion and placement



ELCA coronary
laser atherectomy
catheter

- **Resist** slipping within the vessel
- **Provide** improved luminal gain
- **Increase** focal pressure to reset stents, minimizing the need for future additional stents



AngioSculpt PTCA
scoring balloon
catheter

Guidelines support the use of IVUS for patients with ISR and ST

ACC/AHA/SCAI guidelines for IVUS ³	Class	Level of evidence
To determine the mechanism of stent restenosis	IIa	C
To determine the mechanism of stent thrombosis	IIb	C

Indications support the use of therapeutics for ISR cases

AngioSculpt PTCA scoring balloon catheter is indicated for use in treating significant coronary artery stenosis, including ISR and complex type C lesions.

ELCA coronary laser atherectomy is indicated in single or multi-vessel disease, either as stand-alone modality or in conjunction with PTCA. Indicated for restenosis in 316L stainless steel stents, prior to intravascular brachytherapy.

ELCA important safety information

Indications: The laser catheters are intended for use either as a stand-alone modality or in conjunction with percutaneous transluminal coronary balloon angioplasty (PTCA) in patients who are acceptable candidates for coronary artery bypass graft (CABG) surgery. The following indications for use, contraindications and warnings have been established through multicenter clinical trials. The Philips CVX-300 Excimer laser system and the multi-fiber laser catheter models are safe and effective for the following indications: occluded saphenous vein bypass grafts, ostial lesions, long lesions (greater than 20mm in length), moderately calcified stenosis, total occlusions traversable by a guidewire, lesions which previously failed balloon angioplasty, restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy. These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

Contraindications: Lesion is in an unprotected left main artery. Lesion is beyond acute bends or is in a location within the coronary anatomy where the catheter cannot traverse. Guidewire cannot be passed through the lesion. Lesion is located within a bifurcation. Patient is not an acceptable candidate for bypass graft surgery.

Potential adverse events: Use of the Philips CVX-300 Excimer laser system may contribute to the following complications: dissection of the arterial wall, perforation, acute reocclusion, embolization, aneurysm formation, spasm, coronary artery bypass graft surgery, thrombus, myocardial infarction, arrhythmia, filling defects, death. No long term adverse effects of ELCA are known at this time.

Risks: The primary endpoint defined in the laser angioplasty of restenosis stents (LARS) randomized trial was the absence of major adverse cardiac events (MACE) at 6 months: Death; myocardial infarction; coronary artery bypass surgery. Procedural complications include: any dissection, acute thrombus, haziness, no reflow, arrhythmia, acute vessel closure, occlusion of side branch, occlusion non-target, coronary spasm, coronary embolism, coronary perforation, laser/stent damage, balloon/stent damage, and other serious.

AngioSculpt PTCA important safety information

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.

The AngioSculpt catheter should not be used for coronary artery lesions unsuitable for treatment by percutaneous revascularization, and coronary artery spasm in the absence of a significant stenosis.

Possible adverse effects include, but are not limited to: death; heart attack (acute myocardial infarction); total occlusion of the treated 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 chest pain (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 or 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); and infection.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

Caution: Federal law restricts these devices to sale by or on the order of a physician.

The materials available in this flyer are not intended to be a complete presentation of all information or issues for any topic. Results may vary depending on a variety of patient-specific attributes and related factors and nothing in this flyer is intended to provide specific medical advice or to take the place of written law or regulations.

1. Cassese S, Byrne RA, Tada T, et al. Incidence and predictors of restenosis after coronary stenting in 10,004 patients with surveillance angiography. *Heart* 2014;100:153–9.
2. Incidence, procedural management and clinical outcomes of coronary in-stent restenosis: Insights from the National VA CART Program – Catheter Cardiovascular intervention; 2017;1-9.
3. Levine G et al, 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, Catheterization and Cardiovascular Interventions 00:000–000 (2011).

