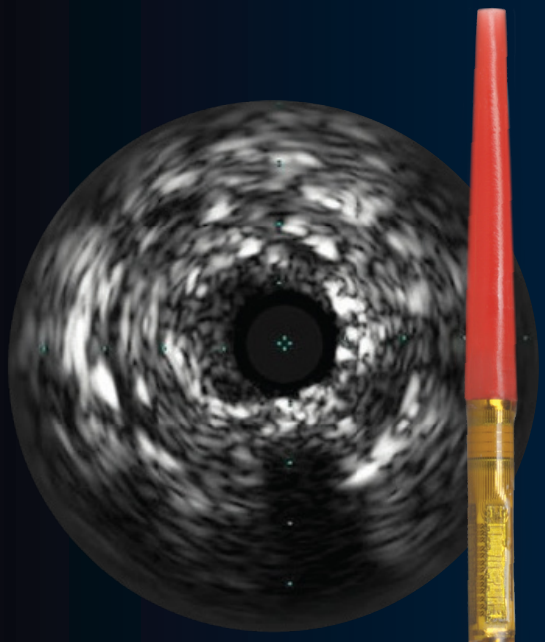
PHILIPS

Image Guided Therapy

Coronary Vascular

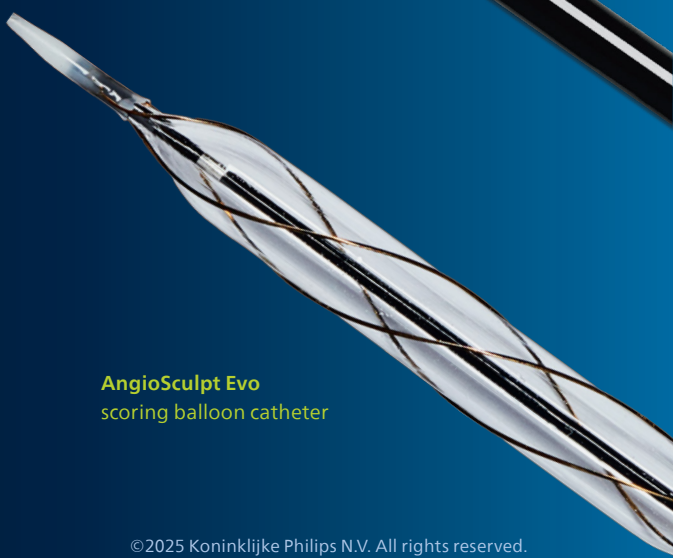
Defeat ISR

Treat in-stent restenosis (ISR) using IVUS guidance, with a scoring balloon up to 25x stronger than a conventional balloon, and the only atherectomy device indicated for ISR*[1]



Eagle Eye Platinum
digital IVUS catheter

ELCA laser
atherectomy catheter



AngioSculpt Evo
scoring balloon catheter

See the Full Picture.

Refer to full device labeling and instructions for important safety information. Caution: Federal law restricts these devices to sale by or on the order of a physician.

*Indicated for restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy for only the 1.4, 1.7, and 2.0mm ELCA catheter models.

See ISR with Eagle Eye Platinum

- The easy-to-use Eagle Eye Platinum, with plug-and-play functionality, facilitates multiple catheter insertions.
  - Utilize IVUS to support the identification of the mechanisms underlying in-stent restenosis (ISR)
    - stent fracture
    - geographic miss
    - stent underexpansion
    - neointimal hyperplasia (NIH) and neoatherosclerosis
- Guide vessel prep strategies and device selection with IVUS

Ablate ISR with ELCA

- The only FDA-approved atherectomy device indicated to treat ISR.*[2]
- Slow advancement (0.5mm/sec to 1mm/sec) with ELCA will assist with softening and changing the morphology enough to result in increased luminal gain.[3,4]
- Ablates both luminal and abluminal NIH resulting in greater MLD facilitating better stent expansion post procedure.[5,6]

Score ISR with AngioSculpt Evo

- Delivers focal forces of up to 25x greater than a conventional balloon[1]
- The helical design of the nitinol scoring elements applies circumferential dilation force against the lesion regardless of device orientation and provides the largest effective scoring area of any specialty balloon[1,7]
- Potential benefits in ISR:
  - Designed to resist slipping in ISR[7,8]
  - In a multicenter randomized clinical trial with 252 patients presenting with DES restenosis, neointimal modification with a scoring balloon improved the efficacy of DCB therapy at 6-months[9]

*Indicated for restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy for only the 1.4, 1.7, and 2.0mm ELCA catheter models.

References

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8. Costa, R. A., Mooney, M. R., Teirstein, P. S., Moses, J. W., Turco, M., Reisman, M., … Leon, M. B. (2006). Final results from the multi-center trial of the angiosculptscoring balloon catheter for the treatment of complex coronary artery lesions. Cardiovascular Revascularization Medicine, 7(2), 112. https://doi.org/10.1016/j.carrev.2006.03.068
9. Kufner, S., et al. (2017). Neointimal Modification With Scoring Balloon and Efficacy of Drug-Coated Balloon Therapy in Patients With Restenosis in Drug-Eluting Coronary Stents. JACC: Cardiovascular Interventions, 11.(13), 1332–1340. https://doi.org/10.1016/j.jcin.2017.04.024

ELCA important safety information

Indications: The Laser Catheters are used in conjunction with the Spectranetics CVX-300 Excimer Laser System or Philips Laser System and are intended for use in patients with single or multivessel coronary artery disease, either as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA), and who are acceptable candidates for coronary artery bypass graft (CABG) surgery. Adjunctive balloon angioplasty was performed, at the clinical investigator's discretion, for 85% of the lesions treated. The following Indications for Use, Contraindications and Warnings have been established through multicenter clinical trials. Clinical experience has provided reasonable assurance that the multifiber 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 stenoses (Heavily calcified stenoses are those lesions that demonstrate complete calcification when identified under fluoroscopy by angiography prior to the procedure. Moderately and slightly calcified stenoses are all others.) · Total occlusions traversable by a guidewire · Lesions which previously failed balloon angioplasty (This includes those lesions that were treated unsuccessfully by PTCA. Lesions that have undergone a complicated PTCA procedure are not included in this category.) · Restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy. (not indicated for X-80 models) 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 · Patient has acute thrombosis (applicable to X-80 models only) · Patient has experienced an acute myocardial infarction (applicable to X-80 models only) · Patient has ejection fraction of less than 30% (applicable to X-80 models only)

See complete IFU for more information before attempting use of ELCA.

Potential Adverse Events:
Use of the Spectranetics CVX-300 Excimer Laser System or Philips Laser System may contribute to the following complications: dissection of the arterial wall, perforation, acute reclosure, 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.

AngioSculpt Evo PTCA important safety information
The AngioSculpt Evo 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 Evo 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); embolism, 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/embolic 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); 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.

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