### **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 pl aque 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 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.

### 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 complications.

### 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.

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## **PHILIPS**

### Image Guided Therapy

**Coronary Vascular** 

# **The standard** for CTO

Recent procedural and technology advances in chronic total occlusion (CTO) PCI have led to procedural success rates over 90%

Philips has innovative solutions to help you see clearly and treat optimally to address these complex lesions and achieve better outcomes.

### Treat optimally with tools ahead of their time

### Philips ELCA laser atherectomy catheters

Are designed to be an effective solution that helps you create a channel and succeed in difficult CTO cases by addressing common issues such as:

- Balloon resistant lesions
- Impenetrable proximal caps
- Device resistant in-stent restenosis
- Difficulty with device tracking in the subintima<sup>2</sup>

ELCA is the only atherectomy device indicated for total occlusions and is delivered over any 0.14" wire and gives you more flexibility allowing a wider adoption in a variety of different scenarios including use in CTO PCI.<sup>3</sup>



ELCA coronary laser atherectomy catheters

### AngioSculpt PTCA scoring balloon catheter

Is the only coronary specialty balloon indicated for type C lesions, providing the power necessary to maximize lumen diameter once a wire crosses these resistant lesions.

### Precision



Proper placement

device in place



- Rectangular scoring edges lock the
- Minimal device slippage or "watermelon seeding," even in ISR<sup>4</sup>
- balloons⁵

### See clearly to guide treatment

A recent RCT of 402 patients showed that after a channel was opened, when IVUS is used to guide treatment in CTOs, there was significantly lower MACE and cardiac death rate vs angiography alone.<sup>7</sup>

One reason for improved outcomes is "vessels distal to CTO's can grow up to 20% after systemic flow is restored".<sup>8</sup> Proper sizing and validating of stents apposition with IVUS may reduce the risk of thrombosis and/ or restenosis.



- implantation<sup>e</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

 Helical nitinol scoring element creates a large luminal expansion for stent

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)4

P=0.035



Eagle Eye Platinum digital IVUS catheter