Treatment versatility for vascular interventions

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: Lesions 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 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 closure, 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, hazy vessel, intra-luminal thrombus, aneurysm, 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.

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

Optimize your treatment options

Proven technology
- Treating patients for more than 20 years
- Optimally spaced fibers for improved performance
- Adjustable laser energy settings to satisfy many clinical needs
- Automatic shut-off feature for advanced patient safety

Broad range of indications
- Total occlusions traversable by a guidewire
- Occluded SVGs
- Ostial lesions
- Moderately calcified stenoses
- Long lesions (>20mm)
- Lesions which previously failed PTCA
- Restenosis in 316L stainless steel stents prior to brachytherapy

Advanced performance
- Saline infusion improves safety outcomes
- Slow advancement increases luminal gain
- Two-thirds vessel sizing rule for predictable outcomes

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Philips ELCA ordering information

<table>
<thead>
<tr>
<th>Model number</th>
<th>0.9 mm X-80</th>
<th>1.4 mm</th>
<th>1.7 mm</th>
<th>2.0 mm</th>
<th>0.9 mm X-80 OTW</th>
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<tr>
<td>Guidewire compatibility (in)</td>
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<td>Guide catheter compatibility (F)</td>
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<td>7</td>
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<td>6</td>
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<td>Minimum vessel diameter (mm)</td>
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<td>Max tip outer diameter (mm)</td>
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<td>Max shaft outer diameter (in)</td>
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<td>Working length (cm)</td>
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<td>Fluence (mJ / mm²)</td>
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<td>30–60</td>
<td>30–60</td>
<td>30–80</td>
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<td>Laser on / off time (sec)</td>
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<td>5 / 10</td>
<td>5 / 10</td>
<td>5 / 10</td>
<td>10 / 5</td>
</tr>
</tbody>
</table>

Saline infusion recommendations for coronary interventions
Always perform 10–20cc bolus infusion of saline through the guide catheter after contrast injections.
During lasing, infuse saline through the guide catheter at a rate of 2–3cc / second.