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 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.

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

1. Tcheng, J.E. et al. (1995). Development of a New Technique for Reducing Pressure Pulse Generation During 308-nm Excimer Laser Coronary Angioplasty. Catheterization and Cardiovascular Diagnosis. 34, 15-22.
2. Topaz, On, et al, 2001. Optimal Spaced Excimer Laser Coronary Catheters Performance Analysis, Journal of Clinical Laser Medicine and Surgery, Vol 19, Issue 1, 9-14.
3. Croce, Kevin J. "Coronary In-Stent Restenosis: An Algorithmic Approach to Diagnosis and Treatment ." Journal of Invasive Cardiology, Oct. 2019.

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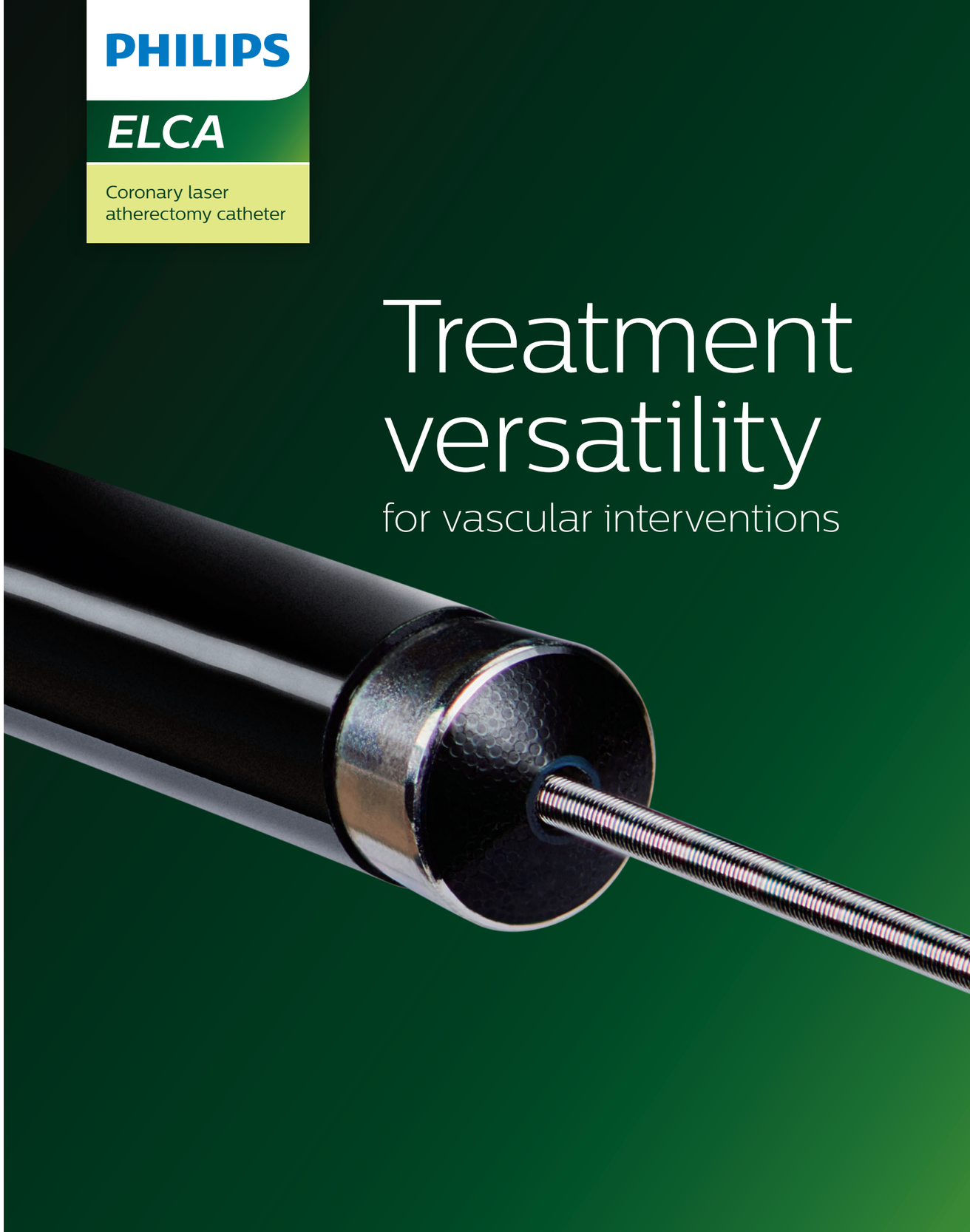
PHILIPS

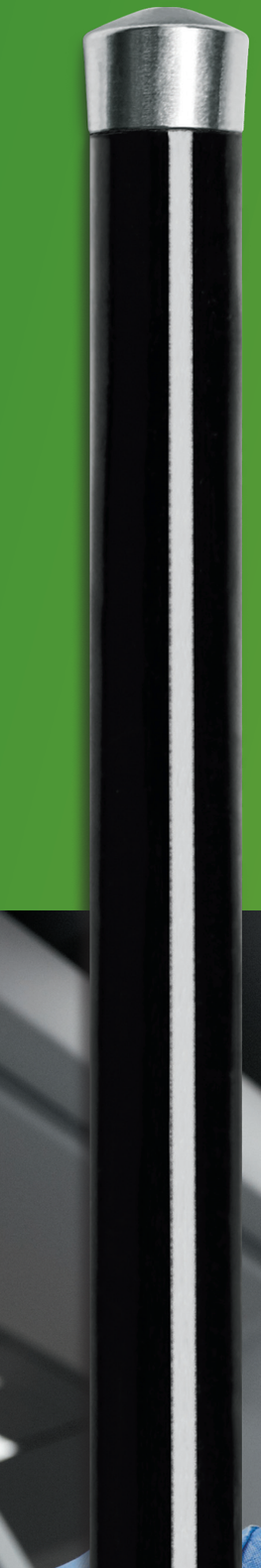
ELCA

Coronary laser atherectomy catheter

Treatment versatility

for vascular interventions





Optimize your treatment options

Proven technology

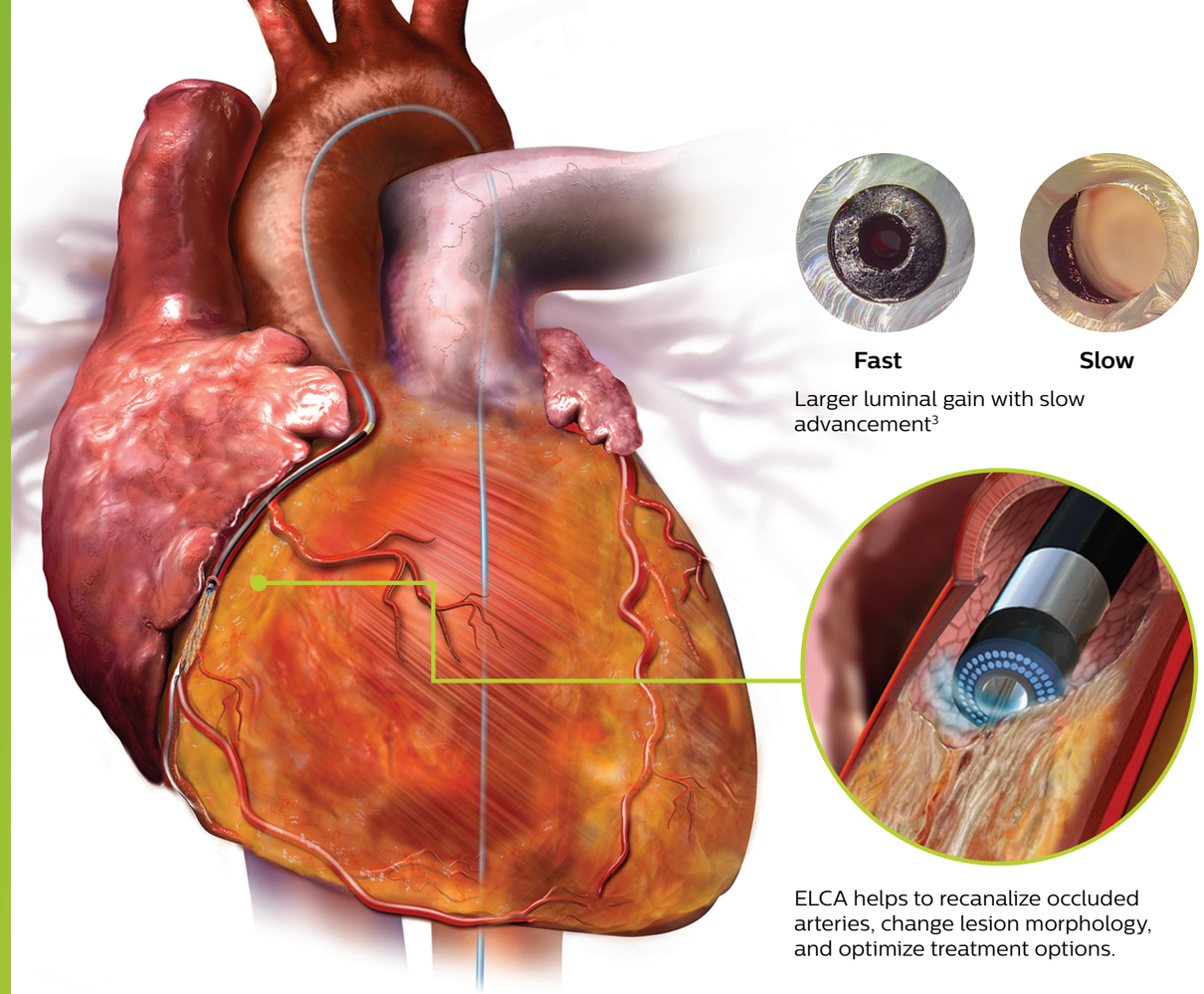
- Treating patients for more than 20 years
- Optimally spaced fibers for improved performance
- Adjustable laser energy settings to satisfy many clinical needs
- Automatic shut-off feature for advanced patient safety

Advanced performance

- Saline infusion improves safety outcomes[1]
- Slow advancement increases luminal gain[2]
- Two-thirds vessel sizing rule for predictable outcomes

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



Larger luminal gain with slow advancement[3]

ELCA helps to recanalize occluded arteries, change lesion morphology, and optimize treatment options.

Philips ELCA ordering information

	0.9 mm X-80	1.4 mm	1.7 mm	2.0 mm	0.9 mm X-80 OTW
Model number	110-004	114-009	117-016	120-009	110-002
Guidewire compatibility (in)	0.014	0.014	0.014	0.014	0.014
Guide catheter compatibility (F)	6	6 / 7	7	8	6
Minimum vessel diameter (mm)	2.0	2.2	2.5	3.0	2.0
Max tip outer diameter (in)	0.038	0.057	0.069	0.080	0.038
Max shaft outer diameter (in)	0.049	0.062	0.072	0.084	0.049
Working length (cm)	130	130	130	130	130
Fluence (mJ / mm2)	30-80	30-60	30-60	30-60	30-80
Repetition rate (Hz)	25-80	25-40	25-40	25-40	25-80
Laser on / off time (sec)	10 / 5	5 / 10	5 / 10	5 / 10	10 / 5

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