PHILIPS

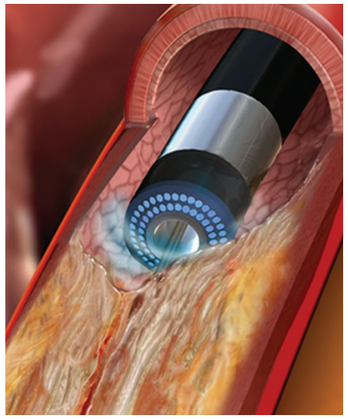
ELCA

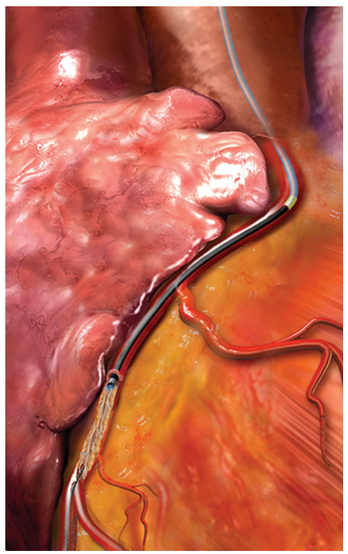
Coronary laser atherectomy catheter

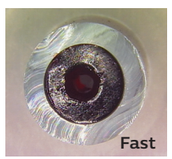
Treatment versatility

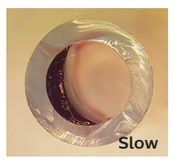
for vascular interventions

Recanalize occluded arteries, change lesion morphology, **optimize treatment options.**









Larger luminal gain with slow advancement[3]

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

Philips ELCA ordering information

	0.9mm X-80	1.4mm	1.7mm	2.0mm	0.9mm 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 / mm^2)	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

Important safety information

ELCA 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 Spectranetics CVX-300® Excimer Laser System and 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.
- 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.

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

Warnings

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training. A clinical investigation of the Spectranetics CVX-300® Excimer Laser System did not demonstrate safety and effectiveness in lesions amenable to routine PTCA or those lesions not mentioned in the Indications for Use, above. The effect of adjunctive balloon angioplasty on restenosis, as opposed to laser alone, has not been studied. The use of the CVX-300® Excimer Laser System is restricted to physicians who are trained in the use of the product.

Precautions

This device has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and must not be resterilized and/or reused. Store in a cool, dry place. Protect from direct sunlight and high temperatures (greater than 60°C or 140°F). During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be administered per the institution's PTCA protocol for a period of time to be determined by the physician after the procedure. Percutaneous Excimer Laser Coronary Atherectomy (ELCA) should be performed only at hospitals where emergency coronary bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. The results of clinical investigation indicated that patients with the following conditions are at a higher risk for experiencing acute complications:

- Patients with diabetes.
- Patients with a history of smoking.
- Lesions with tortuous vessels.

References

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 Data on file at Spectranetics.

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