PHILIPS

ELCA

Coronary laser atherectomy catheter

The Philips ELCA coronary laser atherectomy catheter is a versatile treatment option for recanalizing occluded coronary arteries

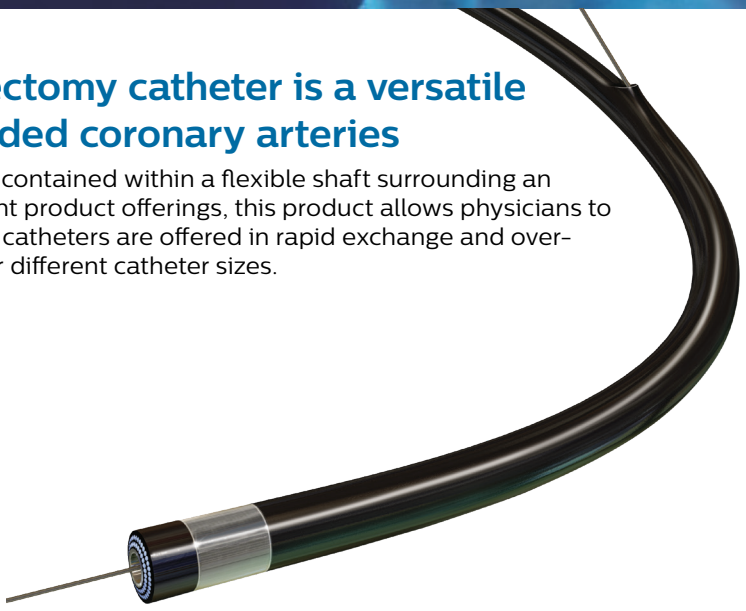
The catheter is constructed of an arrangement of optical fibers contained within a flexible shaft surrounding an 0.014" guidewire lumen. With seven indications and five different product offerings, this product allows physicians to treat even the most complex lesions with precision. ELCA laser catheters are offered in rapid exchange and over-the-wire designs, concentric laser fiber configurations, and four different catheter sizes.

Primary product features

- Optimally spaced fibers for improved performance
- Adjustable laser energy settings to meet many clinical needs
- Automatic shut-off feature for advanced patient safety

Primary product benefits

- Proven patient safety
- Precise treatment of concentric or eccentric lesions
- Broad clinical applications via seven indications



RX rapid exchange catheters

Over-the-wire (OTW) catheters

	0.9 x 80 mm	1.4 mm	1.7 mm	2.0 mm	0.9 mm X-80
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	2.0	2.2	2.5	3.0	2.0
Max tip outer diameter (in)	0.038	0.057	0.066	0.080	0.038
Max shaft outer diameter (in)	0.049	0.062	0.072	0.084	0.049
Minimum 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

Important safety information

Indications for use

The laser catheters are intended for use either as a standalone 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 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

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 Philips 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 lifethreatening 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

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

Caution: federal law restricts this device to sale by or on the order of physician

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