ELCA™

Instructions for Use

OTW and RX Catheter Models

Spectranetics®

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

1. Description

Over the wire (OTW) catheters are constructed of multiple fiber optics arranged concentrically around a guidewire lumen and are intended for use in the coronary vasculature for recanalization of obstructed arteries. A side arm adapter located at the proximal end of the usable length facilitates the use of the laser catheter over 0.014", 0.016" and 0.018" guidewires.

Rapid exchange (RX) catheters consists of optical fibers encased within a polyester shaft. There are two major portions of the laser catheter shaft, the proximal portion which terminates at the laser connector, and the distal portion which terminates at the tip having direct patient contact. The fibers terminate at the distal tip within a polished adhesive end and at the proximal end within the laser connector. A radiopaque marker is located on the distal end of the laser catheter to aid localization within the coronary vasculature in conjunction with fluoroscopy. The guidewire lumen begins at the distal tip and is concentric with the fiber array, and exits the laser catheter 9 cm away from the distal tip which has direct patient contact. A proximal marker is located on the outer jacket of the laser catheter, 104 cm from the distal tip, to assist in the placement of the laser catheter within a femoral guiding catheter without the need for fluoroscopy.

Rapid exchange (RX) eccentric catheters consists of eccentrically aligned optical fibers at the distal tip to allow alignment of the laser catheter tip with the lesion and a stainless steel torque device encased within a polyester shaft. There are two major portions of the laser catheter shaft, the proximal portion which terminates at the laser connector, and the distal portion which terminates at the tip having direct patient contact. The torque device extends from the torque handle, located at the y-adapter, through the entire 140 cm of the distal portion of the catheter, and terminates in the distal tip. There is a mechanism within the torque handle which limits the turns to five full rotations in each direction. The torque handle also has an indicator displaying its range of motion. The laser catheter is packaged with the indicator in the center of its range (see inset below). The torque response is 6:1; six turns of the torque handle result in one 360° turn of the distal tip. A radiopaque marker band with radiolucent window is located on the distal tip of the laser catheter to aid localization within the coronary vasculature in conjunction with fluoroscopy.

Mechanism of Action for ELCA Catheters

The multifiber laser catheters transmit ultraviolet energy from the laser system to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photo-ablate fibrous, calcific, and atheromatous lesions, thus recanalizing diseased vessels (photo ablation is the process by which energy photons cause molecular bond disruption at the cellular level without thermal damage to surrounding tissue). The Spectranetics laser catheters have a proprietary lubricious coating to ease their trackability through coronary vessels.

Glossary of Special Terms

Antegrade Fashion = In the direction of blood flow.

Baseline Angiography = Record of the cardiac muscle and blood vessels prior to a given interventional angioplasty procedure.

Retrograde Fashion = In the direction opposite to blood flow.

OTW and RX Catheter Models

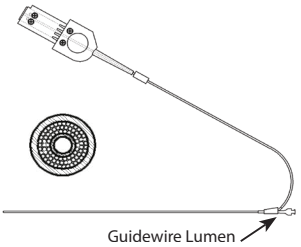

Figure 1: Over the Wire

Table 1.1 ELCA Coronary Laser Atherectomy Catheter Models (OTW)

Device Description	Model Number	Max. Guidewire Compatibility (in.)	Max. Tip Diameter (in.)	Max. Tip Diameter (mm)	Sheath Compatibility (Fr)	Working Length (cm)
OTW Catheter Specifications						
0.9 mm	110-001	0.014	0.038	0.97	4	135 ± 5

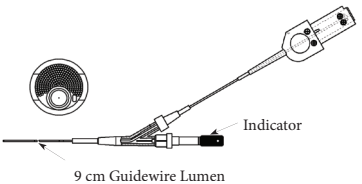

Figure 2: Rapid Exchange Eccentric

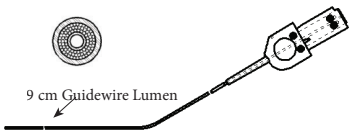

Figure 3: Rapid Exchange

Table 1.2 ELCA Coronary Laser Atherectomy Catheter Models (RX)

Device Description	Model Number	Max. Guidewire Compatibility (in.)	Max. Tip Diameter (in.)	Max. Tip Diameter (mm)	Sheath Compatibility (Fr)	Working Length (cm)
RX Catheter Specifications						
0.9 mm	110-003	0.014	0.038	0.97	4	135 ± 5
1.4 mm	114-009	0.014	0.057	1.45	5	135 ± 5
1.7 mm	117-016	0.014	0.069	1.75	6	135 ± 5
1.7 mm E	117-205	0.014	0.065	1.65	6	135 ± 5
2.0 mm E	120-008	0.018	0.079	2.0	7	135 ± 5
2.0 mm	120-009	0.014	0.080	2.0	7	135 ± 5

2. Indications for Use

The Laser Catheters are used in conjunction with the Spectranetics CVX-300® Excimer Laser System or the Philips Laser System and are intended for use in patients with single or multivessel coronary artery disease, either as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA), and who are acceptable candidates for coronary artery bypass graft (CABG) surgery. Adjunctive balloon angioplasty was performed, at the clinical investigator's discretion, for 85% of the lesions treated. The following **Indications for Use, Contraindications and Warnings** have been established through multicenter clinical trials. Clinical experience has provided reasonable assurance that the multifiber laser catheter models are safe and effective for the following indications:

- Occluded saphenous vein bypass grafts
- Ostial lesions
- Long lesions - (greater than 20 mm in length)
- Moderately calcified stenoses - (Heavily calcified stenoses are those lesions that demonstrate complete calcification when identified under fluoroscopy by angiography prior to the procedure. Moderately and slightly calcified stenoses are all others.)
- Total occlusions traversable by a guidewire
- Lesions which previously failed balloon angioplasty - (This includes those lesions that were treated unsuccessfully by PTCA. Lesions that have undergone a complicated PTCA procedure are not included in this category.)
- 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.

3. 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.

4. Warnings

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

A clinical investigation 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.

Physicians should exercise care when treating patients for coronary artery disease with the CVX-300® Excimer Laser System or the Philips Laser System.

Spectranetics Coronary Laser Atherectomy Catheter require software version 3.712 or 3.812 and higher when used with the CVX-300® and software version 1.0 (b5.0.3) or higher when used with the Philips Laser System.

This device is designated for use solely as a component of the Spectranetics CVX-300® Excimer Laser System or the Philips Laser System.

Adequate instructions for the safe installation of the Spectranetics CVX-300® Excimer Laser System and the Philips Laser System are provided in servicing information provided by Spectranetics and should be followed.

The use of the laser system is restricted to physicians who are trained in angioplasty, Percutaneous Transluminal Coronary Angioplasty (PTCA) and who meet the training requirements listed below. These requirements include, but are not limited to:

1. Training of laser safety and physics.
2. Review of patient films of lesions that meet the indications for use.
3. A review of cases demonstrating the ELCA technique in lesions that meet the indications for use.
4. A review of laser operation followed by a demonstration of the laser system.
5. Hands on training with the laser system and appropriate model.
6. A fully trained Spectranetics representative will be present to assist for a minimum of the first two cases.
7. Following the formal training session, Spectranetics will make available additional training if so requested by the physician, support personnel, the institution or Spectranetics.

5. Precautions

This catheter 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.
DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.
Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

Store in a cool, dry place. Protect from direct sunlight and high temperatures (greater than 60°C or 140°F).

The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the OTW catheter if the integrity of the package has been compromised. Do not use catheter product if its "Use Before Date," found on package labeling, has been passed.

Before use, examine carefully all of the equipment to be used in the procedure for defects. Do not use any equipment if it is damaged.

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially biohazardous materials.

Read the Operator's Manual (CVX-300®: 7030-0035 or 7030-0068, Philips Laser System: P018730) thoroughly before operating the laser system. Pay particular attention to the Warnings and Responsibility section of the manual which explains Notes, Cautions, and Warnings to be followed to ensure safe operation of the laser system.

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 within tortuous vessels

6. Potential Adverse Events

Use of the Spectranetics CVX-300® Excimer Laser System or the Philips Laser System may contribute to the following complications:

- Dissection of the arterial wall
- Acute reclosure
- Perforation
- Embolization

- Aneurysm formation
- Coronary artery bypass graft surgery
- Myocardial infarction
- Filling defects
- Spasm
- Thrombus
- Arrhythmia
- Death

No long term adverse effects of ELCA are known at this time.

7. Clinical Studies

The ELCA Coronary Laser Atherectomy Catheters in these studies were used with the CVX-300® Excimer Laser System. The Philips Laser System provides the same output and operates at the same parameters as the CVX-300® Excimer Laser System; therefore, no new clinical data has been collected for ELCA with the Philips Laser System.

7.1 COMPARISON OF ELCA+PTCA TO PTCA ALONE IN RESTENOSED STENTS

The Laser Angioplasty of Restenosed Stents (LARS) randomized trial was initiated to compare ELCA+PTCA to PTCA alone in diffuse (10-40mm) in-stent restenosis. First instances of restenosis in a subset of commercially available stainless steel stents were treated, with the primary endpoint being absence of Major Adverse Cardiac Events (MACE) at 6 months. An interim analysis of acute results was undertaken to obtain data to support the indication of ELCA in stents prior to the administration of intravascular brachytherapy. Following approval of the indication, LARS Trial recruitment was concluded after enrollment of 138 of the planned 320 patient study group. Sixty-six (66) patients were allocated to the excimer laser group and 72 patients were allocated to the balloon only control group. This cohort represents 43% of the planned study group. Due to the abbreviated study group and underpowered nature of the study analysis, statistical inferences cannot be finalized and accidental significance can occur.

Analysis: Baseline characteristics of 138 LARS patients were similar between the two groups. Trends were observed toward a higher incidence of prior myocardial infarction in the PTCA group and diabetes in the ELCA group. Lesion characteristics and locations were also similar, with approximately 83% of lesions having 11 - 20 mm length. Procedural success was equivalent in both groups. Quantitative coronary angiography (QCA) did not reveal differences between groups in pre- and post-procedural lumen diameters. At 6-month follow-up, in a subgroup of 49 patients who received a 6-month angiographic restudy, prior to removal of the protocol requirement, there was a trend towards improved percent diameter stenosis and fewer late total occlusions in the control group. Similar procedural complications were observed in the two groups. In the PTCA-only group, there was a mild trend towards more balloon-induced dissection and stent damage in the form of stent strut distortion and changes in stent:vessel wall apposition. Adjudicated incidences of MACE were tabulated at hospital discharge, 30-day, 6- and 9-month follow-up intervals. There was a trend towards higher incidences of MACE in the ELCA group at each interval. This incidence was primarily driven by a higher rate of non-Q-wave myocardial infarction. In the ELCA group, two in-hospital deaths were observed, one secondary to renal failure and one secondary to chronic obstructive pulmonary disease (COPD).

Table 7.1.1 Baseline Characteristics

	ELCA	PTCA	p
Patients	66	72	
Age (years)			
Mean (S.D.)	62.9 (12.0)	64.2 (11.7)	0.540
Females	20 (30.3%)	23 (31.9%)	0.835
Current Smoking	15 (23.8%)	12 (17.1%)	0.340
Diabetes	27 (41.5%)	22 (30.6%)	0.180
Hypertension	48 (72.7%)	58 (80.6%)	0.276
Hypercholesterolemia	53 (80.4%)	54 (76.1%)	0.548
Canadian Classification No angina Class I Class II Class III Class IV	 2 (3.0%) 10 (15.2%) 13 (19.7%) 20 (30.3%) 21 (31.8%)	 2 (2.8%) 12 (16.7%) 20 (27.8%) 18 (25.0%) 20 (27.8%)	0.820
Prior MI	23 (43.4%)	31 (55.4%)	0.212
Prior CABG	11 (20.8%)	13 (23.6%)	0.719

ELCA=excimer laser coronary angioplasty, PTCA=percutaneous transluminal coronary angioplasty, MI=myocardial infarction, CABG=coronary artery bypass grafts

Table 7.1.2 Lesion Characteristics and Procedural Details

	ELCA	PTCA	p
Patients	66	72	
Culprit Vessel			
LAD	18 (27.3%)	26 (36.1%)	0.649
LCX	21 (31.8%)	19 (26.4%)	
RCA	21 (31.8%)	19 (26.4%)	
SVG	6 (9.1%)	7 (9.7%)	
Other	0	1 (1.4%)	
Lesion Length			
<10 mm	6 (9.4%)	3 (4.3%)	0.349

11-20 mm	53 (82.8%)	58 (82.9%)	
21-30 mm	5 (7.8%)	9 (12.9%)	
>30 mm	0	0	
Procedural Success †	55 (85.9%)	64 (88.9%)	0.603

LAD=left anterior descending artery, LCX=left circumflex artery, RCA=right coronary artery, SVG=saphenous vein graft

† Procedural success defined as <50% stenosis without major in-hospital complications (death, myocardial infarction, or coronary artery bypass surgery).

Table 7.1.3 Procedural Complications

	ELCA	PTCA	p
Patients	66	72	
Any dissection	7 (10.6%)	8 (11.1%)	1.000
Acute thrombus	0	0	
Haziness	2 (3.0%)	5 (6.9%)	0.444
No Reflow	0	0	
Arrhythmia	0	1 (1.4%)	1.000
Acute Vessel Closure	0	0	
Occlusion of Side Branch	0	0	
Occlusion Non-target	1 (1.5%)	0	0.478
Coronary Spasm	2 (3.0%)	0	0.227
Coronary Embolism	1 (1.5%)	0	0.478
Coronary Perforation	3 (4.5%)	1 (1.4%)	0.349
Other	4 (6.1%)	2 (2.8%)	0.426
Laser/stent damage	0	n/a	
Balloon/stent damage	2 (3.0%)	6 (8.3%)	0.278

Table 7.1.4 Procedural Complications – Bail-out stenting

	ELCA	PTCA	p
Patients	66	72	
Any Bail-out Stenting	12 (18.8%)	8 (11.1%)	0.209
Why bailed-out?			
Residual Narrowing	1 (8.3%)	3 (37.5%)	
Ischemia with ST changes or C dissection	0	0	
D, E or F dissection	1 (8.3%)	2 (25.0%)	1.000
Reduction of TIMI flow at least 1 grade from baseline	0	0	
Elective	5 (41.7%)	1 (12.5%)	
Other	5 (41.7%)	2 (25.0%)	0.478

Table 7.1.5 Quantitative Coronary Angiography and Late Total Occlusion

	ELCA	PTCA	p
Patients			
Pre-Procedure	61	69	
Post-Procedure	60	69	
Follow-up	26	23	
Reference Diameter	mm (SD)	mm (SD)	
Pre-Procedure	2.8 (0.6)	2.6 (0.5)	0.014
Post-Procedure	2.8 (0.5)	2.6 (0.5)	0.059
Follow-up	2.7 (0.5)	2.7 (0.5)	0.891
Mean MLD	mm (SD)	mm (SD)	
Pre-Procedure	0.9 (0.5)	0.8 (0.4)	0.284
Post-Procedure	2.2 (0.5)	2.1 (0.6)	0.499
Follow-up	0.9 (0.7)	1.5 (0.6)	0.008
% Diameter Stenosis	mean (SD)	mean (SD)	
Pre-Procedure	67.0 (13.7)	67.4 (13.4)	0.860

Post-Procedure	22.8 (10.5)	20.7 (13.6)	0.340
Follow-up	64.6 (26.9)	45.9 (17.3)	0.006
Late Total Occlusion*	6 (20.7%)	1 (4.2%)	0.077

MLD=minimum lumen diameter

* Angiographically documented total occlusion at the lesion site >30 days and within 6 months of the index procedure.

Table 7.1.6 Anginal Functional Class

	ELCA	PTCA	p
Baseline			
No angina	2 (3.0%)	2 (2.8%)	
Class I	10 (15.2%)	12 (16.7%)	
Class II	13 (19.7%)	20 (27.8%)	0.820
Class III	20 (30.3%)	18 (25.0%)	
Class IV	21 (31.8%)	20 (27.8%)	
Month 1			
No angina	32 (53.3%)	42 (60.0%)	
Class I	19 (31.7%)	17 (24.3%)	
Class II	3 (5.0%)	5 (7.1%)	0.819
Class III	3 (5.0%)	4 (5.7%)	
Class IV	3 (5.0%)	2 (2.9%)	
Month 6			
No angina	30 (52.6%)	35 (58.3%)	
Class I	11 (19.3%)	15 (25.0%)	
Class II	10 (17.5%)	5 (8.3%)	0.133
Class III	5 (8.8%)	1 (1.7%)	
Class IV	1 (1.8%)	4 (6.7%)	
Month 9			
No angina	35 (62.5%)	34 (58.6%)	
Class I	10 (17.9%)	13 (22.4%)	
Class II	7 (12.5%)	6 (10.3%)	0.964
Class III	3 (5.4%)	4 (6.9%)	
Class IV	1 (1.8%)	1 (1.7%)	

Table 7.1.7 CEC Adjudicated Clinical Endpoints through 30 Days

	ELCA	PTCA	p
Through Discharge:			
Patients with Data	66	72	
CABG	2 (3.0%)	0	0.137
PCI	1 (1.5%)	0	0.295
Death	2 (3.0%)	0	0.137
Myocardial Infarction	11 (16.7%)	4 (5.6%)	0.036
Non-Q-wave MI	9 (13.6%)	3 (4.2%)	
Target Vessel Revasc.	2 (3.0%)	0	0.137
MACE	12 (18.2%)	4 (5.6%)	0.021
Through 30 Days:			
Patients with Data:	47 65	55 72	
CABG	2 (3.0%)	2 (2.8%)	0.930
PCI	2 (3.0%)	1 (1.4%)	0.509
Death	2 (3.0%)	0	0.137
Myocardial Infarction	13 (19.7%)	5 (6.9%)	0.026
Non-Q-wave MI	11 (16.6%)	4 (5.5%)	
Target Vessel Revasc.	3 (4.5%)	3 (4.2%)	0.913
MACE	14 (21.2%)	7 (9.7%)	0.061

Table 7.1.8 Investigator-Indicated Clinical Endpoints at Discharge

	ELCA	PTCA	p
Patients with Data	66	72	
CABG	2 (3.0%)	0	0.227

PCI	1 (1.5%)	0	0.478
Death	2 (3.0%)	0	0.227
Myocardial Infarction	2 (3.0%)	2 (2.8%)	1.000
Target Vessel Revasc.	3 (4.6%)	0	0.107
MACE	5 (7.6%)	2 (2.8%)	0.259

Table 7.1.9 CEC Adjudicated Clinical Endpoints through 6 and 9 Months

	ELCA	PTCA	p
Through 6 Months:			
Patients with Data	60	66	
CABG	6 (9.7%)	4 (5.9%)	0.406
PCI	15 (25.3%)	9 (13.7%)	0.082
Death	2 (3.2%)	1 (1.5%)	0.491
Myocardial Infarction	13 (19.7%)	5 (6.9%)	0.026
Non-Q-wave MI	11 (16.6%)	4 (5.5%)	
Target Vessel Revasc.	18 (29.8%)	13 (19.6%)	0.151
MACE	24 (38.1%)	18 (26.5%)	0.093
Through 9 Months:			
Patients with Data:	59	65	
CABG	6 (9.7%)	5 (7.5%)	0.615
PCI	18 (30.7%)	14 (22.0%)	0.185
Death	4 (6.6%)	1 (1.5%)	0.142
Myocardial Infarction	13 (19.7%)	6 (8.5%)	0.050
Non-Q-wave MI	11 (16.6%)	5 (6.9%)	
Target Vessel Revasc.	21 (35.2%)	19 (29.6%)	0.352
MACE	28 (45.1%)	25 (37.6%)	0.198

7.2 COMPARISON OF ELCA AND PTCA PRIOR TO BRACHYTHERAPY

The following data has been reported by the investigators participating in the Washington Radiation for In-Stent Restenosis Trial (WRIST). Patient data presented in the following tables were compiled from WRIST, Long WRIST (long in-stent restenosis lesions 36-80mm), the γ radiation registries including Long WRIST High Dose (long in-stent restenosis lesions 36-80mm using 18 Gy at 2mm), Plavix WRIST (6 months Clopidogrel therapy post coronary intervention and radiation), Compassionate WRIST (intracoronary localized radiation compassionate protocol for prevention of recurrence of restenosis) and WRIST X-over group (patients who initially failed placebo therapy and were subsequently treated with radiation). All WRIST studies were conducted under an IDE following patient informed consent and were independently monitored.

Analysis:
To make a direct comparison of outcomes between PTCA and ELCA prior to Ir192 brachytherapy for in-stent restenosis, the data analysis was restricted to patients treated with PTCA+Ir192 and ELCA+Ir192. Comparisons between continuous variables were made with a 2-sided T-test and between dichotomous variables with a 2-sided continuity-corrected chi-squared test. A value of $p<.05$ was considered significant.

Baseline characteristics were similar between the two groups, with a trend toward more LCX lesions treated in the PTCA+Ir192 group, but no significant differences in lesion characteristics were evident.

Table 7.2.1 Baseline Characteristics*

	PTCA+Ir192	ELCA+Ir192	p
Age (years)	60 ± 12	63 ± 11	0.100
Males	52 (75%)	68 (68%)	0.688
Smoking	44 (64%)	68 (68%)	0.921
Hypertension	44 (64%)	72 (72%)	0.628
Diabetes	21 (30%)	41 (41%)	0.465
Hypercholester.	52 (75%)	75 (75%)	0.992
Unstable Angina	55 (80%)	82 (82%)	0.985
Previous MI	40 (58%)	55 (55%)	0.975
Previous CABG	54 (78%)	70 (70%)	0.596
Multivessel disease	53 (77%)	63 (63%)	0.223
Prior restenosis	35 (51%)	67 (67%)	0.145

LVEF	0.47 ± 0.1	0.45 ± 0.1	0.203
n=	69	100	

*PTCA = percutaneous transluminal coronary angioplasty, Ir = Iridium, ELCA = excimer laser coronary angioplasty, MI = myocardial infarction, CABG = coronary artery bypass grafting, LVEF = left ventricular ejection fraction

Table 7.2.2 Lesion Characteristics and Procedural Details*

	PTCA+Ir192	ELCA+Ir192	p
Culprit vessel			
LAD	8 (12%)	19 (19%)	0.559
LCX	21 (31%)	15 (15%)	0.086
RCA	19 (27%)	26 (26%)	0.999
SVG	17 (25%)	38 (38%)	0.254
Type B2/C	36 (52%)	37 (37%)	0.198
Lesion length mm	24 ± 11	25 ± 11.4	0.568
Ref Vess Dia mm	3.3 ± 0.6	3.4 ± 0.9	0.387
Dose (Gy)	14.3 ± 0.7	14.4 ± 0.5	0.309
Proc. Success†	69 (100%)	100 (100%)	1.000
Complications	6 (9%)	6 (6%)	0.935
n=	69	100	

*PTCA = percutaneous transluminal coronary angioplasty, Ir = Iridium, ELCA = excimer laser coronary angioplasty, LAD = left anterior descending artery, LCX = left circumflex artery, RCA = right coronary artery, SVG = saphenous vein graft, B2/C = modified AHA/ACC Lesion Classification Score, mm = millimeter, Gy = gray

†Procedure success defined as <50% stenosis without major in-hospital complications (death, myocardial infarction, or coronary artery bypass surgery).

Angiographic analysis was reported for approximately half of the patients treated in the two groups.

Table 7.2.3 Quantitative Coronary Analysis*

	PTCA+Ir192	ELCA+Ir192	p
Ref Dia mm			
Pre	2.9 ± 0.6	2.7 ± 0.6	0.146
Post	2.9 ± 0.6	2.8 ± 0.5	0.434
F-Up	2.9 ± 0.6	3 ± 0.6	0.466
MLD mm			
Pre	1.2 ± 0.5	0.9 ± 0.6	0.018
Post	2 ± 0.5	1.9 ± 0.5	0.382
F-Up	1.9 ± 0.9	1.6 ± 0.9	0.146
DS%			
Pre	57 ± 20	66 ± 20	0.051
Post	30 ± 12	33 ± 12	0.275
F-Up	36 ± 20	46 ± 25	0.052
Late Loss mm	0.2 ± 0.7	0.3 ± 0.8	0.556
Loss index	0.4 ± 1.4	0.2 ± 0.8	0.458
Binary Restenosis	18 (53%)	29 (64%)	0.726
n=	34	45	

*PTCA = percutaneous transluminal coronary angioplasty, Ir = Iridium, ELCA = excimer laser coronary angioplasty, Ref Dia = reference diameter, mm = millimeter, MLD = minimum luminal diameter, DS% = percent diameter stenosis, Late Loss defined as the change in the lesion MLD from the final to the follow-up angiogram. Loss Index (within the lesion) defined as late loss/acute gain. Binary Restenosis (at follow-up, 4-8 months angiogram after treatment) defined as ≥50% diameter narrowing within the segment including the stent and its edges (within 5 mm).

Clinical outcomes appear to be similar between the two groups. Overall TLR, TVR, and MACE rates were very similar between the two groups. More Late Total Occlusions (LTO) were observed in the PTCA+Ir192 group.

Table 7.2.4 Clinical Outcomes*

	PTCA+Ir192	ELCA+Ir192	p
30 days			
MACE	1 (1%)	2 (2%)	0.948
6 months			
Death	1 (1%)	5 (5%)	0.403
QMI	0 (0%)	2 (2%)	0.514
NQMI	9 (13%)	18 (18%)	0.515
TLR	13 (19%)	16 (16%)	0.784
TVR	23 (33%)	25 (25%)	0.314
PTCA	21 (30%)	22 (22%)	0.290
CABG	9 (13%)	8 (8%)	0.418
LTO	6 (9%)	1 (1%)	0.019
MACE	24 (35%)	29 (29%)	0.530
n=	69	100	

*PTCA = percutaneous transluminal coronary angioplasty, Ir = Iridium, ELCA = excimer laser coronary angioplasty, MACE = major adverse cardiac events (death, Q-wave MI or TVR), QMI = Q-wave myocardial infarction, NQMI = non-Q-wave MI, TLR = target lesion revascularization, TVR = target vessel revascularization, CABG = coronary artery bypass grafts, LTO = late total occlusion.

Death defined as all-cause mortality.QMI or NQMI defined as a total creatinine kinase elevation ≥2x normal value and/or elevated creatinine kinase MB fraction ≥20 ng/ml with or without new pathological q waves (>.04 sec) in two or more contiguous leads.

TVR and TLR as characterized by repeat percutaneous intervention (PTCA) or CABG involving the treated vessel, driven clinical signs of ischemia in the presence of angiographic restenosis.

Late total occlusion defined as angiographically documented total occlusion at the lesion site>30 days and within 6 months of the index procedure.

8. Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of ELCA.

Patient selection and clinical techniques should be conducted according to instructions provided in Section 2., "Indications for Use," Section 7, "Clinical Studies," and Section 12, "Directions for Use."

Patient selection factors to be assessed should include a judgment regarding Excimer Laser treatment in the presence of acute myocardial infarction, acute thrombus, and ejection fraction less than 30%.

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9. Comparison of Effectiveness of Excimer Laser Angioplasty in Patients with Acute Coronary Syndromes in Those With – versus – Those Without Normal Left Ventricular Function. Topaz, O. et al. American Journal of Cardiology: 2003: Vol. 91, pp 797-802.

9. Operator's Manual

The devices described in this document can be operated within the following energy ranges on the CVX-300® or the Philips Laser System:

Table 9.1 Energy Parameters

Device O.D.	Model No.	Fluence	Repetition Rate	Laser On/ Off Time (sec)
OTW Catheters				
0.9 mm	110-001	30-60	25-40	5 / 10
RX Catheters				
0.9 mm	110-003	30-60	25-40	5 / 10
1.4 mm	114-009	30-60	25-40	5 / 10
1.7 mm	117-016	30-60	25-40	5 / 10
1.7 mm E	117-205	30-60	25-40	5 / 10
2.0 mm E	120-008	30-60	25-40	5 / 10
2.0 mm	120-009	30-60	25-40	5 / 10

Recommended calibration settings: 45 Fluence, 25 Hz.

10. How Supplied

10.1 Sterilization

For single use only. Do not re-sterilize and/or reuse.

The Spectranetics laser catheters are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

10.2 Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken. All equipment to be used for the procedure, including the catheter, should be examined carefully for defects. Examine the laser catheter for bends, kinks or other damage. Do not use if it is damaged.

11. Compatibility

The Spectranetics' excimer laser catheter is designed and intended to be used exclusively with the Spectranetics CVX-300® Laser System or the Philips Laser System.

Do not use in combination with any other laser system.

Guidewire Compatibility

See Catheter Specification Table in Section 1.

12. Directions for Use

12.1 Procedure Set Up

Some or all of the following additional materials, which are not included in the laser catheter package, may be required for the procedure (these are single use items only—do not resterilize or reuse):

- Femoral guiding catheter(s) in the appropriate size and configuration to select the coronary artery
- Hemostatic valve(s)
- Sterile normal saline
- Standard contrast media
- 0.014" guidewires

Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the laser catheter from the tray while supporting the black laser connector, also known as the proximal end, proximal coupler, or proximal connector. Please note that the proximal end of the laser catheter connects only to the laser system and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the laser system and position the laser catheter in the laser system extension pole or catheter retainer. Calibrate the laser catheter following the instructions provided in the CVX-300® Operator's Manual (7030-0035 or 7030-0068) or the Philips Laser System Operator's Manual (P018730).

12.2 Clinical Technique

1. Use standard Percutaneous Seldinger Technique to insert a 7 Fr or 9 Fr introducer sheath into the common femoral artery in a retrograde fashion. Heparinize intravenously using the PTCA protocol for heparinization. Periodic measurement of activated clotting time (ACT greater than 300 seconds) during the procedure will assist in maintaining optimum anticoagulation levels.

2. Introduce a 6, 7, 8, or 9 Fr guiding catheter (left or right depending on the target coronary artery) using a standard 0.038" guidewire or, if necessary, a 0.063" guidewire when introducing thin wall, large lumen (greater than or equal to .092") guiding catheters.

3. Perform baseline angiography by injecting contrast medium through the guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.

Note: When treating lesion(s) suspected or known to be located within a previously deployed stent, note the proximal and distal stented margins with respect to surrounding anatomical landmarks and morphology in case of resistance to catheter advancement.

Caution: When lasing into a suspected or known deployed 316L stainless steel stent, laser catheter advancement should be steady with constant applied pressure. If laser catheter advancement ceases, stent interference should be suspected. Reassess lesion and/or alignment of catheter to alleviate stent interference. If condition persists, terminate laser procedure.

4. Introduce an appropriately sized guidewire to the coronary arteries via the guiding catheter. Cross the target lesion with the guidewire.

5. Size the laser catheter appropriately:

Table 12.1 Recommended Sizing

Catheter Size	Proximal Vessel Diameter
0.9 mm	≥1.5 mm
1.4 mm	≥2.2 mm
1.7 mm	≥2.5 mm
2.0 mm	≥3.0 mm

6. Inject 5-10cc of heparinized saline or Lactated Ringer's solution through the laser catheter to flush the guidewire lumen. Attach a rotating hemostatic valve to the guidewire port into the guidewire lumen (See Figure 4). Introduce the distal tip of the Spectranetics laser catheter over the selected guidewire. Under fluoroscopic control, guide the laser catheter to the lesion. The laser catheter's radiopaque band marker indicates its position relative to the lesion.

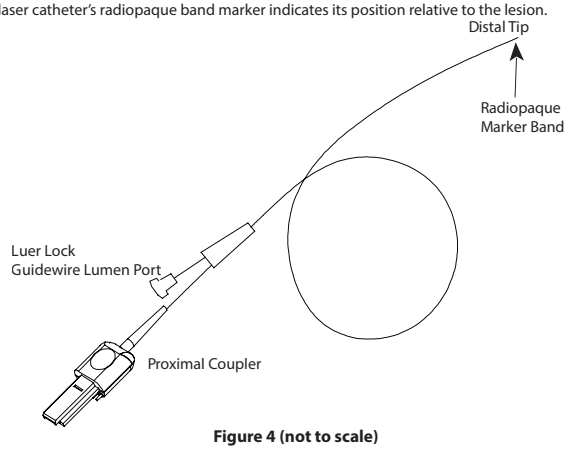

Figure 4 (not to scale)

Note: During use within the body, similar to any device used for vascular intervention, always monitor Laser Catheter movement and the radiopaque tip marker position with fluoroscopy. The movement and rate of advancement of the catheter distal tip should correspond directly with the rate of advancement being applied to the proximal shaft of the catheter. If corresponding movement is not apparent, reassess the lesion morphology, the laser energy being applied and the status of support equipment prior to continued treatment.

7. Insertion techniques (Bare Wiring)
   a. Monitor the guidewire position within the vasculature under fluoroscopy.
   b. Insert the guidewire into the laser catheter by introducing the proximal end of the guidewire into the distal tip of the laser catheter, and carefully advance the laser catheter, in small increments, to avoid kinking the guidewire. Grasp the guidewire as it exits the proximal guidewire port and maintain its position in the patient's circulatory system while advancing the laser catheter.
   c. Loosen the hemostatic valve of the y-adapter being used in conjunction with the introducer inserted during step 1 above.
   d. Carefully insert the laser catheter through the hemostatic valve of the y-adapter into the guide catheter and advance the laser catheter to the guide catheter distal tip while maintaining the guidewire position.
   e. Reconfirm the guide catheter position in the ostium of the coronary artery with contrast media injection and fluoroscopy prior to advancing the laser catheter.
   f. Advance the laser catheter to the lesion site while maintaining the guidewire position in the patient's circulatory system. Inject contrast medium solution through the guiding catheter to verify the positioning of the laser catheter under fluoroscopy.

8. Following confirmation of the laser catheter's position in contact with the target lesion and using normal saline or Lactated Ringer's solution:
a. Flush all residual contrast media from the guide catheter and in-line connectors.
b. Flush all residual contrast media from the lasing site and vascular structures adjacent to the lasing site, prior to activating the laser system.
c. Please refer to the Saline Infusion Protocol and perform saline flush and infusion per the instructions.

9. Depress the footswitch, activating the laser system, and slowly, less than 1 mm per second, advance the laser catheter allowing the laser energy to remove the desired material. Release the footswitch to deactivate the laser system.

Note: Advancing the laser catheter through moderately calcified lesions may require more pulses of laser energy than fibrous atherosclerotic tissue.

Caution: The tip of the laser catheter should not pass beyond the tip of the guidewire during the procedure. Avoid pushing the laser catheter tip beyond the guidewire tip and/or withdrawing the guidewire inside the laser catheter.

10. Pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.

11. Repeat steps 8 through 10 as needed to complete treatment.

12. When withdrawing the laser catheter from the treated vessel, monitor the position of the guidewire in the vessel with fluoroscopy to avoid guidewire prolapse, and exercise care while exiting the hemostatic valve of the y-adapter with the distal tip of the laser catheter.

Note: If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter outer surface and tip in heparinized saline to prevent blood from sticking. Blood remaining on the laser catheter may diminish the efficiency of the laser catheter.

There is no need to remove the laser catheter from the patient in order to increase or decrease either the fluence or pulse repetition rate; as the laser catheter was previously calibrated. Refer to the CVX-300® Excimer Laser System Operator's Manual, 7030-0035 or 7030-0068 or the Philips Laser System Operator's Manual (P018730).

Note: All patients should be monitored for blood pressure and heart rate during the procedure.

RX-E ONLY

13. Torquing/Alignment Procedure

Caution: When advancing or withdrawing the laser catheter, insure the torque handle indicator is returned to the centered position. Failure to center the indicator may impede guidewire movement.

Use of the torque mechanism to align the eccentric fiber bundle with the lesion is optional. This device is designed to achieve a tip rotation of 360 degrees by turning the thumb knob until the desired alignment is achieved. If the distal end of the laser catheter is constricted, the turn ratio may be increased. Alignment should be verified angiographically by determining the position of the wire with respect to the radiopaque tip. The open slot (or radiolucent window) on the radiopaque marker indicates the fiber face is perpendicular to the guidewire and thus aligned with the lesion as seen radiographically (see Figure 5).

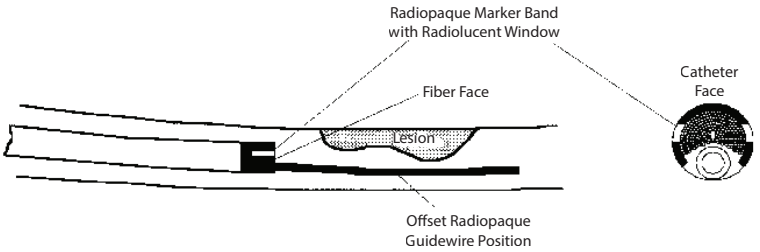

Figure 5

a. Position guidewire into artery beyond lesion.
b. Select a radiographic projection which best demonstrates the geometric lesion morphology (may necessitate multiple projections).
c. Advance laser catheter to lesion location.
d. Align laser catheter fiber face to the bulk of the lesion by slowly rotating the torque knob until the slot in the radiopaque tip is visible.

14. Repeat steps 6 through 13 as needed to complete treatment.

15. Following laser angioplasty, perform follow up angiography and balloon angioplasty, if needed.

RX ONLY

16. The RX laser catheter has been specifically designed for compatibility with rapid device exchanges as needed during a single interventional surgery, done by the same surgical team. The RX laser catheter may be quickly removed from the patient's circulatory system, without removing the guidewire, as outlined below.
    1) Return the torque handle indicator to the centered position. See Figure 2. (Eccentric only)
    2) Loosen the hemostatic valve.
    3) Hold the guidewire and hemostatic valve in one hand, while grasping the laser catheter outer surface in the other hand.
    4) Maintain the guidewire's position in the coronary artery by holding the guidewire stationary, and begin pulling the laser catheter out of the guiding catheter.

Note: Monitor the guidewire position under fluoroscopy during the exchange.

    5) Pull on the laser catheter withdrawing it until the opening in the guidewire lumen just exits the Y-adapter. Carefully and slowly withdraw the last 9 cm of the flexible, distal portion of the laser catheter off the guidewire while maintaining the guidewire's position across the lesion. Close the hemostatic valve.
    6) Prepare the next laser catheter to be used, as previously described.
    7) Again, insert the guidewire into the laser catheter by introducing the proximal end of the guidewire into the distal tip of the laser catheter. The proximal portion of the guidewire, that will be handled by the physician, will exit at the opening 9 cm from the distal tip.
    8) Open the hemostatic valve and advance the laser catheter while maintaining guidewire position in the coronary artery. Be careful not to twist the laser catheter around the guidewire.
    9) Advance the laser catheter to the guiding catheter tip. Continue the laser angioplasty procedure, using the previously described method.
17. Recommended pharmacology follow up to be prescribed by the physician.

Excimer Laser Saline Infusion Protocol
NOTE: This technique requires two operators. It is recommended that the primary physician operator advance the laser catheter and operate the laser system foot pedal. A scrub assistant should manage the saline infusion control syringe and (if appropriate) depress the fluoroscopy pedal.

1. Before the laser procedure, warm a 500cc bag of 0.9% normal saline (NaCl) or lactated Ringer's solution to 37°C. It is not necessary to add heparin or potassium to the saline solution. Connect the bag of warmed saline to a sterile intravenous line and terminate the line at a port on a triple manifold.
2. Cannulate the ostium of the coronary artery or bypass graft with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter **not** have side holes.
3. Under fluoroscopic guidance, advance the laser catheter into contact with the lesion. If necessary, inject contrast to help position the tip of the laser catheter. If contrast appears to have become entrapped between the laser catheter tip and the lesion, the laser catheter may be retracted slightly (1-2 mm) to allow antegrade flow and contrast removal while flushing the system with saline. **(However, before lasing, ensure that the laser catheter tip is in contact with the lesion.)**
4. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline through the manifold into the control syringe.
5. Remove the original control syringe from the manifold and replace it with a fresh 20cc luer-lock control syringe. This new 20cc control syringe should be primed with saline prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20cc control syringes.)
6. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and guide catheter, with at least 20-30cc of saline (several syringes of saline). When this initial flushing is completed, refill the 20cc control syringe with saline.
7. Under fluoroscopy, confirm that the tip of the laser catheter is **in contact** with the lesion (advance the laser catheter if necessary), but do **not** inject contrast.
8. When the primary operator indicates that he/she is ready to activate the laser system, the scrub assistant should turn the manifold stopcock off to pressure and inject 10cc of saline as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood in the coronary tree down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
9. After the injection of the initial 10cc bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3cc/second. This portion of the saline infusion is to displace and/or dilute the antegrade blood flow entering the laser ablation field. **At the instant the scrub assistant slows down the injection rate, the primary operator should activate the laser system by depressing the foot pedal and begin a lasing sequence.**
10. The lasing sequence (train) should last for 2-5 seconds (maximum 5 seconds).
11. Terminate the saline injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20cc of saline in preparation for the next lasing sequence.

NOTE: Any electrocardiographic changes induced by saline infusion should be permitted to resolve before repeating the sequence.

12. Each subsequent laser train should be preceded by a bolus of saline and performed with continuous saline infusion as described in steps 8-11.
13. If contrast is used to assess treatment results during the course of a laser treatment, repeat steps 4-7 prior to reactivation of the laser system (before activating the laser as described in steps 8-11).

13. Manufacturer's Limited Warranty

Manufacturer warrants that the ELCA Coronary Laser Atherectomy Catheter is free from defects in material and workmanship when used by the stated "Use By" date. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective unit of the ELCA Coronary Laser Atherectomy Catheter. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the ELCA Coronary Laser Atherectomy Catheter. Damage to the ELCA Coronary Laser Atherectomy Catheter caused by misuse, alteration, improper storage or handling, or any other failure to follow these Instructions for Use will void this limited warranty. **THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** No person or entity, including any authorized representative or reseller of Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against the Manufacturer. This limited warranty covers only the ELCA Coronary Laser Atherectomy Catheter. Information on Manufacturer's warranty relating to the CVX-300® Excimer Laser System or the Philips Laser System can be found in the documentation relating to that system.

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