Turbo-Elite™

Laser Atherectomy Catheter

Instructions for Use

For OTW and RX Catheter Models

Spectranetics®

7030-0624-B 17FEB25

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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

Spectranetics Turbo-Elite Laser Atherectomy Catheters are percutaneous intravascular devices constructed of multiple optical fibers arranged around a guidewire lumen. Catheter sizing identification is printed on the catheter.

For Turbo-Elite Laser Atherectomy Catheter, Over-The-Wire (OTW) catheters, a luer adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the appropriate sized guidewire (0.014", 0.018", and 0.035"); see inset below.

For Turbo-Elite Laser Atherectomy Catheter, Rapid Exchange (RX) catheters, the guidewire lumen is formed only through the last 9 cm of the distal tip, which has direct patient contact, and is concentric with the fiber array; see inset below.

Mechanism of Action for Turbo-Elite Laser Atherectomy 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 photoablate lesions which may be comprised of atheroma, fibrosis, calcium, and thrombus; thus recanalizing diseased vessels (photoablation 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 arteries.

Glossary of Special Terms
Retrograde Fashion = In the direction opposite to blood flow.
Antegrade Fashion = In the direction of blood flow.
Baseline Angiography = Angiographic record of blood vessels.
Contralateral Approach = Arterial access by a crossover approach.

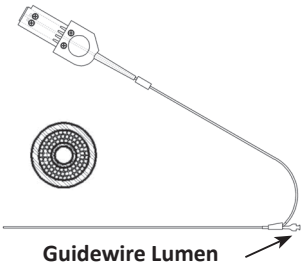

Figure 1: Turbo-Elite Laser Atherectomy Catheter (OTW)

Table 1.1 Turbo-Elite Laser Atherectomy Catheter OTW Models

Device Description	Model Number	Guidewire Compatibility (in.)	Max. Tip Diameter (in.)	Max. Shaft Diameter (in.)	Working Length (cm)	Sheath Compatibility (Fr.)
Over-The-Wire (OTW) Catheter Specifications						
0.9 mm	410-152	0.014	0.038	0.047	150	4
1.4 mm	414-151	0.014	0.055	0.056	150	5
1.7 mm	417-152	0.018	0.068	0.069	150	5
2.0 mm	420-006	0.018	0.080	0.081	150	6
2.3 mm	423-001	0.018	0.091	0.091	125	7
2.5 mm	425-011*	0.018	0.101	0.102	112	8
2.3 mm	423-135-01	0.035	0.091	0.091	125	7
2.5 mm	425-135-01	0.035	0.101	0.102	112	8
*Note: The Philips Laser System is not compatible and cannot be used with the 425-011 model Turbo-Elite catheter						

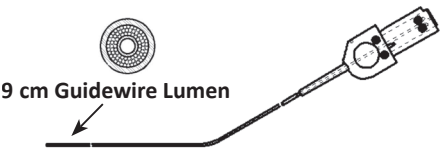

Figure 2: Turbo-Elite Laser Atherectomy Catheter (RX)

Table 1.2 Turbo-Elite™ Laser Atherectomy Catheter RX Models

Device Description	Model Number	Guidewire Compatibility (in.)	Max. Tip Diameter (in.)	Max. Shaft Diameter (in.)	Working Length (cm)	Sheath Compatibility (Fr.)
Rapid Exchange (RX) Catheter Specifications						
0.9 mm	410-154	0.014	0.038	0.049	150	4
1.4 mm	414-159	0.014	0.057	0.062	150	5
1.7 mm	417-156	0.014	0.069	0.072	150	6
2.0 mm	420-159	0.014	0.080	0.084	150	7

2. Indications for Use

The Turbo-Elite devices are indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.

The 0.014” and 0.018” Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the

treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

3. Contraindications

No known contraindications.

4. Warnings

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

Spectranetics' Turbo-Elite Laser Atherectomy Catheters software requirements:

Laser System	Software	Catheter Maximum Rep Rate
CVX-300® Excimer Laser System	V3.8XX	80 Hz
	V3.7XX	40 Hz
Philips Laser System	V1.0 (b5.0.3 and above)	80 Hz

When the laser catheter is in the body, it should be manipulated only while it is under fluoroscopic observation with radiographic equipment that provides high quality images.

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.

Warning: Fluoroscopic monitoring should be performed during use of the laser atherectomy catheter with special attention to identification of possible detachment of the marker band from the catheter tip. If detachment of the marker band is observed by fluoroscopy, it is recommended to leave the guidewire in place to aid in retrieval of the marker band, which can be attempted using balloon catheter inflation or snaring with the guidewire in place. If these techniques are unsuccessful, then stenting can be attempted to secure the marker band in place to avoid distal embolization. Please ensure you report all occurrences of this issue to Philips via a complaint.

1.4-2.0 Rapid Exchange (RX) Turbo-Elite Laser Atherectomy Catheter can become damaged if used within a stent or in the presence of contrast. For treatment of ISR, the 0.014" or 0.018" OTW Turbo-Elite laser catheters should be used. Prior to atherectomy with any Turbo-Elite laser catheter, flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors. Saline must be infused throughout the entire atherectomy procedure.

For the treatment of In-stent Restenosis (ISR), clinical data is not available on the following patient population and alternative therapies should be considered for patients exhibiting the following angiographic criteria:

1. Ipsilateral and/or contralateral iliac (or common fermoral) artery stenosis ≥ 50% diameter stenosis that is not successfully treated prior to index procedure (e.g. where a perforation occurred requiring a covered stent) or with final residual stenosis ≥ 30% documented by angiography.
2. Identification of any native vessel lesion (excludes in-stent restenosis) proximal to the target stent in the femoropopliteal segment >50% that is not successfully treated prior to index procedure (e.g. complication requiring additional treatment) or with final residual stenosis ≥ 30% documented by angiography. The lesion length must be treatable with a single stent (if required). The lesion must not be contiguous with the target lesion; at least 2 cm of normal appearing vessel between the lesion and target lesion/ target stent or between deployed stent (if required) and

the target lesion/ target.

3. Planned or predicted cardiovascular surgical or interventional procedures prior to completion of the 30-day follow-up (including, but not limited to aortic, renal, cardiac, carotid, contralateral femoropopliteal, and contralateral below the knee).
4. Identification of any lesion distal to the stent >50% that will require preplanned or predicted treatment during the index procedure or within 30 days of the index procedure.
5. Grade 4 or 5 stent fracture affecting target stent or proximal to the target stent, or where evidence of stent protrusion into the lumen is noted on angiography in two orthogonal views. Stent integrity may be characterized according to the following scale:

Table 4.1: Stent Integrity Categories

Grade	Description
0	No strut fracture
I	Single tine fracture
II	Multiple tine fracture
III	Stent fracture(s) with preserved alignment of the components
IV	Stent fracture(s) with mal-alignment of the components
V	Stent fracture(s) in a trans-axial spiral configuration

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 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 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 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 vasodilator therapy should be provided to the patient per the institution’s protocol.

Saline must be infused throughout the entire lasing process.

6. Adverse Events

Use of the Spectranetics Turbo-Elite in conjunction with the CVX-300® Excimer Laser or the Philips Laser System may contribute to the following complications:

Events Observed during Clinical Studies (see Section 7)

Procedural Complications	Serious Adverse Events	In-Hospital Complications
• Spasm	• Death	• Re-occlusion
• Major dissection	• Reintervention	• Pseudoaneurysm
• Thrombus	• ALI	• Renal failure
• Distal embolization	• Major amputation	• Bleeding
• Perforation	• Bypass surgery	
• Other	• Hematoma with surgery	

Potential Adverse Events NOT Observed during Clinical Studies (see Section 7)

- Nerve injury
- AV fistula formation
- Endarterectomy
- Infection
- Stroke
- Myocardial infarction
- Arrhythmia

No long-term adverse effects on the arterial vessel wall, due to peripheral excimer laser recanalization, are known at this time.

7. Clinical Studies

The devices 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 the Turbo-Elite Laser Atherectomy Catheter with the Philips Laser System.

7.1 ABLATE Study

Purpose: This trial evaluated the safety and effectiveness of the Turbo-Elite in atherectomy treatment for infrainguinal arteries with appropriate catheter to vessel sizing. Turbo-Elite was used to treat de novo and restenotic lesions in the superficial femoral artery, popliteal and infrapopliteal arteries. Physicians could also use adjunctive therapies, as necessary, as part of the patient treatments.

Methods: This trial is a non-randomized study evaluating the safety and effectiveness of Excimer Laser Atherectomy (ELA) using the Turbo-Elite. The primary safety endpoint was percent freedom from MAE through 30 day follow-up. An MAE is defined as all cause death, major amputation in the target limb, or target lesion revascularization. The primary effectiveness endpoint is defined as a mean reduction in percent stenosis at the time of the procedure by Angiographic Core Lab assessment.

Description of Patients: This prospective, multicenter, trial enrolled 44 patients at 10 investigative sites. Baseline patient characteristics, including demographics, medical history, and risk factors, were comparable between site assessment and core lab assessment. Patients were predominantly male (53.5%), white (95.3%) and elderly (age: 69.3 ± 10.7yr). The most common comorbidities/risk factors were hyperlipidemia (93.0%), hypertension (90.7%), smoking history (81.4%), and history of coronary artery disease (CAD) (60.5%). By core lab assessment, mean lesion length was 94.7 ± 73.0mm, reference vessel diameter was 4.7 ± 1.2mm, and % diameter stenosis (%DS) was 80.0 ± 16.5%.

Results:
The primary safety endpoint of this study was met. The primary safety hypothesis was that the 30 day freedom from Major Adverse Event (MAE) rate would be greater than 80%, which included all-cause death, major amputation in the target limb, or target lesion revascularization (TLR). The 30-day freedom from MAE rate was 97.4%.

The primary effectiveness endpoint of this study was met. The primary effectiveness endpoint was a mean reduction in percent diameter stenosis (%DS) at the time of the procedure by Angiographic Core Lab assessment (average difference between baseline %DS and post Turbo-Elite %DS). The primary effectiveness analysis of the average mean reduction in stenosis post Turbo-Elite was 45.0% ± 2.4%.

Table 7.1.1 Baseline Patient Characteristics

Screening Clinical Assessment CRF	Mean ± SD (N) (Min, Median, Max) or n/N (%)
Gender (% male)	23/43 (53.5%)
Age at Screening (years)	69.3 +/- 10.7 (43) (53.0,67.0,93.0)
Weight (kg)	82.8 +/- 20.6 (43) (45.5,81.8,140.0)
Height (cm)	168.0 +/- 9.1 (43) (147.3,167.6,188.0)
History of Hypertension	39/43 (90.7%)
History of Hyperlipidemia	40/43 (93.0%)
History of Diabetes Mellitus	21/43 (48.8%)
-- Insulin Dependent	10/21 (47.6%)
History of CAD	26/43 (60.5%)
History of CVA	2/43 (4.7%)
Smoking Status:	
-- Never	8/43 (18.6%)
-- Current	9/43 (20.9%)
-- Stopped	26/43 (60.5%)

Table 7.1.2 Target Lesion Characteristics: Angiographic Core Lab Assessment (per lesion)

Procedural Angiographic Core Lab CRF	Mean ± SD (N) (Min, Median, Max) or n/N (%)
Number of Lesions per Patient	# (%) of Patients
-- 0*	1/43 (2.3%)
-- 1	33/43 (76.7%)
-- 2	8/43 (18.6%)
-- 3	1/43 (2.3%)
BASELINE LESION MORPHOLOGY	
Stenosis Length (mm)	94.7 ± 73.0 (45) (9, 76.1, 270)
Diameter Stenosis (%)	80.0 ± 16.5 (52) (50, 78.3, 100)
MLD	0.9 ± 0.8 (52) (0, 0.8, 3)
Reference vessel diameter (mm)	4.7 ± 1.2 (52) (1.6, 5.0, 6.6)

Procedural Angiographic Core Lab CRF	Mean ± SD (N) (Min, Median, Max) or n/N (%)
Lesion Location Within Limb:	
-- Isolated SFA	32/52 (61.5%)
-- Isolated Popliteal	5/52 (9.6%)
-- SFA - Popliteal	2/52 (3.8%)
-- BTK	12/52 (23.1%)
-- ATK & BTK	1/52 (1.9%)
Distal Runoff:	
-- Absent	2/52 (3.8%)
-- 1 Vessel	17/52 (32.7%)
-- 2 or more Vessels	27/52 (51.9%)
-- N/A	6/52 (11.5%)
MORPHOLOGY	
Type of Lesion:	
-- Stenosis	35/52 (67.3%)
-- Occlusion	17/52 (32.7%)
Thrombus Present:	
-- Absent	52/52 (100.0%)
Eccentric Lesion:	
-- Concentric	51/52 (98.1%)
-- Eccentric	1/52 (1.9%)
Aneurysm Present:	
-- Absent	52/52 (100.0%)
Ulcerated Plaque Present:	
-- Absent	51/52 (98.1%)
-- Present	1/52 (1.9%)
Calcification category:	
-- None/Mild	36/51 (70.6%)
-- Moderate	11/51 (21.6%)
-- Severe	4/51 (7.8%)

Table 7.1.3 Primary Safety Endpoint

	n/N (%) N=43
Freedom from MAE	38/39 (97.4%)

Table 7.1.4 Primary Effectiveness Endpoint – Mean Percentage Reduction in Percent Diameter Stenosis post Turbo-Elite

	Mean ± SE
Reduction in %DS	45.0% ± 2.4%

7.2 EXCiTE In-Stent Restenosis (ISR) Study

Purpose: This trial evaluated the safety and effectiveness of Excimer Laser Atherectomy (ELA) using the Spectranetics Turbo-Elite Laser Ablation Catheter to create a pilot channel for lesion treatment using the Spectranetics Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter with adjunctive percutaneous transluminal angioplasty (PTA) in comparison with PTA alone in the treatment of femoropopliteal bare

nitinol in-stent restenosis in vessels ≥5mm.

Methods: This trial was a prospective randomized controlled trial performed respectively in a 2:1 randomization scheme, The primary effectiveness measure was patency, defined as achievement of Procedural Success in the Index Procedure and Freedom from Clinically Driven TLR through 6 months follow-up. The primary safety endpoint was defined as Freedom from Major Adverse Events (MAE) at 30 days. MAE are defined all-cause death, major amputation in the target limb, or target lesion revascularization (TLR) (surgical or interventional) from procedure to 30 days (±7 days). Patients were treated using the Turbo-Tandem Laser Catheter and, if a 2mm pilot channel did not exist prior to treatment, a Turbo-Elite laser catheter was used to create a pilot channel as an accessory to Turbo-Tandem.

Description of Patients: Two hundred and fifty (250) patients were prospectively enrolled at a total of 40 US centers. Comparing ELA+PTA to PTA, patients were predominantly male (63% vs. 62%), and elderly (age: 69±10 vs. 68±10 yr). The most common comorbidities/risk factors were hypertension (96% vs. 94%), hyperlipidemia (96% vs. 95%), and smoking history (85% vs. 91%). Baseline lesion characteristics assessed by the sites were generally comparable between groups. Mean lesion length was 17±12 vs. 16±11 cm, reference vessel diameter was 5.6±0.5 vs. 5.6±0.6 mm, and stenosis diameter was 88±13 vs. 88±14%.

Results:
The primary safety endpoint of this study was met. The primary safety hypothesis was that the rate of major adverse events (MAE) through 30 days with ELA+PTA, which included all-cause death, major amputation in the target limb, or target lesion revascularization (TLR), would be non-inferior to PTA. The 30-day MAE rates were 5.8% for ELA+PTA and 20.5% for PTA. The probability that ELA+PTA was non-inferior to PTA was >0.9999, which was greater than the 0.9975 required for early success. Additionally, the probability that ELA+PTA was superior to PTA was 0.9999, which was also greater than the 0.9975 required for early success.

The primary effectiveness endpoint of this study was also met. The primary effectiveness hypothesis was that freedom from TLR through 6 months with ELA+PTA would be superior to PTA. Freedom from TLR through 6 months was 73.5% for ELA+PTA and 51.8% for PTA. The probability that ELA+PTA was superior to PTA was 0.9994, which was greater than the 0.9975 required for early success.

Table 7.2.1 Baseline Patient Characteristics

	Mean ± SD (N) (Min, Median, Max) or n/N (%)	
Screening Clinical Assessment CRF	**Excimer Laser Atherectomy + PTA**	**PTA Alone**
Patients	**169**	**81**
Gender (% male)	106/169 (62.7 %)	50/81 (61.7 %)
Age at Screening (years)	68.5±9.8 (n=169)	67.8±10.3 (n=81)
Weight (kg)	82.2±18.9 (n=168)	80.4±16.4 (n=80)
Height (cm)	170.0±10.4 (n=168)	168.7±9.7 (n=80)
History of Hypertension	161/168 (95.8 %)	75/80 (93.8 %)
History of Hyperlipidemia	162/168 (96.4 %)	76/80 (95.0 %)
History of Diabetes Mellitus	79/168 (47.0 %)	38/80 (47.5 %)
-- Insulin Dependent	34/79 (43.0 %)	17/38 (44.7 %)
History of CAD	108/168 (64.3 %)	55/80 (68.8 %)
History of CVA	18/168 (10.7 %)	5/80 (6.3 %)

	Mean ± SD (N) (Min, Median, Max) or n/N (%)	
Screening Clinical Assessment CRF	**Excimer Laser Atherectomy + PTA**	**PTA Alone**
Smoking Status:		
-- Never	25/167 (15.0 %)	7/80 (8.8 %)
-- Current	50/167 (29.9 %)	36/80 (45.0 %)
-- Stopped	92/167 (55.1 %)	37/80 (46.3 %)
Lesion Location: Within Limb:		
-- Isolated SFA	137/169 (81.1 %)	72/81 (88.9 %)
-- Isolated Popliteal	3/169 (1.8 %)	4/81 (4.9 %)
-- SFA-Popliteal	29/169 (17.2 %)	5/81 (6.2 %)
% Diameter Stenosis	87.6±12.6 (n=168) (50.0, 90.0, 100.0)	87.8±13.7 (n=81) (50.0, 90.0, 100.0)
Total lesion Length (mm)	173.4±117.8 (n=169) (30.0, 140.0, 550.0)	163.6±106.7 (n=81) (5.0, 140.0, 430.0)
Reference Vessel Diameter (mm)	5.6±0.5 (n=168) (5.0, 6.0, 7.0)	5.6±0.6 (n=80) (5.0, 5.8, 7.0)
Length of Extra Stent Lesion (mm)	15.5±12.3 (n=60) (1.0, 10.0, 70.0)	20.1±14.6 (n=26) (2.5, 20.0, 64.0)
Subjects without extra stent lesion present	109/169 (64.5 %)	55/81 (67.9 %)
Stent Fracture Present:		
-- Grade 0	146/169 (86.4 %)	72/81 (88.9 %)
-- Grade 1	11/169 (6.5 %)	5/81 (6.2 %)
-- Grade 2	6/169 (3.6 %)	3/81 (3.7 %)
-- Grade 3	6/169 (3.6 %)	1/81 (1.2 %)
Target Lesion Thrombus	11/169 (6.5 %)	4/81 (4.9 %)
Target Lesion Aneurysm	0/169 (0.0 %)	0/81 (0.0 %)
Target lesion Calcification:		
-- None	72/169 (42.6 %)	41/81 (50.6 %)
-- Mild	62/169 (36.7 %)	26/81 (32.1 %)
-- Moderate	25/169 (14.8 %)	7/81 (8.6 %)
-- Severe	10/169 (5.9 %)	7/81 (8.6 %)
Anterior Tibial Stenosis:		
-- <= 50% (Patent)	102/168 (60.7 %)	56/81 (69.1 %)
-- >50% (Stenosed)	25/168 (14.9 %)	11/81 (13.6 %)
-- Occluded	41/168 (24.4 %)	14/81 (17.3 %)
Posterior Tibial Stenosis:		
-- <= 50% (Patent)	100/168 (59.5 %)	54/81 (66.7 %)
-- >50% (Stenosed)	21/168 (12.5 %)	10/81 (12.3 %)
-- Occluded	47/168 (28.0 %)	17/81 (21.0 %)
Peroneal Stenosis:		
-- <= 50% (Patent)	117/168 (69.6 %)	62/81 (76.5 %)
-- >50% (Stenosed)	21/168 (12.5 %)	8/81 (9.9 %)
-- Occluded	30/168 (17.9 %)	11/81 (13.6 %)

Table 7.2.2 Post PTA Procedural Outcomes

	Mean ± SD (N) (Min, Median, Max) or n/N (%)	
Procedural Angiographic Core Lab CRF	**Excimer Laser Atherectomy + PTA**	**PTA Alone**
Target Lesion Residual Stenosis post PTA procedure (%)	11.5±13.5 (n=165)	18.1±18.2 (n=81)
Target Vessel Dissection post PTA:		
-- Yes	15/169 (8.9 %)	15/81 (18.5 %)
-- No	148/169 (87.6 %)	66/81 (81.5 %)
-- Not Assessed	6/169 (3.6 %)	0/81 (0.0 %)
Dissection Grade Upon Visual Assessment post PTA:		
-- A	7/15 (46.7 %)	9/15 (60.0 %)
-- B	7/15 (46.7 %)	0/15 (0.0 %)
-- C	1/15 (6.7 %)	4/15 (26.7 %)
-- D	0/15 (0.0 %)	1/15 (6.7 %)
-- F	0/15 (0.0 %)	1/15 (6.7 %)

Table 7.2.3 Primary Safety Endpoint

Freedom from MAE[1]	ELA + PTA	PTA Only	P-value[2]
Intent-To-Treat	146/155 (94.2%)	58/73 (79.5%)	0.0007
Per Protocol	123/130 (94.6%)	50/61 (82.0%)	0.0053
As Treated[3]	148/159 (93.1%)	58/69 (84.1%)	0.0340

[1]Freedom from any MAE defined as TLR, death or amputation through 37 days post procedure
[2]Chi-square
[3]As treated consisted of four subjects randomized to PTA alone that received provisional laser treatment after PTA treatment failure. Two of these subjects also underwent bail-out stenting. These four subjects were assigned to ELA + PTA for the purposes of this analysis.

Table 7.2.4 Primary Effectiveness Endpoint

Freedom from TLR[1]	ELA + ELA + PTA	PTA Only	P-value[2]
Intent-To-Treat	86/117 (73.5%)	29/56 (51.8%)	0.0046
Per Protocol	78/100 (78.0%)	21/45 (46.7%)	0.0002
As Treated[3]	88/121 (72.7%)	29/52 (55.8%)	0.0288

[1]Freedom from TLR through 212 days post procedure
[2]Chi-square
[3]As treated consisted of four subjects randomized to PTA alone that received provisional laser treatment after PTA treatment failure. Two of these subjects also underwent bailout stenting. These four subjects were assigned to ELA + PTA for the purposes of this analysis.

7.3 Other Studies

LACI Studies
This data was based off previous versions of peripheral excimer laser atherectomy catheters. Data presented in this IFU are comprised of a subset of patients pooled from three sources of consecutively treated patients presenting with Critical Limb Ischemia (CLI), who were poor surgical candidates:

- LACI Phase 2 – a subset of patients from a prospective IDE registry conducted in 2001-2002 at 14 sites in the US and Germany. The subset includes 26 limbs (in 25 patients) treated at 7 sites from the US and Germany in which the step-by-step laser recanalization technique was utilized. In 13 of these cases, step-by-step technique was utilized ab initio, that is, without first attempting to cross the occlusion with a guidewire.
- LACI Belgium - a subset of a 51-patient prospective registry conducted at 6 sites in Belgium. The subset includes 9 limbs (in 9 patients) treated at 3 sites in Belgium in which the step-by-step laser recanalization technique was utilized.
- Louisiana case series – a subset drawn from 62 cases included in an on-going data compilation by a single physician group in central Louisiana, the Cardiovascular Institute of the South (CIS). This subset of patients consists of 12 limbs (in 12 patients) in which the step-by-step laser recanalization technique was utilized.

Table 7.3.1 Procedure Information[1]

Locations of vascular lesions (n=205)	
SFA	138 (67%)
Popliteal	23 (11%)
Infrapopliteal	42 (20%)
Angiographic Results (n=47 limbs)	
Lesions per limb	4.4
Average lesion length	73.4 ± 7.3 (mm)
Straightline flow to foot established	37 (79%)
Stent implanted	28 (60%)
Crossing Success Overall*	37 (79%)
Crossing success after guidewire attempt	24/34 (71%)
Crossing success ab initio cases	13/13 (100%)
Procedure success**	34 (72%)

[1] Intent to Treat Analysis: The intent-to-treat (ITT) patient population included all randomized patients who underwent treatment with ELA-PTA or PTA.
Per Protocol Analysis: The per-protocol (PP) population (AT) included all patients who underwent treatment with ELA-PTA or PTA and had no inclusion / exclusion violations or device use that was not allowed (e.g., scoring balloon).
As Treated Analysis: The as treated (AT) analysis reflects the actual treatment received, regardless of randomization assignment.

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.
*Crossing Success data has been stratified for step-by-step cases after conventional guidewire attempts in 24 limbs, and ab initio in 13 limbs.
**Procedure success: ≤50% final residual stenosis

Table 7.3.2 Complications, n=47 limbs

Procedural Complications	
Spasm	1 (2%)
Major dissection	4 (9%)
Thrombus	1 (2%)
Distal embolization	3 (6%)
Perforation	3 (6%)
Other	5 (11%)
In-Hospital Complications	
Reocclusion	1 (2%)
Pseudoaneurysm	1 (2%)
Renal failure	1 (2%)
Bleeding	1 (2%)
Infection	0 (0%)
Other	0 (0%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

Table 7.3.3 Cumulative Serious Adverse Events (SAEs) through 6-month follow-up, for n=47 limbs

Death	3 (6%)
MI or Stroke	0 (0%)
Reintervention	6 (13%)
ALI	1 (2%)
Major amputation	2 (4%)
Bypass surgery	2 (4%)
Endarterectomy	0 (0%)
Hematoma with surgery	2 (4%)
Total	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.
MI = Myocardial Infarction. ALI = Acute Limb Ischemia.

Table 7.3.4 Outcomes by Intention-to-Treat Analysis, n=47

Crossing success	37 (79%)
Procedure success	34 (72%)
Limb salvage	40 (85%)
Death, any cause	3 (6%)
Any SAE	16 (34%)

NOTE: 47 limbs in 46 patients were treated. All percent calculations are based on 47 limbs.

8. Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the Turbo-Elite Laser Atherectomy Catheter device.
Use of Turbo-Elite devices may be considered after initial conventional crossing attempts with guidewires are unsuccessful due to:

- A rounded or eccentric occlusion stump deflecting the guidewire to a subintimal passage.
- The guidewire repeatedly being deflected into a large collateral branch flush with the occlusion stump.
- Calcification obstructing completion of guidewire passage within the obstructed lumen.

Additionally, recanalization of native arteries may be considered in patients presenting with occluded bypass grafts.

Patient selection and clinical techniques should be conducted according to instructions provided in Section 2, “Indications for Use,” and Section 9, “Operator’s Manual.”

9. Operator’s Manual

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

Table 9.1 Energy Parameters

Device Description	Model No.	Fluence	Repetition Rate	Laser On / Off Time
OTW Catheters				
0.9 mm	410-152	30-80	25-80*	Continuous On*
1.4 mm	414-151	30-60	25-80*	Continuous On*
1.7 mm	417-152	30-60	25-80*	Continuous On*
2.0 mm	420-006	30-60	25-80*	Continuous On*
2.3 mm	423-001	30-60	25-80*	Continuous On*
2.5 mm	425-011**	30-45	25-80*	Continuous On*
2.3 mm	423-135-01	30-60	25-80*	Continuous On*
2.5 mm	425-135-01	30-60	25-80*	Continuous On*
RX Catheters				
0.9 mm	410-154	30-80	25-80*	Continuous On*
1.4 mm	414-159	30-60	25-80*	Continuous On*
1.7 mm	417-156	30-60	25-80*	Continuous On*
2.0 mm	420-159	30-60	25-80*	Continuous On*

Recommended calibration settings: 45 Fluence, 25 Hz
* 80 Hz maximum repetition rate is for CVX-300® software V3.8XX and Philips Laser System software version 1.0 (b5.0.3) and above. For CVX-300® software V3.7XX, the maximum repetition rate is 40 Hz.
** Note: The Philips Laser System is not compatible and cannot be used with the 425-011 model Turbo-Elite catheter.

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 Laser Atherectomy Catheter is designed and intended to be used exclusively with the Spectranetics CVX-300® Excimer Laser 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

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):

- Introducer sheaths and/or femoral guiding catheter(s) in the appropriate size and configuration to select the peripheral artery and facilitate largest laser catheter to be used.
- Tuohy-Borst “y” adapter or hemostatic valve(s).
- Sterile normal saline.
- Standard contrast media.
- 0.014”, 0.018”, and 0.035” guidewires.

The use of the laser system is restricted to physicians who are trained in peripheral vascular intervention 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 Excimer Laser Ablation technique in occlusions 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 three 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.

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® Excimer Laser Operator’s Manual or Philips Laser System Operator’s Manual.

1. Use standard femoral puncture technique to insert a 4 Fr. to 9 Fr. (depending on the largest interventional device to be used during treatment) introducer sheath into the common femoral artery in antegrade or retrograde fashion for contralateral approaches. Heparinize intravenously using the protocol for heparinization.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014”, 0.018”, or 0.035” guidewire to the peripheral occlusion via the introducer sheath or guiding catheter.

4. Size and choose the laser catheter appropriately:

Table 12.1 Recommended Sizing

Catheter Size	Proximal Vessel Diameter
0.9 mm	≥1.4 mm
1.4 mm	≥2.1 mm
1.7 mm	≥2.6 mm
2.0 mm	≥3.0 mm
2.3 mm	≥3.5 mm
2.5 mm	≥3.8 mm

5. Hydrate the outer jacket of the catheter to activate the hydrophilic coating. Either dip the catheter in a basin or wipe with wet gauze using an appropriate sterile solution.
6. Flush the guidewire lumen of the laser catheter using 5-10 mL of heparinized saline.
7. 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.

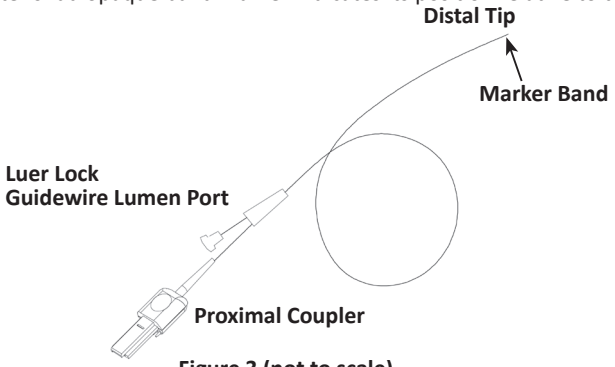

Figure 3 (not to scale)

Note: 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.

In the absence of apparent catheter movement, care should be taken not to deliver excessive laser energy.

8. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
9. Following confirmation that the laser catheter's position is in contact with the target lesion, and using normal saline solution:
   a. Flush all residual contrast media from the introducer sheath or 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.
   Warning: Do not activate the laser in the presence of contrast.
   c. Please refer to the Saline Infusion Protocol section of the Instructions for Use and perform saline flush and infusion per the instructions.

10. When using Turbo-Elite Laser Atherectomy Catheter models, the laser system will continuously deliver energy as long as the footswitch is depressed. The length of the laser train is controlled by the operator. It is generally recommended not to exceed 20 seconds of continuous lasing.

11. **Step-by-Step Method for Total Occlusion**

    a. Depress the footswitch, activating the laser system, and slowly, less than 1 mm per second, advance the laser catheter 2–3 mm into the total occlusion, allowing the laser energy to remove the desired material. Release the footswitch to deactivate the laser system.
    b. Advance the guidewire beyond the distal tip of the laser catheter further into the occlusion, a few millimeters, and reactivate the laser as described in Step a above.
    c. Continue in this step-by-step manner where the guidewire and then the laser catheter are advanced and activated (mm by mm) until the catheter reaches the last 3-5 mm of the occlusion.
    d. Cross the last 3-5 mm of the occlusion and enter the patent distal vessel with the guidewire first, followed by the activated laser catheter over-the-wire.
    e. Leaving the guidewire in position, pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.
    f. Additional laser passes may be performed over-the-wire to achieve greater debulking of the lesion.
    g. If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the laser system. The fluence and repetition rates can be increased in order to advance. To avoid the potential of heat build-up, the catheter must be advanced while lasing.

12. **Standard Method for Treating Stenoses**

    a. Depress the footswitch, activating the laser system, and slowly, less than 1 mm per second, advance the laser catheter through the stenosis. Release the footswitch to deactivate the laser system.
    b. Additional laser passes may be performed over-the-wire to achieve greater debulking of the lesion. If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the laser system. The fluence and repetition rates can be increased in order to advance. To avoid the potential of heat build-up, the catheter must be advanced while lasing.

13. 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 Operator's Manual or the Philips Laser System Operator's Manual.

14. Following laser recanalization, perform follow-up angiography and balloon angioplasty if needed. Stenting may be performed as required, in instances of acute recoil, major perforation, etc.

15. Perform saline infusion protocol as required.

Note: Use of two operators is recommended for this technique. 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.

a. Before the laser procedure, obtain a 500 mL bag of 0.9% normal saline (NaCl),. It is not necessary to add heparin or potassium to the saline solution. Connect the bag of saline to a sterile intravenous line and terminate the line at a port on a triple manifold.
b. If applicable, cannulate the ostium of the artery with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter not have side holes.
c. 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.
d. 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.
e. Remove the original control syringe from the manifold and replace it with a fresh 20 mL luer-lock control syringe. This new 20 mL control syringe should be primed with saline prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20 mL control syringes.)
f. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and introducer sheath or guide catheter, with at least 20-30 mL of saline (several syringes of saline). When this initial flushing is completed, refill the 20 mL control syringe with saline.
g. 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.
h. 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 10 mL of saline as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
i. After the injection of the initial 10 mL bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to minimum of 2-3 mL/second through a combination of the guidewire lumen and/or sheath. 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.
j. The length of the laser train is controlled by the operator. It is generally recommended not to exceed 20 seconds of continuous lasing. Saline must be infused throughout the entire lasing process.
k. Terminate the saline injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20 ccs of saline in preparation for the next lasing sequence.
l. Each subsequent laser train should be preceded by a bolus of saline and performed with continuous saline infusion as described in steps h-k.
m. If contrast is used to assess treatment results during the course of a laser treatment, repeat steps d-g prior to reactivation of the laser system (before activating the laser repeat steps h-k).

Note: Depending on which approach is used, antegrade or contralateral, saline can be administered through the sheath (antegrade approach) or laser catheter inner lumen (contralateral approach). When the contralateral approach is used, smaller diameter guidewires are suggested to allow adequate saline infusion at the treatment site.

13. Warranty Information

MANUFACTURER'S LIMITED WARRANTY

Manufacturer warrants that the Turbo-Elite Laser Atherectomy Catheter is free from defects in material and workmanship when used by the stated "Use By" date and when package is unopened and undamaged immediately before use. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective Turbo-Elite Laser Atherectomy Catheter. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the Turbo-Elite Laser Atherectomy Catheter. Damage to the Turbo-Elite 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 Manufacturer. This limited warranty covers only the Turbo-Elite Laser Atherectomy Catheter. Information on Manufacturer's warranty relating to the CVX-300® Excimer Laser or the Philips Laser System can be found in the documentation relating to that device.

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