Turbo-Tandem™

Laser Guide Catheter with Laser Atherectomy Catheter

Instructions for Use

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. DEVICE DESCRIPTION

The Turbo-Tandem System (Laser Guide Catheter with Laser Atherectomy Catheter) is a laser atherectomy catheter constrained within a guiding catheter to facilitate the offset (biased position) of the laser atherectomy catheter. The Turbo-Tandem System is designed to be used to directionally ablate infrainguinal concentric and eccentric lesions in vessels that are 5.0mm or greater for the 7F Turbo-Tandem System or 5.5mm or greater for the 8F Turbo-Tandem System. The Turbo-Tandem System is not designed to be used in total or sub-total occlusions. A ≥2mm lumen for the 7F Turbo-Tandem or a ≥ 2.5mm lumen for the 8F Turbo-Tandem System should be angiographically evident in the target treatment segment prior to the use of the Turbo-Tandem System.

The guiding catheter portion of the Turbo-Tandem System is used to offset the distal end of the incorporated laser catheter from the central plane of the vessel lumen allowing for circumferential guidance and positioning of the laser catheter within the vessel. The Turbo-Tandem System is available in two sizes. The 7F Turbo-Tandem is 7F sheath compatible with a maximum crossing profile of 0.160 (4.0mm) with the laser catheter extended or offset position. The 8F Turbo-Tandem is 8F sheath compatible with a maximum crossing profile of 0.185" (4.7mm) with the laser catheter extended or offset position. The incorporated laser catheter of both Turbo-Tandem models is constructed of multiple optical fibers arranged circumferentially around a 0.014" (0.35mm) guidewire compatible lumen and has a fiber optic surface area similar to a 2.0mm laser catheter. The laser catheter is connected to the Spectranetics CVX-300 Excimer Laser System by means of an optical coupler and tail-tubing. The guiding catheter portion of the Turbo-Tandem System is comprised of a handle with an incorporated flush port, proximal coupler, tail tubing, strain relief tubing, braided shaft with a hydrophilic coating, two radiopaque marker bands in the distal tip with a platform, and one radiopaque marker band at the distal end of the laser catheter. Figure 1 describes the location of the Turbo-Tandem System components.

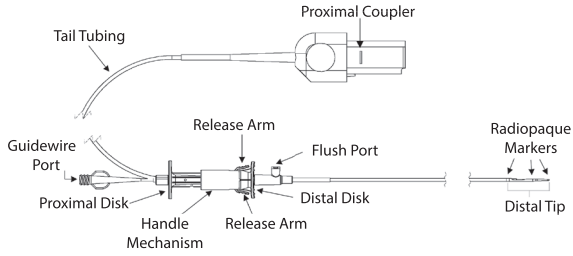

Figure 1. Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter

During use, the laser ablation catheter is advanced from the inner lumen of the guiding catheter to sit on the platform of the distal tip, which offsets the laser catheter. The hydrophilic coating on the outside of the guiding catheter reduces friction during navigation of the Turbo-Tandem System through the vasculature. The braided shaft portion of the guiding catheter transfers torque applied to the proximal end of the Turbo-Tandem System to the distal tip resulting in system rotation around the guidewire axis (Figure 1). Offsetting the distal end of the laser catheter and providing torque capability allows for the system to be directed to the desired treatment plane within the vessel.

The multifiber laser catheter transmits ultraviolet energy from the Spectranetics CVX-300™ Excimer Laser System to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photoablate multiple morphology 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.

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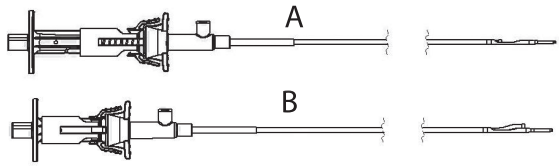

Figure 2. The Turbo-Tandem System in the Retracted (A) and Extended (B) Positions

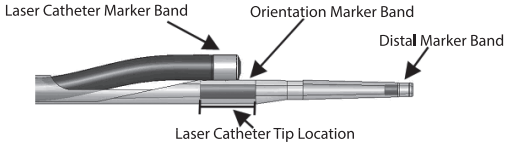

Figure 3. The Turbo-Tandem System Tip Location in the Extended Position

Table 1.1 Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter Specifications

REF #	472-110	482-110
Working length	110cm	110cm
Wire Compatibility	0.014" (0.35mm)	0.014" (0.35mm)
Sheath Compatibility	7F (≥ 0.098" / 2.5mm)	8F (≥ 0.113" / 2.9mm)
Min Crossing Profile (Retracted)	0.094" (2.4mm)	0.107" (2.7mm)
Max Crossing Profile (Extended)	0.160" (4.0mm)	0.185" (4.7mm)
Laser Catheter	2.0mm Over The Wire (OTW)	2.0mm Over The Wire (OTW)

2. INDICATIONS / INTENDED USE

The 7 and 8 French Turbo-Tandem systems are indicated for atherectomy of infrainguinal arteries.

The 7 French Turbo-Tandem System is indicated for laser atherectomy of de novo or restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, with adjunctive Percutaneous Transluminal Angioplasty (PTA). A ≥ 2.0mm pilot channel must be present for treatment using the Turbo-Tandem.

3. CONTRAINDICATIONS

No known contraindications.

4. RESTRICTIONS

- The use of the Turbo-Tandem System requires operation of the CVX-300™ Excimer Laser System. The use of the CVX-300™ Excimer Laser System is restricted to physicians who are trained in peripheral vascular intervention and who meet the training requirements listed in the CVX-300™ Excimer Laser System Operators Manual.
- The Turbo-Tandem System can be operated within 30-60 Fluence range and 25-80 Repetition Rate (Hz) in "Continuous On" mode for the CVX-300™ Excimer Laser System.
- The calibration settings are 45 Fluence, 25 Hz.
- 80 Hz maximum repetition rate occurs for the Turbo-Tandem System when accompanied with the CVX-300™ Excimer Laser System with software version V3.812 or higher. For CVX-300™ Laser System software versions V3.712 or lower, the maximum repetition rate is 40 Hz for the Turbo-Tandem System. Consult your CVX-300™ Laser System to determine its operational version of software.

5. WARNINGS

- Do not use without a guidewire, as vessel injury may result.
- Do not extend the laser catheter distal tip marker band beyond the orientation marker band of the Turbo-Tandem System (Figure 3). This may result in damage to the device tip.
- Only advance and manipulate the Turbo-Tandem System under fluoroscopic guidance to confirm the location and orientation of the tip.
- Do not attempt to advance or retract the Turbo-Tandem System against resistance until the reason for the resistance has been determined by fluoroscopy or other means. This may result in deformation or detachment of the distal tip or kinking of the Turbo-Tandem System.
- If the catheter advances beyond or behind the orientation marker while lasing and advancing the system, stop and re-assess before continuing (Figure 3). Continuing to advance the system or lase may result in damage to the tip of the catheter.
- Do not inject contrast media through the Turbo-Tandem System or guidewire lumen as this could cause the system to lock-up and may lead to complications.
- This device is designated for use solely as a component of the Spectranetics CVX-300® Excimer Laser System.
- Adequate instructions for the safe installation of the Spectranetics CVX-300® Excimer Laser System are provided in servicing information provided by Spectranetics and should be followed.

- 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.
- 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 5.1: 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

6. PRECAUTIONS

- Read the CVX-300™ Excimer Laser System Operator's Manual thoroughly before operating the CVX-300™ Excimer Laser System to ensure safe operation of the system.
- This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and can not be re-sterilized and/or reused.
- 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.
- Always store the devices in a cool, dry place. Protect the device from direct sunlight and high temperatures (greater than 60°C or 140°F).
- After use, all equipment should be disposed of properly in accordance with specific requirements relating to hospital waste, and potentially biohazardous materials.
- During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution's interventional protocols.
- The proximal coupler of the laser catheter connects only to the CVX-300™ Excimer Laser System and is not meant to have any patient contact.
- Ensure the laser catheter tip is dry. A wet laser catheter tip may prevent successful device calibration.
- Do not use the Turbo-Tandem System if any damage is observed.
- If the laser catheter tip does not retract off the ramp, after depressing both release arms, pull the proximal disk back to retract the laser catheter. If the laser catheter does not retract prior to placing in the patient, set the device aside for product complaint management and open another device. If the laser catheter does not retract while in the patient, carefully grasp the distal disk component and slowly pull the proximal disk component away from the distal disk component to detach the handle into two separate parts. Do not move any portion of the system distally as this may cause harm to the vessel. Manually pull the proximal disk component attached to the laser catheter proximal until the laser catheter distal tip is off the ramp and remove both catheters together thru the introducer sheath.
- Ensure contrast media has been flushed from the intended vessel and treatment site prior to activating the laser system.
- Confirm the laser catheter is in the retracted state when advancing or retracting the Turbo-Tandem System without lasing.
- Do not use the device if its "Use By" located on the package labeling has passed.
- The Turbo-Tandem System is not designed to be used in total or sub-total occlusions.

7. POTENTIAL ADVERSE EVENTS

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

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at anytime during and/or after the procedure. Potential complications include but are not limited to: perforation of the vessel wall, major dissection, pseudoaneurysm, arteriovenous fistula, spasm, distal embolization, thrombosis, reocclusion, hematoma at the puncture site, bleeding or Acute Limb Ischemia (ALI), any of which may require a reintervention, bypass surgery or amputation; infection, renal failure, nerve injury, stroke, myocardial infarction, arrhythmia, death and other.

8. CLINICAL STUDIES

8.1 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 8.1.1 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 %)
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)

	Mean ± SD (N) (Min, Median, Max) or n/N (%)	
Screening Clinical Assessment CRF	**Excimer Laser Atherectomy + PTA**	**PTA Alone**
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 8.1.2 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 8.1.3 Primary Safety Endpoint[1]

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 bailout stenting. These four subjects were assigned to ELA + PTA for the purposes of this analysis.

[1] Intent to Treat Analysis: The intent-to-treat patient (ITT) 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.

Table 8.1.4 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.

8.2 Other Studies
LACI Studies
Study Summary: Data presented in this IFU were collected in support of safety and effectiveness for Spectranetics brand Turbo-Booster™ and CLiRpath™ Turbo™ catheters. The CELLO (CLiRpath Excimer Laser System to Enlarge Lumen Openings) Study, IDE #G060015, enrolled 17 training cases and 48 analysis patients or a total of 65 patients at 17 sites. The data presented combines the results from the training and analysis patients.

Effectiveness: The primary effectiveness endpoint (≥ 20 percent reduction in percent diameter stenosis, on average, as assessed by an angiographic core lab) for the analysis cohort demonstrated a 35 percent reduction in diameter stenosis using the Turbo-Booster system compared to pre-procedure in the study. The secondary effectiveness endpoint for acute procedural success (visual assessment of final residual stenosis) was achieved in 98.5 percent of patients as visually assessed by physician.

Table 8.2.1 Patient Demographics

Variable	Mean	Standard Deviation
Age (years)	68.3	10.1
	Number	**Percentage (%) (n=65)**
Gender (Male)	39	60.0
African-American	11	16.9
Caucasian	49	75.4
Hispanic	5	7.7
CAD	42	64.6
MI	16	37.2
Revascularization	26	60.5
Diabetes	26	40.0
Hypertension	57	87.7
Hyperlipidemia	55	84.6
CVA	7	10.8

Table 8.2.2 Lesion Locations

Location of Vascular Lesions	Total (n=65)
Superficial Femoral Artery (SFA)	60
Popliteal Artery	5

Table 8.2.3 Procedure Information
NOTE: All values based on angiographic core laboratory analysis

Angiographic Results (n=65)	Mean	SD
Reference vessel diameter (mm)	4.9	0.8
Average lesion length (mm)	56.0	47.2
Percent diameter stenosis – Pre	77.1	15.7
Percent diameter stenosis – After Turbo-Booster use	42.3	12.8
Percent diameter stenosis - Final	21.1	14.5

Safety: The primary safety endpoint measured was the occurrence of major adverse events, defined as clinical perforation, major dissection requiring surgery, major amputation, cerebrovascular accidents (CVA), myocardial infarction, and death at the time of procedure, prior to release from the hospital (or 24 hours post-procedure, whichever comes first) at 30 days, and six (6) months. The CELLO study had no major adverse events reported through the six month follow-up. One CVA was reported at a 12 month follow-up. There were eleven Serious Adverse Events, only one probably related to the investigational device and there were no Unanticipated Adverse Device Effects. Table 6 presents adverse events that occurred during the procedure through hospital discharge.

Table 8.2.4 Serious Adverse Events (n=65 patients)

n=11	Not Related to Investigational Device	Possibly Related to Investigational Device	Probably Related to Investigational Device
Severe	9	0	0
Moderate	1	0	1
Mild	0	0	0

Table 8.2.5 Acute Adverse Events (n=65 patients)
NOTE: All values are from procedural through discharge

n=10	Not Related to Investigational Device	Possibly Related to Investigational Device	Probably Related to Investigational Device
Major dissection (Grade E or F)	0	0	0
Distal embolization	0	2	0
Hematoma/Bleeding	5	0	0
Other (Hematuria, Sinus tachycardia, Discomfort in treated leg post-procedure)	3	0	0

Conclusions: The effectiveness of the Turbo-Booster was demonstrated by the significant reduction in percent diameter stenosis from baseline to post-Turbo-Booster use. The 35 % reduction in the % diameter stenosis, on average, met the endpoint for showing a ≥20 % reduction in % diameter stenosis.

The study demonstrated that the Turbo-Booster is safe for the treatment of patients with stenoses and occlusions crossable by a guidewire in the superficial femoral artery and popliteal artery as evident by no occurrence of major adverse events through the six-month follow-up.

9. INDIVIDUALIZATION OF TREATMENT

The risks and benefits described above should be carefully considered for each patient before the use of the Turbo-Tandem System.

10. OPERATOR'S MANUAL

RESTRICTIONS

- The use of the Turbo-Tandem System requires operation of the CVX-300™ Excimer Laser System. The use of the CVX-300™ Excimer Laser System is restricted to physicians who are trained in peripheral vascular intervention and who meet the training requirements listed in the CVX-300™ Excimer Laser System Operators Manual.
- The Turbo-Tandem System can be operated within 30-60 Fluence range and 25-80 Repetition Rate (Hz) in "Continuous On" mode for the CVX-300™ Excimer Laser System.
- The calibration settings are 45 Fluence, 25 Hz.
- 80 Hz maximum repetition rate occurs for the Turbo-Tandem System when accompanied with the CVX-300™ Excimer Laser System with software version V3.812 or higher. For CVX-300™ Laser System software versions V3.712 or lower, the maximum repetition rate is 40 Hz for the Turbo-Tandem System. Consult your CVX-300™ Laser System to determine its operational version of software.

11. HOW SUPPLIED

11.1 Sterilization

The Turbo-Tandem System is supplied sterile by the ethylene oxide sterilization process in a double sterile barrier consisting of a peel-open package in a peel-open pouch. Intended for SINGLE USE ONLY; do not resterilize, reprocess, or reuse. Device is sterile if package is unopened or undamaged. Do not use the device if there is doubt as to whether the package is sterile.

11.2 Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken. The Turbo-Tandem System should be carefully examined for defects (i.e. bends, kinks or other damage). Do not use if device is damaged. If the device is considered damaged; reference RETURN PRODUCT section of this IFU.

12. COMPATIBILITY

See "DEVICE DESCRIPTION" section.

13. DIRECTIONS FOR USE

13.1 MATERIALS REQUIRED FOR USE

- The following materials are required to use the 7F Turbo-Tandem System
  - 0.014" guide wires greater than 220cm in length
  - 7F introducer sheaths
  - 7F crossover sheaths (Crossover sheaths with metallic banded designs are NOT recommended.)
  - Control syringe filled with sterile saline
  - Pressurized infusion setup (capable of at least 300 mmHg) with sterile saline
- The following materials are required to use the 8F Turbo-Tandem System
  - 0.014" guide wires greater than 220cm in length
  - 8F introducer sheaths
  - 8F crossover sheaths (Crossover sheaths with metallic banded designs are NOT recommended.)
  - Control syringe filled with sterile saline
  - Pressurized infusion setup (capable of at least 300 mmHg) with sterile saline

13.2 DEVICE PREPARATION

1. Using sterile technique, carefully remove the Turbo-Tandem System from packaging. Remove the packaging wedges from the tray. Lift the system by the black end piece (referred to as the proximal coupler) in the middle of the tray, and hand it outside the sterile field to be inserted into the CVX-300™ Excimer Laser System.

CAUTION: The proximal coupler of the laser catheter connects only to the CVX-300™ Excimer Laser System by means of a length of tail tubing, and is not meant to have any patient contact.

2. Insert the proximal coupler of the laser catheter to the CVX-300™ Excimer Laser System and position a loop of the laser catheter tail tubing into the laser system extension pole.
3. Grasp the Turbo-Tandem Laser Guided Catheter handle from the middle of the packaging tray and remove the rest of the system.

4. Prior to using the Turbo-Tandem System, carefully examine the device for any bends, kinks, or other damage. A slight curvature in the catheter is normal due to packaging and will not impact device performance or safety.

CAUTION: Do not use the Turbo-Tandem System if any damage is observed. If the device is considered damaged; reference RETURN PRODUCT section of this IFU.

5. Prior to calibration, flush the catheter shaft via the handle flush port located on the handle mechanism with sterile saline.
6. Cap the flush port with the luer cap provided in the Turbo-Tandem System package to prevent back bleeding.
7. Confirm the laser catheter is exposed from the inner lumen of the guiding catheter by advancing the laser catheter into its extended position (Figure 2 – B Extended Position). Advance the laser catheter into the extended position by depressing both the proximal and distal disks located on the handle mechanism.
8. Prior to calibration ensure that the laser catheter distal tip is dry.

CAUTION: Ensure the laser catheter tip is dry. A wet laser catheter tip may prevent successful device calibration.

9. Calibrate the laser catheter at 45 Fluence and 25 Hz and according to the instructions provided in the CVX-300™ Excimer Laser System Operator's Manual.
10. Once the laser catheter is successfully calibrated, fully retract the laser catheter back from the distal tip ramp by depressing both of the release arms located on the handle mechanism (Figure 2 – A Fully Retracted Position).
11. Flush the guidewire port of the catheter with sterile saline.

CAUTION: If the laser catheter tip does not retract off the ramp, after depressing both release arms then pull the proximal disk of the handle to retract the laser catheter. If the laser catheter does not retract, discard the device and open another device. If the device is considered damaged reference the RETURN PRODUCT section of this IFU.

12. Hydrate the outer surface of the Turbo-Tandem System to activate the hydrophilic coating. Either dip the working length of the Laser Guide Catheter in a basin or gently wipe the device with gauze saturated by sterile saline.

13.3 PROCEDURE

1. Use standard femoral puncture technique and insert a 7F introducer sheath (for use with the 7F Turbo-Tandem System) or an 8F introducer sheath (for use with the 8F Turbo-Tandem System) into the common femoral artery in the antegrade or retrograde fashion. Ensure patient is anticoagulated per current hospital interventional protocols.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter per standard technique. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014" guidewire thru the intended treatment site via the introducer sheath or guiding catheter. In the presence of a wire refractory obstruction or occlusion, a Turbo-Elite™ laser catheter may be used to assist recanalization of the target treatment site.
4. Confirm the reference vessel is 5.0mm or greater for the 7F Turbo-Tandem System or 5.5mm or greater for the 8F Turbo-Tandem System prior to using the Turbo-Tandem System.
5. A ≥2mm lumen for the 7F Turbo-Tandem or a ≥ 2.5mm lumen for the 8F Turbo-Tandem should be created with a laser catheter or be angiographically evident in the target treatment segment prior to the use of the Turbo-Tandem System.
6. Advance the distal tip of Turbo-Tandem System over the proximal end of the 0.014" guidewire. Once the guidewire advances through the laser catheter tip, continue advancing the guidewire through the Turbo-Tandem System until it is accessible at the proximal end.
7. Under fluoroscopic control, guide the Turbo-Tandem System to the lesion. Figure 1 shows the various radiopaque markers and their relation to the distal end of the device. Ensure the laser catheter tip is in the retracted position (Figure 2, A) to minimize damage to the catheter during advancement of the system to the lesion.

WARNING: Do not attempt to advance or retract the Turbo-Tandem System against resistance until cause of the resistance has been determined by fluoroscopy or other means. The use may result in deformation or detachment of the distal tip or kinking of the Turbo Tandem System.

WARNING: Do not extend the laser catheter distal tip marker band beyond the orientation marker band of the Turbo-Tandem System. This may result in damage to the device tip.

CAUTION: Confirm the laser catheter is in the retracted state when advancing or retracting the Turbo-Tandem System without lasing.

CAUTION: Do not force or excessively torque the Turbo-Tandem System as this may result in deformation of the distal tip or kinking of the device.

8. Set up a saline infusion pressurized system to the introducer sheath or crossover sheath hub. Saline can not be infused through the Turbo-Tandem System but can reach the ablation field via the introducer sheath or crossover sheath. Flush the system and ensure all lines are flushed and then closed until laser ablation is initiated.
9. Once the tip of the Turbo-Tandem System is located at the lesion, advance the laser catheter on to the distal tip platform by depressing both the proximal and distal disks until the laser catheter is advanced onto the desired location along the tip ramp.
10. Inject contrast media through the introducer sheath or crossover sheath to verify the location of the laser catheter under fluoroscopy.

11. Initiate saline flush via infusion pressurized system and clear the intended laser treatment field of contrast media.

CAUTION: Ensure contrast media has been flushed from the intended treatment vessel prior to activating laser.

12. Under fluoroscopic control, depress the footswitch of the CVX-300™ Excimer Laser System and SLOWLY (less than 1mm per second) advance the Turbo-Tandem System 2-3mm into the stenosis, allowing the laser energy to photoablate the desired material. Continue advancing the Turbo-Tandem System over the guidewire at the same rate, less than 1mm per second through the entire length of the intended treatment site. Adjust torque to the system to maintain tip orientation.

WARNING: Only advance the system under fluoroscopic guidance to confirm location and orientation of the tip. Adjust torque to the system to maintain tip orientation.

13. Release the footswitch to deactivate the CVX-300™ Excimer Laser System. It is generally recommended not to exceed 20 seconds of continuous lasing. Continue lasing at less than 1mm per second in 20 second increments until the obstruction has been crossed or an adequate initial path has been created.

14. Retract the laser catheter from the distal tip platform by depressing both of the release arms located on the handle mechanism and re-position the Turbo-Tandem System back to the proximal edge of the lesion.

CAUTION: If the laser catheter tip does not retract off the ramp after depressing both of the release arms, pull the proximal disk of the handle to retract the laser catheter. If the laser catheter does not retract while in the patient, carefully grasp the distal disk component and slowly pull the proximal disk component away from the distal disk component to detach the handle into two separate parts. Do not move any portion of the system distally as this may cause harm to the vessel. Manually pull the proximal disk component attached to the laser catheter proximal until the laser catheter distal tip is off the ramp and remove both catheters together thru the introducer sheath.

15. From the System handle, rotate the device 60-90° and repeat lasing steps (11-14). Continue to rotate the Turbo-Tandem System and repeat lasing steps to accomplish the desired effect. Always rotate the system in the same direction (clockwise or counter-clockwise) to maintain a reference point for system orientation and alignment. Adjust torque to the system to maintain tip orientation.

WARNING: Only advance the system under fluoroscopic guidance to confirm position of the tip. Adjust torque to the system to maintain tip orientation.

WARNING: Do not extend the laser catheter distal tip marker band beyond the orientation marker band of the Turbo-Tandem device (Figure 3). This may result in damage to the device tip.

WARNING: Do not inject contrast media through the Turbo-Tandem System or guidewire lumen as this may cause the system to lock-up and may lead to further complications.

16. To remove the Turbo-Tandem System, under fluoroscopic guidance, retract the laser catheter by depressing both of the release arms located on the handle mechanism and confirm the laser catheter distal tip is adjacent to the catheter and no longer aligned with the distal tip platform. Figure 1 demonstrates the laser catheter tip in the fully retracted mode.

17. Withdraw the Turbo-Tandem System from the patient while maintaining distal guidewire position.

18. All equipment should be disposed in accordance with hospital biohazardous waste regulations.

13.4 RETURN PRODUCT

In the event that the device is to be returned once opened because of a complaint or any allegation of deficiency with the product's performance, please contact Post Market Surveillance for the procedure to return contaminated products at the following contacts: Phone: +31 33 43 47 050 or +1-888-341-0035 · Email: complaints@spectranetics.com.

14. MANUFACTURER'S LIMITED WARRANTY

Manufacturer warrants that the Turbo-Tandem System 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 Turbo-Tandem System. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the Turbo-Tandem System. Damage to the Turbo-Tandem System 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 Turbo-Tandem System. Information on Manufacturer's warranty relating to the CVX-300™ Excimer Laser System can be found in the documentation relating to that system.

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Spectranetics®

www.spectranetics.com

Manufactured by Spectranetics Corporation
9965 Federal Drive, Colorado Springs, CO 80921 USA
Tel: 1-800-231-0978 · Fax: 719-447-2022

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