Turbo-Power™

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-Power System (Laser Atherectomy Catheter) is a laser atherectomy device designed for use with the CVX-300® Excimer Laser System or the Philips Laser System.

The Turbo-Power Laser Atherectomy Catheter is a sterile, single use, prescription only device used for peripheral atherectomy. Turbo-Power is used exclusively with SPNC's CVX-300® Excimer Laser System or the Philips Laser System. and is a Type CF device Defibrillation proof.

Turbo-Power is a laser atherectomy catheter designed for treatment 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). Turbo-Power is used to ablate infrainguinal concentric and eccentric lesions in vessels that are 3.0mm or greater in diameter.

The device is comprised of three parts: the working length of the catheter shaft (also the applied part), the motor drive unit (MDU), and the proximal laser shaft which connects the catheter fiber optics to the laser system. See Figures 1, 2, 3, and 4. Table 1.1 contains a summary of dimensions and accessory compatibilities for the device.

Figure 1. Turbo-Power Laser Atherectomy Catheter

Figure 2. Turbo-Power User Interface

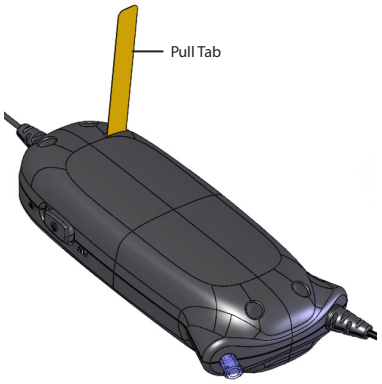


Figure 3. Turbo-Power User Interface

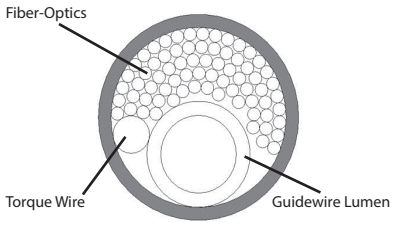


Figure 4. Turbo-Power Distal Tip Cross Section

Table 1.1: Turbo-Power (Model # 420-050 and 423-050) dimensions and compatibilities

Feature	Model #: 420-050	Model #: 423-050
Working length	150cm	125cm
Wire Compatibility	0.018" (0.46mm)	0.018" (0.46mm)
Sheath Compatibility	6F	7F
Laser Catheter	2.0mm Over The Wire	2.3mm Over The Wire

The working length of the Turbo-Power laser catheter is constructed of multiple optical fibers arranged eccentrically around a 0.018" (0.46mm) guidewire-compatible lumen. The guidewire lumen tip is attached to a torque wire which is connected to the MDU at the proximal end of the working length. The MDU allows the user to rotate the torque wire by pressing each of the two rotation buttons individually or simultaneously on the MDU, thereby directing the catheter tip. The position LEDs on the MDU indicate the rotation bias of the proximal end of the torque wire and motor position within the range of allowed rotations in a given direction. The MDU can only be used to rotate the torque wire a limited number of turns in a single direction, indicted by the progression of LEDs. The Home symbol associated with these LEDs indicates when the torque wire is in a neutral state. The device incorporates a micro-processor with software. Software version identification is available to designated individuals with specialized tools and training. The catheter fiber optics are routed through the MDU and into the proximal laser shaft, terminating at the pin-coded coupler, which connects the Turbo-Power device to the laser system. The outer surface of the laser catheter working length is hydrophilic-coated. The distal tip of the catheter contains a radiopaque marker band for in situ visibility.

Mechanism of Action

The multi-fiber laser catheter transmits 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 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.

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 prior to intervention.
Contralateral Approach = Arterial access by a crossover approach.

2. INDICATIONS / INTENDED USE

Turbo-Power 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).

3. CONTRAINDICATIONS

No known contraindications.

4. WARNINGS

- No modification of this equipment is allowed.
- Use of accessories, transducers and cables other than those provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Reciprocal interference: use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Do not use without a guidewire, as vessel injury may result.
- Do not activate laser until all contrast media is flushed from the treatment area.
- Always advance and manipulate the Turbo-Power System under fluoroscopic guidance to confirm the location and orientation of the tip.

- Do not attempt to advance or retract the Turbo-Power System against resistance until the reason for the resistance has been determined by fluoroscopy or other means. This may result in damage to the device and/or lead to complications such as dissections and/or perforations.
- Do not inject contrast media through the Turbo-Power System or guidewire lumen as this could cause the system to lock-up and may lead to complications.
- When used according to the "General Operation", avoid lasing and/or rotating the distal tip over the floppy/spring portion of the guidewire. This may lead to complications such as dissections and/or perforations.
- 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
- This equipment is suitable for use in a professional healthcare facility environment as described in ANSI/AAMI/IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. Use of this equipment outside of this environment could result in improper operation.
- Do not use this device near active high frequency surgical equipment and the Radio Frequency shielded room of a Medical Electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high as this could result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Turbo-Power System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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 femoral) 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. PRECAUTION

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.

- This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and cannot 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 (5 to 95% relative humidity, non-condensing). Protect the device from direct sunlight and high temperatures (storage temperatures 0°C to 60°C). Store device in areas with 11 kPa to 111 kPa atmospheric pressure.
- Device operates at temperatures of 10°C to 40°C in areas with 30 to 75% relative humidity (non-condensing) in areas with atmospheric pressure of 70 kPa to 106 kPa and is rated as a continuous mode operating device.
- Do not use the Turbo-Power System if any damage is observed or the red error indicator light activates.
- Do not use the Turbo-Power System in an oxygen rich environment.
- Do not use the device if its "Use By" located on the package labeling has passed.
- Read the Operator's Manual thoroughly before operating the CVX-300® Excimer Laser System or the Philips Laser System to ensure safe operation of the system.
- The proximal coupler of the laser catheter connects only to the laser system and is not meant to have any patient contact.
- During device calibration, ensure the laser catheter tip is dry. A wet laser catheter tip may prevent successful device calibration.
- During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution's interventional protocols.
- Ensure contrast media has been flushed from the intended vessel and treatment site prior to activating the laser system.
- When infusing through the guidewire lumen, do not exceed an infusion rate greater than 0.5mL/second, or a pressure greater than 131 psi.
- Device rated Type CF defibrillation proof with post defibrillation recovery time of 500 ms. Disconnect catheter from the laser system before defibrillation.
- Device is rated for IPX2 fluid interaction.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- After use, all equipment should be disposed of properly in accordance with specific requirements relating to hospital waste, local regulations, and potentially biohazardous materials.

Table 5.1: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Turbo-Power System is intended for use in the electromagnetic environment specified below. The customer or the user of the Turbo-Power System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1 Class A	The Turbo-Power System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1 Class A	The Turbo-Power System does not connect to AC power supplies.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 5.2: Guidance and Manufacturer's Declaration- Electromagnetic Immunity

The Turbo-Power System is intended for use in the electromagnetic environment specified below. The customer or the user of the Turbo-Power System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment-guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	+ 2 kV, 100kHz for power supply lines +1 kV, 100 kHz for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	0% U_T (100% dip in U_T) for 0,5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	Not applicable	Mains power quality should be that of a typical commercial of hospital environment. If the user of the Turbo-Power System requires continued operation during power mains interruptions, it is recommended that the Turbo-Power System be powered from an uninterruptible power supply or a battery.

The Turbo-Power System is intended for use in the electromagnetic environment specified below. The customer or the user of the Turbo-Power System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment-guidance**
Power Frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the ac mains voltage prior to application of the test level.			

Table 5.3: Guidance and manufacturer's declaration – Electromagnetic Immunity

The Turbo-Power System is intended for use in the electromagnetic environment specified below. The customer or the user of the Turbo-Power System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz 6 V rms ISM Bands between 150 kHz and 80 MHz	3 V rms 150 kHz to 80 MHz 6 V rms 150kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Turbo-Power System including cables, than the recommended 30 cm (12in) separation distance. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m 80 MHZ to 2.7 GHz Telecommunication frequencies as specified in clause 8.10 of IEC 60601-1-2:2014: 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz at 28 V/m 385 MHz at 27 V/m 710, 745, 780, 5240, 5500, 5785 MHz at 9 V/m	3 V/m 28 V/m 27 V/m 9 V/m	

6. 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 listed below. Complications may occur at any time 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.

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-Power 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)
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%)
Procedural Angiographic Core Lab CRF	**Mean ± SD (N) (Min, Median, Max) or n/N (%)**
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 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 %)
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[1]

Freedom from MAE[a]	ELA + PTA	PTA Only	P-value[b]
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[c]	148/159 (93.1%)	58/69 (84.1%)	0.0340

[a] Freedom from any MAE defined as TLR, death or amputation through 37 days post procedure
[b] Chi-square
[c] 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.

Table 7.2.4 Primary Effectiveness Endpoint

Freedom from TLR[a]	ELA + PTA	PTA Only	P-value[b]
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[c]	88/121 (72.7%)	29/52 (55.8%)	0.0288

[a] Freedom from TLR through 212 days post procedure
[b] Chi-square
[c] 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: CELLO Study

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.

[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 7.3.1 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
Prior Coronary Revascularization	26	60.5
Diabetes	26	40.0
Hypertension	57	87.7
Hyperlipidemia	55	84.6
CVA	7	10.8

Table 7.3.2 Lesion Locations

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

Table 7.3.3 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	42.5	13.2
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 7.2.5 presents adverse events that occurred during the procedure through hospital discharge.

Table 7.3.4 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 7.3.5 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 stenosis 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.

8. INDIVIDUALIZATION OF TREATMENT

The risks and benefits described above should be carefully considered for each patient before using the Turbo-Power System.

Although it is recommended that the guidewire fully cross the target lesion, use of the Turbo-Power device may also 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.

9. HOW SUPPLIED

9.1 Sterilization

The Turbo-Power System is supplied sterile by the ethylene oxide sterilization process in a single sterile barrier consisting of tray and lid inside 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.

9.2 Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken. The Turbo-Power 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.

10. 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.

Some or all of the following additional materials, which are not included in the laser catheter package, may be required for the procedure

- 0.018" guide wires greater than 220cm in length
- 6F introducer sheaths (compatibility with Model # 420-050)
- 7F introducer sheaths (compatibility with Model # 423-050)
- 6F crossover sheaths (compatibility with Model # 420-050) (Crossover sheaths with metallic banded designs are NOT recommended.)
- 7F crossover sheaths (compatibility with Model # 423-050) (Crossover sheaths with metallic banded designs are NOT recommended.)
- Control syringe filled with sterile saline
- Pressurized infusion setup with sterile saline

11. DIRECTIONS FOR USE

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.

Following the formal training session, Spectranetics will make additional training available if requested by the physician, support personnel, the institution, or Spectranetics.

11.1 Device Preparation

1. Using sterile technique, carefully remove the Turbo-Power System from sterile packaging. Remove the packaging lid from the packaging tray. Remove the packaging wedges from the tray. Lift the proximal coupler located in the tray, and hand it outside the sterile field to be inserted into the laser system.

CAUTION: The proximal coupler of the laser catheter connects only to the laser system by means of a length of tail tubing, and is not intended to have any patient contact.

2. Insert the proximal coupler of the laser catheter into the laser system and position a loop of the laser catheter tail tubing into the laser system extension pole or catheter retainer.
3. Maintaining sterile technique, grasp the MDU from the middle of the packaging tray and remove the rest of the catheter system.
4. Prior to using the Turbo-Power 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-Power System if any damage is observed. If the device is considered damaged; reference RETURN PRODUCT section of this IFU.

5. Prior to calibration, ensure that the laser catheter distal tip is dry. A wet laser catheter tip may prevent successful device calibration.
6. Calibrate the laser catheter according to the instructions provided in the CVX-300® Excimer Laser System Operator's Manual or the Philips Laser System Operator's Manual.

NOTE: The Turbo-Power 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 with software version V3.812 or higher and for the Philips Laser System with software version 1.0 (b5.0.3) or higher.

NOTE: For CVX-300® Laser System software versions V3.712 or lower, the maximum repetition rate is 40 Hz for the Turbo-Power System. Consult your CVX-300® Laser System to determine its operational version of software.

7. Remove the battery pull-tab from under the MDU and activate MDU power. Ensure the green power indicator light activates. Press "<" rotation button and confirm tip rotation functionality. Press ">" rotation button and confirm tip rotation functionality. Press "<" and ">" rotation buttons simultaneously and confirm tip rotation functionality.

NOTE: If at any point in the procedure the error light on the MDU activates, discontinue use of the device.

8. Flush the catheter guidewire lumen via the flush port located on the side of the MDU with sterile saline to ensure lumen patency.
9. Hydrate the outer surface of the Turbo-Power System to activate the hydrophilic coating by immersing the working length of the laser catheter in a basin or by gently wiping the device with gauze saturated with sterile saline.

CAUTION: Do not dip or submerge the Motor Drive Unit.

11.2 General Operation

1. Use standard femoral puncture technique and insert a 6F or 7F introducer sheath 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 and advance a 0.018" guidewire through the treatment site via the introducer sheath or guiding catheter. In the presence of a wire refractory obstruction or occlusion, refer to the Step-by-Step Method for a Total Occlusion below.
4. Confirm the reference vessel diameter is 3.0mm or greater prior to using the 6F Turbo-Power System. Confirm the reference vessel diameter is 3.5mm or greater prior to using the 7F Turbo-Power System.
5. Advance the distal tip of Turbo-Power System over the proximal end of the 0.018" guidewire by threading the guidewire through the eccentric lumen. After the guidewire is advanced through the laser catheter tip, continue advancing the guidewire through the Turbo-Power System until it is accessible at the MDU's proximal end.
6. Under fluoroscopic control, guide the Turbo-Power System to the lesion.

WARNING: Do not attempt to advance or retract the Turbo-Power System against resistance until cause of the resistance has been determined by fluoroscopy or other means. This may result in damage to the device and/or lead to complications such as dissections and/or perforations.

CAUTION: Do not force or excessively torque the Turbo-Power System as this may result in deformation of the distal tip or kinking of the device or result in damage to the device and/or lead to complications.

7. Set up a saline infusion pressurized system according to the Saline Infusion Protocol below.
8. Inject contrast media through the introducer sheath or crossover sheath to verify the location of the laser catheter under fluoroscopy.
9. 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 according to the Saline Infusion Protocol below prior to activating laser.

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

10. Under fluoroscopic guidance, depress the footswitch of the laser system and SLOWLY (less than 1mm per second) advance the Turbo-Power System into the stenosis, allowing the laser energy to photoablate the desired material.

NOTE: Turbo-Power System rotate buttons may be used during the procedure to accomplish the following:

   a. Orient the distal tip prior to lasing (Step 11)
   b. Momentarily rotate the distal tip or continuously rotate the distal tip while lasing and advancing the catheter (Step 12)

11. If orientation of the distal tip is deemed necessary prior to advancement of the Turbo-Power System, press ">" rotate button to rotate the distal tip clockwise and "<" rotate button to rotate the distal tip counter-clockwise until desired orientation is achieved.

NOTE: The MDU allows a maximum of 6 consecutive rotations in each direction from home position as indicated by the LEDs. Following 6 consecutive rotations in one direction rotate the distal tip in the other direction 6 consecutive times to bring tip position to the center.

12. If momentary or continuous rotation is deemed necessary while advancing the Turbo-Power System, press ">" and/or "<" rotate button to momentarily rotate the distal tip clockwise and/or counterclockwise respectively, or press both buttons simultaneously to continuously rotate the distal tip.

NOTE: During continuous rotation, the distal tip changes direction from clockwise to counter-clockwise when it reaches the guardrail at either end. The direction of distal tip movement is indicated by the LEDs.

13. Continue lasing while advancing the Turbo-Power over the guidewire at less than 1mm per second in 20 second increments until the obstruction has been crossed or an adequate channel has been created. Continue general operation.
14. Release the footswitch to deactivate the laser system. NOTE: 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.

NOTE: 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.

15. Retract the catheter to the proximal cap of the lesion.
16. Additional passes may be completed by repeating steps 10-14 for maximum debulking with or without distal tip rotation.

NOTE: If at any point in the procedure the error light activates, discontinue use of the device

17. Withdraw the Turbo-Power System from the patient while maintaining distal guidewire position.
18. Following laser recanalization, perform follow-up angiography and balloon angioplasty, if needed.
19. All equipment should be disposed in accordance with hospital biohazard waste and local authority regulations.

Step-by-Step Method for Total Occlusion

a. Depress the footswitch, activating the laser system, and slowly, less than 1mm per second, advance the laser catheter 2-3 mm into the total occlusion without distal tip rotation, 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 according to steps 10-14 above with or without distal tip rotation.
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 adjusted in order to advance.

CAUTION: To avoid the potential of heat build-up, the catheter must be advanced while lasing.

Saline Infusion Protocol

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 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.
d. 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.
e. If using a control syringe, expel any residual contrast back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline through the manifold.
f. Remove the original control syringe from the manifold and replace it with a fresh luer-lock control syringe. This new control syringe should be primed with saline prior to connection to reduce the chance for introducing air bubbles.
g. 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.
h. 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. 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 at a rate of 2-3 mL/second through the sheath and/or at a rate no greater than 0.5 mL/second through the guidewire lumen. 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 maintain a rate of injection of 2-3 mL/second through the sheath. In addition, saline can be injected through the guidewire lumen at a rate no greater than 0.5mL/second, or a pressure no greater than 131 psi. 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 initiates this saline infusion, 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.
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.

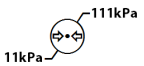
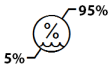
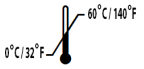
11.3 Return Product

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.

12. MANUFACTURER'S LIMITED WARRANTY

Manufacturer warrants that the Turbo-Power 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-Power System. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the Turbo-Power System. Damage to the Turbo-Power 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-Power System. 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.

13. SYMBOLS

Consult Instructions for Use (IFU)		Sterilized Using Ethylene Oxide	
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.			
Single Use		Use By Date	
Catalog Number		Lot Number	
Do not use if package is damaged		Atmospheric Pressure Limitation	
Humidity Limitation		Temperature Limit	
Keep Dry		Non-Pyrogenic	
Working Length		Guidewire Compatibility	
Max Shaft Diameter		Sheath Compatibility	
Max Tip Diameter		MDU Power On Status	
MDU Error Status	 (triangle has yellow background)	Jog- Directional Selection of Proximal Rotation	< >
Home- Location of Proximal end of catheter		Defibrillation-Proof Type CF Applied Part	
European Authorized Representative	EC REP	Manufacturer	
Interference may occur in the vicinity of other equipment marked with the following symbol		CE Mark	CE
Protected against vertically falling water drops when enclosure tilted up to 15°			IPX2

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