



Instructions for Use

Spectranetics[®]

Spectranetics

**Turbo-Tandem**[®]
Laser Guide Catheter with Laser Atherectomy Catheter

Instructions for Use

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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 5mm or greater at or above the knee. The Turbo-Tandem[®] System is not designed to be used in total or sub-total occlusions. A ≥ 2 mm pilot channel 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.

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 7F sheath compatible with a maximum crossing profile of 0.160" (4.0mm) with the laser catheter extended or offset position. The incorporated laser catheter 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.

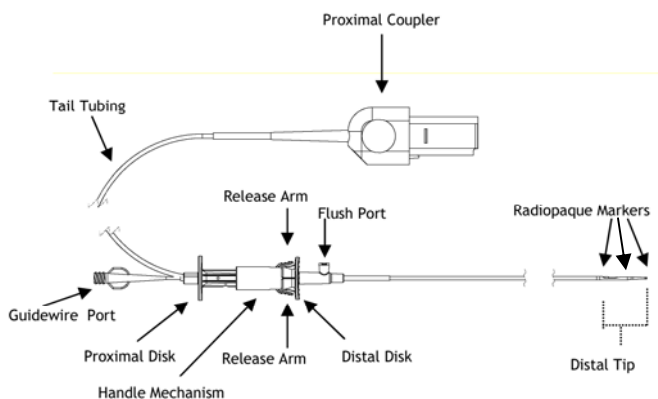


Figure 1. Turbo-Tandem® Laser Guide Catheter with Laser Atherectomy Catheter

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.

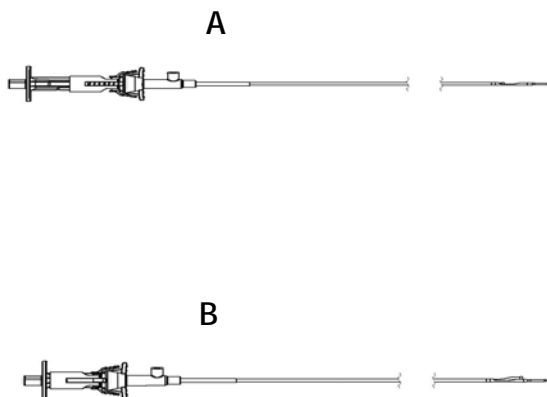


Figure 2. The Turbo-Tandem® System in the Retracted (A) and Extended (B) Positions

Table 1 Turbo-Tandem® Laser Guide Catheter with Laser Atherectomy Catheter Specifications

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

INDICATIONS / INTENDED USE

Indicated for atherectomy of infrainguinal arteries.

CONTRAINDICATIONS

No known contraindications.

RESTRICTIONS

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

WARNINGS

- Do not use without a guidewire, as vessel injury may result.
- Always 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 laser catheter against resistance until the reason for the resistance has been determined by fluoroscopy or other means. Confirm the laser catheter is in the retracted state when advancing or retracting the Turbo-Tandem® System without lasing.
- 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.

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.
- Do not resterilize or reuse this device, as this 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.
- The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised.
- Do not use the device if its "Use By" located on the package labeling has passed.
- 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.
- Advancement, manipulation, withdrawal of the Turbo-Tandem® System, and, advancement, re-positioning or retraction of the laser catheter should always be performed under fluoroscopic guidance.
- 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.
- Always use fluoroscopic guidance when advancing, re-positioning, or retracting the Turbo-Tandem® System.
- Do not force or excessively torque the Turbo-Tandem® Laser Guide Catheter as this may result in deformation or detachment of the distal tip or kinking of the catheter.
- Ensure contrast media has been flushed from the intended vessel and treatment site prior to activating the laser system.

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.

CLINICAL STUDIES

Study Summary: Data presented in this IFU were collected in support of safety and efficacy 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.

Efficacy: The primary efficacy 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 efficacy 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 2 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 3 Lesion Locations

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

Table 4 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 5 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 6 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 efficacy 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.

INDIVIDUALIZATION OF TREATMENT

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

HOW SUPPLIED

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 one-time use; 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. 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.

DIRECTIONS FOR USE

MATERIALS REQUIRED FOR USE

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

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.
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.
CAUTION: A slight curvature in the catheter is normal due to packaging and will not impact device performance or safety.
5. Prior to calibration, flush the catheter shaft via the handle flush port located on the handle mechanism with sterile saline.
6. Once the flush port, located on the handle mechanism, has been flushed with sterile saline the flush port should be capped with either a sterile one way stopcock turned to the off position or a sterile cap 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).
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.
11. Flush the guidewire port of the catheter with sterile saline.
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.

PROCEDURE

1. Use standard femoral puncture technique and insert a 7 F introducer sheath into the common femoral artery in 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 5mm or greater prior to using the Turbo-Tandem® System.
5. 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.
6. 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 to minimize damage to the catheter during advancement of the system to the lesion.

WARNING: Do not attempt to advance or retract the laser catheter against resistance until cause of the resistance has been determined by fluoroscopy or other means. Confirm the laser catheter is in the retracted state when advancing or retracting the Turbo-Tandem® System without lasing.

CAUTION: Always use fluoroscopic guidance when advancing, re-positioning, or retracting the Turbo-Tandem® System.

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.

7. 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.
8. 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.
9. Inject contrast media through the introducer sheath or crossover sheath to verify the location of the laser catheter under fluoroscopy.
10. 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.
11. 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.
WARNING: Always advance the system under fluoroscopic guidance to confirm location and orientation of the tip. Adjust torque to the system to maintain tip orientation.
12. 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.
13. 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.
14. 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.
WARNING: Always advance the system under fluoroscopic guidance to confirm position of the tip. Adjust torque to the system to maintain tip orientation.
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.
CAUTION: Do not force or excessively torque the Turbo-Tandem® System if constrained within the lesion as this may result in deformation of the distal tip or kinking of the catheter.
15. 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.
16. Withdraw the Turbo-Tandem® System from the patient while maintaining distal guidewire position.
17. All equipment should be disposed in accordance with hospital biohazardous waste regulations.

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.

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.

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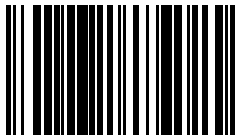
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P003394

Manufactured under one or more of the following patents:

5315614, 5456680, 5429604, 5267993, 5470330,
5321783, 5415653, 5250045, 5429617, 5484433,
5263952, 5414075, 5637460, 6077698, 6278018B1,
6603040B1, 6706408B2, EP566873,
JP3732529, JP3745757, JP3412855

And other patents pending.

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