Turbo-Booster™

Laser Guide Catheter

Instructions for Use

Spectranetics®

Table of Contents

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

1. Description

The Turbo-Booster is a guiding catheter designed to be used exclusively with Spectranetics laser catheters (as specified in Table 2). The Turbo-Booster is used to offset the distal end of the laser catheter from the central plane of the vessel lumen allowing for circumferential guidance and positioning of the laser catheter within the vessel.

Turbo-Booster guiding catheters are available in both 7Fr and 8Fr sheath models and are compatible with Spectranetics laser catheters (Table 2). The Turbo-Booster is comprised of a luer hub, strain relief, braided shaft with hydrophilic coating and a biasing tip that is compatible with 0.014" guide wires.

During use, the laser catheter is passed through the lumen of the Turbo-Booster and the distal tip is advanced onto the ramp of the biasing tip, which offsets the laser catheter. The hydrophilic coated shaft allows for navigation and torque of the Turbo-Booster through the vasculature. The braided shaft transfers torque placed on the proximal end of the Turbo-Booster to the distal tip resulting in rotation of the combined Turbo-Booster and Spectranetics laser catheter around the guide wire axis (Figure 1).

Offsetting the distal end of the laser catheter and providing torque capability allows for the laser catheter to be directed to the desired plane within the vessel.

Figure 1: Rotation of Turbo-Booster system around guide wire axis

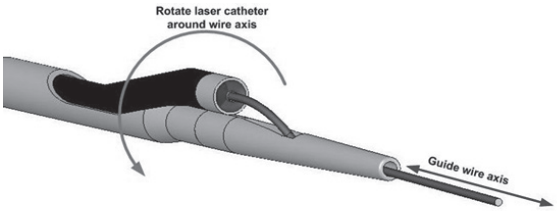


Figure 2: The Turbo-Booster

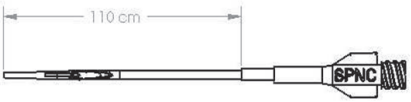


Table 1: Turbo-Booster guiding catheter specifications

Catalog #	518-043	518-063
Min sheath size	7Fr	8Fr
Max guide wire	0.014"	0.014"
Working length	110cm	110cm
Max OD	0.094" (2.39mm)	0.105" (2.67mm)
Min ID	0.072" (1.83mm)	0.082" (2.08mm)

Table 2: Laser catheter compatibility and minimum vessel size

Laser catheter (Model Number)	Turbo-Booster	
	518-043 (7Fr)	518-063 (8Fr)
1.4 Turbo elite (414-151) and	≥ 3.5 mm	≥ 4.0 mm
1.7 Turbo elite (417-152) and	≥ 4.0 mm	≥ 4.5 mm
2.0 Turbo elite (420-006) and	N/A	≥ 5.0 mm

Note: The vessel size recommendation in Table 2 is the minimum vessel diameter that should be treated with the Turbo-Booster and the listed laser catheter.

2. Indications for Use

The Spectranetics Turbo-Booster guiding catheter is designed for directing and supporting Spectranetics laser catheters for use in the treatment of infrainguinal stenoses and occlusions.

Not for use in the carotid and coronary vasculature.

3. Contraindications

No known contraindications.

4. Warnings

The Turbo-Booster is designed for use by physicians trained in the practice of peripheral vascular interventions. Use of this device should be restricted to those specialists trained to perform the procedure. A thorough understanding of the technical principles, clinical applications, and risks associated with percutaneous peripheral interventions is necessary before performing this procedure.

5. Precautions

This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and must not be re-sterilized and/or reused.

DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.

Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

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 Before Date," found on 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).

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

After use, all equipment should be disposed of properly in accordance with specific requirements relating to hospital waste, and potentially biohazardous materials.

Advancement, manipulation, and withdrawal of the Turbo-Booster should always be performed under fluoroscopic guidance.

6. Adverse Events

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 the following:

- Perforation of the vessel wall
- Distal embolization
- Hematoma at the puncture site
- Infection

7. 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 16 training cases and 45 analysis patients at 16 sites.

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 (34 percent in training cohort) 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 97.8 and 100.0 percent of patients as visually assessed by physician in the enrolled and training cohort, respectively.

Table 3: Lesion Locations

Location of vascular lesions	Training (n=16)	Analysis (n=45)	Total (n=61)
SFA	13	43	56
Popliteal	3	2	5

Table 4: Procedure Information

Angiographic Results	Training (n=16)	Analysis (n=45)	Total (n=61)
Reference vessel diameter (mm)	5.19	4.79	4.89
Average lesion length (mm)	72.08	50.89	56.45
Percent diameter stenosis – Pre	78.3	77.3	77.6
Percent diameter stenosis – After Turbo-Booster use	44.0	42.4	42.8
Percent diameter stenosis - Final	25.6	20.9	22.1

NOTE: All values based on angiographic core laboratory analysis

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. Additionally, there were no Serious Adverse Events or Unanticipated Adverse Device Effects.

Table 5: Complications possibly related to the Turbo-Booster

Procedural Complications	Training (n=16)	Analysis (n=45)	Total (n=61)
Major dissection (Grade E or F)	0	0	0 (0%)
Distal embolization	1	2	3 (5%)
Other (Discomfort in treated leg post-procedure)	0	3	3 (5%)

8. Individualization of Treatment

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

9. How Supplied

9.1. Sterilization

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

The Spectranetics Turbo-Booster guiding catheter is supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

9.2. Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken. The Turbo-Booster should be carefully examined for defects (i.e. bends, kinks or other damage). Do not use if device is damaged.

10. Compatibility

The Spectranetics Turbo-Booster guiding catheter is designed and intended to be used exclusively in combination with Spectranetics laser catheters. Please refer to Table 2 for laser catheter compatibility information.

11. Directions for Use

11.1. Parts and Materials

The following parts and materials are required to use the Turbo-Booster guiding catheter.

- 0.014" guide wires that are 300 cm in length
- 7 or 8 Fr introducer sheaths
- 7 or 8 Fr crossover sheaths
- 1.4, 1.7 or 2.0 mm Spectranetics laser catheters
- Rotating hemostatic valves
- 20cc control syringe
- Stopcocks and infusion connecting lines
- NaCl or Lactated Ringer's solution
- Pressurized infusion setup (capable to at least 300 mmHg)

Note: Crossover sheaths that incorporate metallic banded designs are NOT recommended.

11.2. Set Up

11.2.1. Carefully remove the Turbo-Booster guiding catheter from the product box and pouch. Inspect device for any signs of damage. Any devices with visible damage (i.e. kinks) should not be used.

11.2.2. Attach a rotating hemostatic valve (RHV) to the proximal hub on the Turbo-Booster and flush the lumen with saline.

11.3. Pilot Channel

11.3.1. Create a pilot channel (per laser catheter IFU) through the lesion using the largest compatible laser catheter for the specific Turbo-Booster guiding catheter to be used (Table 2).

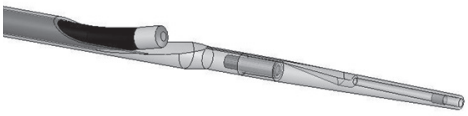
11.3.2. Remove the laser catheter from the patient. Flush and wipe down the outer surface of the laser catheter with saline.

11.3.3. Flush the vessel through the crossover sheath with saline to remove any contrast in the vessel.

11.4. Use of Turbo-Booster

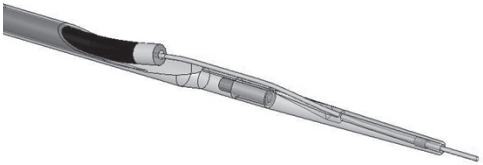
11.4.1. Insert the appropriate (Table 2) laser catheter through the Turbo-Booster until the tip of the laser catheter extends through the opening of the window and half-way up the ramp. (Figure 3).

Figure 3: Laser catheter extended onto ramp



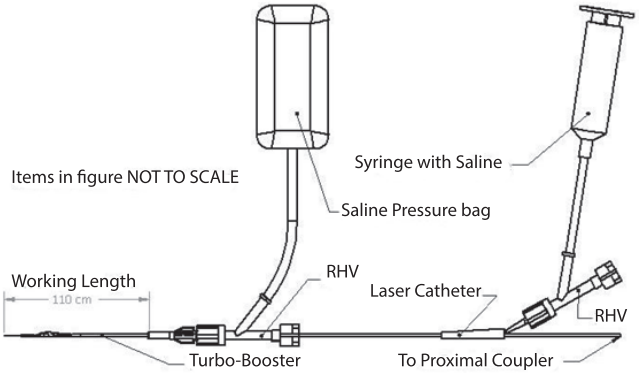
11.4.2. Backload the guide wire through the Turbo-Booster and the laser catheter (Figure 4).

Figure 4: Guide wire loaded through Turbo-Booster tip and laser catheter



11.4.3. Connect a pressurized saline bag to the Turbo-Booster RHV and pressurize the saline bag to at least 300 mmHg. Open the flush line and verify that saline is being flushed through the Turbo-Booster lumen. Close the flush line (Figure 5).

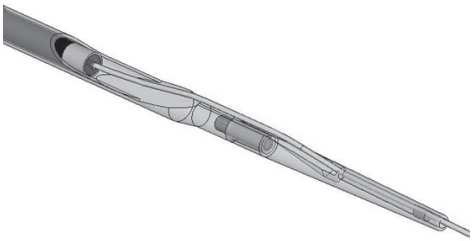
Figure 5: Saline infusion setup



11.4.4. Connect a 10 - 20cc control syringe filled with saline to the laser catheter RHV and manually flush saline through the laser catheter. Verify that saline is being flushed through the laser catheter lumen.

11.4.5. Retract the distal tip of the laser catheter 1.5cm off the ramp and into the Turbo-Booster shaft (Figure 6). Tighten the RHV to lock the system in place. Ensure that the Spectranetics laser catheter is not protruding above the sheath profile onto the ramp.

Figure 6: Turbo-Booster and laser catheter in position for advancing through cross over sheath

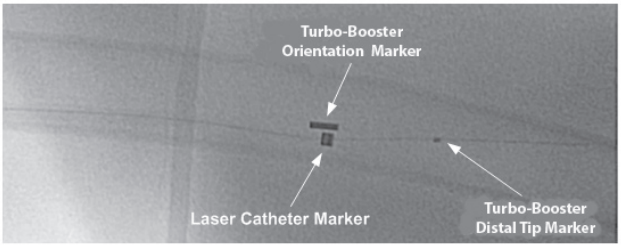


11.4.6. Wet the outer surface of the Turbo-Booster with saline to activate the hydrophilic coating. Advance the system through the compatible crossover sheath (8Fr sheath for 8Fr Turbo-Booster or 7Fr sheath for 7Fr Turbo-Booster) to the proximal edge of the lesion to be treated.

Note: Always use fluoroscopic guidance when advancing or re-positioning the Turbo-Booster.

11.4.7. Loosen the RHV on the Turbo-Booster and position the laser catheter tip over the Turbo-Booster orientation marker as shown in Figure 7. Once the laser catheter is positioned above the orientation marker, tighten the RHV on the Turbo-Booster to lock the laser catheter in position.

Figure 7: Fluoroscopic image of laser catheter in offset position on Turbo-Booster



Note: Do not over tighten the RHV on the Turbo-Booster as this may restrict the ability to infuse through the laser catheter.

11.4.8. Establish an index position (laser catheter medial or lateral to Turbo-Booster orientation marker). Always rotate the system in the same direction (clockwise or counter-clockwise) to maintain a reference for system orientation and alignment. (Figures 8 and 9).

Figure 8: Laser catheter aligned medial to Turbo-Booster

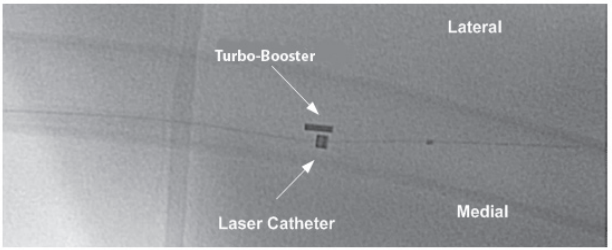


Figure 9: Illustration of Turbo-Booster and the laser catheter as shown in fluoro image (Figure 8)

Note: Rotating the proximal end of the Turbo-Booster in a clockwise direction will rotate the laser catheter around the guide wire axis in the same clockwise direction.

11.4.9. Orient the laser catheter in the desired starting position by rotating the Turbo-Booster.

11.4.10. Begin flushing saline through both the laser catheter and Turbo-Booster.

Caution: Ensure that all contrast has been flushed from vessel prior to activating laser.

11.4.11. Activate the laser and advance the system through the lesion. Refer to the laser catheter IFU for instructions on how to use the laser catheter.

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

11.4.12. Once a pass has been made through the entire length of the lesion, retract the system to the proximal edge of the lesion.

11.4.13. Evaluate the vessel characteristics using angiography. Prior to angiography, loosen the RHV and retract the laser catheter off the Turbo-Booster ramp and into the shaft to minimize the system profile. If additional passes are required, loosen the RHV on the Turbo-Booster and position the laser catheter tip over the Turbo-Booster orientation marker as shown in Figures 7 and 8. Rotate the system to direct the laser catheter to the desired plane and repeat steps 10.4.10 through 10.4.12.

Caution: Never inject contrast through the laser catheter guide wire lumen or Turbo-Booster lumen as this may cause the system to lock-up and may lead to further complications.

Caution: Avoid torquing the device when the tip of the system is constrained within the lesion. If constrained, retract the system such that the tip of the system is proximal to the lesion. Confirm that the tip rotates in correspondence with shaft rotation under fluoroscopic guidance. If the tip of the device does not rotate, stop torquing the shaft. Do not attempt to rotate the shaft more than 360° in either direction if the tip does not also rotate. This could result in both shaft and tip damage.

11.4.14. To remove the Turbo-Booster, loosen the RHV and withdraw the laser catheter 1.5cm off the ramp and into the shaft of the Turbo-Booster (Figure 6).

11.4.15. Withdraw the Turbo-Booster and laser catheter as a system from the patient maintaining guide wire position.

11.5. Disposal

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

12. Manufacturer's Limited Warranty

Manufacturer warrants that the Turbo-Booster is free from defects in material and workmanship when used by the stated "Use By" date and when package is unopened and undamaged immediately before use. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective Turbo-Booster. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the Turbo-Booster. Damage to the Turbo-Booster caused by misuse, alteration, improper storage or handling, or any other failure to follow these Instructions for Use will void this limited warranty. **THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** No person or entity, including any authorized representative or reseller of Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against Manufacturer.

This Page Intentionally Left Blank

This Page Intentionally Left Blank

This Page Intentionally Left Blank

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

P004778