



Turbo Elite[®]
Laser Ablation Catheter

Instructions for Use

Spectranetics[®]

Spectranetics
Turbo Elite[®]
 Laser Ablation Catheter

Over-The-Wire (OTW) and Rapid Exchange (RX) Catheter Models

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Mechanism of Action for TURBO elite[®] Catheters

The multifiber laser catheters transmit 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 fibrous, calcific, and atheromatous lesions, thus recanalizing diseased vessels (photoablation is the process by which energy photons cause molecular bond disruption at the cellular level without thermal damage to surrounding tissue). The Spectranetics laser catheters have a proprietary lubricious coating to ease their trackability through arteries.

Glossary of Special Terms

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

1. Description

Spectranetics TURBO elite[®] excimer laser catheters are percutaneous intravascular devices constructed of multiple optical fibers arranged around a guidewire lumen.

For TURBO elite[®] Over-The-Wire (OTW) catheters, a luer adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the appropriate sized guidewire (0.014" and 0.018"); see inset below.

For TURBO elite[®], Rapid Exchange (RX) catheters, the guidewire lumen is formed only through the last 9 cm of the distal tip, which has direct patient contact, and is concentric with the fiber array; see inset below.

2. Indications for Use

For use in the treatment of infrainguinal stenoses and occlusions.

Note: Successful step-by-step passage of guidewires does not necessarily ensure relief of critical limb ischemia. Additional procedures may be required.

3. Contraindications

- No known contraindications.

Figure 1: TURBO elite™ (OTW)

Figure 2: TURBO elite™ (RX)

Table 1.1 TURBO elite™ Excimer Laser Catheter Models

Device Description	Model Number	Max. Guidewire Compatibility (in.)	Max. Tip Outside Diameter (in.)	Max. Shaft Diameter (in.)	Working Length (cm)	Sheath Compatibility (Fr.)
<i>Over-The-Wire (OTW) Catheter Specifications</i>						
0.9 mm X80	410-152	0.014	0.038	0.047	150	4
1.4 mm	414-151	0.014	0.055	0.056	150	5
1.7 mm	417-152	0.018	0.068	0.069	150	5
2.0 mm	420-006	0.018	0.080	0.081	150	6
2.3 mm	423-001	0.018	0.091	0.091	120	7
2.5 mm	425-011	0.018	0.101	0.102	110	8

Table 1.2 TURBO elite™ Excimer Laser Catheter Models

Device Description	Model Number	Max. Guidewire Compatibility (in.)	Max. Tip Outside Diameter (in.)	Max. Shaft Diameter (in.)	Working Length (cm)	Sheath Compatibility (Fr.)
<i>Rapid Exchange (RX) Catheter Specifications</i>						
0.9 mm X80	410-154	0.014	0.038	0.049	150	4
1.4 mm	414-159	0.014	0.057	0.062	150	5
1.7 mm	417-156	0.014	0.069	0.072	150	6
2.0 mm	420-159	0.014	0.080	0.084	150	7

4. Warnings

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

Spectranetics' TURBO elite™ excimer laser catheters CVX-300® Excimer Laser System software requirements:

<u>Software</u>	<u>Catheter Maximum Rep Rate</u>
V3.812	80 Hz
V3.712	40 Hz

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

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 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 CVX-300® Excimer Laser System.
5. Hands on training with the CVX-300® Excimer Laser System and appropriate model.
6. A fully trained Spectranetics representative will be present to assist for a minimum of the first three cases.
7. Following the formal training session, Spectranetics will make available additional training if so requested by the physician, support personnel, the institution or Spectranetics.

5. Precautions

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

DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing. Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

Store in a cool, dry place. Protect from direct sunlight and high temperatures (*greater than 60°C or 140°F*).

The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised. Do not use catheter product if its "Use Before Date," found on package labeling, has passed.

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

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially biohazardous materials.

Read the Operator's Manual (7030-0035 or 7030-0068) thoroughly before operating the CVX-300® Excimer Laser System. Pay particular attention to the Warnings and Responsibility section of the manual which explains Notes, Cautions, and Warnings to be followed to ensure safe operation of the system.

During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution's PTA protocol.

6. Adverse Events

Use of the Spectranetics CVX-300® Excimer Laser System may contribute to the following complications:

Events Observed during Clinical Studies (see Section 7)

<u>Procedural Complications</u>	<u>Serious Adverse Events</u>
<ul style="list-style-type: none">• Spasm• Major dissection• Thrombus• Distal embolization• Perforation• Other	<ul style="list-style-type: none">• Death• Reintervention• ALI• Major amputation• Bypass surgery• Hematoma with surgery
<u>In-Hospital Complications</u>	
<ul style="list-style-type: none">• Re-occlusion• Pseudoaneurysm	<ul style="list-style-type: none">• Renal failure• Bleeding

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

- | | |
|--|---|
| <ul style="list-style-type: none">• Nerve injury• AV fistula formation• Endarterectomy• Infection | <ul style="list-style-type: none">• Stroke• Myocardial infarction• Arrhythmia |
|--|---|

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

7. Clinical Studies

Data presented in this IFU are comprised of a subset of patients pooled from three sources of consecutively treated patients presenting with Critical Limb Ischemia (CLI), who were poor surgical candidates:

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

in which the step-by-step laser recanalization technique was utilized.

Table 7.1 Procedure Information

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

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

*Crossing Success data has been stratified for step-by-step cases after conventional guidewire attempts in 24 limbs, and ab initio in 13 limbs.

**Procedure success: ≤50% final residual stenosis

Table 7.2 Complications, n=47 limbs

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

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

Table 7.3 Cumulative Serious Adverse Events (SAEs) through 6-month follow-up, for n=47 limbs

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

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

MI = Myocardial Infarction. ALI = Acute Limb Ischemia.

Table 7.4 Outcomes by Intention-to-Treat Analysis, n=47

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

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

8. Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the TURBO elite™ device.

Use of CLiRpath® devices may be considered after initial conventional crossing attempts with guidewires are unsuccessful due to:

- A rounded or eccentric occlusion stump deflecting the guidewire to a subintimal passage.

- The guidewire repeatedly being deflected into a large collateral branch flush with the occlusion stump.
- Calcification obstructing completion of guidewire passage within the obstructed lumen.

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

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

9. Operator's Manual

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

Table 9.1 Energy Parameters

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

Recommended calibration settings: 45 Fluence, 25 Hz.

- * 80 Hz maximum repetition rate is for software V3.812. For software V3.712, the maximum repetition rate is 40 Hz.

10. How Supplied

10.1 Sterilization

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

The Spectranetics laser catheters are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

10.2 Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken. All equipment to be used for the procedure, including the catheter, should be examined carefully for defects. Examine the laser catheter for bends, kinks or other damage. Do not use if it is damaged.

10.3 Procedure Set-Up

Some or all of the following additional materials, which are not included in the laser catheter package, may be required for the procedure (these are single use items only—do not resterilize or reuse):

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

10.4 Compatibility

The Spectranetics excimer laser catheter is designed and intended to be used exclusively with the Spectranetics CVX-300® Excimer Laser System.

Do not use in combination with any other laser system.

Guidewire Compatibility

See Catheter Specification Table in Section 1.

11. Directions for Use

Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the laser catheter from the tray while supporting the black laser connector, also known as the proximal end, proximal coupler, or proximal connector. Please note that the proximal end of the laser catheter connects only to the CVX-300® Excimer Laser System, and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the CVX-300® Excimer Laser System and position the laser catheter in the laser system extension pole. Calibrate the laser catheter following the instructions provided in the CVX-300® Excimer Laser System Operator's Manual (7030-0035 or 7030-0068).

1. Use standard femoral puncture technique to insert a 5 Fr. to 9 Fr. (depending on the largest interventional device to be used during treatment) introducer sheath into the common femoral artery in antegrade or retrograde fashion for contralateral approaches. Heparinize intravenously using the PTA protocol for heparinization.
2. Perform baseline angiography by injecting contrast medium through the introducer sheath or guiding catheter. Obtain images in multiple projections, delineating anatomical variations and morphology of the lesion(s) to be treated.
3. Introduce a 0.014" or 0.018" guidewire to the peripheral occlusion via the introducer sheath or guiding catheter.
4. Size and choose the laser catheter appropriately:

Table 11.1 Recommended Sizing

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

5. Hydrate the outer jacket of the catheter to activate the hydrophilic coating. Either dip the catheter in a basin or wipe with wet gauze using an appropriate sterile solution.
6. Flush the guidewire lumen of the laser catheter using 5-10 ccs of heparinized saline or Lactated Ringer's solution.
7. Introduce the distal tip of The Spectranetics laser catheter over the selected guidewire. Under fluoroscopic control, guide the laser catheter to the lesion. The laser catheter's radiopaque band marker indicates its position relative to the lesion.

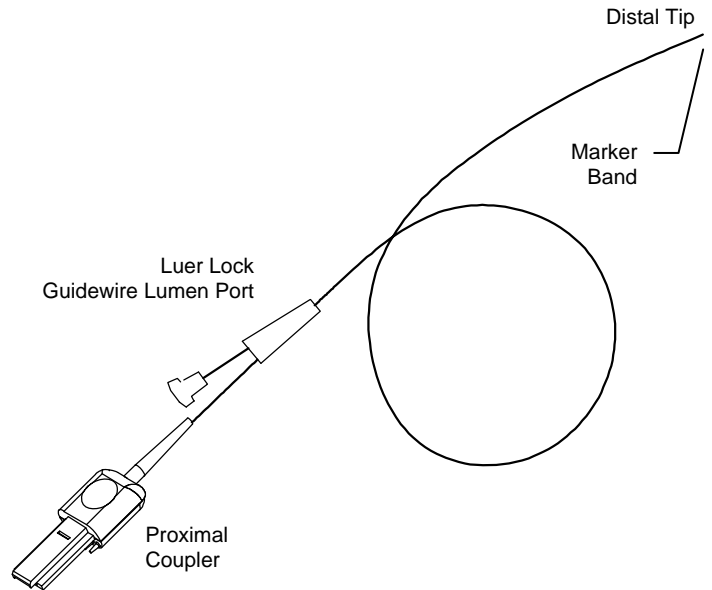


Figure 3 (not to scale)

Note

During use within the body, similar to any device used for vascular intervention, always monitor laser catheter movement and the radiopaque tip marker position with fluoroscopy. The movement and rate of advancement of the catheter distal tip should correspond directly with the rate of advancement being applied to the proximal shaft of the catheter.

If corresponding movement is not apparent, reassess the lesion morphology, the laser energy being applied and the status of support equipment prior to continued treatment.

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

8. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
9. Following confirmation that the laser catheter's position is in contact with the target lesion, and using normal saline or Lactated Ringer's solution:
 - a. Flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors.
 - b. Flush all residual contrast media from the lasing site and vascular structures adjacent to the lasing site, prior to activating the CVX-300® Excimer Laser System.
 - c. Please refer to the Saline Infusion Protocol section of the Instructions for Use and perform saline flush and infusion per the instructions.
10. When using TURBO elite™ catheter models, the CVX-300® Excimer 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

Advancing the laser catheter through moderately calcified lesions may require more pulses of laser energy than fibrous atherosclerotic tissue.

11. Standard Method for Treating Stenoses

- a. Depress the footswitch, activating the CVX-300[®] Excimer Laser System, and **slowly**, less than 1 mm per second, advance the laser catheter through the stenosis. Release the footswitch to deactivate the CVX-300[®] Excimer Laser System.
- b. Additional laser passes may be performed over-the-wire to achieve greater debulking of the lesion. If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the CVX-300[®] Excimer Laser System. The fluence and repetition rates can be increased in order to advance. To avoid the potential of heat build-up, the catheter must be advanced while lasing.

12. Step-by-Step Method for Total Occlusion

- a. Depress the footswitch, activating the CVX-300[®] Excimer Laser System, and **slowly**, less than 1 mm per second, advance the laser catheter 2–3 mm into the total occlusion, allowing the laser energy to remove the desired material. Release the footswitch to deactivate the CVX-300[®] Excimer 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 8 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.

Note

If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter's outer surface, inner lumen, and tip with heparinized saline to prevent blood from sticking. Blood remaining on the laser catheter may diminish the efficiency of the laser catheter.

- g. If resistance to catheter advancement is met (such as calcium), immediately stop lasing by releasing the footswitch to deactivate the CVX-300[®] Excimer Laser System. The fluence and repetition rates can be increased in order to advance. To avoid the potential

of heat build-up, the catheter must be advanced while lasing.

- 13. There is no need to remove the laser catheter from the patient in order to increase or decrease either the fluence or pulse repetition rate; as the laser catheter was previously calibrated. Refer to the CVX-300[®] Excimer Laser System Operator's Manual, 7030-0035 or 7030-0068.

Caution

All patients should be monitored for blood pressure and heart rate during the procedure.

- 14. Following laser recanalization, perform follow-up angiography and balloon angioplasty if needed. Stenting may be performed as required, in instances of acute recoil, major perforation, etc.
- 15. Recommended pharmacology follow-up to be prescribed by the physician.
- 16. Saline infusion protocol

Note

This technique requires two operators. It is recommended that the primary physician-operator advance the laser catheter and operate the laser system foot pedal. A scrub assistant should manage the saline infusion control syringe and (if appropriate) depress the fluoroscopy pedal.

- a. Before the laser procedure, warm a 500 cc bag of 0.9% normal saline (NaCl), or Lactated Ringer's (LR) solution, to 37°C. It is not necessary to add heparin or potassium to the saline/LR solution. Connect the bag of warmed saline/LR to a sterile intravenous line and terminate the line at a port on a triple manifold.
- b. If applicable, cannulate the ostium of the artery with an appropriate "large lumen" guide catheter in the usual fashion. It is recommended that the guide catheter **not** have side holes.
- c. Under fluoroscopic guidance, advance the laser catheter into contact with the lesion. If necessary, inject contrast to help position the tip of the laser catheter. If contrast appears to have become entrapped between the *laser* catheter tip and the lesion, the *laser* catheter may be retracted slightly (1-2 mm) to allow antegrade flow and contrast removal while flushing the system with saline/LR. **However, before lasing, ensure that the laser catheter tip is in contact with the lesion.**
- d. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline/LR through the manifold into the control syringe.
- e. Remove the original control syringe from the manifold and replace it with a fresh 20 cc luer-lock control syringe. This new 20 cc control syringe should be primed with saline/LR prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20 cc control syringes.)

- f. Flush all traces of blood and contrast from the manifold, connector tubing, y-connector, and introducer sheath or guide catheter, with at least 20-30 cc of saline/LR (several syringes of saline/LR). When this initial flushing is completed, refill the 20 cc control syringe with saline/LR.
- g. Under fluoroscopy, confirm that the tip of the laser catheter is in contact with the lesion (advance the laser catheter if necessary), but do **not** inject contrast.
- h. When the primary operator indicates that he/she is ready to activate the laser system, the scrub assistant should turn the manifold stopcock off to pressure and inject 10 ccs of saline/LR as rapidly as possible (within 1-2 seconds). This bolus injection is to displace and/or dilute blood down to the level of the capillaries and limit back-bleeding of blood into the laser ablation field.
- i. After the injection of the initial 10 ccs bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3 ccs/second. This portion of the saline/LR infusion is to displace and/or dilute the antegrade blood flow entering the laser ablation field. **At the instant the scrub assistant slows down the injection rate, the primary operator should activate the CVX-300[®] Excimer 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/LR must be infused throughout the entire lasing process.
- k. Terminate the saline/LR injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20 ccs of saline/LR in preparation for the next lasing sequence.
- l. Each subsequent laser train should be preceded by a bolus of saline/LR and performed with continuous saline/LR 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 CVX-300[®] Excimer Laser System (before activating the laser as described in steps h-k).

Note

Depending on which approach is used, antegrade or contralateral, saline/LR 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/LR infusion at the treatment site.

12. Company Information

The company's standard one-year product warranty and remedy are exclusive and expressly in lieu of all other warranties expressed or implied either in fact or by operation of law, statutory or otherwise, including warranties of merchantability and fitness for use or for any particular purpose and of all other liabilities or obligations on the part of the company relating in any way to the CVX-300[®] Excimer Laser System, whether arising from personal injury, property damage or otherwise. The company neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale, installation, service or use of the CVX-300[®] Excimer Laser System. Notwithstanding the generality of the foregoing, (a) the company shall have no liability whatsoever for special, consequential, incidental or punitive damages of any kind arising out of the sale, installation, service or use of the CVX-300[®] Excimer Laser System, and (b) the company's liability shall in no event exceed the original purchase price of the CVX-300[®] Excimer Laser System.

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5315614, 5456680, 5429604, 5267993, 5470330,
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And other patents pending.

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