

CLiRpath? Excimer Laser Catheters

Cool Laser Revascularization for Peripheral Artery Therapy
Extreme (OTW) and Vitesse (Rx) Catheter Models

DRAFT Instructions For Use

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1. Description

Spectranetics CLiRpath? excimer laser catheters are constructed of multiple fiber optics arranged around a guidewire lumen and are intended for use in the peripheral vasculature for recanalization of obstructed arteries.

For Extreme, over the wire (OTW) catheters, a side arm adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the appropriate sized guidewire (0.014", 0.016", 0.018", 0.025", and 0.035").

For Vitesse, rapid exchange (Rx) catheters, the guidewire lumen begins at the distal tip and is concentric with the fiber array, and exits the laser catheter 9 cm away from the distal tip which has direct patient contact.

For Vitesse-E, eccentric catheters, the laser catheter consists of eccentrically aligned optical fibers and a stainless steel torque device encased within a polyester shaft. There are two major portions of the laser catheter shaft, the proximal portion which terminates at the laser connector, and the distal portion which terminates at the tip having direct patient contact. The torque device extends from the torque handle, located at the y-adapter,

through the entire 140 cm of the distal portion of the catheter, and terminates in the distal tip. There is a mechanism within the torque handle which limits the turns to five full rotations in each direction. The torque handle also has an indicator displaying its range of motion. The laser catheter is packaged with the indicator in the center of its range (see Figure 1). The torque response is 6:1, six turns of the torque handle result in one 360° turn of the distal tip. A radiopaque marker band with radiolucent window is located on the distal tip of the laser catheter to aid localization within the coronary vasculature in conjunction with fluoroscopy (see Figure 2).

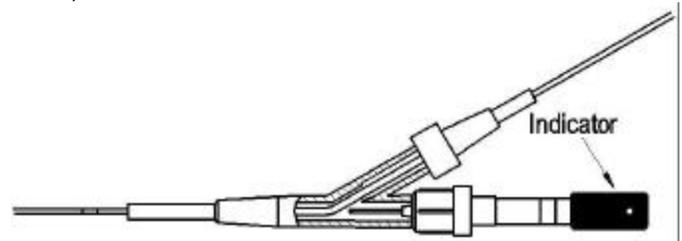


Figure 1

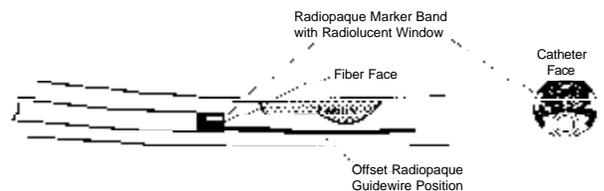


Figure 2

The multifiber laser catheters transmit ultraviolet energy from the Spectranetics CVX-300® to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photo-ablate fibrous, calcific, and atheromatous lesions, thus recanalizing diseased vessels (photo ablation 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.

4. Warnings

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

Spectranetics Excimer Laser Catheters require CVX-300[®] software version 3.7 or higher.

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 atherectomy, Percutaneous Transluminal Coronary Angioplasty (PTCA) 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 CLiRpath catheters in lesions 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.

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 been passed.

Device OD Outer Diameter (mm)	Model Number	Max. Guidewire Lumen (in.)	Max. Tip Outside Diameter (in.)	Min. Tip Inside Diameter (in.)	Max. Shaft Diameter (in.)	Min Tail Tube Length (cm)	Min Workin g Length (cm)
<i>Extreme (OTW) Catheter Specifications</i>							
0.9 mm	110-001	0.014	0.038	0.0155	0.047	183	130
0.9 mm	110-002	0.014	0.038	0.0155	0.047	183	130
1.4 mm	114-001	0.014	0.056	0.017	0.056	183	131
2.0 mm	120-001	0.018	0.077	0.021	0.076	183	131
2.2 mm	222-005	0.035	0.088	0.037	0.089	168	120
2.5 mm	225-004	0.035	0.1	0.037	0.098	168	100
<i>Extreme II (OTW) Catheter Specifications</i>							
2.0 mm	220-006	0.035	0.0775	0.026	0.083	168	131
2.3 mm	223-001	0.035	0.092	0.039	0.094	168	120
2.5 mm	225-010	0.035	0.099	0.039	0.101	168	100
<i>Vitesse (Rx) Catheter Specifications</i>							
0.9 mm	110-003	0.014	0.038	0.0155	0.049	183	131
1.4 mm	114-009	0.014	0.057	0.0175	0.062	183	131
1.7 mm	117-016	0.014	0.0685	0.0175	0.072	183	131
2.0 mm E	120-008	0.018	0.0785	0.0205	0.084	183	129
2.0 mm	120-009	0.014	0.08	0.0175	0.084	183	131

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.

2. Indications for Use

The CLiRpath[®] Excimer Laser Catheters and the Spectranetics CVX-300[®] Excimer Laser System are approved for the following indication:

- For facilitating limb salvage in patients with critical limb ischemia (associated with Rutherford Categories 4, 5 and 6) who have angiographically evident culprit stenoses and/or occlusions in the SFA, popliteal and/or infrapopliteal arteries, who are poor surgical candidates and who are acceptable candidates for revascularization.

3. Contraindications

- No known contraindications.

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 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 CVX-300®.

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

6. Potential Adverse Events

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

- ? Dissection of the arterial wall
- ? Acute reclosure
- ? Aneurysm formation
- ? Nerve Injury
- ? Perforation
- ? AV fistula formation
- ? Embolization
- ? Spasm
- ? Thrombus
- ? Hematoma
- ? Arrhythmia
- ? Death

No long term adverse effects of peripheral excimer laser atherectomy are known at this time.

7. Clinical Studies

7.1 LACI

The LACI Laser Angioplasty in Critical limb Ischemia) Registry Group enrolled 155 limbs exhibiting critical limb ischemia (CLI) of 145 patients who were poor surgical bypass candidates, at 14 sites. Outcomes were compared to the 789-patient Control Group of a randomized trial of prostaglandin E₁ versus standard therapies in CLI patients (Ann Intern Med 1999; 130:412-421). In the Registry Group, treatment was laser atherectomy plus balloon angioplasty and optional stenting in the SFA, popliteal and infrapopliteal arteries. In the Control Group, various therapies were used including bypass surgery, endarterectomy, analgesics and others.

Analysis

The two groups were similar in age, history of coronary artery disease, proportion of high surgical risk and proportion of Rutherford Category 4 patients. The Registry Group had greater history of stroke, hypertension, diabetes, hypercholesterolemia, and obesity; the Control Group had more men and more smokers. Procedural details for the Registry Group are shown in Table 7.1.1, with complications shown in Table 7.1.2.

Table 7.1.1 Procedure Information, Registry Group

Locations of vascular lesions (n=423)	
SFA	174 (41%)

popliteal	64 (15%)
infrapopliteal	174 (41%)
Angiographic results	
Mean lesion stenosis, baseline	92% ? 12%
Stenosis post-laser	55% ? 24%
Final residual stenosis	18% ? 26%

Lesions per limb (n=155 limbs)	2.7 ? 1.4
Laser treatment delivered	153 (99%)
Laser pulses delivered per limb	5371 ? 5871
Balloon catheter used	149 (96%)
Stent implanted	70 (45%)
Procedure success	132 (85%)
Straight line flow to foot established	138 (89%)

Procedure success: ?50% final residual stenosis

Table 7.1.2 Complications, Registry Group, n=155 limbs

Procedural Complications	
Spasm	5 (3%)
Major dissection	6 (4%)
Thrombus	5 (3%)
Distal embolization	5 (3%)
Perforation	4 (3%)
Other	7 (5%)
In-Hospital Complications	
Reocclusion	2 (1%)
Pseudoaneurysm	2 (1%)
Renal failure	2 (1%)
Bleeding	8 (5%)
Infection	2 (1%)
Other	4 (3%)

A comparison of Serious Adverse Events (SAEs) (Table 7.1.3) shows similar rates of death, major amputation, and nonfatal cardiovascular events during the 6-month enrollment period. More frequent reintervention was observed in the Registry Group, 24/ 145 (17%) versus 34/ 789 (4%) for the Control Group (p<.001). The Control Group experienced significantly more surgical interventions (bypass or endarterectomy) than the Registry Group (p<.001). Primary outcomes at 6 months are shown in Table 7.1.4. Amongst limbs with 6-month data, limb salvage was 118/127 (93%) in the Registry Group and 501/577 (87%) in the Control Group, p = .08.

Table 7.1.3 Adjudicated SAEs, Registry and Control Groups

	Registry Group n=145	Control Group n=789	p
Death	15 (10%)	113 (14%)	ns
MI or Stroke*	1 (1%)	10 (1%)	ns
Reintervention	24 (17%)	34 (4%)	<.001
ALI	1 (1%)	DNA	-
Major amputation	9 (6%)	76 (10%)	ns
Bypass	3 (2%)	-	-
Endarterectomy	1 (1%)	-	-
Hematoma with Surgery	1 (1%)	6 (0.8%)	ns
total	55 (38%)	239 (30%)	ns

MI = myocardial infarction. ALI = acute limb ischemia. DNA = data not available. ns = not significant.

Table 7.1.4 Primary Outcomes, Registry and Control Groups

	Registry Group n (%)	Control Group n (%)	p
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Patients enrolled	145 (100%)	673 (100%)	.
Primary Endpoint (see Note)	110 (76%)	494 (73%)	ns
Death, any cause	15 (10%)	96 (12%)	ns

Note: Primary endpoint: limbs without major amputation, death, lost-to-follow-up, or withdrawal. ns = not significant.

8. Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the CliRpath catheters.

Additionally, recanalization of **native** arteries may be attempted in patients presenting with reoccluded synthetic 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

ENERGY PARAMETERS

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

Device O.D.	Model No.	Fluence	Repetition Rate	Laser On/Off Time
Extreme (OTW) Catheters				
0.9 mm	110-001	30-60	25-40	5 sec on/10 sec off
0.9 mm	110-002	30-80	25-80	10 sec on/5 sec off
1.4 mm	114-001	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-001	30-60	25-40	5 sec on/10 sec off
2.2 mm	222-005	30-60	25-40	5 sec on/10 sec off
2.5 mm	225-004	30-50	25-40	5 sec on/10 sec off
Extreme II (OTW) Catheters				
2.0 mm	220-006	30-60	25-40	10 sec on/5 sec off
2.3 mm	223-001	30-60	25-40	10 sec on/5 sec off
2.5 mm	225-010	30-50	25-40	10 sec on/5 sec off
Vitesse (Rx) Catheters				
0.9 mm	110-003	30-60	25-40	5 sec on/10 sec off
1.4 mm	114-009	30-60	25-40	5 sec on/10 sec off
1.7 mm	117-016	30-60	25-40	5 sec on/10 sec off
2.0 mm E	120-008	30-60	25-40	5 sec on/10 sec off
2.0 mm	120-009	30-60	25-40	5 sec on/10 sec off

Recommended calibration settings: 45 Fluence, 25 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—do not re-sterilize 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
- ☞ Standard contrast media
- ☞ 0.014", 0.016", 0.018", 0.025", or 0.035" guidewires

10.4 Compatibility

The Spectranetics' excimer laser catheter is designed and intended to be used exclusively with the Spectranetics CVX-300® 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®, and is not meant to have any patient contact.

Connect the proximal end of the laser catheter to the CVX-300® and position the laser catheter in the laser system extension pole. Calibrate the laser catheter following the instructions provided in the CVX-300® 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", 0.016", 0.018", 0.025", or 0.035" guidewire to the peripheral vasculature via the introducer sheath or guiding catheter. Cross the target lesion with the guidewire.

Note:

As an alternate method of recanalization, laser ablation can be used in a step-by-step manner where the guidewire and then a laser catheter are sequentially advanced and activated (mm by mm) until the occlusion or stenosis is crossed.

4. Size the laser catheter appropriately:

Catheter Size	Vessel Diameter and Location			
	Reference Vessel Normal		Total Occlusion or Bend >30°	
	Distal	Proximal	Distal	Proximal
0.9 mm 110-001, 110-003	?1.5 mm	?1.5 mm	Cannot be determined	?1.5 mm
0.9 mm 110-002	?2.0 mm	?2.0 mm	Cannot be determined	?2.0 mm
1.4 mm	?2.0 mm	?2.0 mm	Cannot be determined	?2.2 mm
1.7 mm	?2.3 mm	?2.3 mm	Cannot be determined	?2.5 mm
2.0 mm	?2.6 mm	?2.6 mm	Cannot be determined	?3.0 mm
2.2 mm	?2.9 mm	?2.9 mm	Cannot be determined	?3.2 mm
2.3 mm	?2.9 mm	?2.9 mm	Cannot be determined	?3.2 mm
2.5 mm	?3.1 mm	?3.1 mm	Cannot be determined	?3.5 mm

5. Inject 5-10cc of heparinized saline solution through the laser catheter to flush the guidewire lumen. Attach a rotating hemostatic valve to the guidewire port into the guidewire lumen (See Figure 3). 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.

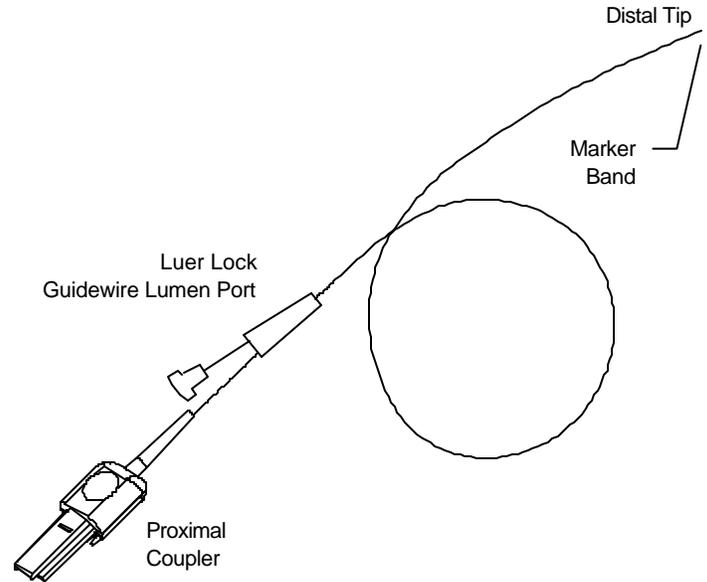


Figure 3 (not to scale)

6. Inject contrast medium solution through the introducer sheath or guiding catheter to verify the positioning of the laser catheter under fluoroscopy.
7. Following confirmation of the laser catheter's position 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® laser system.
 - c. Please refer to the Saline Infusion Protocol section of this Instructions for Use and perform saline flush and infusion per the instructions.
8. Depress the footswitch, activating the CVX-300®, and **slowly**, less than 1 mm per second, advance the laser catheter allowing the laser energy to remove the desired material. Release the footswitch to deactivate the CVX-300®.

Note

Advancing the laser catheter through moderately calcified lesions may

require more pulses of laser energy than fibrous atherosclerotic tissue.

9. Pull back the laser catheter and inject contrast medium through the guiding catheter and examine the lesion via fluoroscopy.
10. Repeat steps 6 through 9 as needed to complete treatment.

Note

If the laser catheter is removed from the vessel for any reason, thoroughly clean the laser catheter 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.

11. 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.

12. Following laser atherectomy, perform follow up angiography and balloon angioplasty if needed.
13. Recommended pharmacology follow up to be prescribed by the physician.

EXCIMER LASER 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 500cc bag of 0.9% normal saline (NaCl) to 37°C. It is not necessary to add heparin or potassium to the saline solution. Connect the bag of warmed 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. 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 (1-2mm) 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.**
- D. Expel any residual contrast from the control syringe back into the contrast bottle. Clear the triple manifold of contrast by drawing up saline through the manifold into the control syringe.
- E. Remove the original control syringe from the manifold and replace it with a fresh 20cc luer-lock control syringe. This new 20cc control syringe should be primed with saline prior to connection to reduce the chance for introducing air bubbles. (Merit Medical and other vendors manufacture 20cc 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 20-30cc of saline (several syringes of saline). When this initial flushing is completed, refill the 20cc control syringe with saline.
- 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 10cc of saline 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 10cc bolus and without stopping the motion of injection, the scrub assistant should next slow down the rate of injection to 2-3cc/second. 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 slows down the injection rate, the primary operator should activate the laser system by depressing the foot pedal and begin a lasing sequence.**
- J. Terminate the saline injection at the end of the lasing train. Turn the manifold stopcock back to pressure and refill the control syringe with 20cc of saline in preparation for the next lasing sequence.
- K. Each subsequent laser train should be preceded by a bolus of saline and performed with continuous saline infusion as described in steps H-J.

- L. 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 as described in steps H – J).

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.

operation of law, statutory or otherwise, including warranties of merchant ability 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.

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



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