Turbo-Elite™

Laser Atherectomy Catheter

Instructions for Use

For OTW and RX Catheters

Spectranetics®

Instructions for Use - Sections by Language

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US Federal law restricts this device to sale or on the order of a physician who has received appropriate training.

1. PRODUCT DESCRIPTION

Spectranetics Turbo Elite® disposable laser optical fiber catheter is a percutaneous intravascular appliance, which contains a fiber bundle that forms a circle by surrounding the guidewire lumen plate.

For the Turbo Elite® Over-The-Wire (OTW) catheter, a luer connector adapter is installed at the proximal end of effective length so as to use the laser catheter installed with a guidewire of correct size (0.014", 0.018" and 0.035"). See the figure below.

For the Turbo Elite® Rapid Exchange (RX) catheter, the guidewire lumen coaxial with the fiber bundle is located at the last 9 cm of the distal end and can come into direct contact with patient. See the figure below.

Action Mechanism of the Turbo Elite® catheter

The multi-fiber laser catheter transmits ultraviolet energy from the Spectranetics CVX-300 excimer laser system to the arterial obstruction. The ultraviolet energy is sent to the laser catheter tip and performs light resection of Fibrous, calcified and atherosclerotic lesions, thus probing the vessel with lesions (during light resection, high energy photons break molecular bonds at the cellular level, without causing thermal damage to the surrounding soft tissues). Spectranetics laser catheter is provided with a special lubricant coating and can pass through the artery more easily.

Glossary of Special Terms

Retrograde mode = Opposite to the blood flow direction
Anterograde mode = Blood flow direction
Baseline angiography = Angiography record
Contralateral approach = Access to the artery using the crossing method

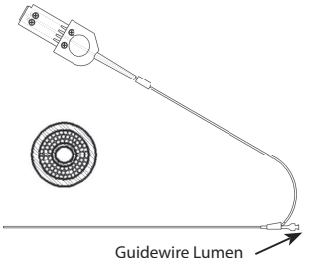

Figure 1: Turbo Elite disposable laser optical fiber catheter (OTW type)

Table 1.1 Turbo Elite disposable laser optical fiber catheter model

Device Description	Model	Maximum Guidewire Compatibility (in.)	Maximum tip outer-diameter (in.)	Maximum shaft diameter (in.)	Working length (cm)	Sheath compatibility (Fr)
OTW catheter specifications						
0.9 mm	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	125	7
2.5 mm	425-011	0.018	0.101	0.102	112	8
2.3 mm	423-135-02	0.035	0.091	0.091	125	7

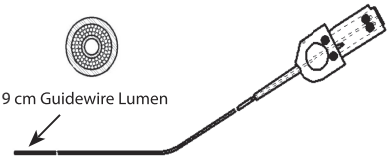

Figure 2: Turbo Elite disposable laser optical fiber catheter (RX type)

Table 1.2 Turbo Elite disposable laser optical fiber catheter models

Device Description	Model	Maximum guidewire compatibility (in.)	Maximum tip outer-diameter (in.)	Maximum shaft diameter (in.)	Working length (cm)	Sheath compatibility (Fr)
RX catheter specifications						
0.9 mm	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

2. INDICATIONS

The device is indicated for use with the Spectranetics CVX-300 excimer laser system and applies to the recanalization therapy of severe lower extremity arterial stenosis and occlusive lesions. The vascular reference diameter should be equal to or greater than 2 mm.

Note: When the guidewire is pushed step by step successfully, alleviation of severe limb ischemia cannot be guaranteed

3. CONTRAINDICATIONS

No known contraindications

4. WARNINGS

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Requirements for the CVX-300 excimer laser system software of Spectranetics Turbo Elite® disposable laser optical fiber catheter:

Software	Maximum repetition rate of catheter
V3.8xx	80 Hz
V3.7xx	40 Hz

When the laser catheter is in human body, use fluorescence microscopy equipped with X-ray photographic apparatus to perform observation so as to get HD images.

The laser catheter should not be operated in the presence of contrast. Prior to use, flush all residual contrast media from the introducer sheath or guide catheter and in-line connectors. For the 1.4-2.0 RX design, failure to do so may result in damage or dislodgement of the tip. Saline must be infused throughout the entire lasing process.

5. PRECAUTIONS

This catheter has been sterilized using ethylene oxide and is a sterile product .This device is designed as a **disposable product,** so it cannot be re-sterilized or reused.

Do not re-sterilize or re-use this device, because incorrect re-treatment may hurt performance of the device and increase the risk of cross-infection.

Using this disposable device repeatedly may lead to serious casualties of patients and invalidates the manufacturer's warranty.

Store the device at a cool and dry place. Avoid direct sunlight and high temperature heat source (exceeding 60 degrees Celsius or 140 degrees Fahrenheit).

The product sterility can be ensured only when the package is not opened and not damaged. Before use, check the sterile package carefully, and make sure that the seal is not torn. If the package integrity has been damaged, do not use this catheter. If the expiry date on the package label has passed, do not use this catheter product.

Before use, carefully check whether all the devices to be used during operation have any defects. Do not use the device if it has been damaged.

After use, dispose of all the devices according to the special requirements for hospital waste and hidden bio-hazardous materials.

Before operating the CVX-300 excimer laser system, please read through the sections related to warnings and responsibilities to be assumed in the operator manual carefully. These sections elaborate the notes, precautions and warnings to be observed to ensure the safe operation of the system.

During the procedure, provide the patient with the correct anticoagulant and vasodilator therapy according to the PTA protocol of the medical institution.

6. POTENTIAL ADVERSE EVENTS

Spectranetics CVX-300 excimer laser system may lead to the following complications:

Events observed in the clinical research (see section 7)

Surgery complications	Serious adverse events	Complications during hospitalization
• Spasm	• Death	• Reocclusion
• Aortic dissection	• Interventional therapy	• Renal failure
• Thrombus	• ALI	• Aneurysmal hematoma
• Distal embolization	• Major amputation	• Bleeding
• Perforation	• Bypass grafting	
• Others	• Hematoma operation	

Potential adverse events not observed in the clinical research (see section 7)

- Nerve injury
- Formation of AV fistula
- Endarterectomy
- Infection
- Apoplexia
- Myocardial infarction
- Arrhythmia

Since peripheral excimer laser recanalization is adopted, it is currently learned that long-term negative effects will not be caused to the arterial vascular wall.

7. CLINICAL RESEARCH

The data in this IFU are obtained from one subset of patients who come from three sources, and all have Critical Limb Ischemia (CLI). Therefore, they received continuous treatment, and operation is not suitable for them:

· LACI stage 2 – Patients for prospective IDE registration at 14 sites in America and Germany from 2001 to 2002 formed a subset. This subset included 26 lower limbs with lesions (25 patients) for treatment at 7 sites in America and Germany, and the stepping laser probing technology was adopted for all. Among these cases, 13 used the stepping technology in the very beginning, namely, the guidewire didn't get round the infarction as an attempt in the beginning.

· LACI Belgium – The 51 patients for prospective registration at 6 sites in Belgium formed a subset. This subset included 9 lower limbs with lesions (9 patients) for treatment at 3 sites in Belgium, and the stepping laser probing technology was adopted for all.

· Louisiana case series – A professional physician team continued data compilation at the Cardiovascular Institute of the South (CIS) in the middle of Louisiana, and selected 62 cases to form a subset. This subset included 12 lower limbs with lesions (12 patients), and the stepping laser probing technology was adopted for all.

Table 7.1 Procedure information

Arterial lesion location (*n* = 205)	
SFA	138 (67%)
Posterior knee	23 (11%)
Inferior genicular artery	42 (20%)
Results of arteriography (n= 47 cases of lower limbs)	
Lesions of each lower limb	4.4
Average damage length	73.4 ± 7.3 (mm)
Linear flow used for foot fixation	37 (79%)
Implanted stents	28 (60%)
Total number of successful penetration*	37 (79%)
Penetration success after guidewire insertion	24/34 (71%)
Cases with successful penetration counted from the beginning	13/13 (100%)
Operation success**	34 (72%)

Note: Totally 47 lower limbs with lesions of 46 patients were treated. The calculation of all the percentages was based on 47 cases.

* Traditional guidewires were inserted into 24 lower limbs. After an initio calculation was adopted for 13 lower limbs, the penetration success data of stepping cases was graded.
** Operation success: ≤ 50% terminal residual stenosis.

Table 7.2 Complications (*n* = 47 cases of lower limbs)

Surgical Complications	
Spasm	1 (2%)
Aortic dissection	4 (9%)
Thrombus	1 (2%)
Distal embolization	3 (6%)
Perforation	3 (6%)
Others	5 (11%)
Complications during hospitalization	
Reocclusion	1 (2%)
Aneurysmal hematoma	1 (2%)
Renal failure	1 (2%)
Bleeding	1 (2%)
Infection	0 (0%)
Others	0 (0%)

Note: Totally 47 lower limbs with lesions of 46 patients were treated. The calculation of all the percentages was based on 47 cases.

Table 7.3 Accumulated Serious Adverse Events (SAEs) in the follow-up period of 6 months
(*n* = 47 cases of lower limbs)

Death	3 (6%)
MI or apoplexia	0 (0%)
Interventional therapy	6 (13%)
ALI	1 (2%)
Large resection	2 (4%)
Bypass surgery	2 (4%)

Endarterectomy	0 (0%)
Hematoma operation	2 (4%)
Total	16 (34%)

Note: Totally 47 lower limbs with lesions of 46 patients were treated. The calculation of all the percentages was based on 47 cases.

MI = Myocardial Infarction ALI = Acute Limb Ischemia

Table 7.4 Intentional analysis results (n = 47)

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

NOTE: Totally 47 lower limbs with lesions of 46 patients were treated. The calculation of all the percentages was based on 47 cases.

8. INDIVIDUALIZED THERAPY

Before each patent uses the Turbo Elite® device, all of the above risks and benefits must be balanced carefully.

When traditional guidewire penetration fails in the beginning, the CLiRpath® device can be considered because:

- The stump of circular or eccentric occlusion made the guidewire inclined to the vascular subintimal pathway.
- The guidewire was offset repeatedly and entered the large collateral branch flush with the stump of occlusion.
- Calcification blocked the guidewire path formed in the blocking cavity.

Select patients and apply clinical technologies according to instructions provided in section 2 "Indications" and section 9 "Operator Manual".

9. OPERATOR MANUAL

The device operated in this document can be operated within the energy range of the CVX-300 excimer laser system:

Table 9.1 Energy Parameters

Device description	Model	Energy density	Repetition frequency	Laser on / off time
OTW Catheter				
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*
2.3 mm	423-135-02	30-60	25-80*	Continuous On*
RX Catheter				
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 energy density, 25 Hz.

* The maximum repetition frequency of software V3.812 is 80 Hz. The maximum repetition frequency of software V3.712 is 40 Hz.

10. HOW TO STORE

10.1 Sterilization

This device is for single use only. Do not re-sterilize or re-use this device.

The Spectranetics disposable laser optical fiber catheter is a sterilized product. Its sterilization performance can be guaranteed only when the package is not opened and not damaged.

10.2 Check before Use

Before use, check the sterile package, and make sure that the seal is not opened. Carefully check all the devices including the catheter to be used during the operation to see whether any defect exists. Check the laser catheter for bending, twisting or other damages. Do not use the device once it is damaged.

11. COMPATIBILITY

- The Spectranetics disposable laser optical fiber catheter is specially used with the Spectranetics CVX-300 excimer laser system.
- Do not use it with other laser systems.
- Guidewire Compatibility
- See the catheter specification table in section 1.

12. INSTRUCTIONS FOR USE

Installation procedure

The laser catheter package does not include the following additional materials, but some or all of these materials may be used during the procedure (all these materials are for single use only – do not re-sterilize or reuse them):

- Guiding sheath and femoral artery guiding catheter with the correct size and configuration, used to select peripheral artery and facilitate use of large laser catheters.
- Tuohy-Borst "y"-adapter or hemostatic valve
- Sterile saline solution
- Standard comparison media.
- 0.014" and 0.018" guidewires

Only the radiologists with experience of peripheral vascular intervention can use the CVX-300 excimer laser system, and they must have received the required training, including but not limited to:

1. Safe laser emission.
2. Evaluate a patient' injuries based on the film and according to the use instructions.
3. Evaluate various situations of applying the laser ablation technology to embolism according to the use instructions.
4. Evaluate the laser operation performed using the CVX-300 excimer laser system.
5. Personally practice using the CVX-300 excimer laser system of proper model.
6. Good practice of representative Spectranetics products will help to handle the first three situations.
7. Organized training together with exercise by physicians or exercises using the Spectranetics products through personal support will ensure efficiency of Spectranetics products.

Using sterilization techniques to open the aseptic package. Take down the packaging wedge from the bracket, lift the laser catheter from the bracket gently, and support the black laser connector at the same time, which is also called proximal adapter or proximal interface. Note that the proximal end of laser catheter can only be connected to the CVX-300 excimer laser system, but cannot come into the contact with patient.

Connect the proximal end of laser catheter to the CVX-300 excimer laser system, and fix the laser catheter to the laser system extension rod. Calibrate the laser catheter according to the instructions for use in the operation manual of CVX-300 excimer laser system.

1. Use the standard femoral artery puncture technique to insert a guiding sheath of 4Fr. To 9Fr. (depending on the largest interventional device used during treatment) into the common femoral artery, and perform contralateral approach in the antegrade or retrograde manner. Adopt the heparinized PTA method to perform intravenous heparinization.
2. Inject contrast agent through the guiding sheath or guiding catheter, and carry out the baseline angiography. Use a composite projection device to obtain images, and describe the anatomic variation and morphology of the diseased region.
3. Insert a 0.014", 0.018" or 0.035" guidewire into the peripheral obstruction through the guiding sheath or guiding catheter.
4. Select a proper laser catheter according to the dimension arrangement:

Table 12.1 Recommended dimensions

Catheter dimension	The closest 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. Effect hydration on the catheter housing to activate the hydrophilic coating. Or immerse the catheter in a basin containing suitable sterile solution, or use wet gauze to wipe the catheter.
6. Use 5-10 ml of heparinized saline or lactated Ringer's solution to rinse the guidewire lumen of the laser catheter.
7. Use the selected guidewire to drag the distal end of the Spectranetics laser catheter. Use a fluoroscope to conduct monitoring, and guide the laser catheter to the lesion. The radiopaque marker of laser catheter displays the corresponding position of the catheter and the lesion.

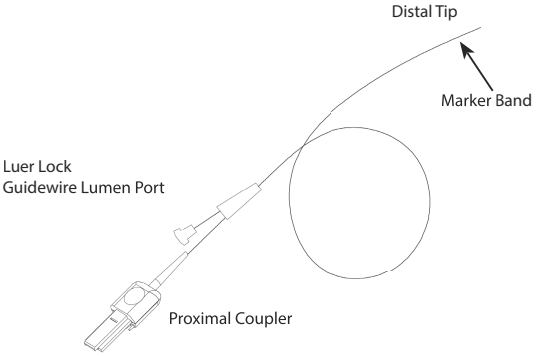

Figure 3 (not based on proportion)

Note: During the use in human body, usually a fluoroscope is used to monitor moving of the laser catheter and position of the radiopaque tip position, similar to other intravascular interventional devices. The movement and advance rate of the distal end of catheter should be directly corresponding to advance rate of the upper shaft of catheter.

If the corresponding movement is not significant, operate more carefully, without excessively delivering the laser energy.

If the catheter movement is not significant, operate more carefully, without excessively delivering the laser energy.

8. Inject contrast agent through the guiding sheath or guiding catheter, and use the fluoroscope to confirm the laser catheter position .
9. After making sure that the laser catheter has come into contact with the target lesion, use normal saline or lactated Ringer's solution to:
    a. Rinse the residual contrast agent from the guiding sheath or guiding catheter and the internal connector.
    b. Before activating the CVX-300 excimer laser system, rinse the residual contrast agent from the laser emission point and adjacent vascular structure. **Warning: Do not activate laser in the presence of contrast.**
    c. Perform saline solution flushing and infusion operation by referring to the content related to the saline infusion method in the use instructions.
10. Once the foot switch is pressed during use of the Turbo Elite® catheter, the CVX-300 excimer laser system will release energy continuously. The operator can control the laser chain length. Generally, the recommended duration of continuous laser emission cannot exceed 20s.
11. **Stepping method of treating total occlusion**
    a. Press the foot switch to activate the CVX-300 excimer laser system, and then slowly insert the laser catheter into 2-3 mm at the position of total occlusion, enabling the laser energy to resect the target substance. Release the foot switch to stop the CVX-300 excimer laser system.
    b. Drag the guidewire beyond the distal end of laser catheter, further insert it into the occlusion by about several millimeters, and then activate the laser again according to the description in the above step 8.
    c. Continue the operation in the stepping manner to make the guidewire and laser catheter move forward and activated (with the increment of millimeter), till the catheter reaches the last 3-5 mm of occlusion.
    d. When passing through the last 3-5 mm of the occlusion, make the guidewire enter the distal vessel first, and then the activated OTW laser catheter.
    e. Fix the guidewire in place, withdraw the laser catheter, use the guiding catheter to inject contrast agent, and monitor the lesion through the fluoroscope.
    f. To remove more lesion, the additional laser transmittance test needs to be performed for the OTW catheter.

g. If the catheter meets an obstacle (e.g., calcium) when moving forward, release the foot switch immediately to interrupt operation of the CVX-300 excimer laser system and stop laser emission. To move forward the catheter continuously, increase the energy density and repetition frequency. To avoid heat accumulation, the catheter must be pushed during laser emission.

12. **Standard method of stenosis treatment**
    a. Press the foot switch to activate the CVX-300 excimer laser system, and then make the laser catheter pass through the stenosis slowly at a speed smaller than 1 mm per second. Release the foot switch to stop the CVX-300 excimer laser system.
    b. To remove more lesion, the additional laser transmittance test needs to be performed for the OTW catheter. If the catheter meets an obstacle (e.g., calcium) when moving forward, release the foot switch immediately to interrupt operation of the CVX-300 excimer laser system and stop laser emission. To move forward the catheter continuously, increase the energy density and repetition frequency. To avoid heat accumulation, the catheter must be pushed during laser emission.
13. To increase/reduce the energy density and pulse repetition frequency, the laser catheter does not need to be removed from the patient's body because the laser catheter has been calibrated beforehand. Refer to the operation manual of CVX-300 excimer laser system.
14. If necessary, the follow-up angiography and balloon angioplasty should be performed after the laser probing. A stent can be placed for cases such as acute contraction and severe perforation according to requirements.
15. Saline infusion method.

Note: This technique requires two operators. It is recommended that the main physician – operator should drag the catheter, and control the foot pedal of laser system. The assistant responsible for wiping should use the control syringe of saline infusion, and press the fluoroscope pedal (if applicable).

a. Before the laser surgery, heat one bag of 500 ml 0.9% normal saline (NaCl) or lactated Ringer's solution to 37°C. Heparin or potassium does not need to be added to the normal saline/LR solution. Connect this bag of hot normal saline/LR solution to the sterile venous catheter, and connect one end of the catheter to the triplicate three-way connector.

b. If applicable, use a conventional method to insert an appropriate guiding catheter with a "large lumen" into the opening of artery. It is advised to avoid side holes for the guiding catheter.

c. Push the laser catheter under guidance of the fluoroscope, till it comes into contact with the lesion. If necessary, inject contrast agent to help to position the tip of laser guide. If contrast agent stays between the tip of laser guide and the lesion, the laser catheter needs to be slightly retracted (by 1 to 2 mm) so that normal saline/LR solution can implement anterograde flow and remove contrast agent when being used to flush the system. Before laser emission, however, make sure that the tip of laser guide has come into contact with the lesion.

d. Discharge the remaining contrast agent from the control syringe, and place it back to the contrast agent bottle. Suck the normal saline/LR solution into the control syringe through a three-limb tube, and clear the contrast agent from the triplicate three-way connector.

e. Remove the control syringe preliminarily installed on the three-limb tube, and replace it with a new control syringe of Luer lock with a capacity of 20 ml. Before connection, this new 20 ml controllable syringe should suck normal saline/LR solution to reduce the occurrence probability of bubbles. (Merit Medical and other manufacturers who produce 20 ml control syringes).

f. Use at least 20-30ml of normal saline/LR solution (several syringes of saline/LR) to rinse the blood and contrast agent from the three-limb tube, connector pipe, Y type connector and the guiding sheath or guiding catheter. After the first rinsing process is completed, inject normal saline/LR solution into the 20 ml control syringe again.

g. Use the fluoroscope to confirm that the tip of laser catheter has come into contact with the lesion (push to move the catheter when necessary). Do no inject contrast agent here.

h. When the main operator indicates that he/she has got ready for activation of the laser system, the assistant responsible for wiping should turn the three-limb tube piston rapidly to eliminate its pressure, and inject 10 ml of normal saline/LR solution (within 1 to 2 seconds). This kind of bolus injection aims to transfer the blood or dilute it to the level of blood capillary, and restrict blood reflux of the laser ablation area.

i. When the injection activity still continues after the initial 10 ml bolus injection is performed, the assistant responsible for wiping should slow down the injection to 2-3 ml/second. This proportion of normal saline/LR solution injection aims to transfer or dilute the antegrade blood flow entering the laser ablation area. Now, the assistant responsible for wiping should press the foot switch properly to activate the CVX-300 excimer laser system and start emitting the laser beam.

j. The operator controls the laser chain length. Generally, the recommended duration of continuous laser emission cannot exceed 20 seconds. The normal saline/LR solution injection must last throughout the laser emission process.

k. Stop injecting normal saline/LR solution when the laser chain ends. Turn the three-limb tube piston to make it feed back pressure, and suck 20 ml of normal saline/LR solution again using the control syringe, getting ready for the next time of laser beam emission.

l. Before emitting each beam of laser chain subsequently, use normal saline/LR solution to perform bolus injection, and inject normal saline/LR solution continuously according to the description in steps h-k.

m. If contrast agent is used to evaluate the therapeutic effect during laser therapy, reactivate the CVX-300 excimer laser system (repeat steps h-k before activating the excimer laser system).

Note: Normal saline/LR solution can be injected through the sheath (anterograde method) or laser catheter lumen (contralateral method) according to the used method, anterograde or contralateral. When the contralateral method is used, it is advised to use a guidewire with a smaller diameter to inject normal saline/LR solution into the procedure site thoroughly.

13. WARRANTY INFORMATION

Limited warranty of the manufacturer

The manufacturer ensures that the Turbo Elite® disposable laser optical fiber catheter does not have any defect in materials and processes provided that it is used in the validity period and its package has not be opened or damaged before use. According to this warranty, the manufacturer's responsibility is limited to replacement of the defective Turbo Elite® disposable laser optical fiber catheter, or refunding according to the purchase price only. The manufacturer shall not be responsible for any accidental, special or consequential damages due to use of the Turbo Elite® disposable laser optical fiber catheter. This limited warranty shall become invalid if the Turbo Elite® disposable laser optical fiber catheter is damaged due to misuse, transformation, improper storage or operation, or other faults occur due to the failure of performing operations according to the use instructions. **This limited warranty can be in lieu of all the other explicit or implicit warranties, including any implied merchantability or fitness for a particular purpose.** Any individual or entity, including the agent or intermediary authorized by the manufacturer, shall not have the right to expand or extend this limited warranty, and any attempt made out of this purpose shall have no binding force to the manufacturer. This limited warranty covers the Turbo Elite® disposable laser optical fiber catheter only. The manufacturer's warranty information for this system can be found in the related documents of CVX-300 excimer laser system.

Series	Model	Guidewire compatibility (mm)	Outer diameter of tip (mm)	Maximum outer diameter of catheter (mm)	Transmission efficiency (%)	Effective length (cm)
OTW	410-152	0.356	≤0.965	≤1.19	≥2.94	150
	414-151	0.356	≤1.40	≤1.42	≥6.89	150
	417-152	0.457	≤1.73	≤1.75	≥11.56	150
	420-006	0.457	≤2.03	≤2.06	≥17.28	150
	423-001	0.457	≤2.31	≤2.31	≥27.78	150
	425-011	0.457	≤2.57	≤2.59	≥41.67	150
	423-135-02	0.89	≤2.31	≤2.31	≥20.28	120
RX	410-154	0.356	≤0.965	≤1.24	≥2.94	150
	414-159	0.356	≤1.50	≤1.57	≥6.50	150
	417-156	0.356	≤1.75	≤1.83	≥9.44	150
	420-159	0.356	≤2.03	≤2.13	≥16	150

[Sterilization Method] Ethylene oxide sterilization

[Validity Period] 2 years

[Manufacturer] Spectranetics Corporation

9965 Federal Drive Colorado Springs Colorado 80921 USA

[Agent] Philips (China) Investment Ltd. Co.

[Address] Building A1, #718 Lingshi Road, JingAn District, Shanghai

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[After-sales Service Organization] Philips (China) Investment Ltd. Co.

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[Tel.] 8008100038

[Production Date] See the Label.

[Product Standard Serial Number] Imported Medical Instrument 20163012942

[Medical Device Registration Certificate No.] Imported Medical Instrument 20163012942

目录

联邦法律（美国）限制此设备仅能由接受过适当培训的医师销售，或者仅接受经过适当培训的医师的订购。

1. 产品描述

Spectranetics Turbo Elite®一次性使用激光光纤导管是一种经皮血管内用具，内部是绕着导丝腔盘成圆形的光纤束。

关于 Turbo Elite 整体型（OTW）型导管，在有效长度的近端装有鲁尔接头适配器，便于使用装有正确尺寸导丝（0.014” 0.018” 和0.035”）的激光导管；见下图。

关于 Turbo Elite 快速交换型(RX) 型导管，导丝腔位于远端的最后9厘米处，能够直接接触病人，并且与纤维束同轴；见下图。

Turbo Elite 导管的作用机理

复型纤维激光导管将紫外线能量，从 Spectranetics CVX-300 准分子激光系统传输到动脉梗阻。紫外线能量发送到激光导管的尖端，对纤维状、钙化和粥样硬化病变进行光切除，从而探通病变脉管（光切除是这样一种过程，高能量光子在细胞水平上打断分子键，同时对周围软组织不会造成热损伤）。Spectranetics激光导管具备特有的润滑涂层，更易于通过动脉。

专用术语表
逆行模式＝与血流方向相反
顺行模式＝血流方向
基线血管造影术＝血管的血管造影记录
对侧入路＝采用交叉法进入动脉

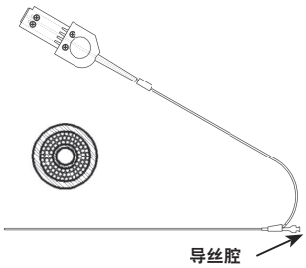

图1：Turbo Elite一次性使用激光光纤导管（OTW型）

表1.1 Turbo Elite一次性使用激光光纤导管型号

设备描述	型号	最大导丝兼容性（in）	最大尖端外径 （in）	最大轴直径（in）	工作长度（cm）	鞘兼容性（Fr）
整体性（OTW）导管规格						
0.9 mm	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	125	7
2.5 mm	425-011	0.018	0.101	0.102	112	8
2.3 mm	423-135-02	0.035	0.091	0.091	125	7

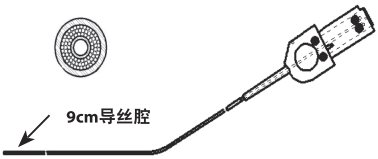

图2：Turbo Elite一次性使用激光光纤导管（RX型）

表1.2 Turbo Elite一次性使用激光光纤导管型号

设备描述	型号	最大导丝兼容性（in）	最大尖端外径（in）	最大轴直径（in）	工作长度（cm）	鞘兼容性（Fr）
0.9 mm	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

2. 适应症

预期与Spectranetics CVX-300准分子激光系统一起使用，适用于严重下肢动脉硬化狭窄与闭塞病变的开通治疗，血管参考直径应大于等于2mm。

注：成功地逐步推移导丝，不能确保重度下肢缺血会减轻。

3. 禁忌症

- 无已知禁忌

4. 警告

联邦法律（美国）限制此设备仅能由接受过适当培训的医师销售，或者仅接受经过适当培训的医师的订购。

Spectranetics Turbo Elite 一次性使用激光光纤导管CVX-300准分子激光系统软件要求：

软件	导管最大重复频率
V3.8XX	80 Hz
V3.7XX	40 Hz

当激光导管处于人体内，操作时应当采用配备X光线照相设备的荧光镜透视进行观察，这样可以提供高清图像。

激光导管不应在造影剂存在 的情况下使用。使用以前，用生理盐水 冲洗所有含有残余造影剂的鞘管或指引导管及连接器。对于1.4-2.0 RX设计，盐水灌注必须伴随整个激光 发射过程，否则可能会导致血管损伤或导管尖端移位。

5. 注意事项

该导管已经采用环氧乙烷灭菌，属于无菌产品。该装置的设计属于一次性用品，因此不得再次灭菌或重复使用。

请勿对本装置进行再次灭菌或重复使用，原因是由于不正确的再处理，可能会损害装置的性能，增加交叉感染的危险。

重复使用这种一次性装置，可能会造成病人的严重伤亡，使得生产商的担保无效。

放于阴凉、干燥处贮存。避免阳光直射及高温热原（高于60摄氏度或140华氏度）。

只有包装未打开且未损坏时，方能保证本产品的无菌性。使用之前，仔细检查灭菌包装，确保封条没有撕破。如果包装完整性被破坏，请勿使用该导管。如果包装标签上的有效期已过，请勿使用该导管产品。

使用之前，仔细检查操作过程使用的所有设备是否有缺陷。如果设备损坏，请勿使用。

用完之后，根据适用于医院废物、隐藏生物危害材料的特殊要求，处理所有设备。

操作CVX-300准分子激光系统之前，详细阅读操作员手册手册中的警告和承担责任部分值得特别注意，因为这部分内容说明了需要遵守的注释、注意事项和警告，以便确保操作系统的安全性。

在操作过程中，根据医疗机构的PTA协议，应当为病人提供正确的抗凝剂和血管扩张治疗。

6. 潜在的不良事件

使用Spectranetics CVX-300准分子激光系统可能引发下列并发症：

临床研究中观察到的事件（见第7部分）

手术过程并发症	严重不良事件	住院期间并发症
• 痉挛	• 死亡	• 再闭塞
• 主动脉剥离	• 再介入性治疗	• 肾衰竭
• 血栓	• ALI	• 假动脉瘤
• 远端栓塞	• 大切断术	• 出血
• 穿孔	• 旁路移植术	
• 其它	• 血肿手术	

临床研究中没有观察到的潜在不良事件（见第7部分）

- 神经损伤
- 形成AV瘘管
- 动脉内膜切除术
- 感染
- 中风
- 心肌梗塞
- 心律不齐

由于采用外围准分子激光再通，所以目前已知情况是，不会对动脉血管壁造成长期的负面影响。

7. 临床研究

本IFU中出现的数据，由一个子集的病人组成，这些病人的来源有三种，均患有重度下肢缺血（CLI），因此接受连续的治疗，并且不适合进行手术：

- LACI 阶段2－于2001－2002年在美国和德国的14个试点，进行前瞻性IDE注册的病人组成一个子集。该子集包括美、德两国7个试点治疗的26个病变下肢（25个病人），均采用步进式激光探通技术。这些病例中有13例从头开始采用步进式技术，即，起初没有尝试采用导丝绕过梗塞。

- LACI比利时－比利时6个试点进行前瞻性注册的51位病人组成一个子集。该子集包括比利时3个试点治疗的9个病变下肢（9位病人），均采用步进式激光探通技术。

- Louisiana病例系列－在Louisiana中部的美国南方心血管研究所（CIS），由专业医师小组进行的持续数据汇编，从中选出62例组成一个子集。这一子集包括12个病变下肢（12位病人），均采用步进式激光探通技术。

表7.1 **程序信息**

动脉病变的位置（n=205）	
SFA	138（67%）
膝后弯处	23（11%）
膝下动脉处	42（20%）
动脉造影结果（n=47例下肢）	
各下肢的病变	4.4
平均损伤长度	73.4 ± 7.3 (mm)
直线流动用于足部固定	37（79%）
植入支架	28（60%）
穿透成功总数*	37（79%）
插入导丝之后穿透成功	24/34（71%）
从头计算病例穿透成功	13/13（100%）
手术成功**	34（72%）

注：治疗46位病人的47例病变下肢。所有百分数的计算均以47例为基础。

*24例下肢插入传统导丝，13例下肢采用从头计算之后，将步进式病例的穿透成功数据分成等级。

**手术成功：≤50%终端残留量狭窄。

表7.2并发症，n=47例下肢

手术并发症	
痉挛	1（2%）
主动脉剥离	4（9%）
血栓	1（2%）
远端栓塞	3（6%）
穿孔	3（6%）
其它	5（11%）
住院期间并发症	
再闭塞	1（2%）
假动脉瘤	1（2%）
肾衰竭	1（2%）
出血	1（2%）
感染	0（0%）
其它	0（0%）

注：治疗46位病人的47例病变下肢。所有百分数的计算均以47例为基础。

表7.3 6个月随访期间，重大不良事件累积（SAE）n＝47例下肢

死亡	3（6%）
MI或中风	0（0%）
再介入性治疗	6（13%）
ALI	1（2%）
大切除	2（4%）
分流手术	2（4%）
动脉内膜切除术	0（0%）
血肿手术	2（4%）
总计	16（34%）

注：治疗46位病人的47例病变下肢。所有百分数的计算均以47例为基础。
MI＝心肌梗塞　　ALI＝急性下肢缺血

表7.4 意向性分析的结果，n=47

穿透成功	37（79%）
手术成功	34（72%）
保肢	40（85%）
死亡，任何原因	3（6%）
任何SAE	16（34%）

注：治疗46位病人的47例病变下肢。所有百分数的计算均以47例为基础。

8. 治疗的个性化

每位病人使用Turbo Elite 装置之前，必须仔细考虑上述各方面的风险与受益。
起初，使用传统导丝穿透不成功时，可以考虑使用CLiRpath 装置，原因在于：

- 圆形或偏心闭塞残肢使导丝倾向血管内膜下通路。
- 导丝重复偏移，进入与闭塞残肢齐平的大型侧副支。
- 钙化物阻断了阻塞腔内形成的导丝通路。

根据第2部分“适应症”和第9部分“操作者手册”提供的说明，选择病人，应用临床技术。

9. 操作者手册

本文件描述的装置，可以在CVX-300准分子激光系统的能量范围内操作：

表9.1 能量参数

装置说明	型号	能量密度	重复频率	激光开/关时间
OTW型导管				
0.9mm	410-152	30-80	25-80′	持续开
1.4mm	414-151	30-60	25-80′	持续开
1.7mm	417-152	30-60	25-80′	持续开
2.0mm	420-006	30-60	25-80′	持续开
2.3mm	423-001	30-60	25-80′	持续开
2.5mm	425-011	30-45	25-80′	持续开
2.3mm	423-135-02	30-60	25-80′	持续开
RX型导管				
0.9mm	410-154	30-80	25-80′	持续开
1.4mm	414-159	30-60	25-80′	持续开
1.7mm	417-156	30-60	25-80′	持续开
2.0mm	420-159	30-60	25-80′	持续开

推荐校准设置：45 能量密度， 25Hz。
*软件V3.812的最大重复频率为80Hz。软件V3.712的最大重复频率为40Hz。

10. 如何贮存

10.1 灭菌

限单次使用。请勿再次灭菌或重复使用。
Spectranetics一次性使用激光光纤导管属于灭菌产品。只有包装未打开且没有损坏，才能保证其灭菌性。

10.2 使用前的检查

使用之前，请检查灭菌包装，确保封条没有打开。操作过程使用的所有设备，包括导管在内，应当仔细检查是否存在缺陷。检查激光导管是否弯曲、扭结或其他损伤。一旦损坏，请勿使用。

11. 兼容性

Spectranetics一次性使用激光光纤导管专门与Spectranetics CVX-300准分子激光系统配合使用。
不得与其它激光系统配合使用。
导丝兼容性
见第1部分的导管规格表。

12. 使用说明

安装程序

下列附加材料没有包含于激光导管包装内，操作过程可能需要其中一部分或全部材料（这些材料仅限单次使用－不得再次灭菌或重复使用）：

1. 尺寸和构型正确的引导鞘和股动脉指引导管，用以选择周围动脉，便于大型激光导管的应用。
2. Tuohy-Borst “y”型适配器或止血阀。
3. 无菌生理盐水
4. 标准比对媒介
5. 0.014”和 0.018”导丝

只限经过末梢血管介入的放射科医生使用CVX-300准分子激光系统，并且要训练以下要求，包括但不限于这些：

1. 安全的发射激光
2. 根据胶片按照使用说明评估病人的损伤
3. 根据使用说明评估激光消融技术应用到栓塞的各种情况。
4. 评估使用CVX-300准分子激光系统进行的激光手术。
5. 亲手练习使用合适型号的CVX-300准分子激光系统。
6. 充分的练习有代表性的Spectranetics公司产品将会有助于处理前三种情况。
7. 伴随有条理的训练再加上经常受内科医生、或者个人支持做Spectranetics公司产品练习，Spectranetics的产品会很有效。

运用灭菌技术，打开无菌包装。从托架上取下包装楔子，将激光导管从托架上轻轻抬起，同时支撑黑色激光接头，也称为近端、近端适配器或近端接口。请注意：激光导管的近端只能连接CVX-300准分子激光系统，切不可与病人接触。

将激光导管的近端接通CVX-300准分子激光系统，并且将激光导管固定于激光系统的延长杆上。按照CVX-300准分子激光系统操作手册的使用说明，校准激光导管。

1. 运用标准股动脉穿刺技术，将一根4Fr.到9Fr.（取决于治疗过程中使用的最大型介入性装置）引导鞘插入股总动脉，以顺行或逆行的方式进行对侧入路。采用肝素化PTA法进行静脉内肝素化。
2. 通过引导鞘或指引导管注射造影剂，进行基线血管造影术。采用复合投影装置获取图像，描绘病变部位的解剖学变异和形态。
3. 通过引导鞘或指引导管，将一根0.014” 、0.018”或0.035”导丝插入外周阻塞。
4. 按大小排列，选择适用的激光导管：

表12.1 推荐尺寸

导管尺寸	最接近的脉管直径
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. 导管外壳进行水合作用，激活亲水涂层。也可以将导管浸泡在装有适用无菌溶液的盆中，或者用湿纱布擦拭导管。
6. 采用5－10ml肝素化盐水或乳酸盐林格氏溶液，冲洗激光导管的导丝腔
7. 使用选定的导丝牵引Spectranetics激光导管的远端。采用荧光镜进行监测，将激光导管指引到病变。激光导管的不透射线标志显示出导管与病变对应的位置。

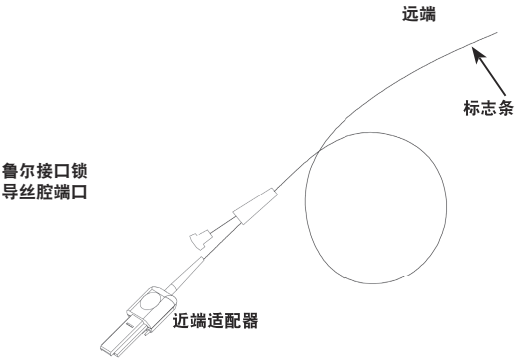

图3（不按比例）

注：在人体内使用期间，类似于其它血管内介入性装置，通常采用荧光镜监测激光导管的移动和不透射线尖端标志的位置。导管远端的移动和推进率，应当直接对应导管上段轴的推进率。

如果对应移动不明显，则需要重新评估病变形态、使用的激光能量和支持设备的状态，方可继续治疗。
如果导管移动不明显，应当加倍小心，不得过度地输送激光能量。

8. 通过引导鞘或指引导管注射造影剂，采用荧光镜确认激光导管的位置。
9. 确认激光导管已接触到目标病变之后，使用生理盐水或乳酸盐林格氏溶液：
   a. 冲洗残留在引导鞘或指引导管和内部接头上的造影剂。
   b. 激活CVX-300准分子激光系统之前，将激光发射点和邻近血管结构上残留的造影剂冲洗干净。
      警示：在有造影剂的情况下 勿启动激光.
   c. 请参照使用说明中盐水输注法的相关内容，根据说明，进行盐水冲洗和输注。
10. 使用Turbo Elite 型导管时，一旦按压脚踏开关，CVX-300准分子激光系统就会连续地释放能量。操作员就可以控制激光链的长度。一般来说，建议连续发射激光不得超过20秒。
11. 治疗完全闭塞的步进式方法
    a. 按压脚踏开关，激活CVX-300准分子激光系统，然后以每秒钟小于1毫米的速度，缓慢地将激光导管插入完全闭塞处2－3毫米，使得激光能量可以切除目标物质。松开脚踏开关， CVX-300准分子激光系统停止运行。
    b. 牵引导丝超出激光导管的远端，进一步插入闭塞物大约几毫米，然后按照上述步骤8所述，再次激活激光器。
    c. 以步进式的方式继续操作，使得导丝及激光导管前移，并且被激活（增量为毫米），直至导管达到闭塞物的最后3－5毫米处。
    d. 穿过闭塞物的最后3－5毫米，使得导丝首先进入远端血管，然后是被激活的激光导管整体型
    e. 将导丝固定就位，抽回激光导管，采用指引导管注射造影剂，通过荧光镜监测病变。
    f. 为了更多地切除病变，需要对整体型进行额外的激光透过率测试

g. 如果导管前移时遇到阻碍（比如钙），应当立即松开脚踏开关， CVX-300准分子激光系统运行中断，停止发射激光。若要继续前移，可以增加能量密度和重复频率。为了避免热积聚，发射激光时必须推移导管。

12. 治疗狭窄的标准方法

a. 按压脚踏开关，激活CVX-300准分子激光系统，然后以每秒钟小于1毫米的速度，将激光导管缓慢地穿过狭窄。松开脚踏开关，CVX-300准分子激光系统停止运行。

b. 为了更多地切除病变，需要对整体型进行额外的激光透过率测试。如果导管前移时遇到阻碍（比如钙），应当立即松开脚踏开关， CVX-300准分子激光系统运行中断，停止发射激光。若要继续前移，可以增加能量密度和重复频率。为了避免热积聚，发射激光时必须推移导管。

13. 为了增加/减少能量密度或脉冲重复频率，无需将激光导管从病人体内拔除：原因是事先已经校准了激光导管。参照CVX-300准分子激光系统操作手册，

14. 激光探通术之后，如果有必要，应当进行随访血管造影术和气囊血管成形术。按要求，对于急性收缩、重度穿孔等病例，可以安放支架。

15. 盐水输注法

a. 进行激光手术之前，将一袋500ml的0.9%生理盐水（NaCL）或乳酸盐林格氏溶液加热到37摄氏度。盐水/LR溶液中无需添加肝素或钾。将这袋热盐水/LR接通灭菌静脉导管，导管的一头连接三联三通。

b. 如果适用，以惯用的方法，将适用的“大腔”指引导管插入动脉的开口部。建议指引导管没有侧孔。

c. 在荧光镜的导引下，推移激光导管，直至接触病变。如果有必要，注射造影剂，有助于定位激光导管的尖端。如果造影剂滞留于激光导管尖端和病变之间，那么，需要将激光导管稍微缩回（1－2毫米），从而使用盐水/LR冲洗系统时，能够顺行流动，除去造影剂。但是，在发射激光之前，要确保激光导管的尖端已经接触病变。

d. 将残留造影剂从可控注射器中排出，放回造影剂瓶中。将盐水/LR通过三通管吸入可控注射器，清除三联三通中的造影剂。

e. 取下最初装于三通管上的可控注射器，换成一支容量为20ml的新鲁尔锁可控注射器。连接之前，这支新的20ml可控注射器应当吸入盐水/LR，以便减少出现气泡的机率。（生产20ml可控注射器的Merit Medical和其他厂家）

f. 使用至少20-30ml 的盐水/LR （several syringes ofsaline/LR），冲洗三通、连接器管道、Y型接头和引导鞘或指引导管上的血迹和造影剂。当完成初次冲洗时，20ml可控注射器中再注入盐水/LR。

g. 借助于荧光镜，确认激光导管的尖端已经接触病变（如果有必要，推移激光导管），但是不要注射造影剂。

h. 当主要操作员提出自己已经准备好激活激光系统时，负责擦拭的助理应当迅速地旋转三通的活塞，使其压力消除，并注射10ml盐水/LR（1－2秒钟内）。这种弹丸注射的目的在于：将血液转移或稀释到毛细血管的水平，限制激光消融区的血液回流。

i. 起初进行10ml弹丸注射之后，且注射活动没有停止，接下来，负责擦拭的助理应当把注射速度放慢到2－3ml/秒。这种注射盐水/LR的比例，其目的是转移或稀释进入激光消融区的顺行血流。此时，负责擦拭的助理应当放慢注射速度，主要操作员应当按压脚踏开关，激活CVX-300准分子激光系统，开始发射激光束。

j. 操作员控制激光链的长度。一般来说，建议连续发射激光不得超过20秒。盐水/LR的注射必须贯穿发射激光的全程。

k. 激光链结束时停止注射盐水/LR。旋转三通的活塞，使其回授压力，可控注射器再次吸入20ml盐水/LR，为下一次发射激光束做好准备。

l. 随后发射每一束激光链之前，均应使用盐水/LR进行弹丸注射，而且按照步骤h-k所述，连续注入盐水/LR。

m. 在激光治疗的过程中，如果使用造影剂评估治疗效果，再次激活CVX-300准分子激光系统（激活准分子激光系统之前应当重复步骤h-k）。

注意：根据使用的方法，顺行或对侧，可以通过鞘（顺行法）或激光导管内腔（对侧法）注入盐水/LR。使用对侧法时，建议使用直径较小的导丝，使得盐水/LR充分地注入手术点。

13. 担保信息

生产商有限担保

生产商保证在有效期内使用的Turbo Elite 一次性使用激光光纤导管，并且使用前包装未打开、没有损坏，其材料和工艺没有缺陷。根据本担保，生产商的责任仅限于更换Turbo Elite 一次性使用激光光纤导管的次品，或者按购买价格退款。生产商不负责由于使用Turbo Elite 一次性使用激光光纤导管造成的任何偶然性、特殊性或结果性损坏。由于误用、改造、不当贮存或操作造成Turbo Elite 一次性使用激光光纤导管的损坏，以及按照本使用说明进行操作而引起其它故障，此时本有限担保无效。本有限担保可以代替其它所有明确或暗含的担保，包括暗含的适销性或特殊目的适合性。任何个人或实体，包括生产商授权的代理或中间商，均无权扩充或延伸本有限担保，任何出于此目的所进行的尝试，对于生产商不具有约束力。本有限担保仅涵盖Turbo Elite 一次性使用激光光纤导管。在CVX-300准分子激光系统的相关文件中，可查找该系统的生产商担保信息。

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代理人地址及联系方式：上海市静安区灵石路718号A1幢
电话：8008100038 **中国**

P012574

系列	型号	导丝兼容性 (mm)	尖端外径 (mm)	最大导管外径 (mm)	传输效率（%）	有效长度 (cm)
OTW	410-152	0.356	≤0.965	≤1.19	≥2.94	150
	414-151	0.356	≤1.40	≤1.42	≥6.89	150
	417-152	0.457	≤1.73	≤1.75	≥11.56	150
	420-006	0.457	≤2.03	≤2.06	≥17.28	150
	423-001	0.457	≤2.31	≤2.31	≥27.78	150
	425-011	0.457	≤2.57	≤2.59	≥41.67	150
	423-135-02	0.89	≤2.31	≤2.31	≥20.28	120
RX	410-154	0.356	≤0.965	≤1.24	≥2.94	150
	414-159	0.356	≤1.50	≤1.57	≥6.50	150
	417-156	0.356	≤1.75	≤1.83	≥9.44	150
	420-159	0.356	≤2.03	≤2.13	≥16	150

【灭菌方式】环氧乙烷灭菌
【有效期】2年
【生产商】Spectranetics Corporation 史派克公司
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【电话】 8008100038
【生产日期】见标签
【产品标准编号】国械注进20163012942
【医疗器械注册证书编号】国械注进20163012942

符号及含义

	制造商		产品编号
	有效期		批号
	不得二次使用		经环氧乙烷灭菌
	欧盟授权代表		怕雨
	无热原		查看使用说明
	仅凭处方销售		如包装破损切勿使用
 0086	CE 标志		温度上限60℃/140