“音術科技”威塑超音波手術吸引系統

“Sound Surgical Technologies” Vaser System

衛署醫器輸字第 020595 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

產品敘述：

本系統包含注射液控制系統、選擇性組織的乳化控制、探針及套管。本系統具有注入、乳化及吸引功能。

用途：

用於震碎、乳化及吸引軟組織，可用於以下科別：

- 神經外科
- 腸胃及相關器官手術
- 泌尿外科
- 整形及重建手術
- 一般外科手術
- 整形外科
- 婦科手術
- 胸科手術
- 消化系統手術

系統組成：

- 注射液流量控制器
- 抽出物收集架
- 威塑超音波供應器
- 注射液幫浦
- Ventx 吸引幫浦
- 無線腳踏板
- 吸引幫浦腳踏板
- 備用腳踏板(選擇性)
- 配件：滅菌托盤、Vaser 手握把、Vaser 扳手、Vaser 頭錐、Vaser 探針、Vaser 切口保護套組、Ventx 套管及握把。
- 滅菌配件(僅限單次使用)：

吸引導管(單支包裝)

注射液導管(單支包裝)

抽出物收集器及導管套組。

規格：

Vaser System (Ventx)	
操作環境	溫度：12℃～40℃/54°F～104°F。溼度：15%～80%，非凝結。
體積	79×46×43cm(W×H×D)
輸入能量	115VAC, 60Hz@300VA 230VAC, 50Hz@300VA
吸力	21 in. Hg(最小)
控制	AC 電源開關、注射液速率控制、注射液正轉/倒轉開關、吸力級數控制、重設按鈕(PFMS)、無線腳踏板接收開關
顯示器	注射液速率、吸引強度、注射液體積(PFMS)、無線腳踏板啟動、無線腳踏板電量、無線腳踏板運作顯示
連接	In-Line HEPA 吸引濾片、吸引接孔、AC 電源線、Vaser 及 PFMS 電源線、注射液流量控制器無線腳踏板、無線腳踏板接收器、吸引幫浦腳踏板
電源線	3 m(醫用等級)
備用腳踏板/注射液流量控制器腳踏板	注射液流量控制器及備用腳踏板必須為"GEM 開關"同時符合以下規格: 3A, 25VAC, 50/60Hz, 最小 IP68(防水)
保險絲	T 6.3 A 250V (2x) (5mm × 20mm)

Vaser System (Amplifer)	
操作環境	溫度：12℃～40℃/54°F～104°F。溼度：15%～80%，非凝結。
體積	10×40×36cm(H×W×D)
輸入能量	115VAC, 60Hz@300VA 230VAC, 50Hz@300VA
操作頻率	36 kHz(視手握把而定)
控制	AC 電源、振幅控制、連續性/Vaser 模式選控按鈕、擴音器開關、計時器重設按鈕、Vaser 測試開關、無線腳踏板接收啟動開關
顯示器	振幅顯示器、連續性/Vaser 模式、超音波震動(圖示)、超音波震動(音效)、超音波震動時間、LED 狀態顯示、接收器啟動顯示、無線腳踏板電量顯示、腳踏板運作顯示
警示	錯誤狀態顯示(圖示及音效二種)
連接	Vaser 手握把、Vaser 腳踏板、AC 電源線、無線腳踏板接收器
電源線	醫用等級
Vaser 腳踏板	Vaser 腳踏板必須為"GEM 開關"同時符合以下規格: 3A, 25VAC, 50/60Hz, 最小 IP68(防水)
保險絲	T 3.1 A 250V (2x) (5mm × 20mm)
週期	間歇性, 15 秒 開, 30 秒 關

Vaser (Handpiece)	
操作環境	溫度：12℃～40℃/54℉～104℉。溼度：15%～80%，非凝結。
輸入功率	75W
振動頻率	36,000 Hz±1000Hz
直徑	2.5cm
長度	17.5cm
Vaser 探針	4.5mm, 3.7mm, 2.9mm, 2.2mm
手握把纜線	3 m, 矽樹酯包覆

警告注意事項

- 所有本系統的操作者皆需詳讀並遵守操作指示。
- 本系統只限販售予合格醫師。
- 本系統可能受到其他電子儀器的干擾。
- 本系統只限於合格醫師操作。
- 術後結果會因病患年齡、治療部位及醫師經驗而有所不同。
- 本儀器所有可重複使用的零件皆需消毒。拋棄式零件在進行新的治療時皆需更換。
- 治療有慢性病史，如糖尿病、心臟、肺部或循環系統疾病或肥胖的病患時應特別謹慎。
- 血液及組織液的流失可能影響術後血液循環的穩定性及病患的安全。
- 本儀器不會有顯著的減重效果。
- 手術中勿將震動的探針與金屬物接觸，其可能造成探針的毀損。
- 勿於空氣中操作手握把及探針，其可能造成產品的毀損。

製造廠名稱：Sound Surgical Technologies, LLC
製造廠地址：357 S. McCaslin Blvd. Suite 100, Louisville, CO80027-2932, U.S.A
藥商名稱：曜亞國際股份有限公司
藥商地址：台北縣中和市中正路 872 號 4 樓之 1

Indications for Use

The VASER System is indicated for use in the following surgical specialties when the fragmentation and aspiration of soft tissue is desired:

√ Neurosurgery
√ Gastrointestinal and Affiliated Organ Surgery
√ Urologic Surgery
√ Plastic and Reconstructive Surgery
√ General Surgery
√ Orthopedic Surgery
√ Gynecologic Surgery
√ Thoracic Surgery
√ Laparoscopic Surgery

Fault (Alarm) Conditions

The VASER Amplifier is equipped with audible and visual indicators (alarms) for a fault condition. The audible alarm is an intermittent tone (on/off bursts). The visual indicator is a red 'F' on the display. The fault indicators will be triggered if:

1. The Footswitch has been depressed and ultrasonic vibration has not been initiated within about one second. See Troubleshooting page 11.
2. Ultrasonic vibration has been initiated and a stall condition is encountered lasting longer than about one second. See Troubleshooting page 11.
3. Excessive VASER Probe loading is encountered. The VASER Amplifier senses the loading present on the vibrating probe. If the VASER Probe loading is excessive, as might occur with overly fibrous tissue for a selected VASER Probe or from 'torquing' of the VASER Handpiece, an alarm will sound. If there is a failure of the equipment, such as a faulty or disconnected Handpiece, an alarm will sound. See Troubleshooting page 11 for more details.

Figure 5. Complete VASER System

1. PFMS
2. Canister Rack
3. VASER Amplifier
4. Infusion pump
5. VentX suction pump
6. Wireless Footswitches
7. Suction Footswitch
8. Back-up Footswitch (if needed)

This user's guide and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

Caution: Federal law (USA) restricts this device to sale to or on the order of a physician.

Instruments and Equipment covered in this User's Guide:

Sterilization Tray	SST PN 130 0028
VASER Handpiece	SST PN 130 0124
VASER Wrench	SST PN 130 0156
VASER Nosecone, 3.7 mm	SST PN 410 0102
VASER Nosecone, 2.9 mm	SST PN 410 0101
VASER Probe, 3.7 mm, 3-groove, 26 cm	SST PN 130 0004
VASER Probe, 3.7 mm, 2-groove, 26 cm	SST PN 130 0016
VASER Probe, 3.7 mm, 1-groove, 26 cm	SST PN 130 0020
VASER Probe, 2.9 mm, 3-groove, 26 cm	SST PN 130 0018
VASER Probe, 2.9 mm, 3-groove, 18 cm	SST PN 130 0019
VentX Cannula, 3.0 mm, SST-6, 26 cm	SST PN 130 0106
VentX Cannula, 3.7 mm, SST-6, 26 cm	SST PN 130 0103
VentX Cannula, 4.6 mm, SST-6, 26 cm	SST PN 130 0100
VentX Suction Handle	SST PN 130 0125
Sound Surgical™ Skin Port Tool and Incision Opener	SST PN 130 0094
4.6 mm Sound Surgical Corkscrew Skin Port (4pk)	SST PN 130 0096
4.6 mm Sound Surgical Skin Port w/White Disks (4pk)	SST PN 130 0017
3.2 mm Sound Surgical Skin Port w/Orange Disks (4pk)	SST PN 130 0120
VASER Probe, 3.7 mm, 1-groove, 33 cm	SST PN 130 0086
VASER Probe, 3.7 mm, 2-groove, 33 cm	SST PN 130 0089
VASER Probe, 2.2 mm, 3-groove, 18 cm	SST PN 130 0091
VASER Probe, 2.2 mm, 3-groove, 12 cm	SST PN 130 0092
VASER Nosecone, 2.2 mm	SST PN 410 0121
VASER Probe, 4.5 mm, 2-groove, 26 cm	SST PN 130 0152
VASER Nosecone, 4.5 mm	SST PN 410 0147
VASER Probe, 3.7 mm, 2-groove, 26 cm, sharp	SST PN 130 0153
VentX Cannula, 2.4 mm, SST-6, 17 cm	SST PN 130 0109
VentX Cannula, 3.0 mm, SST-6, 17 cm	SST PN 130 0105
VentX Cannula, 3.7 mm, SST-6, 17 cm	SST PN 130 0102
VentX Cannula, 3.7 mm, SST-6, 34 cm	SST PN 130 0104
VentX Cannula, 4.6 mm, SST-6, 34 cm	SST PN 130 0101
VentX Cannula, 3.0 mm, Ghost, 17 cm	SST PN 130 0073
VentX Cannula, 3.7 mm, Ghost, 17 cm	SST PN 130 0075
VentX Cannula, 3.0 mm, Ghost, 26 cm	SST PN 130 0062
VentX Cannula, 3.7 mm, Ghost, 26 cm	SST PN 130 0064
VentX Cannula, 3.7 mm, Ghost, 34 cm	SST PN 130 0079
VentX Cannula, 4.6 mm, Ghost, 26 cm	SST PN 130 0066

7.0 Specifications and Standards

This section contains electrical, mechanical, and operating technical specifications for the VentX Console and Accessories. Voluntary compliance standards are listed following the technical specifications.

Technical Specifications

Table 3. Environmental Operating Specifications

Operating Temperature	12° to 40°C/54° to 104°F
Operating Humidity	15% to 80% relative humidity non-condensing

The VentX Console, PFMS and Wireless Footswitch System require a minimum of one hour exposure at their operating temperature range before use.

Table 4. VentX Console and Accessories Specifications

Dimensions (H × W × D)	79 × 46 × 43 cm
Input Power	115 VAC, 60 Hz @ 300VA 230 VAC, 50 Hz @ 300VA
Suction	21 in. Hg (minimum)
Controls	AC power ON/OFF Irrigation Rate Control Irrigation Forward/Reverse Switch Suction Level Control Reset Button (PFMS) Wireless Footswitch Receiver ON Switch
Indicators	Irrigation Rate Suction Gauge Weight Display (PFMS) Wireless Footswitch Receiver Power ON Wireless Footswitch Receiver and Transmitter low battery Wireless Footswitch functioning
Connections	In-line HEPA Suction Filter Suction Port AC Power Cord VASER and PFMS Power Cords Wireless Irrigation Footswitch Wireless Footswitch Receiver Suction Footswitch

continued on next page

Table 4. VentX Console and Accessories Specifications (continued)

Power Cord	3 m Hospital Grade (see details in Table 5)
Back-up Footswitch Irrigation Footswitch, if applicable	The Irrigation and Back-up Footswitch must be "GEM SWITCH" with the following markings: 3A, 25 VAC, 50/60 Hz IP68 minimum (watertight rating) UL registered and CE mark
Wireless Footswitches	See Linemaster® Operators Manual
Fuse	T 6.3 A 250 V (2x) (5mm × 20mm)
IEC Classification	Class I, Type BF, Ordinary Equipment with Respect to Ingress of Water

Table 5. VentX AC Power Cord Specifications

The power supply cord used for this device must be a Hospital Grade detachable cord meeting the following specifications:

	USA and Canada	Europe	Other Countries
Agency Approval	UL - USA and CSA/CUL - Canada	HAR listed	Country Specific
Technical Data	125 VAC, 3 × 18 AWG min., SJT or equivalent	250 VAC 1.33 mm^2, min.	125 or 250 VAC (Country Specific) 1.33 mm^2, min.
Appliance Coupler	Interpower IEC 60320 Connector (right angle optional)		

7.0 Specifications and Standards

Technical Specifications

This section contains electrical, mechanical, and operating technical specifications for the VASER Amplifier. Voluntary compliance standards are listed following the technical specifications.

Table 3. Environmental Operating Specifications

Operating Temperature	12° to 40°C/54° to 104°F
Operating Humidity	15% to 80% relative humidity non-condensing

Table 4. VASER Amplifier Specifications

The VASER Amplifier requires a minimum of one hour exposure at its operating temperature range before use.

Dimensions (H × W × D)	10 × 40 × 36 cm
Input Power	115 VAC, 60 Hz @ 300VA 230 VAC, 50 Hz @ 300VA
Operating Frequency	36 kHz (Handpiece dependent)
Controls	AC power ON/OFF Amplitude Control Continuous/VASER (pulse) Mode Selection Button Speaker ON/OFF Switch Timer Reset Button VASER Test Switch Wireless Footswitch Receiver ON Switch
Indicators	Amplitude Display Continuous/VASER (pulse) Mode Ultrasound Vibration Active (Visual) Ultrasound Vibration Active (Audible) Ultrasound Vibration Time Green Upload Status Indication LED Receiver Power ON Transmitter low battery Footswitch function
Alarms	Fault Condition Visual Indicator Fault Condition Audible Indicator
Connections	VASER Handpiece, VASER Footswitch, AC Power Cord, Wireless Footswitch Receiver

continued on next page

Table 4. VASER® Amplifier Specifications (continued)

Power Cord	Hospital Grade (see details in Table 5)
VASER Footswitch, if applicable	The VASER Footswitch must be "GEM SWITCH" with the following markings: 3A, 250 VAC, 50/60 Hz IP68 minimum (watertight rating) UL registered and CE mark
Wireless Footswitches	See Linemaster® Operators Manual
Fuse	T 3.1 A 250 V (2x) (5mm × 20mm)
IEC Classification	Class I, Type BF, Ordinary Equipment with Respect to Ingress of Water
Duty Cycle	Intermittent use 15 seconds on, 30 seconds off

Table 5. VASER AC Power Cord Specifications

The power supply cord used for this device must be a Hospital Grade detachable cord meeting the following specifications:

	USA and Canada	Europe	Other Countries
Agency Approval	UL - USA and CSA/CUL - Canada	HAR listed	Country Specific
Technical Data	125 VAC, 3 × 18 AWG min., SJT or equivalent	250 VAC 0.83 mm^2, min.	125 or 250 VAC 0.83 mm^2, min.
Appliance Coupler	Interpower IEC 60320 Connector (right angle optional)		

7.0 Specifications

This section contains electrical, mechanical, and operating technical specifications for the VASER Handpiece. Voluntary compliance standards are listed in 7.0 Specifications and Standards in the VASER Amplifier User's Guide.

There are no operating technical specifications for VASER and VentX System Instruments other than the VASER Handpiece.

Technical Specifications

Table 3. Environmental Operating Specifications

Operating Temperature	12° to 40°C/54° to 104°F
Operating Humidity	15% to 80% relative humidity non-condensing

Table 4. VASER Handpiece Specifications

Electrical Input Power (max)	75W
Vibration Frequency	36,000 Hz ± 1000 Hz
Diameter	2.5 cm
Length	17.5 cm
VASER Probe Compatibility	4.5 mm, 3.7 mm, 2.9 mm, 2.2 mm
Controls	None
Handpiece Cable	3 m, silicone jacket

Operator Cautions

Caution: The safe and effective use of this ultrasonic surgical device depends to a large degree on factors solely under the control of the operator. It is important that all operators of this surgical system read, understand, and follow the operating instructions supplied with this equipment.

Caution: Federal (USA) law restricts this device to sale to or on the order of a physician.

Caution: During surgery do not bring the vibrating surgical probe into contact with metal objects such as hemostats, clips, or other metal instruments. Probe damage may result.

Caution: This device complies with the electromagnetic compatibility standard IEC EN60601-1-2. It is possible that this device may interfere with or be disturbed by other electrical devices.

Caution: This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

Caution: Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.

Caution: Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.

Caution: The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

Caution: All reusable components of the device must be sterilized and all disposable components replaced before using the device on another patient.

Operator Warnings

Warning: This device will not, in and of itself, produce significant weight reduction.

Warning: This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes, heart, lung, or circulatory system disease, or obesity.

Warning: The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

Operator Cautions

Caution: The safe and effective use of this medical device depends to a large degree on factors solely under the control of the operator. It is important that all operators of this surgical system read, understand, and follow the operating instructions supplied with this equipment.

Caution: Federal (USA) law restricts this device to sale to or on the order of a physician.

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Operator Warnings

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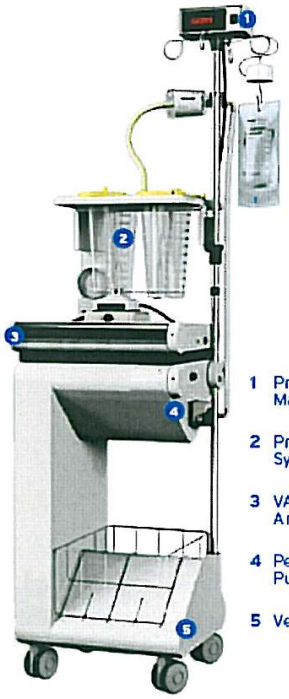
Warning: The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

A Single Integrated System Makes It Easy for You

Specifications

Ventx Console	
Dimensions	79×46×43cm
Input Power	115VAC, 60Hz@300VA 230VAC, 50Hz@300VA
Suction	21 in. Hg(minimum)
Back-up Footswitch Irrigation Footswitch (if applicable)	The irrigation and back-up Footswitch must be"GEM SWITCH" with the following markings: 3A, 25VAC, 50/60Hz IP68 minimum(watertight rating) UL registered and CE mark
Fuse	T6.3A 250V(2x)(5mm×20mm)
Amplifier	
Dimensions	10×40×36cm
Input Power	115VAC, 60Hz@300VA 230VAC, 50Hz@300VA
Operating Frequency	36kHz(Handpiece dependant)
Vaser Footswitch (if applicable)	The Vaser Footswitch must be"GEM SWITCH"with the following markings: 3A, 25VAC, 50/60Hz IP68 minimum(watertight rating) UL registered and CE mark
Fuse	T3.1A 250V(2x)(5mm×20mm)
Duty Cycle	Intermittent use 15 seconds on, 30 seconds off

VASER® LIPO
Sound Surgical Technologies LLC



1 Precision Fluid Management System™
2 Precision Canister System
3 VASER Ultrasonic Amplifier
4 Peristaltic Infusion Pump
5 VentX® Aspiration

Sound Surgical Technologies, LLC
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