

**tyco**

Healthcare

**Valleylab**

October 6, 2000

Lori Windsor  
Freedom of Information Staff, HFZ-82  
Center for Devices and Radiological Health, FDA  
2094 Gaither Rd.  
Rockville, MD 20850

Records Processed under FOIA Request # 2015-6754; Released by CDRH on 09-02-2015  
6999 Longbow Drive  
Boulder, CO 80301-3299

Tel. 800 255-8522  
www.valleylab.com

K981916

REDACTED BY MFR

Re: PDN Notice 98-25229 ✓

Dear Ms. Windsor;

Enclosed is the redacted 510(k) (K981916) in accordance with the above referenced PDN.

Should you have any questions, please contact me at 303-530-6343.

Sincerely,



Charles Copperberg  
Senior Regulatory Associate  
Valleylab



AUG 28 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Charles Copperberg  
Senior Regulatory Affairs Associate  
ValleyLab, Inc.  
5920 Longbow Drive  
Boulder, Colorado 80301

Re: K981916  
Trade Name: Ligasure Vessel Sealing System  
Regulatory Class: II  
Product Code: GEI  
Dated: May 29, 1998  
Received: June 1, 1998

Dear Mr. Cooperberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

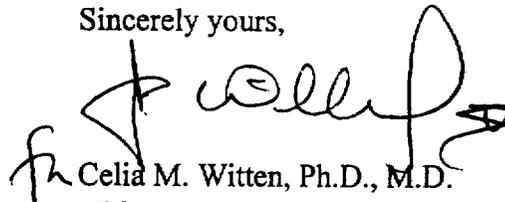
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Charles Copperberg

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and includes a large loop at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known): K981916

Device Name: Valleylab LigaSure™ Vessel Sealing System

Indications For Use:

The LigaSure™ Vessel Sealing System includes a bipolar electro-surgical generator and dedicated bipolar electro-surgical instruments intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation (seal) by the application of bipolar electro-surgical RF energy (coagulation) to vessels interposed between the jaws of the device.

The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general, (including urologic, thoracic, plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over-The-Counter Use   
(Per 2.1 CFR 801.109)

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number

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Senior Regulatory Affairs Associate  
ValleyLab, Inc.  
5920 Longbow Drive  
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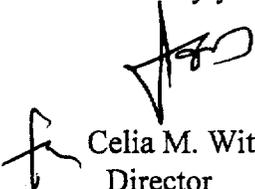
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Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
 Director  
 Division of General and Restorative Devices  
 Office of Device Evaluation  
 Center for Devices and Radiological Health

FILE  
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
3410	Witten	8/28/10			

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Memorandum

From: Reviewer(s) - Name(s) Neil Ogden

Subject: 510(k) Number 6981916

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review \_\_\_\_\_.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?  YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)?  YES  NO

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

A 510(k) summary OR  A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

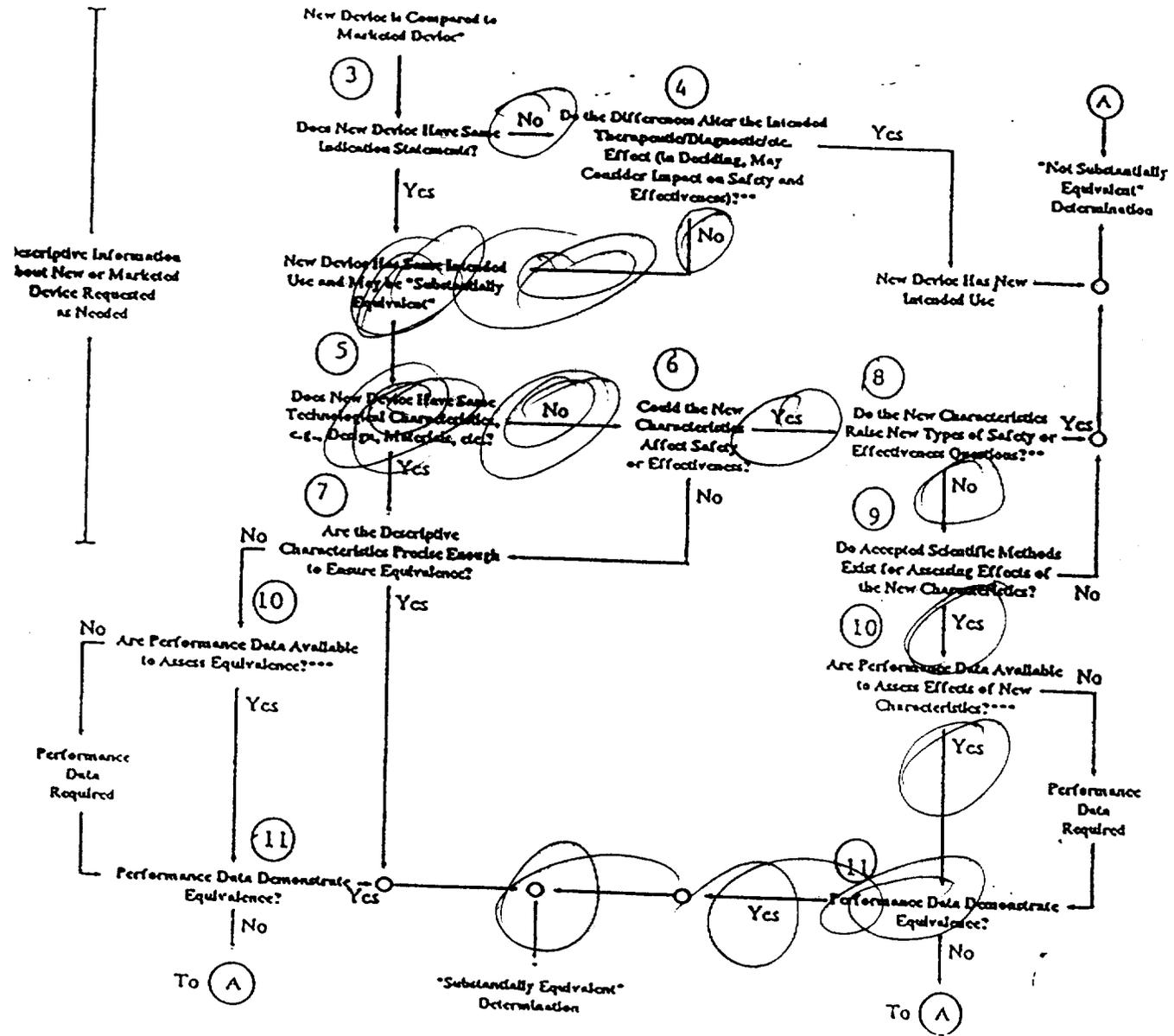
Predicate Product Code with class: GEI Class II, 79 Additional Product Code(s) with panel (optional):

Review: Neil R.P. Ogden (Branch Chief) (GSDB) (Branch Code) 8/27/98 (Date)

Final Review: [Signature] (Date) 8/28/98

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## 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\* Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

## 510K MEMO RECORD

DATE: August 27, 1998

TO: The record, K981916.MEM

FROM: Neil R. P. Ogden, Biomedical Engineer, (HFZ-411).

SUBJECT: ValleyLab, Inc. has submitted information for their premarket notification (510(k) for their Ligasure™ Vessel Sealing System.

CONTACT: Mr. Charles Copperberg, Senior RA Associate, (303) 530-6343.

---

The sponsor wants to introduce this device into interstate commerce.

### Summary:

The LigaSure™ Vessel Sealing System includes a bipolar electrosurgical generator and dedicated bipolar electrosurgical instruments. The system is intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. This system offers an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar device where bipolar cutting and/or coagulation are required. Specifically this system consists of the LigaSure™ Vessel Sealing Generator,

LigaSure™ Footswitches (Model LS0010 & LS0020),

LigaSure™ Standard Instrument (LS2070),

LigaSure™ "MAX" Instrument (LS3090),

LigaSure™ Disposable 5mm "Lap" Instrument w/ cord (LS1000),

LigaSure™ Disposable Electrode & Cord Assembly for the Standard Instrument (LS2071),

LigaSure™ Disposable Electrode & Cord Assembly for the "MAX" Instrument (LS3091), and

LigaSure™ Instrument Sterilizer Case (LS0100).

The indications for use include general, (including urologic, ~~cardiovascular~~, thoracic, plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The device can be used on vessels up to 7 mm and bundles as large as will fit in the jaws of the instruments. These indications are SE to the cited Cabot predicate bipolar device.

**The sponsor needs to add a statement that this device is NOT effective for use in tubal sterilization/tubal coagulation for sterilization procedures.** This wording has been added to their labeling and the indications are SE to the predicates.

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I spoke with Mr. Collin Pollard, Branch Chief OGDB, and Ms. Kathy Dawes-Kopp, Lead Reviewer for Electrosurgical devices in OGDB. They both told me that this technology is reviewed under Tier 1 status if the above bolded contraindication/statement is included. They have no issues regarding GYN indications. I spoke with Dr. Schultz about the "bowel resections" wording and he has no issues with that wording.

Labeling:

Valleylab makes the following recommendations with regard to the use of the LigaSure™ Vessel Sealing System:

- Pacemakers and implanted cardioverter/defibrillators can be adversely affected by RF signals. Consult the pacemaker/cardioverter/defibrillator manufacturer for further information when use of electrosurgical equipment is planned in patients with these devices. If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer instructions before performing electrosurgery. This treatment may cause multiple activations of an IM's.
- Valleylab recommends against the use of laparoscopic surgery on pregnant patients.
- Valleylab recommends against the use of electrosurgery for circumcisions.

The user manual contains detailed instructions on set-up and operation of the system/handpieces, adequate cautions and warnings, trouble shooting and alarm signal definitions. The manual does a good job of provided the necessary information for safe and effective operation of this system by a qualified professional. The labeling is adequate.

Sterility:

The tips and cord assembly will be provided sterile for single use only. The reusable base handles will be sold non-sterile. Sterile products will be sterilized via either 100% EtO or Gamma radiation to an SAL of  $10^{-6}$  following AAMI EtO (ST27-1988) or Electron Beam radiation guidelines (ST31-1990). EtO residuals will be 25, 25, 250 ppm for EtO, Et-Chlorohydrin, & Et-Glycol respectively. Sterile device will be packaged in thermoformed PETG trays with a Tyvek lid. Adequate instructions for cleaning and sterilizing the reusable handles are given in the user manual. No sterility issues remain.

Predicate Device:

ValleyLab claims SE to the Circon Cabot 5mm Seitzinger Tripolar Cutting Forceps (K932293) indicated for use during operative laparoscopic procedures for bipolar coagulation of tissue followed by mechanical cutting of the tissue. Typical indications for laparoscopic bipolar coagulation followed by cutting include laparoscopic cholecystectomy, laparoscopically assisted vaginal hysterectomies (LVAH), Laparoscopic myomectomy, Uterosacral nerve ablation, Colectomy, Nissen fundoplication, adhesiolysis, oophorectomy, laparoscopic supra cervical

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hysterectomy, Salpingectomy. Valleylab also claims SE to their own predicate bipolar generator devices cleared under K944602, K953195, & K946177. Each of these predicates use the same bipolar waveform and have SE output parameters. 510(k) Section 10 holds additional information. Market SE is shown.

Technical:

The generator produces output power from 0-200 watts for bipolar their delivery system. The LigaSure™ Vessel Sealing Generator has three output modes; standard, Macro, and Vessel Sealing mode. The output powers range from 0-95 for the Std. and Macro and 0-150 watts in Vessel Sealing mode. The current maximums are 3.0 amps for Std. & Macro, and 5.0 Amps for Vessel Sealing. All output has a 470 kHz sinusoidal frequency and waveform. The maximum output for the predicate bipolar generators is 70 Watts and 2.0 Amps. **So we have a 2.5 times increase in current maximum, 2.143 times increase in power maximum over the predicates, and about the same voltage output.**

The generator is an isolated, microprocessor based, bipolar device. The generator operates through a closed loop control implemented in microcontroller firmware. As tissue impedance rises from a short circuit to an open circuit, the algorithm first implements constant current, then constant power, and finally constant voltage. The vessel sealing process is software controlled. Impedance sensors triggers the predetermined output cycle. When the automated cycle is completed the generator gives an audio and visual indication. The generator will read encoded connectors to determine the type of delivery system to which it is attached. Only vessel sealing delivery systems will enable the vessel sealing mode of the generator. Other delivery systems will enable the standard bipolar modes of the generator allowing the use of any bipolar handpieces. The primary fail-safe system in the generator is the dosage error circuit(DEC). The DEC monitors the output performance characteristic as a function of the generator set-up and warns the user if the unit is operating out of specified ranges. The generator is then disabled.

The instruments provided with this system are bipolar forceps type devices with scissors action & flat jaws to apply the bipolar energy. The tips are similar to "Pean" and "Heaney" hemostats. The base instruments are reusable and the tips are disposable.

The sponsor states that this system and its components have been designed and tested to meet IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, and AAMI/ANSI HF-18 standards. EMC issues have also been adequately addressed by the sponsor.

The sponsor has provided animal data to demonstrate the equivalence of performance. They did a side-by-side comparison of their device, Ethicon's Ultracision Laparoscopic coagulating shears, and the Cabot predicate tissue coagulation in vivo porcine blood vessels from 0-2mm, 2-4mm, & 4-7mm in size. Average thermal spread for the LigaSure™ devices (10 vessels in each size) was equal to or less than the tested predicates. Burst strength measurements for these vessels showed the LigaSure™ device performance to be SE.

Valleylab did a side-by-side comparison of their device and the Cabot predicate tissue coagulator in vivo canine blood vessels from 1-7mm in size. 56 seals with LigaSure™ and 34 with Cabot were made. No seals failed (fail=blood flow through seal) with the Ligasure™ and 7

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failed with the Cabot device. Histological examination of the coagulated vessels showed generally uniform fusion sites with intima to intima fusion in both arteries and veins. A chronic study in canines was performed to verify performance, reliability, & safety between these same two devices. Vessel sealing during small bowel resection, splenectomy, and right or left salpingo-oophorectomy was performed. Vessels from 1-7mm were sealed, the animals were closed and observed for 7 days. All 3 animals survived with a total of 86 seals. The animals were euthanized and the seals examined. 3 seal failures were observed, one due to user error and two due to device malfunction unrelated to sealing performance. All other seals were intact and dry.

This study information shows the performance of this system to be as good or better than the currently marketed bipolar devices with the same indications even with the increase in current and power output. Technical SE is shown.

Materials:

The LigaSure™ Standard Instruments are made of AISI stainless steel (SS). The tips are SS with insulation. The LigaSure™ Laparoscopic Instrument handle & lever are thermoplastic. The electrode is SS. The push rod and outer tube are SS. The sponsor states that all patient contacting materials have been or are currently being tested under ISO 10993-1 for biocompatibility and must pass prior to release. The test include cytotoxicity, delayed sensitization, implantation, hemolysis, and . No materials issues remain.

Software Verification and Validation:

The sponsor has correctly chosen the moderate level of concern for the software in this system. They state that they have designed and validated this software in accordance with our guidelines (FDA Reviewer Guidance for Computer Controlled Medical Devices). Valleylab has provided their Design Input Document, Software Requirements document, System Risk Analysis, Software Development Process description, Software Verification Plan, and Software Certification Statement. The information provided in these documents is sufficient to meet the requirements of our software guidance and assure that the software will perform as desired.

I spoke with Mr. Copperberg on 8-19-98 and 8-25-98 about the indications for use statements and the promotional labeling. The indications needs the above bolded additional contraindication for tubal ligation, the cardiovascular claim needs to be removed. The sponsor has provided revised labeling as requested.

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**Recommendation:**

I recommend that this application be found SE to the cited predicates. GEI - 79, Class II, Electrosurgical devices.



Neil R. P. Ogden, M.S.

nrpo:K981916.MEM

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## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2. Did we grant expedited review?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. Have you verified that the Document is labeled Class III for GMP purposes?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4. If, not, has POS been notified?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. Is the device exempt from 510(k) by regulation or policy?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7. Is the device subject to review by CDRH?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8. Are you aware that this device has been the subject of a previous NSE decision?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9. If yes, does this new 510(k) address the NSE-issue(s); (e.g., performance data)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
10. Are you aware of the submitter being the subject of an integrity investigation?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
11. If, yes, consult the ODE Integrity Officer.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

MB

## Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: <i>Ligasure Vessel Sealing System</i>						K971966	
Submitter (Company): <i>Valley Lab.</i>							
Items which should be included <i>(circle missing &amp; needed information)</i>	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>1. Cover Letter clearly identifies Submission as:</b> a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)							
	GO TO # 2,4		GO TO # 3,4,5		K	GO TO # 4,5	
<b>2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE</b>							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) <b>STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>							
c) <b>STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>							
d) Design Control Activities Summary							
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis							
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied							
iii) A declaration of conformity with design controls. The declaration of conformity should include:							
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met							
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.							

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Page 1

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS</b>							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

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**GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS**

✓ IF ITEM IS NEEDED AND IS MISSING

	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, address of manufacturer, device class					/		
b) OR a statement that the device is not yet classified							FDA - may be a classification request; see coordinator
c) identification of legally marketed equivalent device	NA				/		
d) compliance with Section 514 - performance standards	NA				/		
e) address of manufacturer					/		
f) Truthful and Accurate Statement					/		
g) Indications for Use enclosure					/		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					/		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					/		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					/		
k) Proposed Labeling:					/		
i) package labeling (user info)					/		
ii) statement of intended use					/		
iii) advertisements or promotional materials					/		
i) MRI compatibility (if claimed)					/		
m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					/		
i) labeling					/		
ii) intended use					/		
iii) physical characteristics					/		
iv) anatomical sites of use					/		
v) performance (bench, animal, clinical) testing	NA				/		
vi) safety characteristics	NA				/		
n) If kit, kit certification					/		
<b>5. Additional Considerations: (may be covered by Design Controls)</b>							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials					/		
iii) biocompatibility of final sterilized product					/		
b) Sterilization and expiration dating information:							
i) sterilization method					/		
ii) SAL					/		
iii) packaging					/		
iv) specify pyrogen free					/		
v) ETO residues					/		
vi) radiation dose					/		
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 6/27/14

Reviewer: \_\_\_\_\_  
 Concurrence by Review Branch: \_\_\_\_\_

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Valleylab Inc  
5920 Longbow Drive  
Boulder, CO 80301 USA  
Tel 303 530 2300

Records Processed under FOIA Request # 2015-6754; Released by CDRH on 09-02-2015



## FAX TRANSMITTAL

**Date:** 08/27/98

**To:** Neil Ogden  
FDA/ODE/DGRD  
Fax # 301-827-4350

**From:** Charles Copperberg  
Valleylab RAQA  
303-530-6343  
Fax 303-530-6313

**Subject:** K981916 LigaSure 510(k)

**Total Pages:** 21

Attached you will find the information you requested. If you need anything from me, please let me know.

A handwritten signature in black ink, appearing to read "Charles Copperberg". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Charles Copperberg  
Senior Regulatory Affairs Associate

*A Division of United States Surgical Corporation*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8188

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5920 Longbow Drive  
Boulder, CO 80301-3299 USA  
Tel 800 255 8522

August 27, 1998

Neil Ogden  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
Office of Device Evaluation/DGRD  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Submission K981916 LigaSure Vessel Sealing System

Mr. Ogden:

Subsequent to our discussions of August 26th and 27th, I am submitting the following modifications to the above referenced 510(k) submission:

1. Section G, Intended Use, has been modified to remove the cardiovascular indication. (Paragraph 2, line 1). A copy of the modified page is included under Attachment # 1 to this letter. In addition, the "Indications for Use" statement, page 21 of the 510(k) and the Summary of Safety and Effectiveness have also been changed to reflect this modification. These documents are also included in Attachment # 1.
2. The labeling for the products has been modified to include the following statement in the warnings sections:  

"The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulations for sterilization procedures. Do not use this system for these procedures"

Copies of representative labeling including this statement can be found in Attachment # 2.
3. The proposed/draft advertisement included in the original 510(k) submission was provided only as an example of how the information may be presented. It was prepared in the early stages of the project when specific claims had not yet been identified or substantiated. Based on our discussions I have deleted those claims which are not substantiated by test data. The draft advertisement with the deletions can be found in Attachment # 3. These are as follows:

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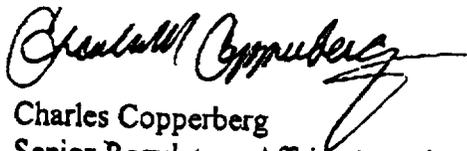
Records Processed under FOIA Request # 2015-6754; Released by CDRH on 09-02-2015

- Page 3 - "Speed" The reference to sealing with an average of 5 seconds will be eliminated.
- Page 5 - "Skeletonized vessels" refers to vessels that have had the surrounding tissue removed. Examples of vessel sizes may be provided which will have the specific vessel name and its associated (approximate) diameter. No vessels will be shown that are larger than 7 mm.
- Page 6 - The statement containing the average completed seal time of 5 seconds will be eliminated as will the statement indicating an average reduction in procedural time.
- Page 7 - The phrase "Reduces Costs" will be eliminated.

Any substantiation of claims such as these will be the subject of future submissions.

Please let me know if you have any additional questions on the 510(k) submission or on the modifications noted above. I will also be sending you a hard copy of this information. Thank you for your attention and assistance.

Sincerely,



Charles Copperberg  
Senior Regulatory Affairs Associate

# **ATTACHMENT # 1**

Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery for the devices used in general surgery, and,

Class II, 21 CFR884.4120, Gynecologic Electrocautery and Accessories, for the electrosurgical actives used in gynecological procedures.

**D. Conformance with Section 514 Performance Standards**

Performance standards have not yet been promulgated for this device classification, therefore, Section 514, Performance Standards, of the Food Drug and Cosmetic Act, as amended, does not apply.

**E. Product Labeling**

Labeling for the LigaSure™ Vessel Sealing System includes product identification, cautions to the operator, warnings, contraindications, medical claims as well as instructions for use. Product labeling for the LigaSure™ system is provided in Attachment # 1. This attachment also includes an outline of the contents of the Service Manual which will be completed prior to market introduction.

**F. Advertising**

Attachment # 2 to this submission contains a copy of proposed/draft advertising literature for the LigaSure™ Vessel Sealing system. The information contained in this literature is supported by preclinical and bench testing. Reference Section L, "Safety and Performance" in this submission.

**G. Intended Use**

The LigaSure™ Vessel Sealing System includes a bipolar electrosurgical generator and dedicated bipolar electrosurgical instruments. The system is intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. This system offers an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting and/or coagulation are required.

The indications for use include general, (including urologic, thoracic plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic choleystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

21

510(k) Number (if known): K981916

Device Name: Valleylab LigaSure™ Vessel Sealing System

Indications For Use:

The LigaSure™ Vessel Sealing System includes a bipolar electrosurgical generator and dedicated bipolar electrosurgical instruments intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation (seal) by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device.

The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general, (including urologic, thoracic, plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 2.1 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

0.5 72

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION  
VALLEYLAB LIGASURE™ VESSEL SEALING SYSTEM**

**I. Submitter Information**

Valleylab Inc  
a division of United States Surgical Corporation  
5920 Longbow Drive  
Boulder, Colorado 80301  
Contact: Charles M. Copperberg  
Telephone No.: 303-530-6343

Date Summary Prepared: 08/27/98

**II. Name of Device**

Proprietary Name: LigaSure™ Vessel Sealing System including the LigaSure™ Vessel Sealing Generator and LigaSure™ Open and Laparoscopic Instruments

Common or Usual Name: Bipolar Electrosurgical Generator with bipolar electrosurgical open and laparoscopic instruments

Classification Name: CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories and 21 CFR 884.4120 Gynecologic Electrocautery and Accessories

**III. Predicate Devices**

The LigaSure™ Vessel Sealing Generator is a bipolar generator which is substantially equivalent to the following Valleylab electrosurgical generators: Force FX (K944602), Force 300 (K953195) and NS2000 (K946177).

The LigaSure™ Open and Laparoscopic Instruments are substantially equivalent to the Cabot Seitzinger Tripolar Forceps, the Cabot Bipolar Cutting Forceps (K932293 and K946109) and the Storz Bipolar Forceps (K960009). All of these devices perform the coagulation of tissue via bipolar RF energy applied through the electrodes of the devices.

**IV. Device Description**

The LigaSure™ Vessel Sealing Generator is an isolated, microprocessor based, bipolar only electrosurgical generator which incorporates three bipolar modes; standard, macro and vessel sealing. The generator will accept standard bipolar devices. In addition, the generator will also accept dedicated LigaSure™ Open and Laparoscopic Instruments for use in vessel sealing.

The LigaSure™ Open instruments are reusable forceps type devices with "snap-in" single use, disposable electrodes which are placed in the jaws of the devices. The LigaSure™ laparoscopic

instrument is a sterile, single use device for use in grasping and vessel sealing in laparoscopic procedures. The device outer diameter is 5 mm and the working length is approximately 32 cms.

The system creates vessel ligation by the application of bipolar electrosurgical RF energy (coagulation/desiccation) to vessel tissue or vascular bundles interposed between the electrodes of the device.

#### **V. Intended Use**

The LigaSure™ Vessel Sealing System is intended for use in general, laparoscopic, and gynecologic procedures where ligation of vessels is desired and as an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

Indications for use for this type of ligation include general, laparoscopic and gynecological procedures such as urological, thoracic, plastic and reconstructive, bowel resections, hysterectomies (LAVH and abdominal) cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

#### **VI. Summary of Technological Characteristics**

The LigaSure™ Vessel Sealing generator and instruments have the same basic technological characteristics as the predicate devices noted above. The LigaSure™ generator provides bipolar RF energy to bipolar devices for coagulation/desiccation of vessels.

#### **VII. Performance Data**

Preclinical laboratory (acute and chronic studies) and performance testing were performed to ensure the devices functioned as intended and met design specification. Sufficient data was obtained to show the LigaSure™ Vessel Sealing system was equivalent to or better than the predicate devices and meet safety and effectiveness criteria.

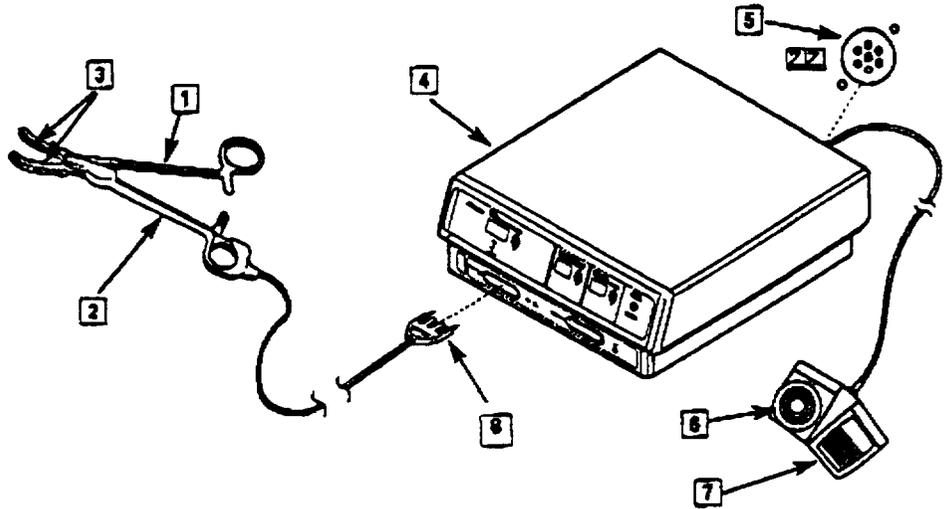
## **ATTACHMENT # 2**

**LigaSure™ System  
Vessel Sealing Electrode/Cord  
Assembly**

for use with LigaSure Vessel Sealing Handsets

- SEE CAT. LS2071 for use with LS2070 LigaSure Standard Handset, 7 in.
- LS3091 for use with LS3090 LigaSure Max Handset, 9 in.

Single Use



- 1 Reusable LigaSure Handset
- 2 Electrode Wire Guide
- 3 Snap-in Electrodes
- 4 LigaSure Generator
- 5 Vessel Sealing Footswitch receptacle
- 6 Vessel Sealing Footswitch
- 7 Standard Bipolar Footswitch
- 8 Smart Connector

**DRAFT**



**Prior to surgery, read all instructions and precautions provided with the electrode, handset, and electro-surgical generator to be used.**

**Warnings**

This device has been specifically designed for sealing vessels and tissue in open surgical procedures only. The LS2070 and LS3090 LigaSure Handsets are intended for use ONLY with the Valleylab LigaSure Vessel Sealing System. Use of these handsets with other Valleylab generators or with generators produced by other manufacturers could result in injury to the patient or surgical team or cause damage to the instrument. The LS2070 LigaSure Handset can only be used with LS2071 Electrodes. The LS3090 LigaSure Handset can only be used with LS3091 Electrodes. Use of these handsets with any other electrodes or use of these electrodes with any other handset could result in injury to the patient or surgical team or cause damage to the instrument.

*Handwritten note:* C. Rosenberg 8/27/98

The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulations for sterilization procedures. Do not use this system for these procedures.

Before installing or removing the electrodes, ensure that the handset is not connected to the electro-surgical generator and the generator is OFF or in Standby mode. Do not wrap accessory cords around metal objects; doing so may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

**Fire Hazard.** Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electro-surgical accessories that are activated or hot from use can cause a fire. When not using active accessories, place them in a holster or in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

**Electric Shock Hazard.** Do not connect wet accessories to the generator.

**Inspect accessories and cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.**

Single Use Only

**STERILE**

*Handwritten signature:* 87 26



# Patient and Operating Room Safety

**DRAFT**

The **safe and effective use** of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been used safely in numerous procedures. Before starting any surgical procedure, the surgeon should be trained in the particular technique and surgical procedure to be performed, should be familiar with the medical literature related to the procedure and potential complications, and should be familiar with the risks versus the benefits of utilizing electrosurgery in the procedure.

28 27

## General

**Warning:** Accidental and unintended burn injury has occurred during procedures in small surgical fields and on small appendages. Catastrophic results have been reported in the context of neonatal and pediatric circumcisions.<sup>1</sup> In those cases of confirmed thermal injury during neonatal and pediatric circumcisions, the mechanism of injury appears to have been associated with contact between a metal clamp (such as a Gomco clamp or a Kocher clamp) in the surgical field and the active electrode, which greatly increased current flow.<sup>2</sup> (See *Contact with Metal Objects* later in this section for further information on the dangers of contact with metal instruments.)

It has also been reported that properly trained physicians use electrosurgery safely in the performance of circumcisions, and that pediatric urologists use electrosurgery with surgical procedures performed on the genitals of male neonates. In performing such procedures, it is reported that many physicians use the electrosurgical generator in a coagulation mode to achieve hemostasis of bleeders, however "buzzing" hemostats clamped to bleeders may increase the risk of thermal injury.

**Warning:** Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.

**Warning:** If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activations of ICDs.

*CM Copperberg  
8/27/18*

**Warning:** The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulations for sterilization procedures. Do not use this system for these procedures.

**Warning:** Valleylab recommends against the use of laparoscopic surgery on pregnant patients.

**Warning:** Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

1 The American National Standard for Electrosurgical Devices (ANSI/AAMI HF 18-1993) provides: "Electrosurgery should not be used to perform circumcisions."

2 Information on the safe use and thermal hazards associated with the use of high frequency electricity (electrosurgical machines) in health care facilities appears in NFPA 99, Annex 2, reference in the JCAHO Accreditation Manual for Hospitals.

28

**Warning: Hazardous Electrical Output** — This equipment is for use only by trained, licensed physicians.

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3 U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). *Control of Smoke from Laser/Electric Surgical Procedures*. HAZARD CONTROLS, Publication No. 96-128, September, 1996.

30 29

## **ATTACHMENT # 3**



**Surgical cases aren't  
always predictable...  
but occlusion should be.**



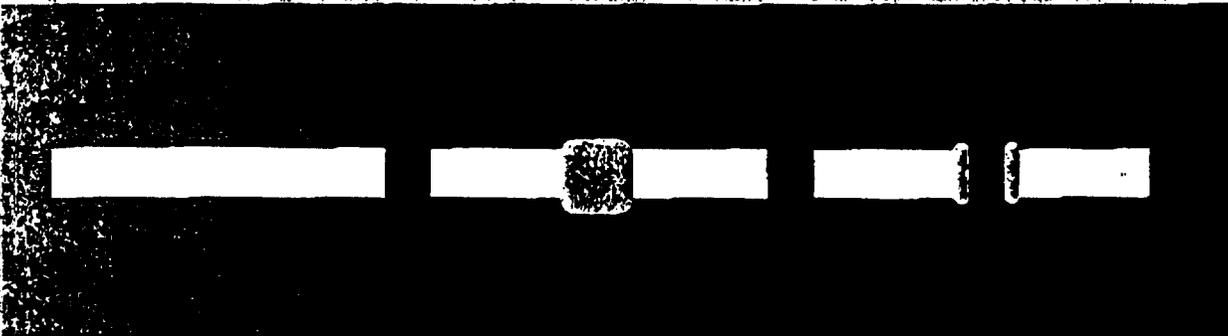
...the most common  
cause of bleeding  
is the lack of  
adequate hemostasis  
at the surgical site.

**LigaSure**

132 -  
31

**An added degree of confidence in virtually any surgical procedure.**

# *Ligasure Vessel Sealing*



Caption will be placed here for the first image illustration

Caption will be placed here for the middle image illustration

Caption will be placed here for the third image illustration

*Ligasure Vessel Sealing* provides fast, reliable seals on a wide range of open and laparoscopic procedures including:

- > Abdominal hysterectomies
- > Vaginal hysterectomies
- > Laparoscopic vaginal hysterectomies
- > Salpingo-oophorectomies
- > Small bowel resections
- > Large bowel resections
- > Small intestine resections

You can use *Ligasure Vessel Sealing* on a wide range of vessel and tissue thicknesses to create a permanent seal proven to withstand up to three times the patient's physiological blood pressure.

33  
32

**Handle a range of vessel sizes and tissue bundles.**

**Minimize collateral tissue damage with on-target vessel sealing every time.**

*CM Copperberg  
8/27/18*

**Added reassurance with a seal you can see...and a signal you can hear.**

**Ensure burst strength up to three times the patient's physiologic blood pressure.**

**Get in and out with minimal invasiveness wherever you need access.**

**No sutures, staples, clips or clamps to leave behind.**

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOI@FDA.HHS.GOV

*34  
33*

**No other occlusion method offers LigaSure Vessel Sealing's  
combination of versatility, strength, safety and speed.**

35  
3h



Compared to everything from sutures, clips, and staples to energy-based occlusion systems, LigaSure Vessel Sealing provides surgeons with the widest range of possibilities while significantly reducing risks. The patented system uses a unique combination of energy and pressure precisely confined to only the targeted tissue. It fuses vessel walls to create a permanent seal

**Work equally well on a range of vessel sizes and tissue bundles.**

- *Skeletonized vessels or tissue bundles*
- *Seal vessels from 1mm to 7mm*
- *Ideal for open and lap procedures*
- *Faster and more efficient than other methods*

**Keep collateral damage to an absolute minimum.**

- *Highly precise tissue targeting*
- *Automatic shut-off when seal is completed*
- *Correct pressure is set automatically*



*1mm to 7mm*



*1mm to 7mm*



*1mm to 7mm*



*1mm to 7mm*



*1mm to 7mm*



*1mm to 7mm*

36  
35



**Complete a successful procedure as quickly as possible.**

*CM Copperberg  
8/27/98*

**See...and hear...the difference.**

- *Where visualization is possible, translucent seal gives you visual assurance of completion*
- *Audible verification always confirms seal and tells you the system is off*

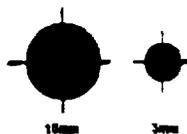
**Proven strong, reliable, permanent.**

- *Proven burst strength of 3x physiologic blood pressure*
- *Strength is the same, regardless of vessel size*

- *No suturing, stapling, clamping, cutting or tying*

**Get into confined spaces conveniently.**

- *Better access and less invasive than other methods*
- *5 mm lap instrument*
- *Ideal for delicate situations*



*37  
36*

**Reduce risks by leaving nothing behind.**

- *No clips, clamps, sutures or staples*
- *Reduces risks*

*Chopperberg  
8/27/98*



To see how good LigaSure Vessel Sealing really is, you have to try it on your kind of cases. Just call your VALLEYLAB sales representative for an evaluation. Or call customer service 1-800-255-8522 for our clinical information package.

**LigaSure**<sup>™</sup>  
VESSEL SEALING

June 02, 1998

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

VALLEYLAB, INC.  
5920 LONGBOW DR.  
BOULDER, CO 80301  
ATTN: CHARLES COPPERBERG

510(k) Number: K981916  
Received: 01-JUN-1998  
Product: LIGASURE VESSEL  
SEALING SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff  
Office of Device Evaluation  
Center for Devices and Radiological Health

h981914



5920 Longbow Drive  
Boulder, CO 80301-3299 USA  
Tel 800 255 8522

May 29, 1998

Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

RECEIVED  
FDA/CDRH/ODE/DMC  
398

Re: Section 510(k) Notification

Attention: Documentation Clerk

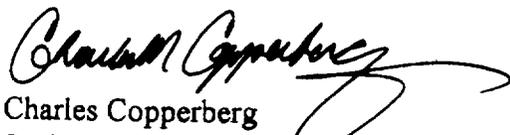
Valleylab Inc is submitting two (2) copies of the information required for notification under Section 510(k) of the Food, Drug and Cosmetic Act, as amended, for distribution of the Valleylab LigaSure™ Vessel Sealing System. The Valleylab LigaSure™ Vessel Sealing System is classified as Class II devices under 21CFR878.4400 Electrosurgical Cutting and Coagulation Device and Accessories and 21CFR884.4120 Gynecologic Electrocautery and Accessories.

Valleylab considers our intent to market this device for the indications described herein to be confidential information, and therefore, exempt from public disclosure. Portions of this submission may be considered to be trade secrets and/or confidential information. These sections, if any, have been marked as confidential and should be treated as such even after marketing commences.

All correspondence related to this submission should be addressed to the attention of the undersigned.

Sincerely,

VALLEYLAB INC

  
Charles Copperberg  
Senior Regulatory Affairs Associate  
Valleylab Inc

JUN 1 8 59 AM '98

SK-14

SC  
CLASS II



5920 Longbow Drive  
Boulder, CO 80301-3299 USA  
Tel 800 255 8522

**PREMARKET NOTIFICATION**  
**TRUTHFUL AND ACCURATE STATEMENT**

**(As required by 21CFR807.87(j))**

I certify that, in my capacity as Senior Regulatory Affairs Associate of Valleylab, Inc, I believe to the best of my knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and no material fact has been omitted.

  
Signature

Charles M. Copperberg  
Senior Regulatory Affairs Associate  
Valleylab Inc

May 29, 1998

41 60

**Section 510(k) Notification**

**LigaSure™ Vessel Sealing System**

Valleylab Inc  
5920 Longbow Drive  
Boulder, Colorado 80301

4/2 h1

**Valleylab LigaSure Vessel Sealing 510(k)**  
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Attachment # 2	Proposed Advertisement
Attachment # 3	Device Drawings
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Attachment # 6	Safety Testing
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Attachment # 12	LigaSure Instrument Comparison Chart
Attachment # 13	Storz Safety and Effectiveness Summary

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h2

**Section 510(k) Notification**

Valleylab Inc  
5920 Longbow Drive  
Boulder, CO 80301

**A. Name of Device**

Proprietary Name:

LigaSure™ Vessel Sealing System

Common, Usual or Classification Name:

Bipolar Electrosurgical Generator with Electrosurgical open and laparoscopic instruments

**B. Establishment Registration**

Valleylab Inc  
5920 Longbow Drive  
Boulder, CO 80301  
Registration Number 1717344

The sterile devices of this system are designed to be sterilized by any of the following three companies:

Sorex Medical (Ethylene Oxide Gas)  
5725 W. Harold Gatty Road  
Salt Lake City, UT 84116  
Registration Number 1721676

Isomedix (Gamma Irradiation)  
1435 Isomedix Place  
El Paso, TX 79936  
Registration Number 1643817

Titan Scan Systems (Electron Beam)  
6750 E. 46th Avenue Drive  
Denver, CO 80216  
Registration Number 1722530

**C. Classification**

Based on the intended uses of these devices, the classifications will be:

Class II, 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery for the devices used in general surgery, and,

Class II, 21 CFR 884.4120, Gynecologic Electrocautery and Accessories, for the electrosurgical actives used in gynecological procedures.

**D. Conformance with Section 514 Performance Standards**

Performance standards have not yet been promulgated for this device classification, therefore, Section 514, Performance Standards, of the Food Drug and Cosmetic Act, as amended, does not apply.

**E. Product Labeling**

Labeling for the LigaSure™ Vessel Sealing System includes product identification, cautions to the operator, warnings, contraindications, medical claims as well as instructions for use. Product labeling for the LigaSure™ system is provided in Attachment # 1. This attachment also includes an outline of the contents of the Service Manual which will be completed prior to market introduction.

**F. Advertising**

Attachment # 2 to this submission contains a copy of proposed/draft advertising literature for the LigaSure™ Vessel Sealing system. The information contained in this literature is supported by preclinical and bench testing. Reference Section L, "Safety and Performance" in this submission.

**G. Intended Use**

The LigaSure™ Vessel Sealing System includes a bipolar electrosurgical generator and dedicated bipolar electrosurgical instruments. The system is intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. This system offers an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting and/or coagulation are required.

The indications for use include general, (including urologic, cardiovascular, thoracic plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

MS  
hh

Valleylab makes the following recommendations with regard to the use of the LigaSure™ Vessel Sealing System:

- Pacemakers and implanted cardioverter/defibrillators can be adversely affected by RF signals. Consult the pacemaker/cardioverter/defibrillator manufacturer for further information when use of electrosurgical equipment is planned in patients with these devices. If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer instructions before performing electrosurgery. This treatment may cause multiple activations of an ICD's.
- Valleylab recommends against the use of laparoscopic surgery on pregnant patients.
- Valleylab recommends against the use of electrosurgery for circumcisions.

#### **H. Product Description**

The LigaSure™ Vessel Sealing System consists of the following devices:

- LigaSure™ Vessel Sealing Generator
- LigaSure™ Footswitches (Catalog Number LS0010 and LS0020)
- LigaSure™ Standard Instrument (LS2070)
- LigaSure™ "MAX" Instrument (LS3090)
- LigaSure™ Disposable 5 mm "Lap" (Laparoscopic) Instrument with cord assembly (LS1000)
- LigaSure™ Disposable Electrode and Cord Assembly for the Standard Instrument (LS2071)
- LigaSure™ Disposable Electrodes and Cord Assembly for the "MAX" Instrument (LS3091)
- LigaSure™ Instrument Sterilizer Case (LS0100)

##### **1. The LigaSure™ Vessel Sealing Generator**

This electrosurgical unit is an isolated, microprocessor based, bipolar electrosurgical generator which will provide three separate modes; Vessel Sealing, Bipolar and Macrobipolar. The generator will provide only bipolar output. The operation of the generator is through closed loop control implemented in microcontroller firmware. As tissue impedance increases from a short circuit to an open circuit, the algorithm first implements constant current, then constant power and, finally, constant voltage.

The vessel sealing process is controlled by an internal microprocessor and associated software within the generator. The system senses the tissue impedance and initiates a predetermined RF energy cycle which fuses the tissue to form the

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ligation (seal). At the end of this controlled cycle, the RF output is automatically ended and the user is alerted by audio and visual indicators. The generator also monitors various conditions where sealing may not occur such as if the electrodes are shorted, impedance levels do not change, or impedance levels are too high. If either of these conditions are detected, a "Regrasp" light (located above the vessel sealing output receptacle) will flash, an audio tone will sound, and RF output is disabled. Vessel sealing must be rekeyed to continue.

The generator will also provide bipolar electrosurgery energy to accommodate standard bipolar cutting and coagulation instruments.

The generator will be able to recognize the instruments by using "smart" connectors that are specific to the instrument type. The codes will tell the generator that a vessel sealing instrument is present which, in turn, allows the vessel sealing output to be accessed. Standard and macro bipolar outputs can also be accessed by use of an adapter which plugs into the bipolar receptacle on the front of the generator. This will allow customers to use existing footswitching and/or handswitching bipolar instruments.

a. Physical Characteristics: The LigaSure™ Vessel Sealing Generator is housed in a metal enclosure and will have an angled front control panel. The front panel will be divided into two sections, one for the vessel sealing function controls and the second for bipolar controls. The front panel displays and controls will be sealed to facilitate cleaning and minimize the problems caused by accidental spills. The receptacle area for the accessories will be recessed to conform to IEC 601 requirements as will the control and display colors. Each button on the front panel will provide a mechanical (tactile) feedback when pressed. A carrying handle on the rear panel will also be provided. The approximate overall dimensions for the generator will be:

Depth:	15 inches
Width:	15 inches
Height:	5 inches
Weight:	Less than 14 Lbs.

Attachment # 3 contains representative drawings of the generator. Diagrams of the front and rear panels of the generator can be found in the User's Guide, Section # 2, included in Attachment # 1.

b. Power Specifications and Ranges: The LigaSure™ Vessel Sealing Generator will operate at line frequencies of 50 or 60 Hz. It will automatically switch to operate from either a 115 or 230/240 mains voltage. The operation range for the 115 mains voltage is 85-140 VAC and for the 230/240, 170-264 VAC. AC power is input through a line cord at the rear of the unit and RF output is available from the front panel receptacles. The generator will contain a battery for maintaining

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calibration and statistical values in battery backed RAM. It will have no other internal back-up power systems.

c. **Performance Specifications:** Performance specifications can be found in Appendix A of the User's Guide included under Attachment # 1. For all modes, the waveform is sinusoidal at a frequency of 470kHz.

d. **Power Control Modes:** As noted above, the front panel of the generator will be divided into two sections; Vessel Sealing and standard Bipolar/Macro-bipolar. Power control is provided by up/down buttons allowing the operator to increment or decrement to the desired power. For Bipolar and Macro-bipolar, the power setting can be adjusted from 1 watt to a maximum of 95 watts. Power settings will be incremented/decremented by 1 watt from 1 to 40 watts. Above 40 watts, depressing the up or down buttons will cause a 5 watt increment/decrement. Power for the standard Bipolar/Macro-bipolar will be displayed using independent, seven segment, green numerical displays. When maximum or minimum power is reached, an audio tone sounds. Simultaneous adjustment of the power settings will not be allowed in standard Bipolar/Macro-bipolar. When the generator is activated, only a single step change in the cut/coag power setting will be allowed per up/down button depression.

The surgeon can control the energy (intensity) level of the vessel sealing function, depending on his/her experience and knowledge of the vessels/tissue being sealed. There are six sealing levels that will be represented on the front panel by a 6 segment bar graph display. The first (left most) bar indicates there is no power and the system is in stand-by. Five additional levels are available with the lowest sealing intensity being provided when the second bar from the left and the highest the bar to the far right. No changes will be allowed in the vessel sealing intensity level during activation.

e. **Handset Indicators:** Bicolor (red/green) handset lamps will indicate when an acceptable instrument plug has been inserted into an RF output receptacle. There will be two handset lamps above each receptacle. These lamps will remain blank until a plug is inserted into the receptacle. When this occurs, the handset lamp above the connector will illuminate green if the smart connector code is acceptable for that output and red if the code is not acceptable. If red is illuminated, RF output to that receptacle will be disabled. Therefore, a green handset lamp means RF output to the receptacle is enabled and a blank or red lamp means RF output is disabled.

f. **RF Output Receptacles:** Two RF output receptacles are located on the front of the generator; the vessel sealing receptacle and the bipolar receptacle. Macro-bipolar and standard bipolar outputs are available only from the bipolar receptacle. The vessel sealing output will be activated

using footswitches. The bipolar outputs will be activated through handswitching or footswitching. Simultaneous activation of vessel sealing and bipolar outputs will not be possible.

g. Visual and Audio Requirements: Activation of RF output will be indicated by various frequency audio tones which can be adjusted from a minimum of 48 dBA to a maximum of 68 dBA. Alarm tones will not be adjusted and will be set at 68 dBA at a frequency of 985 Hz. For vessel sealing, a continuous audio tone will sound which will change to a discontinuous on/off signal when the sealing process is complete. If the tines of the device are shorted, a fourth audio tone will sound accompanied by the illumination of the Regrasp lamp described above.

Activation of any of the three modes will also be indicated on the front panel by the illumination of the corresponding indicator bar. Alarm conditions will be displayed on the front panel as numeric codes. Definitions of these codes are provided in the generator User's Guide.

h. Rear Panel: The rear panel of the generator has the following:

- AC line receptacle for connection of the line cord,
- Volume control potentiometer for adjustment of the activation tones,
- An option panel which covers the serial port connector used for calibration and receiving diagnostic information, expansion port, and RF activation connector,
- A grounding lug,
- Endpoint monitor connection, and,
- Footswitch connectors (two)

i. Dosage Error: The primary fail-safe system within the generator is the dosage error circuit. The dosage error circuit monitors the output performance characteristic as a function of the generator set-up and sounds an alarm (three audio tones) if the unit is operating out of specified tolerance ranges. A numeric error code is displayed and the output power is disabled.

j. Memory Button: A memory button will be included on the front panel which allows the user to restore the power settings to the last settings prior to when the generator AC power was last shut off.

## 2. The LigaSure™ Vessel Sealing Instruments

a. LigaSure Standard and Max Instruments: These devices are similar to bipolar forceps type devices in that the devices have a scissors type closing action with flat jaws in which vessels/tissues are grasped and through which bipolar RF energy is applied. The styles (tip configurations) are

similar to "Pean" and "Heaney" style hemostats. The Standard instrument (Pean style) is used for general open procedures and the "Max" (Heaney style) is used for open gynecological procedures.

The base instruments are reusable devices, capable of being cleaned and steam sterilized between procedures. The "jaws" are disposable electrodes, which are part of an electrode and cord assembly, and are snapped into the distal tines of the instrument. The disposable electrodes feed into the "wire guide" which contains the lead wires and snaps to the handle of the device. After use, the electrodes/cord assembly is removed and disposed.

The standard (Pean style) instrument will be approximately 7 inches in length and will weigh no more than 0.5 lbs. The "Max" (Heaney style) will be approximately 9 inches in length with the same maximum weight. Cable length will be 10 feet with an approximate diameter of 0.125 inch and terminates in the dedicated (smart) connector plug. See Attachment # 3 which includes representative drawings of the device.

The base instrument will be provided in a non-sterile configuration. The Disposable electrodes and wire guide and cord assembly will be provided together in a sterile, single use configuration.

b. LigaSure 5mm Laparoscopic Instrument: The laparoscopic instrument will be provided as a sterile, single use device. It is a multifunctional device capable of vessel sealing, grasping or dissecting. It will be available with a smooth, curved, Maryland style jaws. The outer diameter of the instrument shaft will be 5 mm. with a working length of 32 cms. The shaft of the device has a rotation knob at the proximal end which allows for 360° rotation of the electrode jaws. The handle of the device provides a moveable finger lever with a fixed thumb hole. The design of the handle allows for both the ring motion (with the thumb inserted into the thumb hole) and also palming, per user preference. The handle also includes a latching mechanism to control the applied pressure. Power is delivered to the device electrodes (jaws) by a two conductor cord contained within the handle. Electrical isolation is accomplished by covering the conductive surfaces with heat shrink material and a dielectric coating.

As the LigaSure laparoscopic device is a single use device, it will not require the disposable electrodes and wire guide detailed in the previous section for the LigaSure Standard instruments.

The cord of the device is 10 feet in length and terminates in a dedicated (smart) connector plug. See Attachment # 3 for representative drawings of the laparoscopic instrument.

## **I. Device Components**

1. The LigaSure™ Vessel Sealing Generator is comprised of the following components: (See Attachment # 4 which is an Interconnection block diagram showing the various circuit boards and their relationships.)

a. Front Bezel, Chassis and Cover: These components of the generator are made of materials currently in use for Valleylab electrosurgical generators. The chassis and cover are sheet metal painted with a water base paint. The front bezel is

b. Front Panel Controls: The front panel is a polyester film overlay containing the displays and the control buttons. The displays and controls are connected to the CPU and provide user-machine interface for input of operational modes, power control, etc.

c. Controller Board: This circuit board is primarily responsible for operator interface and dosage error monitoring. This board also controls alarm handling, audio control, self-tests, calibration and diagnostics control, button and keying interface, segment display drivers and LED updates. This board controls output power levels.

d. Display Board: This circuit board contains all buttons, lights, indicators and supporting circuitry used in the front panel.

e. RF Board: The RF board is the main board of the unit connecting to most of the other assemblies. It contains the following circuits: RF output stage, volt/current sense circuits, Iso-Bloc power supplies, handswitching circuits and Regrasp circuits.

f. Other Boards: Other boards contained within the generator control the high voltage power supply, footswitching and audio, "smart" connectors, low voltage power supply, and keyboard.

2. The LigaSure™ Vessel Sealing Instruments are comprised of the following:

a. The LigaSure™ Standard Instruments:

Base Instrument: Each member is made of AISI Stainless Steel with the connection pin made of AISI Stainless Steel  
Electrodes: AISI Stainless Steel with the insulation being a

Flex Relief:  
Wire Guide:  
Cord:  
Plug:

b. The LigaSure™ Laparoscopic Instrument:

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Handle:  
Lever:  
Electrodes:  
Electrode Coating:  
Insulator:  
Outer Tube:  
Heatshrink Insulation:  
Pushrod:  
Rotation Knob:  
Inner Insulator Tube:  
Yoke/Rod Overmold:

**J. Packaging Materials**

Packaging materials for the LigaSure Vessel Sealing generator are identical to those used for current Valleylab products. The generator will be packaged in protective foam cushioning and placed inside a corrugated container. Packaging is designed to protect the generator from damage during transport, storage and handling.

The LigaSure disposable electrodes and wire guide will be packaged in a single unit PETG tray with a Tyvek lid which is designed to allow penetration of Ethylene Oxide gas during sterilization or can be irradiation sterilized. Six unit packages will be placed in a dispenser package made from solid bleached sulfate board.

The LigaSure Standard and Max instruments, non-sterile devices, will be packaged in polyethylene bags and placed in a protective shipping containers.

Similar to the disposable electrodes, the LigaSure disposable, laparoscopic instrument will be packaged in a single unit PETG tray with a Tyvek lid which is designed to allow penetration of Ethylene Oxide gas during sterilization or can be irradiation sterilized.

In all cases, the packaging materials are identical to those used for current Valleylab sterile, single use accessories.

**K. Method of Sterilization**

Both the disposable LigaSure electrodes and wire guides and the laparoscopic LigaSure device are designed to be sterilized using either 100% Ethylene Oxide or irradiation sterilization. EtO sterilization will be performed in accordance with validated and periodically audited sterilization procedures using the "overkill" method, according to the AAMI Guideline for Industrial EtO Sterilization of Medical Devices (ST27-1988). Sterility testing is conducted on each sterilization run using B. subtilis var. niger spore strips.

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Irradiation sterilization will be performed using validated and periodically audited procedures according to the current Association for the Advancement of Medical Devices (ST32-1991) and/or the current AAMI Guideline for Electron Beam Radiation Sterilization of Medical Devices (ST31-1990).

For all sterile devices, the sterility assurance level (SAL) will be  $10^{-6}$ .

Bioburden monitoring of the manufacturing area and of the finished product is performed on an ongoing basis. EtO decay curves are determined to ensure that residuals are at safe levels prior to product release. All products sterilized by EtO will have appropriate release limits for EtO and associated residuals as listed in the Federal Register June 23, 1978 Part V. These release limits will be 25 ppm ethylene chlorohydrin, 25 ppm ethylene oxide, 250 ppm ethylene glycol.

**L. Safety and Performance**

Safety and Performance of the LigaSure™ Vessel Sealing System has been evaluated and verified through materials biocompatibility testing, electrical testing, software validation, performance verification, and preclinical testing. In addition, a hazard/risk analysis has been compiled on the entire system including the instruments, the generator and its software. This analysis can be seen in Attachment # 7. Each of these areas is summarized below.

**1. Biocompatibility Testing**

The biological safety of the LigaSure instruments has been assured through the selection of patient contact materials which demonstrate appropriate levels of biocompatibility. All patient contacting materials have been or are in the process of being tested in accordance with ISO Standard 10993-1, Biological Evaluation of Medical Devices, Part 1 and must pass these requirements prior to release of the materials. The LigaSure instruments are categorized, per this standard section 5.1.3 and 5.2, as "Externally Communicating Devices, Blood Path Indirect, Contact Duration Category A".

See Attachment # 5 for the listing of biocompatibility testing being performed on patient contact components.

**2. Electrical Testing**

The LigaSure generator has been designed to conform to applicable sections of the following standards:

IEC 601-1 (1988), Medical Electrical Equipment Part 1: General Requirements for Safety

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IEC 601-1-2 (1993), Medical Electrical Equipment, Collateral Standard, Electromagnetic Compatibility - Requirements and Tests

IEC 601-2-2 (1991 and 1996 (draft)), Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment

IEC 1000-4-1, Part 4 (1992): Testing and Measuring Techniques - Section 1: Overview of Immunity Tests

IEC 1000-4-2 Part 4 (1995): Testing and Measuring Techniques - Section 2: Electrostatic Discharge Immunity Test

IEC 1000-4-3 Part 4 (1995): Testing and Measuring Techniques - Section 3: Radiated radio frequency, electromagnetic field immunity test

IEC 1000-4-4 Part 4 (1995): Testing and Measuring Techniques - Section 4: Electrical fast transient/burst immunity test

IEC 1000-4-5 Part 4 (1995): Testing and Measuring Techniques - Section 5: Surge immunity tests

ANSI/AAMI HF18 (1993), Electrosurgical Devices

CISPR 11 (1990) Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment

UL2601-1 (1994) Medical Electrical Equipment, Part 1: General Requirements for Safety

ISTA (1996) Procedure 2A Preshipment Test Procedure

Electrical safety testing performed on prototype LigaSure generators showed the generator met product specifications and the applicable requirements of the above referenced standards. A copy of the test report can be found in Attachment # 6.

The LigaSure open and laparoscopic devices have also been designed to conform with the applicable sections of the following standard(s):

IEC 601-1 (1988), Medical Electrical Equipment Part 1: General Requirements for Safety

IEC 601-1-2 (1993), Medical Electrical Equipment, Collateral Standard, Electromagnetic Compatibility - Requirements and Tests

ANSI/AAMI HF18 (1993), Electrosurgical Devices

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This testing confirmed conformance to product specifications and safety requirements. A copy of this test report is also included in Attachment # 6.

### 3. Software

Software for the LigaSure generator has been designed and will be validated in accordance with internal Valleylab procedures including the FDA guidance "General Principles of Software Validation". The level of concern appropriate for the LigaSure generator is "moderate" as defined in the FDA's Reviewer Guidance for Computer Controlled Medical Devices. This is based on the following considerations:

- The operator (surgeon) controls the use of the generator and instruments,
- The generator provides alarm conditions (audio and visual) that could pose a risk to the patient, and,
- The operator (surgeon) set the appropriate mode and output settings for the device.

Refer to Attachment # 7 for information on the software development and validation process.

### 4. Performance Verification

To verify the performance of the LigaSure™ system specific to the fusion of vessel tissue, an in vivo canine blood vessel study was done and histological sections were examined. The histological examination showed the fusion sites were generally uniform with intima to intima fusion in both arteries and veins. The photographs on the following pages show vessel fusion and the thermal damage associated with the sealing process achieved in this study.

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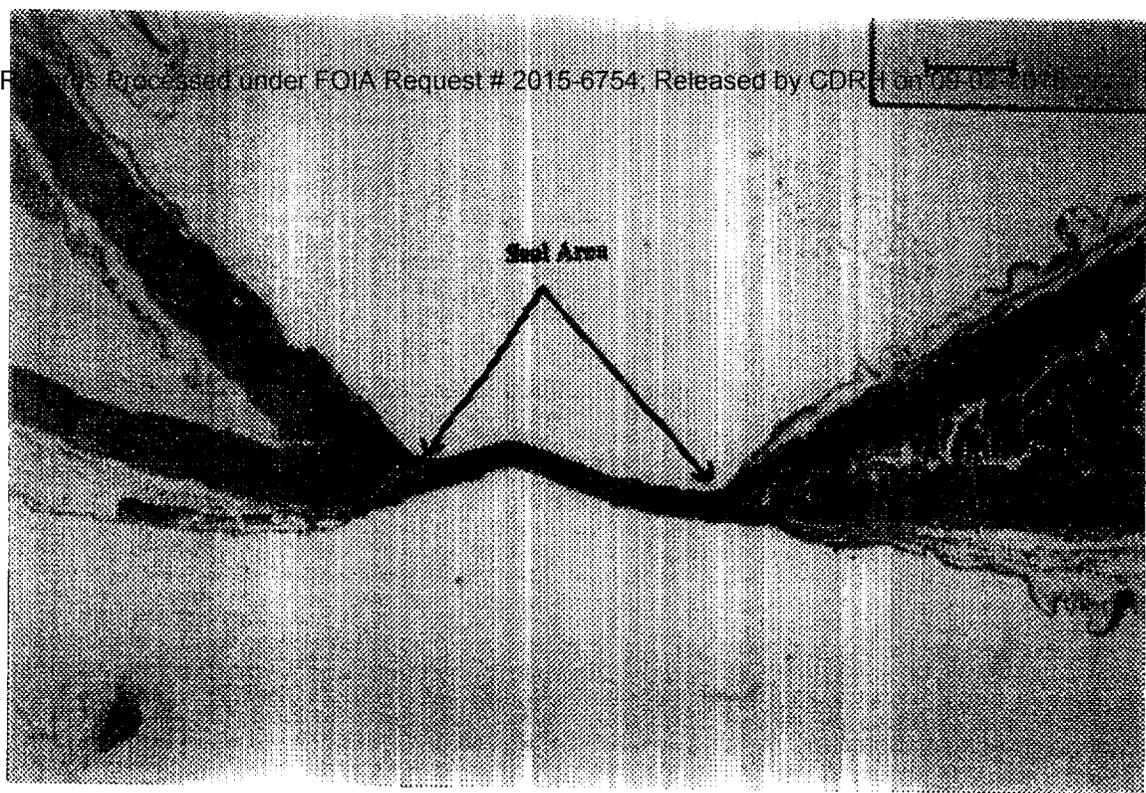


Photo # 1. Longitudinal section of canine Splenic artery showing complete fusion of the vessel walls. (Sample # 98VL-68A, H&E stain under polarized light, 6.25x, Bar = 410µm)

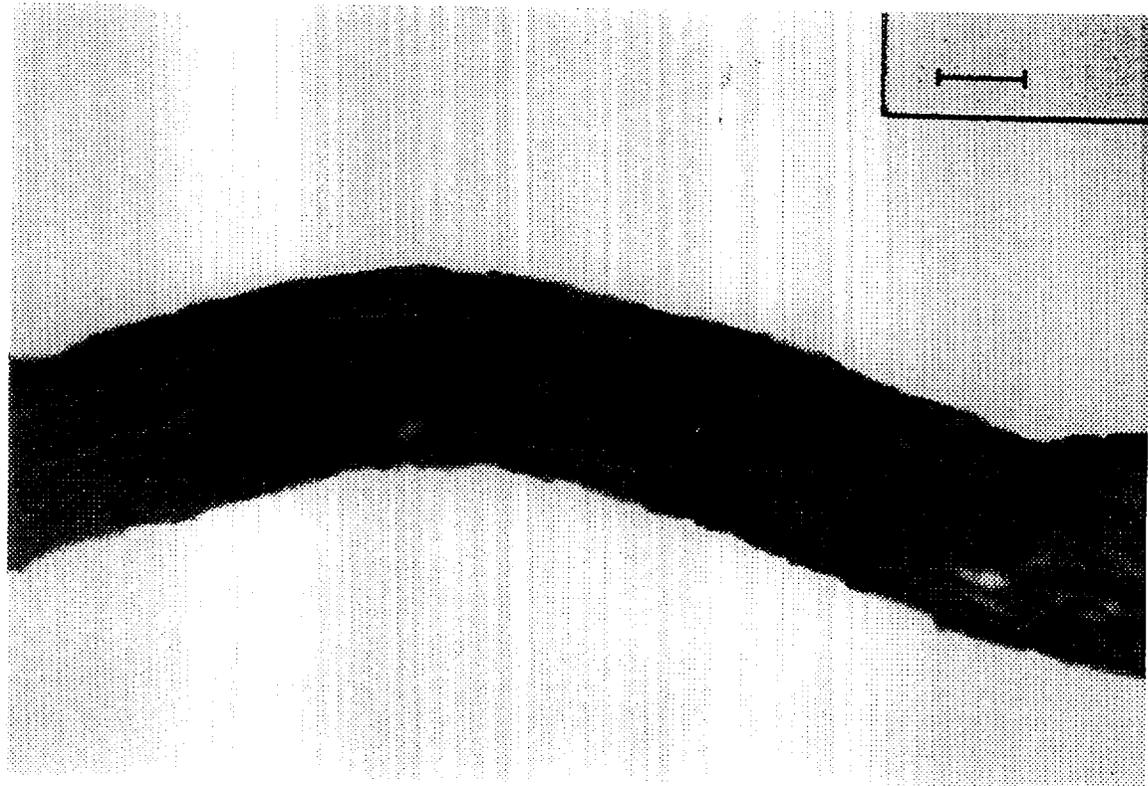
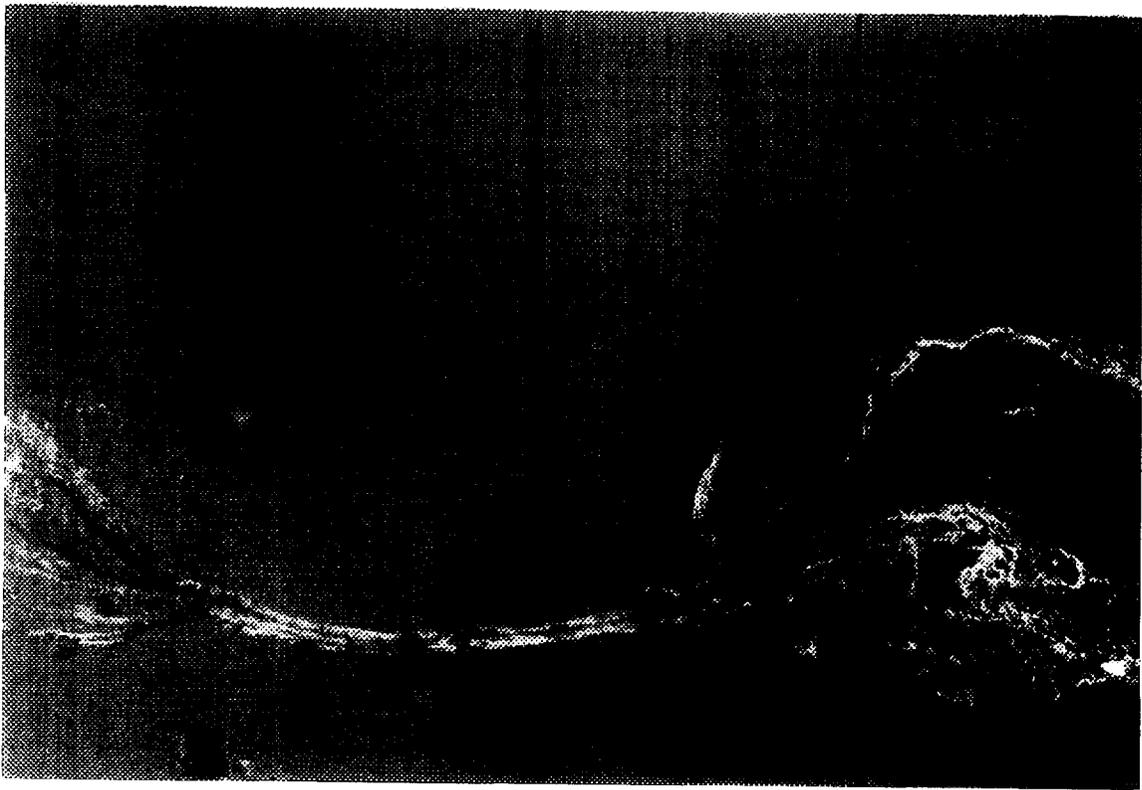


Photo # 2. Close-up view of canine Splenic artery shown in Photo # 1 showing fusion of vessel walls. (Sample # 98VL-68A, H&E stain, 50x, Bar = 50µm)

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**Photo # 3. Longitudinal section of canine Splenic vein showing complete fusion of the vessel walls. (Sample # 98VL-68B, H&E stain, 50x, Bar = 410 $\mu$ m)**



**Photo # 4. Edge of Splenic vein (from Photo # 3) showing extent of thermal damage to be approximately 400 $\mu$ m. (Sample # 98VL-68B, H&E stain, under polarized light, 25x, Bar = 100 $\mu$ m)**

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A copy of the study summary is included in Attachment # 8.

Performance verification testing was done to demonstrate sealing capabilities of the LigaSure instruments and also to show equivalency to other bipolar devices currently on the market. The test instruments included prototype Valleylab LigaSure standard and laparoscopic devices and prototype LigaSure generator, an Ultracision Laparoscopic Coagulating Shears manufactured by Ethicon, Somerville, N.J. and Cabot Tripolar (5 mm and 10 mm) forceps manufactured by Cabot Medical, Langhorne, PA.

The vessels used for the testing were isolated porcine renal arteries which were categorized in groups by sizes (Less than 2.0 mm, 2.0 to 4.0 mm, and 4.0 to 7.0 mm). The actual range of vessels sealed was from 1.2 mm to 6.9 mm. Each instrument was used to seal a total of approximately 30 seals, 10 in each category. Thermal spread was measured following the sealing procedure. The vessel seals were then pressure tested to maximum burst strength (measured in mmHg) using water at a flow rate of 50 ml/hr.

Evaluation of the thermal spread data showed comparable results with the averages being:

**Average Thermal Spread (mm)**

LigaSure Standard:	2.1
LigaSure Laparoscopic:	1.5
Cabot 5mm Tripolar:	3.0
Ultracision:	2.0

Burst testing of the vessels across the size categories revealed the following results: (Note: Normal systolic blood pressure is 120 mmHg)

Instrument	Burst Strength Data	Vessel Size			
		0 - 2 mm	2 - 4 mm	4 - 7 mm	All
LigaSure Standard	Sample Size	10	10	13	33
	Average Burst Pressure (mmHg)	843	1434	1423	1251
	Burst Pressure Range (mmHg)	397 - 1391	665 - 2514	474 - 3392	397 - 3392
LigaSure Lap	Sample Size	10	10	21	41
	Average Burst Pressure (mmHg)	1062	1069	1006	1035
	Burst Pressure Range (mmHg)	472 - 1724	541 - 2012	0 - 3313	0 - 3313

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Instrument	Burst Strength (mmHg)	Vessel Size			
		0 - 2 mm	2 - 4 mm	4 - 7 mm	All
Cabot Seitzinger Tripolar 10mm	Sample Size	10	10	16	36
	Average Burst Pressure (mmHg)	944	1424	468	866
	Burst Pressure Range (mmHg)	415 - 1283	585 - 3396	0 - 1578	0 - 3396
Cabot Seitzinger Tripolar 5mm	Sample Size	10	10	10	30
	Average Burst Pressure (mmHg)	394	444	227	355
	Burst Pressure Range (mmHg)	116 - 940	33 - 659	0 - 712	0 - 940
Ultracision	Sample Size	10	9	11	30
	Average Burst Pressure (mmHg)	825	226	21	351
	Burst Pressure Range (mmHg)	0 - 2270	0 - 554	0 - 130	0 - 2270
Total Sample Size		50	49	71	170

Statistical analysis of the LigaSure™ data revealed that the overall probability of achieving burst pressures greater than 360 mmHg was approximately 0.92 for the LigaSure Standard devices and approximately 0.87 for the LigaSure Laparoscopic device. The probability of exceeding 360mmHg for the Cabot 10 mm device was determined to be approximately 0.81.

See Attachment # 8 for a copy of the summary report covering this performance testing.

5. Preclinical testing

Preclinical testing was performed on canines to gather additional safety and performance data on the LigaSure Vessel Sealing System (instruments and generator). This was accomplished in acute and chronic animal labs.

a. Acute Study: The objectives of the acute animal lab were to evaluate and compare the sealing capabilities on vessels and vascular bundles in the size range of 1-7 mm. Canine models were used because of the close approximation of vessel sizes and locations to human anatomy. The animals underwent partial small bowel resections, splenectomy and salpingo-oophorectomy. The actual surgeries were performed by surgical consultants. In addition, the Cabot 5 mm. Tripolar forceps was also used to gain comparative data.

Similar to the performance testing detailed above and using the same rating scales, the seals were evaluated for desiccation and clarity. In addition, the

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seals were also evaluated for tissue sticking and charring using the following rating scales:

**Sticking**

- 0 - No adherence
- 1 - Minor adherence to one or both jaws
- 2 - Moderate difficulty in disengaging from the application site
- 3 - Tissue attached to jaws, considerable difficulty in disengaging

**Charring**

- 0 - No charring
- 1 - Minimal (browning rather than blackening)
- 2 - Moderate blackening
- 3 - Severe charring

A total of 56 seals were made with the LigaSure instruments and 34 with the Cabot Tripolar forceps. There were no seal failures (defined as blood flow through the seal) in any of the seals made with the LigaSure devices. Seven instances of blood flow through the seals were observed with the Cabot Tripolar device.

The other (average) tissue results for all seals are as follows:

<u>Device</u>	<u>Clinic</u>	<u>Dissection</u>	<u>Sticking</u>	<u>Charring</u>	<u>Thermal Spread (mm)</u>
LigaSure	2.7	2.8	0.6	0.3	2.3
Cabot Tripolar	1.2	1.5	0.6	0.7	3.1

The LigaSure devices produced seals that ranged from semi-transparent to transparent with almost full desiccation. Sticking and charring were observed to be minimal and thermal spread was comparable slightly better than the Cabot device.

b. Chronic Study

To further verify the performance, reliability and safety of the LigaSure devices, a chronic animal study was performed using the canine model because of their close approximation in vessel size and anatomical location to those in humans. Three canines were used. The surgical procedures performed were small bowel resection, splenectomy, and a right or left salpingo-oophorectomy. Vessels in the range of 1 - 7 mm. were targeted for sealing. After sealing, all sites were observed for adequate hemostasis before the abdomen was closed. The canines were then allowed to recover and were monitored for seven days. They were then euthanized and the treated sites were identified and evaluated by the surgeon investigator.

All three animals survived the study with a total of 86 seals being performed. Consistent and successful seals were observed in all three procedures (small bowel resection, splenectomy, and oophorectomy). Out of the 86 seals, three seal failures were observed. One was due to user

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error and the remaining were due to device malfunction unrelated to sealing performance.

Of the 86 applications, 40 seal sites were marked to allow for easy identification after the canines were euthanized. After the 7 day survival, all 40 marked seals were intact with no visible bleeding. There was evidence of a small hematoma in the region of the left ovary on one animal. It was the opinion of the surgeon that this was caused by mechanical damage during dissection near the seal site. All seals were intact and dry.

As with the acute study, the identified seals were evaluated for seal quality, i.e. clarity, thermal spread, desiccation in addition to any seal failures. The same rating system as used for the acute study was employed in the chronic study. Average seal quality, per the rating system, is summarized in the following tables:

**Seal Assessment for Partial Small Bowel Resection**

<u>Device</u>	<u>Clarity</u>	<u>Desiccation</u>	<u>Thermal Spread (mm)</u>
LigaSure Lap Device	1.8	2.3	3.1
LigaSure Standard Device	2.9	2.9	3.3

**Seal Assessment for Splenectomy**

<u>Device</u>	<u>Clarity</u>	<u>Desiccation</u>	<u>Thermal Spread (mm)</u>
LigaSure Lap Device	2.4	2.4	1.8
LigaSure Standard Device	2.8	2.8	2.9

**Seal Assessment for Unilateral Salpingo-Oophorectomy**

<u>Device</u>	<u>Clarity</u>	<u>Desiccation</u>	<u>Thermal Spread (mm)</u>
LigaSure Max Device	2.7	2.5	3.8

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**M. Summary of Safety and Effectiveness**

A summary of safety and effectiveness information for the LigaSure™ Vessel Sealing System can be found in Attachment # 9.

**N. Statement of Substantial Equivalence**

The LigaSure™ Vessel Sealing generator is a bipolar electro-surgical generator that is substantially equivalent to the following Valleylab electro-surgical generators in function and intended use:

<u>Predicate Device</u>	<u>510(k) Number</u>	<u>Concurrence Date</u>
Valleylab Force FX Electrosurgical Generator	K944602	June 1995
Valleylab Force 300 Electrosurgical Generator	K953195	August 1995
Valleylab NS2000 Electrosurgical Generator	K946177	June 1995

Both the Force FX and the Force 300 electro-surgical generators incorporate bipolar modes along with the standard monopolar cut and coag modes. The NS2000 is strictly a bipolar generator. All three generators provide bipolar coagulation through the application of electro-surgical energy through bipolar instruments. The Force 300 has a single bipolar mode, the NS2000 has a low and high bipolar output, and the Force FX has three power modes within the bipolar function; Low, Medium and Macro. The vessel sealing function contained within the LigaSure Vessel Sealing generator uses the standard bipolar waveform used in the above three generators. A comparison of generator features can be found in Attachment # 10.

The LigaSure Standard and Laparoscopic bipolar instruments are substantially equivalent to the Cabot Seitzinger Tripolar Cutting Forceps and Cabot Medical Bipolar Cutting Forceps manufactured by Circon Cabot, Racine Wisconsin. The Cabot Tripolar Cutting Forceps is a bipolar device used for grasping and coagulating and also incorporates a cutting function. The device is offered in 5 and 10 mm cannula diameters in lengths of 32 cms. (for laparoscopic use) and 15 cms. (for open procedures). The Tripolar device has advertised uses for procedures such as laparoscopically assisted vaginal hysterectomies, myomectomies, adhesiolysis, oophrectomies, and others. Attachment # 11 contains copies of this device's advertising information and instructions for use.

Similarly, the Cabot Bipolar Cutting Forceps is also indicated in procedures for coagulation and cutting of tissue. This device was found to be substantially equivalent to other bipolar instruments under accession #K932293. A reusable

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version of the device was determined to be equivalent under K946109. Attachment # 11 contains a copy of the Summary of Safety and Effectiveness for the K932293 Cabot Bipolar Cutting Forceps.

Comparative bench testing on the LigaSure instruments and the Cabot Tripolar Forceps was performed and is detailed in section L.4. above. Testing include maximum burst pressure determination, and a rating of the vessel seal for clarity, desiccation, sticking, charring and thermal spread. This testing showed the LigaSure system and instruments to be at least equivalent to the Cabot Tripolar Forceps device. (Reference Attachment # 8 for this test report.)

Preclinical testing performed on canines also compare the LigaSure devices to the Cabot Tripolar Forceps. The summary of this information is in section L. 5. above. Again, the testing showed the LigaSure devices to be at least equivalent in seal quality to the Cabot device.

See Attachment # 12 for a product comparison between the LigaSure devices and the Cabot Tripolar Forceps.

A third device to which the LigaSure system is substantially equivalent is the Storz S2050 Bipolar Forceps, including a Bipolar coagulator generator. These devices are manufactured by Storz Instrument Co., St. Louis, Missouri. (Accession # K960009) The intended use for these devices is the control of bleeding during surgery. Operation of the device is similar in that tissue is grasped between the forceps tips through which bipolar energy is applied achieving coagulation. Attachment # 13 is a copy of the Summary of Safety and Effectiveness for these devices.

**O. Further Information**

In the event that additional information is required, please contact:

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Senior Regulatory Affairs Associate  
Valleylab Inc  
5920 Longbow Drive  
Boulder, CO 80301

Phone: (303) 530-6343  
Fax: (303) 530-6313

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510(k) Number (if known): \_\_\_\_\_

Device Name: Valleylab LigaSure™ Vessel Sealing System

Indications For Use:

The LigaSure™ Vessel Sealing System includes a bipolar electro-surgical generator and dedicated bipolar electro-surgical instruments intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation (seal) by the application of bipolar electro-surgical RF energy (coagulation) to vessels interposed between the jaws of the device.

The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general, (including urologic, cardiovascular, thoracic plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 2.1 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

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**LigaSure™**  
**Vessel Sealing Generator**  
**User's Guide**

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***User's Guide***

**DRAFT**

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**Valleylab LigaSure™ Vessel Sealing  
Generator**

**510K DRAFT**

225 110 232

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## **Foreword**

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This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the Valleylab LigaSure Vessel Sealing Generator only. Additional technical information is available in the **LigaSure Vessel Sealing Generator Service Manual**.

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

**Equipment covered in this manual:**

Valleylab LigaSure Vessel Sealing Generator - 120 V, 240 V

**Valleylab Part Number:** 945 102 033

**Effective Date:** May 1998

**Trademark Acknowledgments:**

LigaSure™ and Instant Response™ are trademarks of Valleylab Inc.

**Patents Pending**

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## How the User's Guide is Organized

This User's Guide should contain the sections listed below. If any section is missing, please contact Valleylab.

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## Conventions Used in this Guide

**Important**  
Indicates an operating tip or maintenance suggestion.

### Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

### Caution

Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

### Notice

Indicates a hazard which may result in product damage.

**DRAFT**

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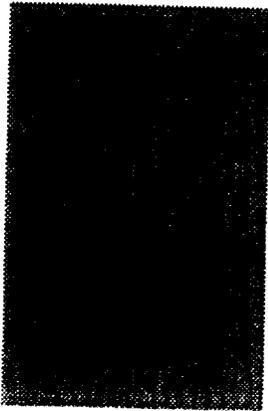
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# Introducing the LigaSure Vessel Sealing Generator

This user's guide provides instructions for using the Valleylab LigaSure Vessel Sealing Generator. This section introduces the generator, discusses its capabilities, and lists the precautions associated with using the generator.

This 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.

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## Product Description

The LigaSure generator is an isolated output electrosurgical generator that provides the power for vessel sealing and bipolar electrosurgery.

Features include:

- vessel sealing
- regrasp indicator to alert you if the tissue does not respond correctly to the application of RF energy or if the tissue impedance is too high
- bipolar and macrobipolar modes
- Instant Response Technology
- unique interface for connecting only a Valleylab LigaSure handset
- adjustable activation tone volume
- handswitch or footswitch activation
- an RF activation port, RS-232 serial port, and expansion port

Specific details about all the generator's features and their functions are provided in Section 2, *Controls, Indicators, and Receptacles*.

## Surgical Applications

Electrosurgery is the passage of high frequency (radio frequency), electrical current through tissue for coagulating, or sealing tissue.

During electrosurgery, radio frequency (RF) current flows from the generator to an active electrode, which delivers the current to the patient. The resistance to the current, provided by the patient's tissue, produces the heat that is necessary for the surgical effect. The RF current flows from the active electrode, through the patient's body tissue to the return electrode, which recovers the current and returns it to the generator. The LigaSure generator provides bipolar RF current only. Therefore, the active electrode and the return electrode are both contained in the instruments that connect to the generator. A separate patient return electrode is not required.

*Vessel Sealing* fuses vessel walls to create a permanent seal.

*Bipolar electrosurgical desiccation* dehydrates and destroys tissue without sparking or cutting. More current reaches the patient because the active electrode directly touches the tissue.

*Macrobipolar* may be used for bipolar cutting or rapid coagulation. Voltage is higher and there is more power than with the standard bipolar mode.

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## Instant Response Technology

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The LigaSure generator senses resistance and automatically adjusts the output voltage to maintain a consistent tissue effect across different types of tissue. The adjustment is based on the power setting and the level of tissue resistance. As tissue impedance increases from zero, the generator outputs constant current followed by constant power. This is followed by a substantially reduced constant power level to initiate a cooling period for bipolar hemostasis. The maximum output voltage is controlled to reduce interference and to minimize sparking.

## Bipolar Electrosurgery

Bipolar electrosurgery combines the functions of the active and return electrodes in a single surgical instrument—the bipolar handset. Current flows from the active side, through the tissue grasped by the tines, to the return side of the instrument.

Bipolar systems provide desiccation and minimize damage to tissue adjacent to the active forceps by incorporating the active and return electrodes in the same device and by limiting the amount of tissue involved in the electrosurgical circuit. Bipolar procedures are often performed in confined surgical sites and under magnification.

## Vessel Sealing Electrosurgery

- The LigaSure Vessel Sealing System provides low voltage, high current for hemostasis with minimal thermal spread to adjacent tissue.
- The possibility of sparking increases as desiccated tissue dries and becomes more resistant. The LigaSure Vessel Sealing System protects against sparking by limiting the bipolar voltage at relatively high levels of tissue resistance.
- When used with the appropriate instrument, the LigaSure Vessel Sealing System provides for the application of precise intensity and electrode pressure to vessels for a controlled time period to achieve a complete and permanent sealing of vessel lumens.

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## Patient and Operating Room Safety

The safe and effective use of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been used safely in numerous procedures. Before starting any surgical procedure, the surgeon should be trained in the particular technique and surgical procedure to be performed, should be familiar with the medical literature related to the procedure and potential complications, and should be familiar with the risks versus the benefits of utilizing electrosurgery in the procedure.

### General

**Warning:** Accidental and unintended burn injury has occurred during procedures in small surgical fields and on small appendages. Catastrophic results have been reported in the context of neonatal and pediatric circumcisions.<sup>1</sup> In those cases of confirmed thermal injury during neonatal and pediatric circumcisions, the mechanism of injury appears to have been associated with contact between a metal clamp (such as a Gomco clamp or a Kocher clamp) in the surgical field and the active electrode, which greatly increased current flow.<sup>2</sup> (See "Contact with Metal Instruments" on page 1-9, *infra*, for further information on the dangers of contact with metal instruments.)

It has also been reported that properly trained physicians use electrosurgery safely in the performance of circumcisions, and that pediatric urologists use electrosurgery with surgical procedures performed on the genitals of male neonates. In performing such procedures, it is reported that many physicians use the electrosurgical generator in coagulation mode to achieve hemostasis of bleeders, however "buzzing" hemostats clamped to bleeders may increase the risk of thermal injury.

**Warning:** Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced with the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.

**Warning:** If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activations of ICDs.

**Warning:** Valleylab recommends against the use of laparoscopic surgery on pregnant patients.

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**Warning:** Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

**Warning:** Hazardous Electrical Output. This equipment is for use only by trained, licensed physicians.

**Caution:** Always use the lowest output setting necessary that achieves the desired surgical effect. The active electrode should be utilized only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small appendages.

**Caution:** Read all instructions, warnings, and cautions provided with this generator before using.

#### Fire/Explosion

**Danger:** Explosion Hazard. Do not use electrosurgery in the presence of flammable anesthetics.

**Warning:** Fire/Explosion Hazard. The following substances will contribute to increased fire and explosion hazards in the operating room:

- flammable substances (such as alcohol based skin prepping agents and tinctures)
- naturally occurring flammable gases which may accumulate in body cavities such as the bowel
- oxygen enriched atmospheres
- oxidizing agents (such as nitrous oxide [N<sub>2</sub>O] atmospheres)

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.

1. The American National Standard for Electrosurgical Devices (ANSI/AAMI HF 18-1993) provides: "Electrosurgery should not be used to perform circumcisions."
2. Information on the safe use and thermal hazards associated with the use of high frequency electricity (electrosurgical machines) in health care facilities appears in NFPA 99, Annex 2, reference in the JCAHO Accreditation Manual for Hospitals.

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### **Fire Hazard with Oxygen Circuit Connections**

**Warning:** Fire/Explosion Hazard. Verify that all oxygen circuit connections are leak free before and during the use of electrosurgery. Verify that endotracheal tubes are leak free, and that the cuff is properly sealed to prevent oxygen leaks. Enriched oxygen atmospheres may result in fires and burns to patients or surgical personnel.

### **Electrosurgical Smoke**

**Caution:** Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and surgical personnel. These studies recommend using surgical masks and adequately ventilating the smoke by using a surgical smoke evacuator or other means.<sup>3</sup>

### **Inadvertent Radio Frequency Burns**

**Warning:** Electrodes and probes used with monitoring, stimulation, and imaging devices (or similar equipment) can provide a path for high frequency current even if the electrodes or probes are isolated at 50-60 Hz, insulated, and/or battery operated.

To reduce the risk of an inadvertent electrosurgical burn at the electrode or probe site, place the electrode and/or probe as far away as possible from the electrosurgical site. Protective impedances (resistors or RF inductors) installed in the monitoring leads may reduce the risk of such burns. Consult the hospital biomedical engineer for further information.

### **Ensure Proper Connections**

**Caution:** Examine all accessories and connections to the electrosurgical generator before using. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

### **Accessories**

**Warning:** Do not wrap the accessory cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical personnel.

**DRAFT**

### **Servicing**

**Warning:** Electric Shock Hazard. Do not remove the cover. Contact authorized personnel for service.

**Notice:** Refer to this generator's service manual for maintenance recommendations and function and output power verification procedures.

### **Before Surgery**

#### **Active Accessories**

**Warning:** Electric Shock Hazard. Do not connect wet accessories to the generator.

**Warning:** Connect accessories to the proper receptacle. Improper connection may result in inadvertent accessory activation or other potentially hazardous conditions. Follow the instructions provided with electro-surgical accessories for proper connection and use.

**Warning:** Electric Shock Hazard. Ensure that all accessories and adapters are correctly connected and that no metal is exposed.

**Warning:** The instrument receptacles on this generator are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

**Caution:** Set power or intensity levels to the lowest setting before testing an accessory.

**Caution:** Inspect accessories and cords (especially reusable accessories and cords) for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operating room personnel.

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3. U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). *Control of Smoke from Laser/Electric Surgical Procedures*. HAZARD CONTROLS, Publication No. 96-128, September, 1996.

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**DRAFT**

## Generator

**Warning: Patient Safety.** Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

**Warning: Electric Shock Hazard.** Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.

**Warning: Fire Hazard.** Do not use extension cords.

**Caution:** Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow for adequate cooling.

**Caution:** When using a smoke evacuator in conjunction with the electrosurgical generator, place the smoke evacuator a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

**Caution:** Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

**Caution:** Do not turn the activation tone down to an inaudible level. The activation tone alerts personnel when an accessory is active.

**Caution:** Nonfunction of the generator may cause interruption of surgery. A backup generator should be available for use.

**Notice:** If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

**Notice:** Connect the power cord to a wall outlet having the correct voltage. Otherwise, product damage may result.

## During Surgery

### Generator Power Settings

**Warning:** Confirm proper power or intensity settings before proceeding with surgery. Use the lowest setting possible for the minimum time necessary to achieve the desired effect.

**Warning:** Never increase the power settings without first checking the active electrode and its connection. Use the active electrode only for the minimum time necessary to achieve the desired surgical effect in order to minimize the possibility of burns. This is especially true in pediatric and neonatal patients or in any patient where small appendages are involved.

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**Caution:** The LigaSure generator works effectively at bipolar power settings lower than previous models offered by Valleylab. If the proper setting is not known, set the generator at a very low setting and cautiously increase the power until the desired effect is achieved.

### Contact with Metal Objects

**Warning:** Contact of the active electrode with any metal (such as hemostats, Gomco clamps, Kocher clamps, etc.) will greatly increase current flow and can result in unintended, catastrophic burn injury.

**Warning:** While using electrosurgery, the patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.). If this is not possible during certain procedures (e.g., those in which noninsulated head frames are used), use extreme caution to maximize patient safety:

- Use the lowest power or intensity setting that achieves the desired effect.
- Place dry gauze between the patient and the grounded object if possible.
- Continually monitor the contact point(s).

### Active Accessories

**Warning:** When not using active accessories, place them in a holster or in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

**Warning: Fire Hazard.** Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories that are activated or hot from use can cause a fire. Use a holster to hold electrosurgical accessories safely away from patients, surgical personnel, and flammable materials.

**Warning:** Do not activate the generator in the vessel sealing mode until the vessel sealing instrument has been applied with the proper pressure setting for that instrument. Activating the generator before this is done will result in an improper seal with increased thermal spread to tissue outside the surgical site.

**Warning:** Simultaneously activating suction/irrigation and electrosurgical current may result in increased arcing at the electrode tip, burns to unintended tissues, or shocks and burns to the surgical team.

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## Laparoscopic Procedures

**Warning:** For laparoscopic procedures, be alert to these potential hazards:

- Laparoscopic surgery may result in gas embolism due to insufflation of gas in the abdomen.
- The electrode tip may remain hot enough to cause burns after the electro-surgical current is deactivated.
- Inadvertent activation or movement of the activated electrode outside of the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects (such as cannulas or scopes). Electrical current may be generated in conductive objects by direct contact with the active electrode, or by the active accessory (electrode or cable) being in close proximity to the conductive object.
- Do not use hybrid trocars that are composed of both metal and plastic components. For the operative channel, use all metal or all plastic systems. At no time should electrical energy pass through hybrid systems. Capacitive coupling of RF current may cause unintended burns.
- When using laparoscopic instrumentation with metal cannulas, the potential exists for abdominal wall burns to occur due to direct electrode contact or capacitive coupling of RF current. This is most likely to occur in instances where the electro-surgical generator is activated for extended periods at high power levels inducing high current levels in the cannula.
- Ensure that the insulation of disposable and reusable laparoscopic instrumentation is intact and uncompromised. Compromised insulation may lead to inadvertent metal-to-metal sparking and neuromuscular stimulation and/or inadvertent sparking to adjacent tissue.
- Do not activate electrodes while in contact with other instruments as unintended tissue injury may occur.
- Do not activate the generator in an open circuit condition. To reduce the chances of unintended burns, activate the generator only when the active electrode is near or touching the target tissue.
- Use the lowest power or intensity setting that achieves the desired surgical effect and use a low voltage waveform (pure cut or desiccate) to lessen the potential for the creation of capacitive currents.
- Carefully insert and withdraw active electrodes from cannulas to avoid possible injury to the patient or damage to the devices.

## After Surgery

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**Warning:** Electric Shock Hazard. Always unplug the generator before cleaning.

**Caution:** Do not reuse or resterilize accessories labeled "disposable" or "single use only."

**Notice:** Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

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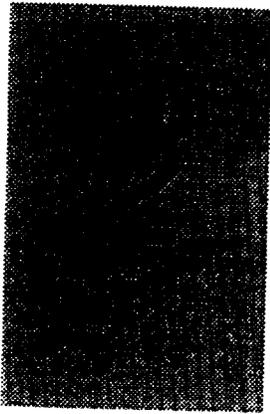
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# Controls, Indicators, and Receptacles

The controls, indicators, and receptacles for accessories are located on the front and rear panels of the LigaSure Vessel Sealing Generator. This section describes each component of the generator and its function.

Detailed procedures for setting up the generator are in Section 3.

**Caution**

Read all warnings, cautions, and instructions provided with the Valleylab LigaSure Vessel Sealing Generator before using.

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## Changing the Power or Intensity Settings

### Vessel Sealing Intensity Module

You can change the sealing intensity setting when the generator is on but not when it is activated. When you press and release the Sealing Intensity button, the vessel sealing intensity changes by one setting (1 light bar), with a range of 1 to 5 bars in intensity. Increasing the intensity increases the total energy delivered to the tissue for the duration of the cycle.

To reach the maximum or minimum setting, press and hold the Up (  $\Delta$  ) or Down (  $\nabla$  ) power button.

### Bipolar Power Module

You can change the power setting when the generator is on, including when it is activated. When you press and release the power button, the power changes in 1 watt increments from 1 to 40, and in 5 watt increments from 40 to 95.

To reach the maximum or minimum power setting, press and hold the Up (  $\Delta$  ) or Down (  $\nabla$  ) power button. The power setting changes slowly at first, then more rapidly. Each time you press the power button while the generator is activated, the power changes by only one setting to prevent rapid increases or decreases in power delivered to the surgical site.

## Recalling the Previous Settings

When you turn off the generator or disconnect the power cord, the generator automatically saves the most recently used settings.

When the generator is on, press Memory to reset to the most recently used settings.

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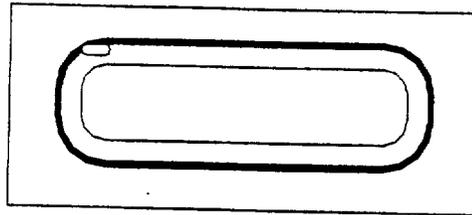
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## Bipolar/Macro bipolar Receptacles

### Bipolar Handset Receptacle (blue)

You can connect either a footswitching or handswitching bipolar/macro bipolar instrument to the Bipolar Handset receptacle.

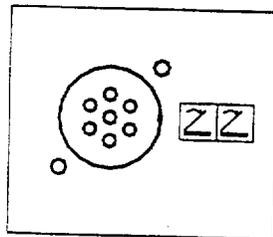


Connect a footswitching instrument with a two-pin connector.  
or  
Connect a handswitching instrument with a three-pin connector.

This receptacle is designed to accept a Valleylab Smart Connector. If the bipolar instrument you select does not have a Smart Connector, you must use the Valleylab Smart Connector Adapter (p/n LS0500).

### Bipolar Footswitch Receptacle (blue)

You must connect the bipolar/macro bipolar footswitch if you connect a bipolar footswitching instrument to the generator.



Connect the two-pedal bipolar footswitch to the Bipolar Footswitch receptacle.

The connected footswitch activates bipolar output for the instrument that is connected to the Bipolar Handset receptacle on the front panel.

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**Macrobipolar Power B**

- Press  $\Delta$  to increase th
- Press  $\nabla$  to decrease th

**Macrobipolar Power Display**

Shows the power setting for the Macrobipolar mode.

**Regrasp Indicator**

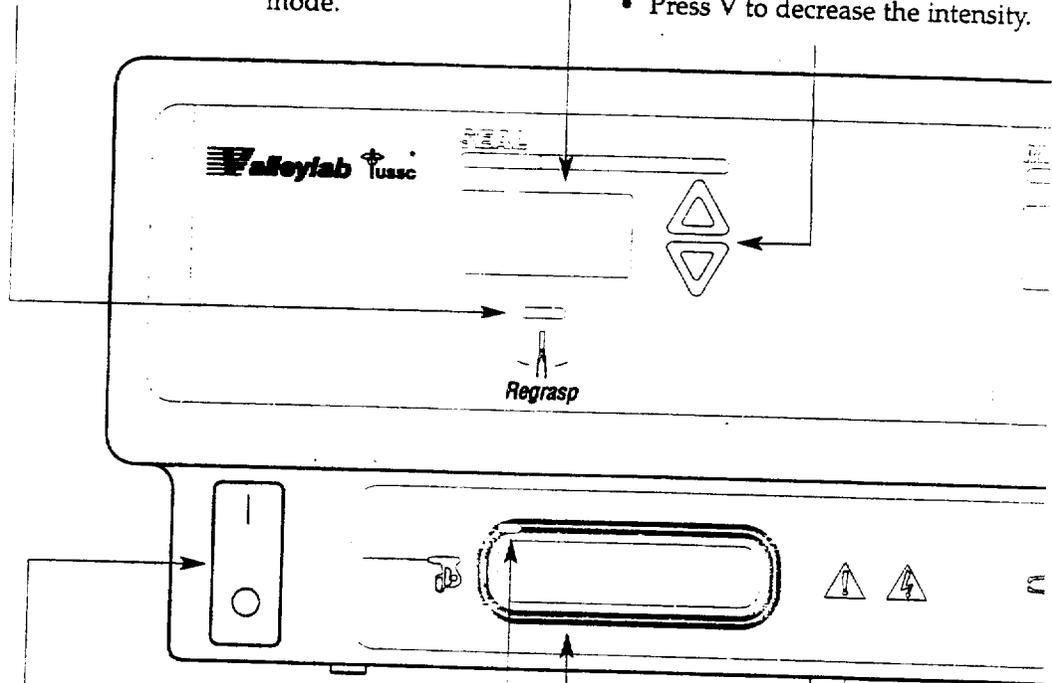
Illuminates if the tissue does not respond correctly to the application of RF energy or if the tissue impedance is too high. A pulsed tone sounds and vessel sealing output is disabled.

**Vessel Sealing Intensity Display**

Bar graph indicates the relative sealing intensity setting for the Vessel Sealing mode.

**Vessel Sealing Intensity Buttons**

- Press  $\Delta$  to increase the intensity.
- Press  $\nabla$  to decrease the intensity.



**Power On/Off Switch**

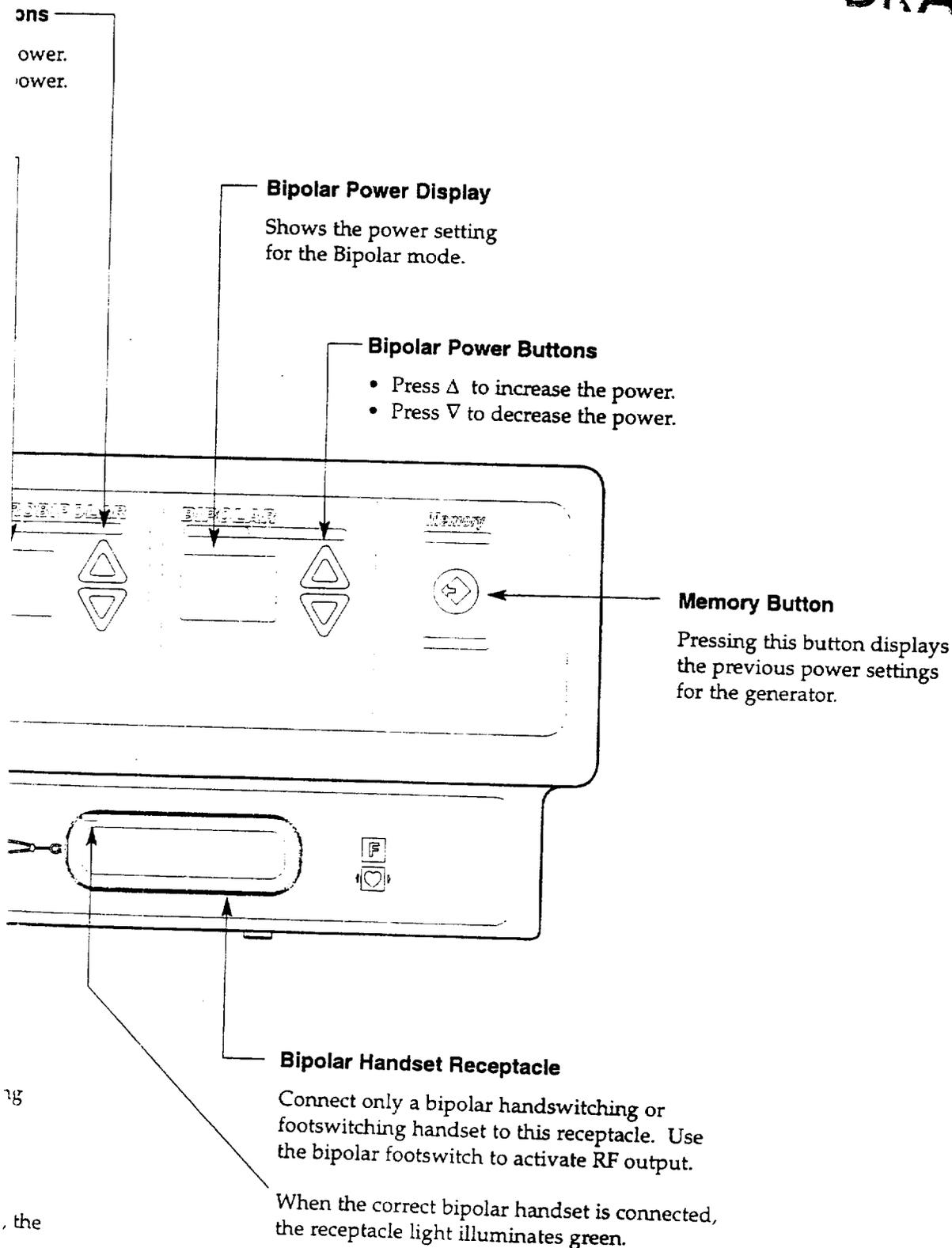
- Press On (I) to turn on the generator.
- Press Off (O) to turn off the generator.

**Vessel Sealing Handset Receptacle**

Connect either a LigaSure Vessel Se Handset or a bipolar handset to this receptacle. Use the vessel sealing footswitch to activate RF output.

When the correct handset is connect receptacle light illuminates green.

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**Figure 2-1 Generator Front Panel**

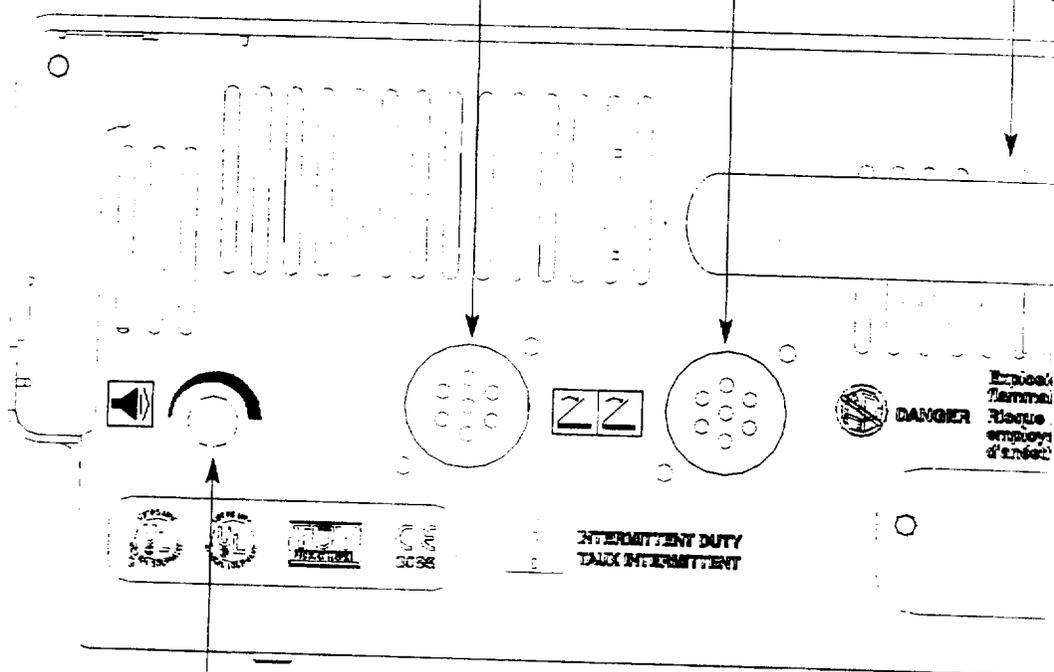
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**Bipolar Footswitch Receptacle**

Connect the two-pedal bipolar footswitch to this receptacle; allows bipolar or macrobipolar output to a bipolar handset connected to the Bipolar receptacle on the front panel. Cord connector and receptacle are keyed to prevent incorrect connection. (color coded BLUE)

**Vessel Sealing Foots**

Connect the two-pedal receptacle; allows vessel sealing handset receptacle on the front panel receptacle are keyed to (color coded PURPLE)



**Volume Knob**

- To increase the volume, turn the knob clockwise.
- To decrease the volume, turn it counterclockwise.

You cannot deactivate the activation tone or adjust the alarm tone volume.

**Option Panel**

A removable plate on the rear panel covers a serial activation port, and an expansion port. To review each port, refer to Appendix A.

**Serial Port** – Allows connection of a computer to the generator and obtain information using RS-232 communications protocol.

**RF Activation Port** – Allows connected device to receive information during RF activation of the generator, which can generate a response in the

# DRAFT

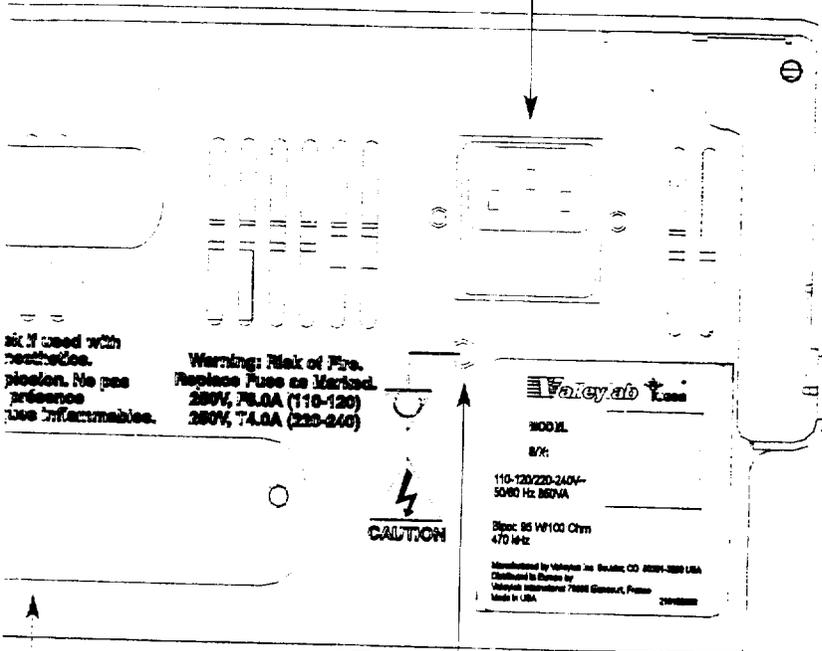
## ch Receptacle

essel sealing footswitch to this  
ealing or bipolar output to a  
nected to the Vessel Sealing  
el. Cord connector and  
event incorrect connection.

## Power Entry Module

Contains a fuse drawer, with  
two fuses, and a receptacle  
for connecting the generator  
power cord.

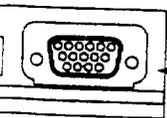
aker



## Grounding Lug

If required by your institution, use to  
connect the generator to earth ground  
with an equipotential grounding cable.

port, an RF (radio frequency)  
e technical specifications for

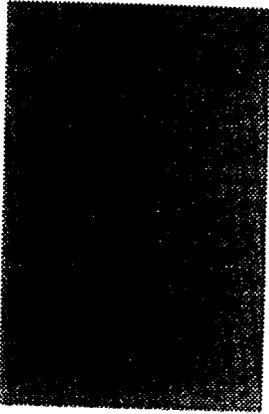


**Expansion Port -**  
Allows a connected  
device to receive  
information about RF  
output from the  
generator.

Figure 2-2 Generator Rear Panel

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# Before Surgery

**DRAFT**

This section contains procedures for setting up and verifying the operation of the LigaSure Vessel Sealing Generator. Specific instructions for preparing the generator for bipolar electrosurgery or vessel sealing are provided.

## Cautions

Read all warnings, cautions, and instructions provided with the Valleylab LigaSure Vessel Sealing Generator before using.

Read the instructions, warnings, and cautions provided with the active accessories before using. Specific instructions are not included in this manual.

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# Preparing the LigaSure Vessel Sealing Generator for Surgery

## Step 1 – Set up the Generator

1. Verify the generator is off by pressing the power switch off (O).

**Caution**

Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow for adequate cooling.

Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

2. Place the generator on a stable flat surface, such as a table, platform, or Valleylab cart. Carts with conductive wheels are recommended. For details, refer to the procedures for your institution or to local codes.

Provide at least four to six inches of space from the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when the generator is used continuously for extended periods of time.

**Notice**

If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

3. Plug the generator power cord into the rear panel receptacle.

**Warnings**

Electric Shock Hazard. Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.

Fire Hazard. Do not use extension cords.

**Caution**

Connect the power cord to a wall outlet having the correct voltage. Otherwise product damage may result.

4. Plug the generator power cord into a grounded receptacle.

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## Step 2 – Verify the Operation of the Generator

# DRAFT

Turning on the generator initiates an internal self-test to verify the calibration. The self-test also checks the operation of the speaker, all visual indicators, and the displays.

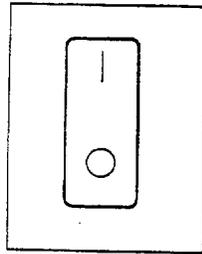
### Warning

**Patient Safety.** Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

### Caution

Nonfunction of the generator may cause interruption of surgery. A backup generator should be available for use.

1.



Turn on the generator by pressing the power switch on ( I ). Verify the following:

- A tone sounds to indicate the self-test is in progress.
- All visual indicators and the display on the front panel illuminate.

### Caution

Do not turn the activation tone down to an inaudible level. The activation tone alerts personnel when an accessory is active.

When using a smoke evacuator in conjunction with the electrosurgical generator, place the smoke evacuator a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

2. If the self-test is successful, two tones sound. The power displays show the minimum safe recommended output power setting.

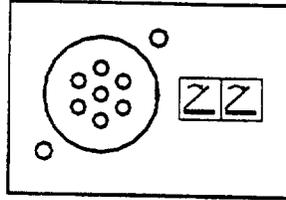
If the test is not successful, an alarm tone sounds. A number and "E" flash in the power display and RF output is disabled. Note the number and refer to *Responding to Alarms* in Section 6.

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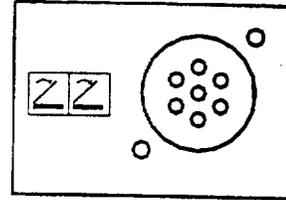
**DRAFT**

### Step 3 – Connect the Footswitch

Connect the appropriate footswitch to the corresponding receptacle on the rear panel.



**Bipolar Footswitch  
Receptacle  
(blue)**



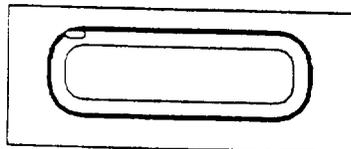
**Vessel Sealing  
Footswitch  
Receptacle (purple)**

### Step 4 – Connect the Instrument

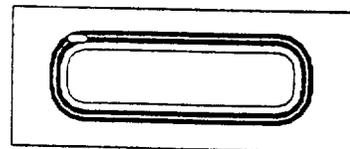
The LigaSure System can be used in several different configurations. You may choose to operate the system:

- with only a vessel sealing handset attached to the Vessel Sealing Handset receptacle;
- with only a bipolar handset attached to the Bipolar Handset receptacle;
- with both a vessel sealing handset and a bipolar handset attached to their respective receptacles (simultaneous activation is not available);
- with two bipolar handsets attached, one to the Bipolar Handset receptacle and one to the Vessel Sealing receptacle (simultaneous activation is not available).

*When using two bipolar handsets, the instrument connected to the Bipolar Handset receptacle is activated in either the bipolar or macrobipolar mode utilizing the Bipolar Footswitch. However, the instrument connected to the Vessel Sealing Handset receptacle can only be activated in the bipolar mode and utilizes the blue bipolar pedal on the Vessel Sealing Footswitch.*



**Vessel Sealing  
Handset Receptacle  
(purple)**



**Bipolar Handset  
Receptacle  
(blue)**

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9h

DRAFT

### Warning

#### Electric Shock Hazard.

- Do not connect wet accessories to the generator.
- Ensure that all accessories and adapters are correctly connected and that no metal is exposed.

### Caution

Inspect accessories and cords (especially reusable accessories and cords) for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operating room personnel.

1. Prepare the surgical instrument to be used for the procedure. Refer to the instructions provided with the instrument.
2. Connect the handset to the proper receptacle on the front panel, using a Smart Connector Adapter as necessary

Verify that the receptacle indicator illuminates green to confirm a proper connection.

## Step 5 – Set the Output for the Selected Mode

1. (Optional) To display the previous settings, press the Memory button on the front panel.
2. To set the bipolar or macrobipolar output power or the vessel sealing intensity:

To increase the power or intensity, press the Up (  $\Delta$  ) button.

To decrease the power or intensity, press the Down (  $\nabla$  ) button.

In the bipolar or macrobipolar modes, the power level changes numerically, in 1 watt increments from 1 to 40, and in 5 watt increments from 40 to 95.

In the vessel sealing mode, the sealing intensity level changes in 1 light bar increments, with a range of 1 to 5 bars. Increasing the intensity increases the total energy delivered to the tissue for the duration of the cycle.

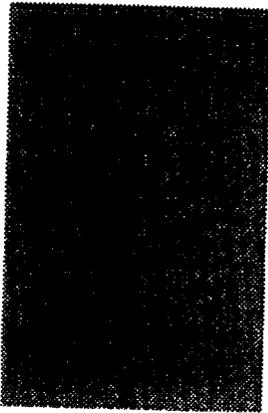
*When using two bipolar handsets, output power for the instrument connected to the Bipolar Handset receptacle is available from both the Bipolar or Macrobipolar modules. However, only bipolar output power is available to the instrument connected to the Vessel Sealing Handset receptacle. Simultaneous activation is not available.*

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**Notes**

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# During Surgery

**DRAFT**

Prior to surgery, review the general precautions and check the connections of all accessories. Verify the generator settings with the surgeon and review the information on using low power or intensity settings.

## General Precautions

### Patients with Pacemakers

Monitor pacemakers and keep a defibrillator available during surgery.

#### Warning

Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced with the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.

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## Electrosurgical Smoke

### Caution

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and surgical personnel. These studies recommend using surgical masks and adequately ventilating the smoke by using a surgical smoke evacuator or other means.

## Active Accessories

### Warnings

When not using active accessories, place them in a holster or in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

**Fire Hazard.** Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories that are activated or hot from use can cause a fire. Use a holster to hold electrosurgical accessories safely away from patients, surgical personnel, and flammable materials.

## Contact with Metal Objects

### Warnings

Contact of the active electrode with any metal (such as hemostats, Gomco clamps, Kocher clamps, etc.) will greatly increase current flow and can result in unintended, catastrophic burn injury.

While using electrosurgery, the patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.). If this is not possible during certain procedures (e.g., those in which noninsulated head frames are used), use extreme caution to maximize patient safety:

- Use the lowest power or intensity setting that achieves the desired effect.
- Place dry gauze between the patient and the grounded object if possible.
- Continually monitor the contact point(s).

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## Checking Accessory Connections

**DRAFT**

### Warning

Do not wrap the accessory cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

### Caution

Examine all accessories and connections to the electrosurgical generator before using. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

Verify that all accessories are properly connected to the generator. When multiple accessories are used, keep cords separate. To reduce cross coupling, do not twist, bundle, or clamp them together.

## Changing the Power or Intensity Setting

### Warning

Confirm proper power or intensity settings before proceeding with surgery. Use the lowest setting possible for the minimum time necessary to achieve the desired effect.

### Caution

The LigaSure Vessel Sealing Generator works effectively at bipolar power settings lower than other generators offered by Valleylab. If the proper setting is not known, set the generator at a very low setting and cautiously increase the power until the desired effect is achieved.

### Using Low Power or Intensity Settings

Keep the power or intensity settings as low as possible to produce the desired surgical effect. Low settings:

- enhance patient and user safety
- reduce the amount of current delivered to the patient and protect the patient and surgical team from accidental burns and shocks.

*To increase the power or intensity, press the Up (  $\Delta$  ) button for the selected mode.*

*To decrease the power or intensity, press the Down (  $\nabla$  ) button for the selected mode.*

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Vessel Sealing: When you press and release the intensity button, the sealing intensity changes by one light bar. Increasing the intensity increases the total energy delivered to the tissue for the duration of the cycle. Changing the setting during activation is not permitted.

Bipolar or Macrobipolar: When you press and release the power button, the power changes in 1 watt increments between 1 and 40, and in 5 watt increments between 40 and 95. Each time you press the power button while the generator is activated, the power changes by one setting only to prevent rapid changes in power delivered to the surgical site.

*To reach the maximum or minimum power or intensity setting for the selected mode, press and hold the Up (  $\Delta$  ) or Down (  $\nabla$  ) button. The setting changes slowly at first, then more rapidly. Release the button when the desired setting is displayed.*

## Activating the Surgical Instrument

### Warnings

Do not activate the generator until the vessel sealing forceps have been applied with the proper pressure setting for the instrument. Activating the generator before this is done will result in an improper seal with increased thermal spread to tissue outside the surgical site.

Use the forceps only until you achieve the desired surgical effect in order to minimize the possibility of burns. This is especially true in pediatric and neonatal patients or in any patient where small appendages are involved.

To activate the generator:

- Press the pedal on the footswitch, or
- Activate the handswitch if the instrument has one.

When you activate the generator, the corresponding indicator illuminates blue and a continuous tone sounds to indicate the presence of RF output. Keep your foot on the pedal until you hear two short tones. The RF output is disabled and hemostasis is complete.

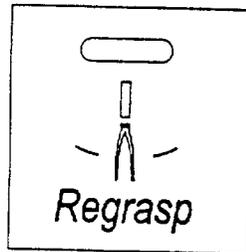
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## Regrasp Indicator

# DRAFT

The Regrasp indicator illuminates if tissue does not respond correctly to the application of RF energy, or if tissue impedance is too high. A pulsed tone sounds and RF output is disabled.



If the Regrasp indicator illuminates and a tone sounds while sealing:

RF current is automatically discontinued. You should:

1. Release the footswitch pedal.
2. Open the jaws and inspect the tissue for a successful seal. Repeat the procedure if necessary.

Possible Regrasp alarm triggers include:

*Pooled fluids around the tip* – Minimize fluids. Inspect the tissue for a successful seal and repeat the procedure if necessary.

*Thin tissue* – Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure, or repeat the procedure by closing the handle without latching it in the locked position.

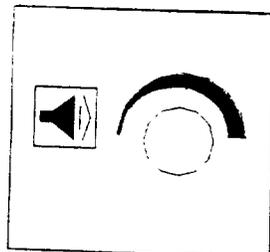
You may also choose to continue the procedure using traditional bipolar current. Set the Bipolar power level on the front panel of the generator; refer to the LigaSure Vessel Sealing Generator User's Guide for instructions. Grasp the tissue in the jaws but do not latch the handle in the locked position. Step on the blue pedal of the vessel sealing footswitch. Release the pedal when done.

## Adjusting the Volume of Activation Tones

### Caution

Do not turn the activation tone down to an inaudible level. The activation tone alerts personnel when an accessory is active.

Turn the Volume knob, located on the rear panel, to change the volume of activation tones.



To increase the volume of activation tones, turn the Volume knob clockwise.

To decrease the volume, turn the knob counterclockwise.

You cannot silence the activation tones or adjust the alarm tone volume.

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## Responding to Alarms

**DRAFT**

When the generator senses a system alarm condition, an alarm tone sounds and the generator is deactivated. An alarm number flashes in the display on the front panel.

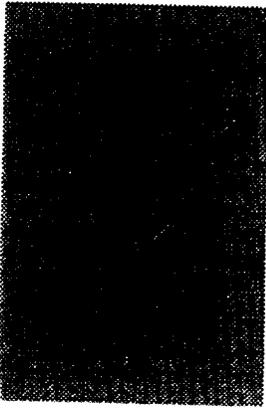
1. Turn off the generator.
2. Turn on the generator and verify that the self-test is completed successfully. If the alarm number reappears, note the number and refer to *Responding to System Alarms* in Section 6.

If you are unable to correct the system alarm condition, use a backup generator to complete the surgical procedure.

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**DRAFT**



# After Surgery

After surgery, prepare the generator for reuse. To do so, disconnect all accessories and clean the generator. If you plan to store the generator, refer to the information in this section regarding storage considerations.

## Preparing the Generator for Reuse

### Step 1 – Disconnect the Accessories

1. Turn off the generator.
2. Disconnect the surgical instrument from the front panel.

**Caution**

Accessories labeled “disposable” are single use only. Do not reuse or resterilize.

- If the instrument is disposable (single use only), dispose of the instrument according to the procedures for your institution.
  - If the instrument is reusable, clean and sterilize it according to the manufacturer’s instructions for the instrument.
  - Do not dispose of the Smart Connector Adapter(s).
3. Disconnect and store the footswitch(es), if applicable.

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## Step 2 – Clean the Generator

**DRAFT**

The generator cannot be sterilized.

### Warning

Electric Shock Hazard. Always unplug the generator before cleaning.

1. Unplug the generator power cord from the wall outlet.

### Notice

Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

2. Using a mild cleaning solution or disinfectant on a damp cloth, thoroughly wipe the generator surfaces and power cord. Do not allow fluids to enter the chassis.

Follow the procedures approved by your institution or use a validated infection control procedure.

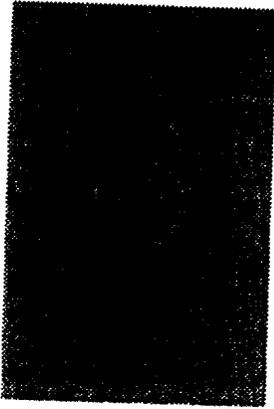
## Storing the Generator

The LigaSure Vessel Sealing Generator can be stored indefinitely. However, if you store the generator longer than one year, you must perform specific checkout procedures before use (refer to the service manual).

If you store the generator at a temperature that is outside its normal operating range of 50° to 104° F (10° to 40° C), allow one hour for the generator to reach room temperature before use.

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# Troubleshooting

**DRAFT**

Troubleshooting gives instructions for identifying and correcting malfunctions and responding to alarms.

## General Troubleshooting Guidelines

If the LigaSure generator malfunctions, check for obvious conditions that may have caused the problem.

- Check the generator for visible signs of physical damage.
- Verify that all cables are connected and attached properly.

If the malfunction persists, the generator may require service.

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## Correcting Malfunctions

If the solution is not readily apparent, use the table below to help you identify and correct specific malfunctions. After you correct the malfunction, verify that the generator completes the self-test as described in Section 3.

Situation	Possible Cause	Solution
Abnormal neuromuscular stimulation ( <i>stop surgery immediately</i> ).	1. Metal-to-metal sparking.	1. Check all connections to the generator, patient return electrode, and active electrodes.
	3. Abnormal 50-60 Hz leakage currents.	3. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance.

Situation	Possible Cause	Solution
Generator does not respond when turned on.	1. Disconnected power cord or faulty wall outlet.	1. Check power cord connections (generator and wall outlet). Connect the power cord to a functional outlet.
	2. Faulty power cord.	2. Replace the power cord.
	3. Fuse drawer is open or fuses are blown.	3. Close the fuse drawer. Replace the blown fuse(s). Contact Valleylab service for fuse replacement.
	4. Internal component malfunction.	4. Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance.

Situation	Possible Cause	Solution
Generator is on, but did not complete the self-test.	1. An alarm condition exists.	1. Check the display for an alarm number. Note the number and refer to <i>Responding to Alarms</i> in this section.
	2. Internal component malfunction.	2. Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance.

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## Correcting Malfunctions

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Situation	Possible Cause	Solution
Generator is on and accessory is activated, but generator does not deliver output.	1. Malfunctioning footswitch or handswitching instrument.	1. Turn off the generator. Check and correct all accessory connections.  Turn on the generator. Replace the accessory if it continues to malfunction.
	2. Power set too low.	2. Increase the power or intensity setting. Follow the procedures in Section 4 under <i>Changing the Power or Intensity Setting</i> .
	3. An alarm condition exists.	3. Check the display for an alarm number. Note the number and see <i>Responding to System Alarms</i> later in this section.
	4. Internal component malfunction.	4. Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance.

Situation	Possible Cause	Solution
The <i>Regrasp</i> indicator illuminates, a pulsed tone sounds, and RF output is disabled.	1. Pooled fluids around the tip.	1. Minimize fluids. Inspect the tissue for a successful seal and repeat the procedure if necessary.
	2. Thin tissue or no tissue present.	2. Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure, or repeat the procedure by closing the handle without latching it in the locked position. You may also choose to continue the procedure using traditional bipolar current. Set the Bipolar power level on the front panel of the generator; refer to the LigaSure Vessel Sealing Generator User's Guide for instructions. Grasp the tissue in the jaws but do not latch the handle in the locked position. Step on the blue pedal of the vessel sealing footswitch. Release the pedal when done.

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## Correcting Malfunctions

**DRAFT**

Situation	Possible Cause	Solution
Continuous monitor interference.	1. Faulty chassis-to-ground connections.	1. Check and correct the chassis ground connections for the monitor and for the generator.  Check other electrical equipment in the room for defective grounds.
	2. Electrical equipment is grounded to different objects rather than a common ground. The generator may respond to the resulting voltage differences between grounded objects.	2. Plug all electrical equipment into line power at the same location. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance.
	3. Malfunctioning monitor.	3. Replace the monitor.

Situation	Possible Cause	Solution
Interference with other devices only when generator is activated.	1. Metal-to-metal sparking.	1. Check all connections to the generator and accessories.
	2. Electrically inconsistent ground wires in the operating room.	2. Verify that all ground wires are as short as possible and go to the same grounded metal.
	3. If interference continues when the generator is activated, the monitor is responding to radiated frequencies.	3. Ask your Biomedical Engineering Department to check with the manufacturer of the monitor.  Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference when the generator is activated and minimize the potential for an electrosurgical burn at the site of the monitor electrode.

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## Correcting Malfunctions

**DRAFT**

Situation	Possible Cause	Solution
Pacemaker interference.	1. Intermittent connections or metal-to-metal sparking.	<p>1. Check all connections to the generator.</p> <p>It may be necessary to reprogram the pacemaker prior to surgery.</p> <p>Always monitor patients with pacemakers during surgery and keep a defibrillator available.</p> <p>Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.</p>

Situation	Possible Cause	Solution
Vessel Sealing Intensity Display and Intensity Buttons do not function. Only the first yellow light bar is illuminated.	The vessel sealing intensity module needs a Smart Connector to function. If a different connector is plugged into the Vessel Sealing Handset receptacle, current output power is not available.	Only use a Valleylab LigaSure Vessel Sealing instrument or a bipolar instrument with the Smart Connector attached.

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## Responding to Alarms

**DRAFT**

When an alarm condition exists, an alarm tone sounds and a number appears in the front panel display. The generator is disabled until the condition is cleared. Some alarm conditions self-correct automatically, but most require some action on your part.

Use the table below to determine how to correct the alarm condition. After correcting the alarm condition, verify that the generator completes the self-test as described in Section 3.

Number	Description	Recommended Action
0-7	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
10	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
11	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
12	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
13-14	Diagnostics/microcontroller malfunction.	Contact your Biomedical Engineering Department.
16	Diagnostics/microcontroller malfunction.	Contact your Biomedical Engineering Department.
17-18	Internal component malfunction.	Do not attempt the use the generator. Record the number and call the Valleylab Service Center.
19	Internal component malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
30-32 40 60-66	Software malfunction.	
67	Internal diagnostics	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.

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**DRAFT****Responding to Alarms**

<b>Number</b>	<b>Description</b>	<b>Recommended Action</b>
69-71 80	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
81	Dosage error.	Do not attempt to continue using the generator. Record the number and call the Valleylab Service Center.
90 95	Microprocessor ROM inconsistency.	Contact your Biomedical Engineering Department.
110-114	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
120	Calibration malfunction.	Contact your Biomedical Engineering Department.
121	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
123-126	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
130-132 134 136-138 150	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.

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## Responding to Alarms

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Number	Description	Recommended Action
151	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
152-153	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
154	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
160-163	Dosage error.	Do not attempt to continue using the generator. Record the number and call the Valleylab Service Center.
164-166 170-173	Calibration or microcontroller malfunction.	Contact your Biomedical Engineering Department.
174	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
180-185	Internal diagnostics.	Contact your Biomedical Engineering Department.
186-187	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.

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**Responding to Alarms****DRAFT**

<b>Number</b>	<b>Description</b>	<b>Recommended Action</b>
189	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
198	Pedal on bipolar footswitch may be stuck.	<ol style="list-style-type: none"> <li>1. Turn off, then turn on the generator. Do not press accessory activation devices during the self-test.</li> <li>2. If the alarm number reappears, disconnect all accessories. Turn off, then turn on the generator again.</li> </ol> <p>If the number reappears, record the number and call the Valleylab Service Center.</p>
199-205	Internal diagnostics.	Contact your Biomedical Engineering Department.
206-207	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
208-209	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
210-211	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
212-213 220-226	Internal diagnostics or microcontroller malfunction.	Contact your Biomedical Engineering Department.

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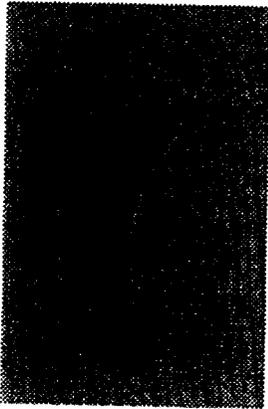
## Responding To Alarms

**DRAFT**

Number	Description	Recommended Action
230-231	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
232	Microcontroller Malfunction.	Contact your Biomedical Engineering Department.
240-245	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
246-247 260	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
451	The internal temperature limit was exceeded due to length of activation time.	Verify that the location of the generator allows for adequate cooling.  Use the lowest power setting that achieves the desired effect.  Limit activation times, if possible.

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# Maintenance and Repair

**DRAFT**

This section lists the responsibilities assumed by Valleylab for the correct performance of the LigaSure Vessel Sealing Generator. It also describes when and how to perform routine maintenance. Instructions for returning the generator to Valleylab are provided.

## Responsibility of the Manufacturer

Valleylab is responsible for safety, reliability, and performance of the generator only under the following circumstances:

- Installation and setup procedures in this manual are followed.
- Assembly operation, readjustments, modifications, or repairs are carried out by persons authorized by Valleylab.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as the IEC and BSI.
- The equipment is used in accordance with the Valleylab instructions for use.

For details regarding the warranty, refer to the Warranty at the end of this guide.

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## Routine Maintenance

**DRAFT**

### When should the Generator be checked or serviced?

Valleylab recommends that the generator be inspected by qualified service personnel at least twice a year. This inspection should include checking the calibration of the generator.

### When should the power cord be checked or replaced?

Check the power cord each time you use the generator or at the intervals recommended by your institution. Replace the power cord if you find exposed wires, cracks, frayed edges, or a damaged connector.

### When should the fuses be replaced?

An internal component malfunction can damage the fuses. You may need to replace the fuses if the generator fails the self-test or if the generator stops functioning, even though it is receiving power from a wall outlet. Contact Valleylab service for assistance.

## Returning the Generator for Service

Before you return the generator, call your Valleylab Representative for assistance. If you are instructed to send the generator to Valleylab, first obtain a Return Authorization Number. Then, clean the generator and ship it to Valleylab for service.

### Step 1 – Obtain a Return Authorization Number.

Call the Valleylab Customer Service Center for your area to obtain a Return Authorization Number. Have the following information ready when you call:

- hospital/clinic name/customer number
- telephone number
- department/address, city, state, and zip code
- model number
- serial number
- description of the problem
- type of repair to be done

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**DRAFT**

## Step 2 – Clean the generator.

The generator cannot be sterilized.

### Warning

Electric Shock Hazard. Always unplug the generator before cleaning.

1. Turn off the generator by pressing *Off* ( O ).
2. Unplug the generator power cord from the wall receptacle.

### Notice

Do not clean the generator with abrasive cleaning or disinfectant compounds; solvents, or other materials that could scratch the panels or damage the generator.

3. Using a mild cleaning solution or disinfectant on a damp cloth, thoroughly wipe the generator surfaces and power cord. Do not allow fluids to enter the chassis.

Follow the procedures approved by your institution or use a validated infection control procedure.

## Step 3 – Ship the generator.

1. Attach a tag to the generator that includes the Return Authorization Number and the information (hospital, phone number, etc.) listed earlier in *Step 1 – Obtain a Return Authorization Number*.
2. Be sure the generator is completely dry before you pack it for shipment. Package it in its original shipping container, if available.
3. Ship the generator prepaid to the Valleylab Service Center.

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## Service Centers

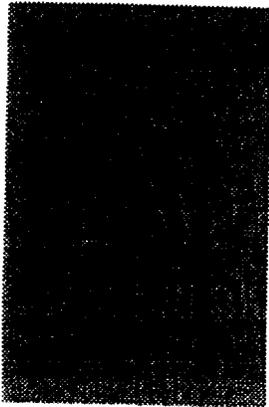
Valleylab Inc  
Boulder, Colorado, USA  
800-255-8522

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# Technical Specifications

All specifications are nominal and subject to change without notice. A specification referred to as "typical" is within  $\pm 20\%$  of a stated value at room temperature (25° C / 77° F) and a nominal input power voltage.

## Performance Characteristics

### General

Output configuration: isolated output

Cooling: natural convection

Display: two (2) digital seven-segment displays: 1.9 cm (0.75 in.) each  
six (6) bar graph displays: 1.0 cm (0.4 in.) each

Mounting: a Valleylab cart (UC8009, E8006, or E8008) or a stable flat surface

### Dimensions and Weight

Width: 38.1 cm (15.0 in.)

Depth: 40 cm (15.75 in.)

Height: 12.7 cm (5.0 in.) not including feet

Weight: 5.9 Kg (13 lbs) typical

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## Operating Parameters

**DRAFT**

Ambient temperature range: 10° to 40° C (50° to 104° F)

Relative humidity: 15% to 90%, noncondensing

Atmospheric pressure: 700 to 1060 millibars

Warm-up time: If transported or stored at temperatures outside the operating temperature range, allow one hour for the generator to reach room temperature before using.

## Transport and Storage

Ambient temperature range: -34° to 70° C (-29° to 158° F)

Relative humidity: 0% to 95%, noncondensing

Atmospheric pressure: 500 to 1060 millibars

Duration of storage: If stored over one year, check the battery to measure the Vdc minimum and complete a full checkout (including calibration) before use. Contact Valleylab Service for information.

## Duty Cycle

Under maximum output settings and rated load conditions (100 ohm load) the generator is suitable for activation times of 10 seconds on, 30 seconds off, for 1 hour. With lesser settings and loads, you can activate the generator for greater durations without generating excessive internal temperatures.

## Internal Memory

Nonvolatile, battery-backed RAM

Battery type: 3 V lithium button cell

Battery life: 5 years

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(20)

## Audio Volume

**DRAFT**

The stated audio level is for the activation tone and alarm tone at a distance of one meter.

### Activation Tone

Volume (adjustable): 45 dB minimum

Frequency (nominal): Seal Mode - 440 Hz  
Macrobipolar Mode - 520 Hz  
Bipolar Mode - 660 Hz

Duration: continuous while the generator is activated; changes to two short tones when hemostasis is complete

### Alarm Tone

Volume (not adjustable): 65 dB minimum

Frequency: 985 Hz - 780 Hz - 985 Hz nominal

## Serial Port

RS-232 compatible; 9600 baud, 8 data bits, 1 stop bit, no parity

9-pin connector supporting the following signals:

- pin 2 – isolated transmit (serial data output transmit line)
- pin 3 – isolated receive (serial data input receive line)
- pin 5 – isolated ground (reference for transmit and receive)

## RF Activation Port

The RF activation port is a subminiature phone jack attached to the contacts of a small relay. The contacts are closed when the output is energized and open at all other times. This port provides a means to tell other equipment that RF current is being generated. This may be useful when making EEG or ECG measurements.

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**Expansion Port**

15-pin connector; supports the following signals:

- pin 2 – isolated transmit (serial data output transmit line)
- pin 3 – isolated receive (serial data input receive line)
- pin 5 – isolated ground (reference for transmit and receive)
- pin 9 – RF disable: input signal which, when activated by an external device, disables active RF output
- pin 10 – RF current: output signal proportional to active RF current
- pin 11 – RF voltage: output signal proportional to active RF voltage

Expansion power (from the low voltage power supply):

+ 5 V (pin 6), - 12 V (pin 14), + 12 V (pin 15), and ground (pins 12 & 13)

**Low Frequency (50-60 Hz) Leakage Current (AAMI HF-18-1993)**

Enclosure source current, ground open: < 300  $\mu$ A

Source current, patient leads, all outputs:

Normal polarity, intact ground: < 10  $\mu$ A

Normal polarity, ground open: < 50  $\mu$ A

Reverse polarity, ground open: < 50  $\mu$ A

Sink current at high line, all inputs: < 50  $\mu$ A

**High Frequency (RF) Leakage Current (IEC 601-2-2)**

Bipolar RF leakage current:  $\leq$  86 mA<sub>rms</sub>

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### Input Power

# DRAFT

#### 120 Volt

#### 240 Volt

Maximum power at nominal line voltage:

- Idle: 35 VA
- Bipolar: 360 VA
- Seal: 600 VA

Full regulation range:

90 to 135 Vac

Operating range: 85 to 140 Vac

Mains current maximum:

- Idle: 300 mA<sub>rms</sub>
- Bipolar: 3.0 A<sub>rms</sub>
- Seal: 5.0 A<sub>rms</sub>

Mains line frequency range (nominal): 50 to 60 Hz

Fuses (2): 4 A, 250 V, 3 AG, SLO-BLO

Power plug: 3-prong hospital grade connector

Maximum power at nominal line voltage:

- Idle: 35 VA
- Bipolar: 360 VA
- Seal: 600 VA

Full regulation range:

186 to 264 Vac

Operating range: 170 to 264 Vac

Mains current maximum:

- Idle: 300 mA<sub>rms</sub>
- Bipolar: 1.5 A<sub>rms</sub>
- Seal: 2.5 A<sub>rms</sub>

Mains line frequency range (nominal): 50 to 60 Hz

Fuses (2): 4 A, 250 V, 3 AG, SLO-BLO

Power plug: 3-prong locally approved connector

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## Standards and IEC Classifications



**ATTENTION**  
Consult accompanying documents.



The generator output is floating (isolated) with respect to ground.



Danger  
Explosion risk if used with flammable anesthetics.



To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel.

### Class I Equipment (IEC 601-1)

Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

### Type CF Equipment (IEC 601-1)



The LigaSure generator provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF isolated (floating) output and may be used for procedures involving the heart.

### Drip Proof (IEC 601-2-2)

The LigaSure generator enclosure is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wetted, are likely to affect adversely the safety of the generator.

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## Standards and IEC Classifications

**DRAFT**

### Static Electricity Discharge Interference (IEC 601-1-2 and IEC 801-2)

The enclosure can withstand an 8 kV electrostatic air discharge.

### Electromagnetic Interference

When placed near an activated Valleylab electrosurgical generator, the LigaSure generator operates without interference. The generator minimizes electromagnetic interference to video equipment used in the operating room.

**Caution**

Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow for adequate cooling.

### Electromagnetic Compatibility (IEC 601-1-2)

The LigaSure generator complies with the appropriate IEC 601-1-2 specifications regarding electromagnetic compatibility.

### Voltage Transients (Emergency Generator Mains Transfer)

The LigaSure generator operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

### Defibrillator Proof



The LigaSure generator complies with the ANSI/AAMI HF18 specifications for "defibrillator proof" designation.

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## Output Characteristics

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### Maximum Generator Output

Output	Maximum Open Circuit $V_{pp}$	Maximum Short Circuit Arms	Maximum Power Watts	Crest Factor*
Bipolar cut	760	2.2	95	1.5
Bipolar coag	335	2.2	95	1.5
Vessel seal	575	4.4	150	1.5

\* Crest factor is an indication of a waveform's ability to coagulate bleeders without a cutting effect.

### Output Waveform

473 kHz sinusoid. 100% duty cycle.

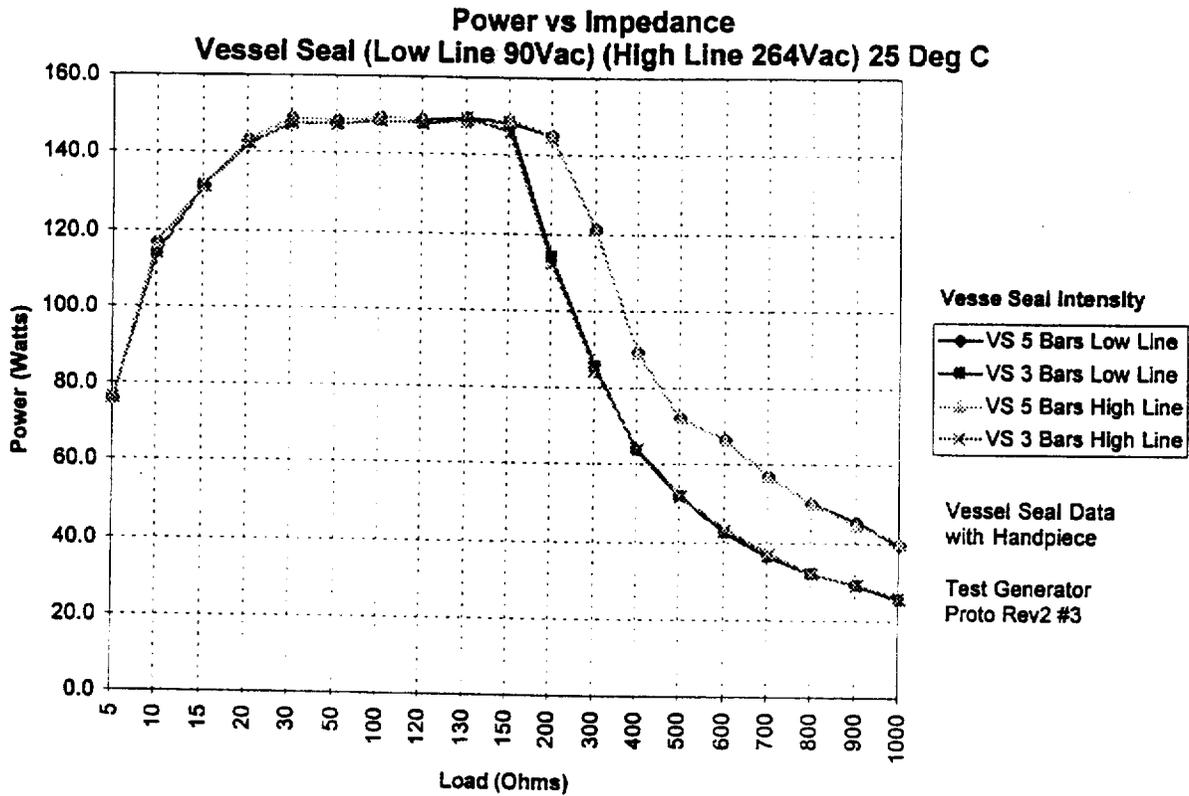
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## Output Power vs. Resistance Graphs

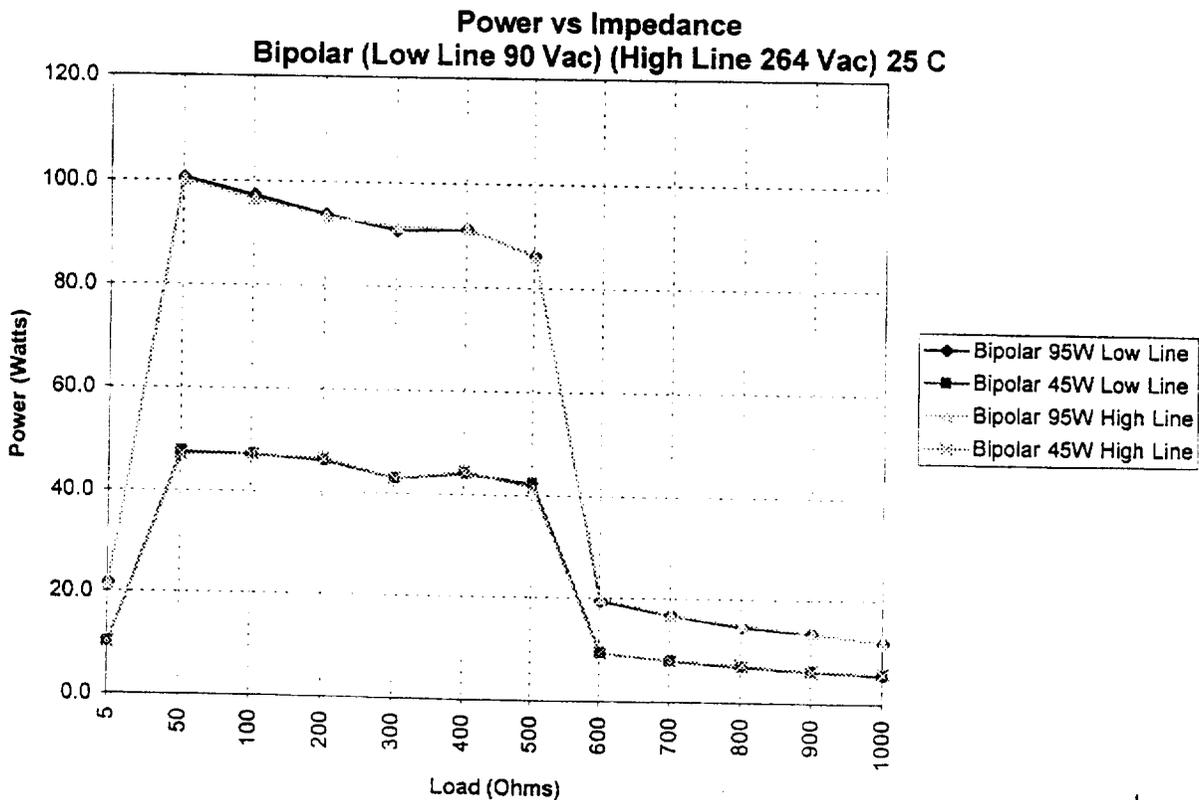
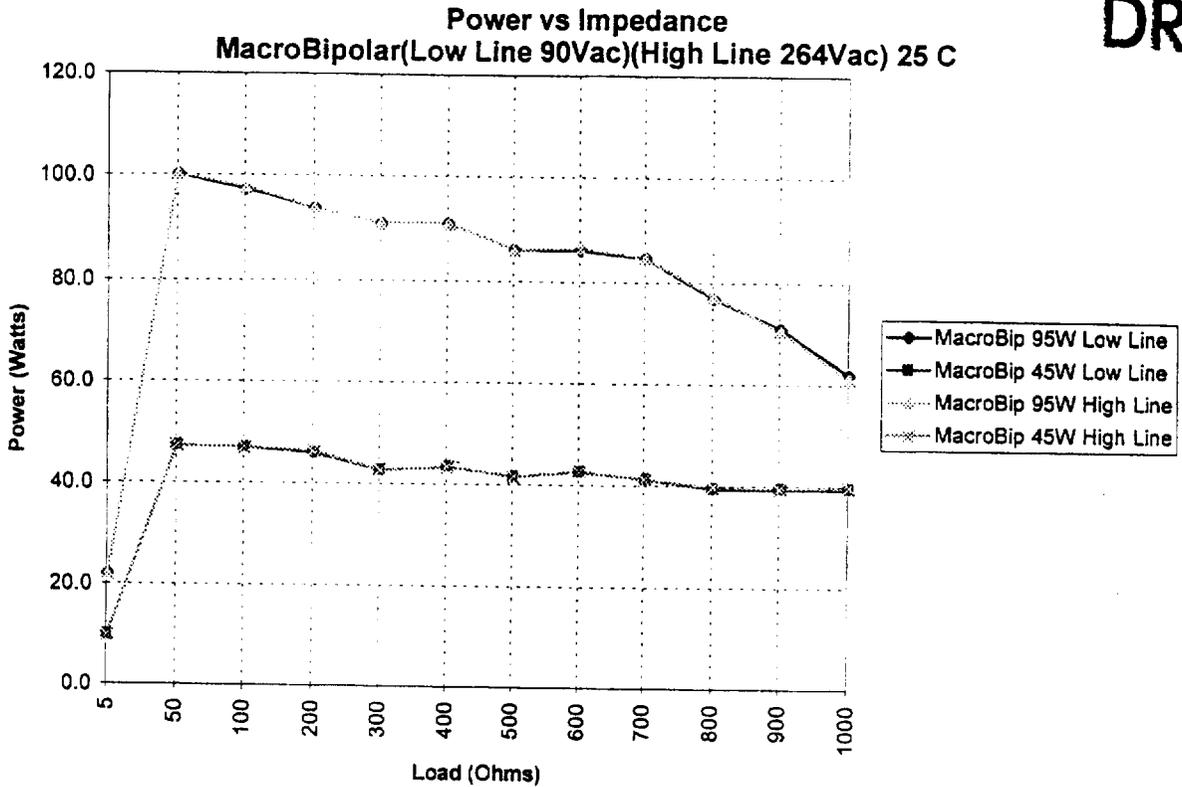
The following graphs depict the RF output as applied to tissue resistance for generator operative modes of seal, macrobipolar, and bipolar outputs.



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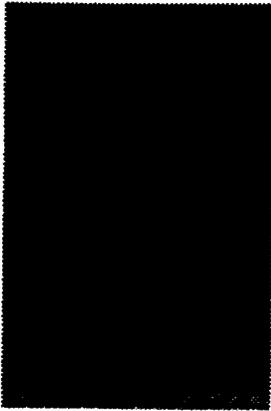
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# Accessories

**DRAFT**

The accessories listed in this section are recommended for use with the Valleylab LigaSure Vessel Sealing Generator.

<u>Catalog No.</u>	<u>Valleylab Accessory</u>
LS0010	LigaSure Vessel Sealing Footswitch
LS0020	Bipolar Footswitch
LS0100	LigaSure Instrument Sterilization Tray
LS0500	LigaSure Bipolar Smart Connector Adapter
LS1000	LigaSure Laparoscopic Handset w/cord, 5mm, disposable
LS2070	LigaSure Standard Handset, reusable (7")
LS2071	LigaSure Standard Electrode/Cord Assembly, disposable (for use with LS2070 Handset)
LS3090	LigaSure Max Handset, reusable (9")
LS3091	LigaSure Max Electrode/Cord assembly, disposable (for use with LS3090 Handset)
UC8009, E8006 or E8008	Mounting Cart

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**Notes**

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# Glossary

## A

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- active electrode** An electrosurgical instrument or accessory that concentrates the electric (therapeutic) current at the surgical site.
- adapter** A connector between incompatible plugs (connectors) and jacks (receptacles) that allows correct connection and completion of the electric circuit.
- alternate site burn** An electrosurgical burn on the patient at a grounded site, other than the surgical site or the patient return electrode, caused by a division of current. *See also* electrosurgical burn.
- ampere (A)** The unit of measurement for electric current. One ampere (A) equals  $6.242 \times 10^{18}$  electrons per second.

## B

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- bipolar electrosurgery** Electrosurgery where current flows between two bipolar electrodes that are positioned around tissue to create a surgical effect (usually desiccation). Current passes from one electrode, through the desired tissue, to another electrode, thus completing the circuit without entering any other part of the patient's body.
- bipolar instrument** An electrosurgical instrument or accessory that incorporates both an active and return electrode.
- bipolar output** An isolated output that removes the ground reference from the electrosurgical circuit and restricts current flow to the surgical instrument.

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## C

- capacitance** The property of an electrical circuit that enables it to transfer an electrical charge from one conductor to another even when separated by an insulator.
- capacitive coupling** Occurs when electrical current is transferred from one conductor (the active electrode), through intact insulation, into adjacent conductive materials (tissue, trocars, etc.).
- circuit** The path along which electricity flows.
- coagulation** The clotting of blood or destruction of tissue with no cutting effect; electro-surgical desiccation and fulguration.
- conductor** A substance that conducts electricity.
- crest factor** The ratio of the peak voltage of a waveform to the root mean square (rms) voltage; an indication of the degree of fulguration provided by the waveform. Generally, waveforms with high crest factors provide a high degree of fulguration.
- cross coupling** The transfer of power between two adjacent circuits.
- current** The number of electrons moving past a given point per second, measured in amperes (A).
- current density** The amount of current flow per unit of surface area; current concentration is directly proportional to the amount of heat generated.
- current division** Electrical current leaving the intended electro-surgical circuit and following an alternate path of least resistance to ground; typically the cause of alternate site burns on grounded generators.
- cutting** The electro-surgical effect that severs tissue with electric sparks, focusing intense heat at the surgical site and exploding cell walls.

## D

- desiccation** The electro-surgical effect of tissue dehydration and destruction caused by direct contact between the electro-surgical electrode and tissue.
- duty cycle** The ratio of the amount of time a given waveform is on to the total period of time; typically expressed as a percentage.

## E

- effect mode** A feature of the generator in which the output voltage of the generator is constantly changed as a function of tissue resistance to maintain a consistent tissue effect across different tissue types.
- electrode** A conductor through which electro-surgical current is transmitted or received. *See also* active electrode; patient return electrode.

- electrosurgery** The passage of high frequency (RF) electric current through tissue from an electrode that concentrates the current to produce a surgical effect (cutting or coagulating) to a larger electrode that disperses the current and returns it to the generator; surgical diathermy.
- electrosurgical burn** Tissue destruction caused by the concentration of high frequency electric current, including the surgical effect but usually referring to accidental injury. *See also* alternate site burn.
- electrosurgical circuit** The path traveled by the therapeutic current from the generator to the active electrode and through body tissue to the return electrode and back to the generator.
- electrosurgical current** See radio frequency (RF).
- electrosurgical unit (ESU)** The electrosurgical generator and its connecting cables.

**endoscope** A fiberoptic tube used to examine body cavities or organs.

F

**frequency** In electrosurgery, the number of cycles per second (hertz) that current alternates; the rate at which a cycle repeats itself.

**fulguration** The electrosurgical effect of tissue coagulation using electrical arcs (sparks) that jump from the electrode through the air to the tissue.

G

**generator** The machine that converts low frequency alternating current to high frequency current used for electrosurgery; electrosurgical unit (ESU).

**ground** The universal conductor and common return point for electric circuits; earth ground.

H

**hemostasis** In electrosurgery, the stopping of bleeding with heat produced by the electrosurgical circuit; coagulation.

**hertz (Hz)** The unit of measurement for frequency; cycles per second.

**holster** An insulated receptacle designed to hold active electrodes safely, when not in use during electrosurgery.

I

**impedance** Resistance to the flow of alternating current, including simple direct current resistance and the resistance produced by capacitance or inductance.

**insufflation** The pumping of gas into a body cavity or organ.

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- insulator** A substance that does not conduct electrical current.
- isolated output** The output of an electrosurgical generator that is not referenced to earth ground.
- L**
- 
- laparoscopy** The examination of the abdominal cavity with an endoscopic instrument.
- leakage current** Current that flows along an undesirable path, usually to ground; in isolated electrosurgery, radio frequency (RF) current that regains its ground reference.
- load** In electrosurgery, the body tissue involved in the electrosurgical circuit; the source of electrical impedance in a circuit that uses electrical energy for some purpose.
- M**
- 
- monopolar electrosurgery** A surgical procedure in which only the active electrode is in the surgical wound; electrosurgery that directs current through the patient's body and requires the use of a patient return electrode.
- monopolar instrument** An electrosurgical instrument or accessory that represents only one electrode; an active electrode.
- N**
- 
- necrosis** The destruction of tissue.
- O**
- 
- ohm ( $\Omega$ )** The unit of measurement for electrical resistance; volts per ampere.
- output** The current, voltage, or power produced by an electrical device, such as an electrosurgical generator (ESU).
- P**
- 
- patient return electrode** A conductive plate or pad (dispersive electrode) that recovers the therapeutic current from the patient during electrosurgery, dispersing it over a wide surface area, and returns it to the electrosurgical generator. Plates are usually rigid and made of metal or foil-covered cardboard; pads are usually flexible.
- peak voltage** The maximum voltage of a waveform from zero (0) in either the positive or negative direction.
- peak-to-peak voltage** The voltage of a waveform measured from its maximum negative value to its maximum positive value.
- power** The amount of heat energy produced per second, expressed in watts.

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R

- radio frequency (RF)** Frequencies above 550 kHz that transmit radio signals; the high frequency current used in electrosurgery.
- resistance** The lack of conductivity or the opposition to the flow of electric current, measured in ohms.
- return electrode** The conductive element that receives electrosurgical current and returns it to the generator. In monopolar electrosurgery, the patient return electrode; in bipolar electrosurgery, one pole of the bipolar instrument, usually one tine of a forceps.
- rms voltage** Root mean square voltage; the effective average voltage (the average amount of voltage present at any instant) of a waveform.

S

- self-limiting power** A performance feature on the generator that limits power output to certain tissue resistance levels.
- short circuit** The status of an electrosurgical circuit when the generator is activated and the active electrode directly touches the return electrode. An electric circuit with no load and, therefore, essentially no resistance.
- spark** A discharge of electric current across an air gap; essential to electrosurgical cutting and fulguration.

T

- transformer** In electrosurgical generators, electrical circuitry that changes the ratios of current to voltage, converting low voltage, high current waveforms to high voltage, low current waveforms.

V

- vessel sealing** The fusing of vessel walls with RF current to create a permanent seal.
- volt (V)** The unit of measurement for electric potential (voltage); watts (power) per ampere.
- voltage** The force that pushes electric current through resistance; electromotive force or potential difference expressed in volts.

W

- watt (W)** The unit of measurement for power in a circuit in which a current of one ampere flows across a potential difference of one volt; heat energy per second.
- waveform** A graphic depiction of electrical activity that can show how voltage varies over time as current alternates.

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**Notes**

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**DRAFT**

## ***Service Manual***

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# **Valleylab LigaSure™ Vessel Sealing Electrosurgical Generator**

## **510 K Outline**

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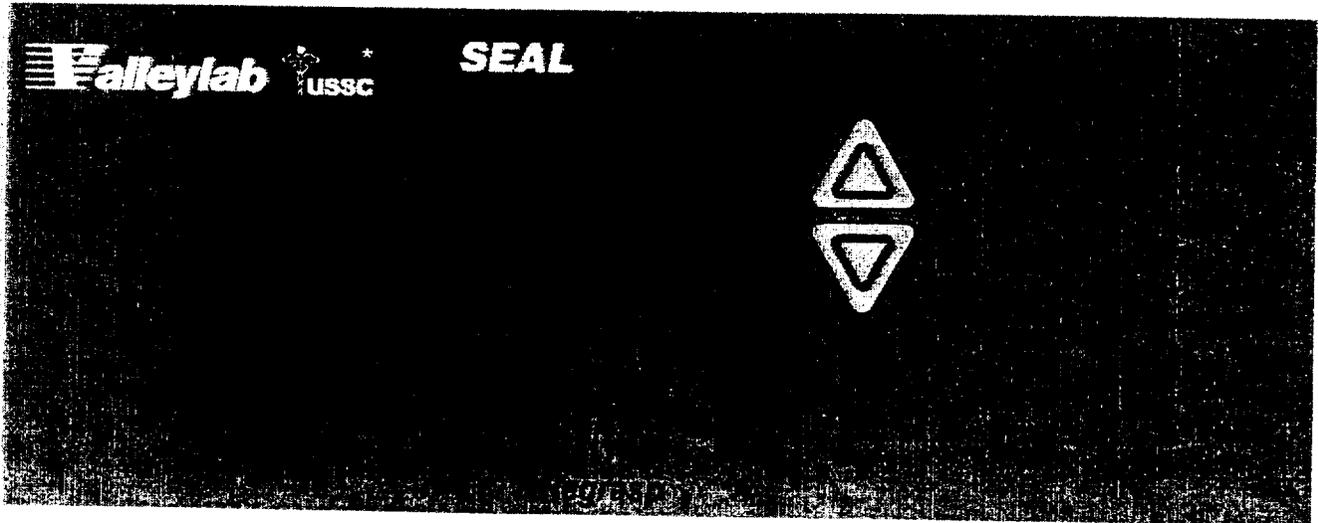
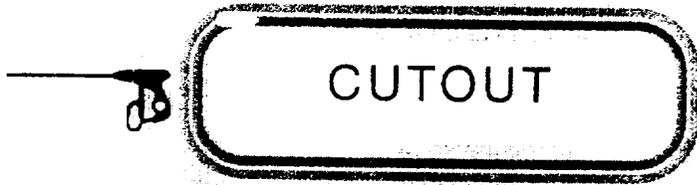
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**LigaSure™**  
**Vessel Sealing Generator**  
**Front Panel Graphics**

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**DRAFT**

CUTOUT



**MACROBIPOLAR**



**BIPOLAR**



*Memory*



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**LigaSure™ Vessel Sealing Generator**  
**Rear Panel Graphics**

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**LigaSure™**  
**Vessel Sealing Generator**  
**Generator Cover Graphics**

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# LigasSure<sup>TM</sup>

vessel sealing system

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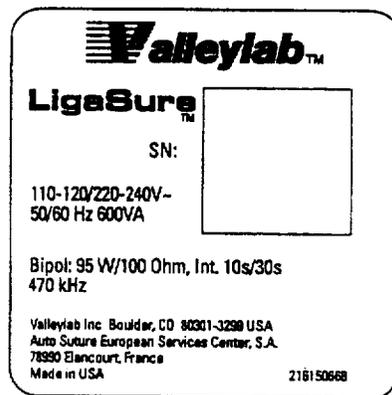
**LigaSure™  
Vessel Sealing Generator**

**Generator Serial Number  
Plate Graphics**

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**LigaSure™**  
**Vessel Sealing Generator**  
**Generator Shipping Carton Label**

**DRAFT**

REF **LigaSure**  
CAT.



**LigaSure™**  
Vessel Sealing Generator



Manufactured for  
Valleylab Inc  
a division of United States Surgical Corporation  
Boulder, CO 80301-3299 USA  
Auto Suture European Services Center, S.A.  
78990 Elancourt, France  
Assembled in USA

LOT 12345678



CE  
0086

Mfg Date 1998-05

Label P/N

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

15h

**LigaSure™  
Vessel Sealing  
Standard and Max Instruments**

**Unit Labels**

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REF CAT. **LS2070**

**NONSTERILE**



LigaSure™  
Standard Instrument



Manufactured by  
Valleylab Inc  
a division of United States Surgical Corporation  
Boulder, CO 80301-3299  
Distributed in Europe by  
Auto Suture European Services Center, S.A.  
78990 Elancourt, France  
Made in USA

LOT 12345678



CE  
0086

Exp Date 2003-05

Label P/N

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

REF CAT. **LS3090**

**NONSTERILE**



LigaSure™  
Max Instrument



Manufactured by  
Valleylab Inc  
a division of United States Surgical Corporation  
Boulder, CO 80301-3299  
Distributed in Europe by  
Auto Suture European Services Center, S.A.  
78990 Elancourt, France  
Made in USA

LOT 12345678



CE  
0086

Exp Date 2003-05

Label P/N

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

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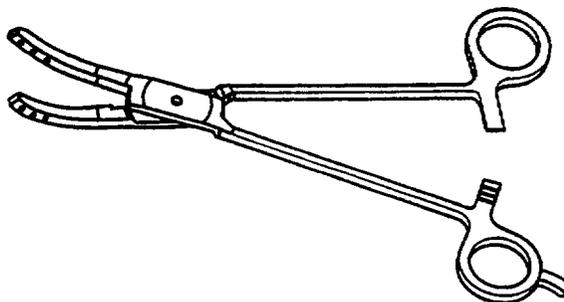
**LigaSure™  
Vessel Sealing Handsets  
(Standard and Max)**

**Instructions for Use**

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**LigaSure™ Reusable Vessel Sealing Handsets**  
for use with the LigaSure Vessel Sealing System

- REF CAT. LS2070 Standard, 7 in. for use with LS2071 LigaSure Electrodes
- LS3090 Max, 9 in. for use with LS3091 LigaSure Electrodes



**Prior to surgery read all instructions and precautions provided with the electrode, handset, and electro-surgical generator to be used.**

**Warnings**

This device has been specifically designed for sealing vessels and tissue in open surgical procedures only.

The LS2070 and LS3090 LigaSure Handsets are intended for use only with the Valleylab LigaSure Vessel Sealing System. Use of these handsets with other Valleylab generators or with generators produced by other manufacturers could result in injury to the patient or surgical team.

The LS2070 LigaSure Handset can only be used with LS2071 electrodes. The LS3090 LigaSure Handset can only be used with LS3091 electrodes. Use of these handsets with any other electrodes could result in injury to the patient or surgical team.

Before installing or removing the electrodes, ensure that the handset is not connected to the electro-surgical generator, or that the generator is OFF (Standby).

**Caution**

Inspect accessories and cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

**Steam Sterilization Recommendations**

Using a mild cleaning solution or blood dissolving detergent, remove all gross matter (blood, mucous, tissue) from the handset. Rinse with water and dry prior to sterilization. Refer to the sterilizer manufacturer for recommended loading instructions and drying times.

**Important**

Remove and discard the disposable electrode assembly prior to sterilizing the handset.

Using autoclave supply water with high mineral content may reduce the useful life of the product.

To prolong the life of the handset, keep it from contacting other metal instruments during sterilization. Valleylab recommends using a dedicated sterilization tray to prevent mechanical damage during handling.

Unlatch the handset prior to sterilization.

**Gravity-Displacement Steam Sterilization - Wrapped:**

132-135 °C (270-275 °F) - 10-15 minutes minimum, or  
121-123 °C (250-254 °F) - 15-30 minutes minimum

**Gravity-Displacement Steam Sterilization - Unwrapped ("Flash" Sterilization):**

132 °C (270 °F) - 10 minutes minimum

**Pre-Vacuum Steam Sterilization - wrapped:**

132-135 °C (270-275 °F) - 4 minutes minimum

**Pre-Vacuum Steam Sterilization - Unwrapped ("Flash" Sterilization):**

132 °C (270 °F) - 4 minutes minimum

157

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

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158

**LigaSure™  
Vessel Sealing  
Standard and Max Instruments**

**Vessel Sealing Electrode  
Unit Labels**

158  
159

**DRAFT**



**LigaSure<sup>TM</sup> Max**  
vessel sealing electrode

REF  
CAT. **LS3091**

 **Read Instructions  
Before Use**

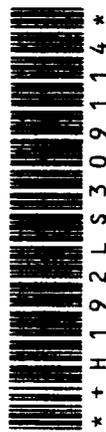
Caution: Federal (USA) law restricts  
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of a physician.

**STERILE R**

 **Single Use  
Only**

 **Latex  
Free**

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Auto Suture European  
Services Center, S.A.  
78990 Elancourt, France  
Made in USA



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0086



225 102 XXX

**LOT**

 **EXP.  
DATE**

159

160

**DRAFT**



**LigaSure<sup>TM</sup> Std**  
vessel sealing electrode

REF  
CAT. **LS2071**

**Read Instructions  
Before Use**

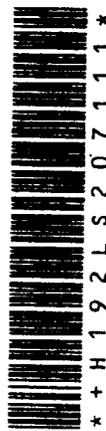
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Only**

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**LOT**

**EXP.  
DATE**

160

161

**LigaSure™**  
**Vessel Sealing**  
**Standard and Max Instruments**

**Vessel Sealing Electrode**  
**Case Labels**

161

162

**DRAFT**

REF **LS2071**  
CAT.

STERILE R

12 Units



\* + H 1 9 2 L S 2 0 7 1 4 4 \*

LigaSure™ Std  
Vessel Sealing Electrode



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Label P/N

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REF **LS3091**  
CAT.

STERILE R

12 Units



\* + H 1 9 2 L S 3 0 9 1 4 7 \*

LigaSure™ Max  
Vessel Sealing Electrode



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Exp Date 2003-05

Label P/N

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162

163

**LigaSure™**  
**Vessel Sealing Electrodes**  
**(Standard and Max)**

**Instructions for Use**

163  
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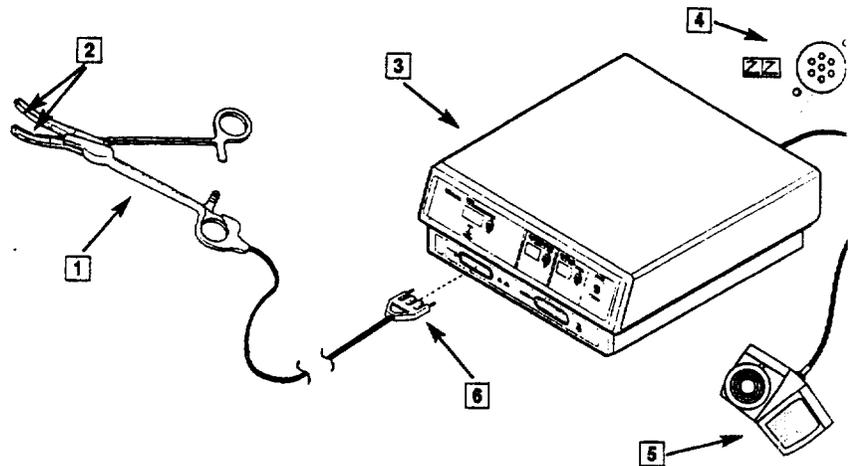
### LigaSure™ System Vessel Sealing Electrode/Cord Assembly

for use with LigaSure Vessel Sealing  
Handsets

REF. CAT. LS2071 for use with LS2070 LigaSure  
Standard Handset, 7 in.

LS3091 for use with LS3090 LigaSure  
Max Handset, 9 in.

Sterile, Single Use



- 1 Electrode wire guide
- 2 Snap-in electrodes
- 3 LigaSure generator
- 4 Vessel Sealing Footswitch receptacle
- 5 Vessel Sealing Footswitch
- 6 Smart Connector



**Prior to surgery, read all instructions and precautions provided with the electrode, handset, and electro-surgical generator to be used.**

**Warnings**

This device has been specifically designed for sealing vessels and tissue in open surgical procedures only.

The LS2070 and LS3090 LigaSure Handsets are intended for use ONLY with the Valleylab LigaSure Vessel Sealing System. Use of these handsets with other Valleylab generators or with generators produced by other manufacturers could result in injury to the patient or surgical team.

The LS2070 LigaSure Handset can only be used with LS2071 Electrodes. The LS3090 LigaSure Handset can only be used with LS3091 Electrodes. Use of these handsets with any other electrodes or use of these electrodes with any other handset could result in injury to the patient or surgical team.

Before installing or removing the electrodes, ensure that the handset is not connected to the electro-surgical generator, or that the generator is OFF (Standby).

Do not wrap accessory cords around metal objects; doing so may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

**Fire Hazard.** Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electro-surgical accessories that are activated or hot from use can cause a fire. When not using active accessories, place them in a holster or in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

**Electric Shock Hazard.** Do not connect wet accessories to the generator.

**Caution**  
Inspect accessories and cords (especially reusable accessories and cords) for breaks, cracks, nicks, or damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

Single Use  
Only

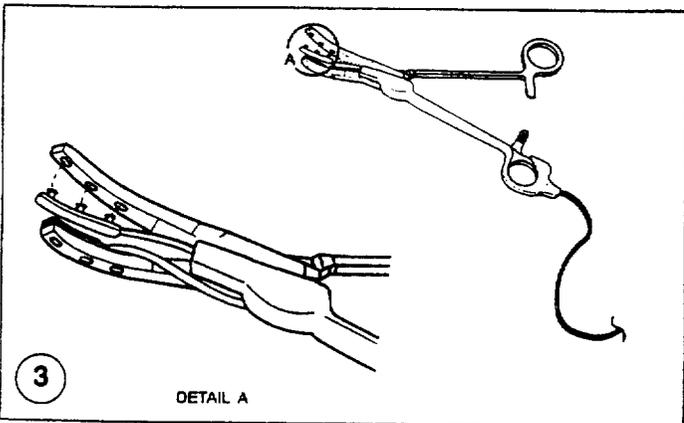
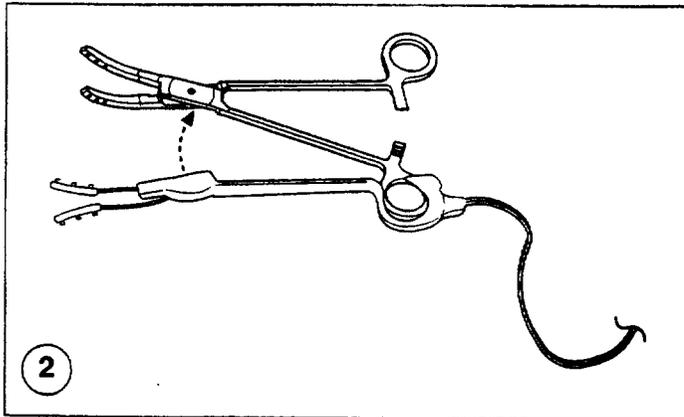
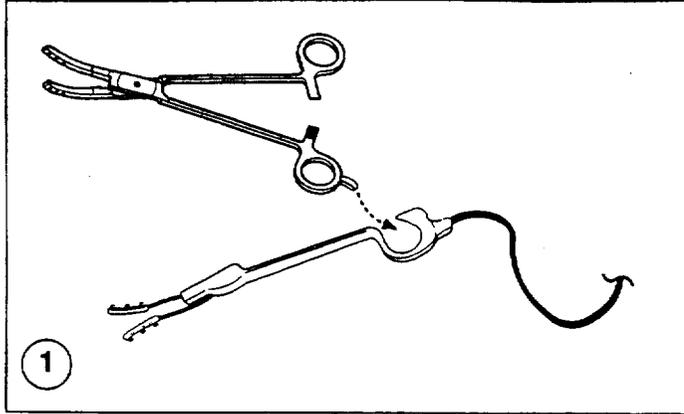
**STERILE**

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DRAFT

### Applying the Electrode/Cord Assembly

1. Slip the base of the wire guide onto the handset ring handle with the retaining post.
2. Snap the body of the wire guide onto the handle.
3. Snap each electrode into the appropriate handset jaw, matching electrode curvature to jaw curvature. Ensure there is no visible gap between the electrode and jaw.
4. Plug the Smart Connector into one of the receptacles on the front panel of the generator.

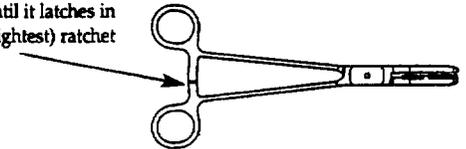
Refer to the LigaSure Vessel Sealing Generator User's Guide for proper operation of the generator.



### During Surgery

1. Place the tissue in the center of the jaws. *Do not grasp beyond the electrode surface.*

2. Close the handle until it latches in place in the third (tightest) ratchet position.



3. Activate the instrument by stepping on the purple pedal of the vessel sealing footswitch. A tone sounds to indicate that the vessel is being sealed. When vessel sealing is complete, two short end tones sound and the RF output is disabled.
4. Release the foot pedal.
5. Release the handle by squeezing it until it unlocks.
6. Inspect the tissue to ensure proper sealing.

#### **If the Regrasp indicator illuminates and a tone sounds while sealing:**

RF current is automatically discontinued. You should:

1. Release the footswitch pedal.
2. Open the jaws and inspect the tissue for a successful seal. Repeat the procedure if necessary.

#### Possible Regrasp alarm triggers include:

*Pooled fluids around the tip* - Minimize fluids. Inspect the tissue for a successful seal and repeat the procedure if necessary.

*Thin tissue* - Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure, or repeat the procedure by closing the handle without latching it in the locked position.

You may also choose to continue the procedure using traditional bipolar current. Set the Bipolar power level on the front panel of the generator; refer to the *LigaSure Vessel Sealing Generator User's Guide* for instructions. Grasp the tissue in the jaws but do not latch the handle in the locked position. Step on the blue pedal of the vessel sealing footswitch. Release the pedal when done.

### After Surgery

1. Remove the electrode/cord assembly:
  - Unsnap the electrodes from the handset.
  - Pull the wire guide away from the handset body.
  - Discard electrode/cord assembly.
2. Follow the procedures approved by your institution for cleaning the handset. Refer to the LigaSure Handset instructions for recommended sterilization parameters.

# DRAFT

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

Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.

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**LigaSure™  
Laparoscopic  
Vessel Sealing Instrument**

**Unit (Lidstock) Label**

166

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# LigaSure<sup>TM</sup> Lap

vessel sealing instrument

REF  
CAT. LS1000



# DRAFT

Read  
Instructions  
before Use

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order of a physician.

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E R

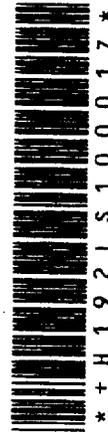
Single Use Only

Latex Free

CE  
0086



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EXP. DATE

LOT

168  
169

**LigaSure™  
Laparoscopic  
Vessel Sealing Instrument**

**Case Label**

**DRAFT**

REF CAT. **LS1000**

STERILE R

6 Units



Single Use Only

Latex Free

LigaSure™ Lap  
Laparoscopic Instrument



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Exp Date 2003-05

Label P/N

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170 [7]

**LigaSure™  
Laparoscopic Vessel Sealing  
Instrument**

**Instructions for Use**

171

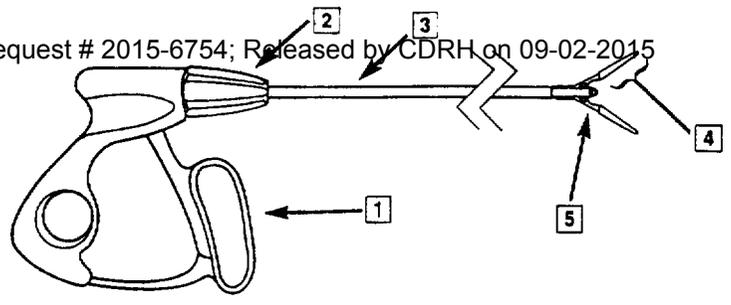
172

# LigaSure Lap

Vessel Sealing Instrument

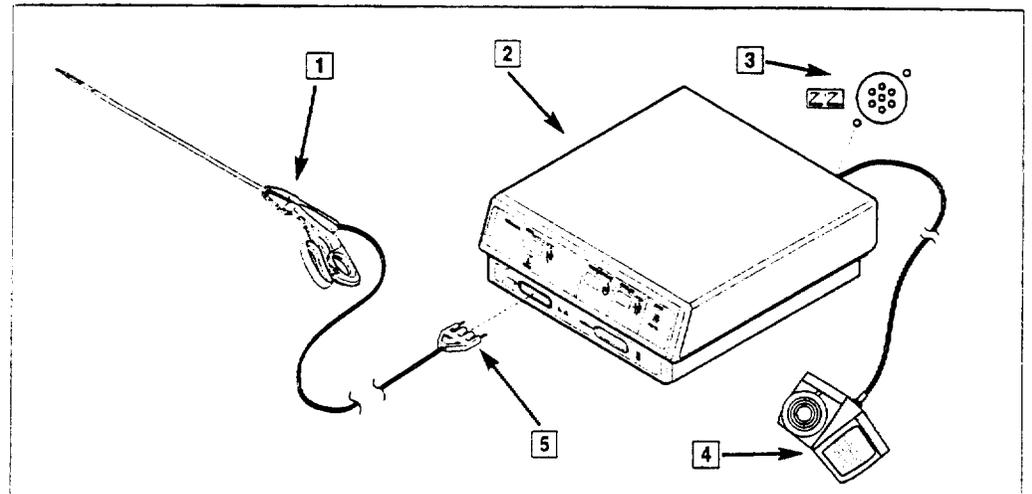
## Laparoscopic Handset, 5 mm for use with the LigaSure™ Vessel Sealing System

REF LS1000  
CAT  
Sterile, Single Use



### Parts of the Handset

- 1 handle
- 2 rotation knob
- 3 shaft
- 4 electrode surface
- 5 jaws



### Before Surgery

- 1 LigaSure Lap Handset
- 2 LigaSure Generator
- 3 Vessel Sealing Footswitch receptacle
- 4 Vessel Sealing Footswitch
- 5 Smart Connector

Single Use Only

**STERILE**

17B

172-

## Warnings

This product has been specifically designed for sealing vessels and tissue in laparoscopic procedures. **Do not use in open procedures.**

The LS1000 Laparoscopic Handset is intended for use ONLY with the Valleylab LigaSure Vessel Sealing System. Use of this handset with other Valleylab generators or with generators produced by other manufacturers could result in injury to the patient or surgical team.

Place the vessel or tissue in the center of the jaws. Do not grasp beyond the electrode surface. Incomplete vessel sealing may occur.

Do not wrap accessory cords around metal objects; doing so may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

**Electric Shock Hazard.** Do not connect wet accessories to the generator.

**Fire Hazard.** Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories that are activated or hot from use can cause a fire. When not using active accessories, place them in a holster or in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

For laparoscopic procedures, be alert to these potential hazards:

- Laparoscopic surgery may result in gas embolism due to insufflation of gas into the abdomen.
- The electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of the activated electrode outside of the field of vision may result in injury to the patient.
- Do not activate electrodes while in contact with, or in close proximity to, other instruments, including metal cannulas, as localized burns to the patient or physician may occur.
- Do not use hybrid trocars that are comprised of both metal and plastic components. For the operative channel, use all metal or all plastic systems. At no time should electrical energy pass through hybrid systems. Capacitive coupling of RF current may cause unintended burns.
- Ensure that the insulation of disposable and reusable laparoscopic instrumentation is intact and uncompromised. Compromised insulation may lead to inadvertent metal to metal sparking and neuromuscular stimulation and/or inadvertent sparking to adjacent tissue.
- Do not activate the generator in an open circuit condition. Activate the generator only when the active electrode is near or in direct contact with the target tissue, to lessen the possibility of creating unintended burns.
- Using the lowest power or intensity setting that achieves the desired surgical effect lessens the potential for the creation of capacitive currents.
- Carefully insert and withdraw active electrodes from cannulas to avoid possible damage to the devices and/or injury to the patient.

Confirm proper electrosurgical generator settings before proceeding with surgery. Use the lowest power or intensity settings and the shortest activation times that will achieve the desired surgical effect.

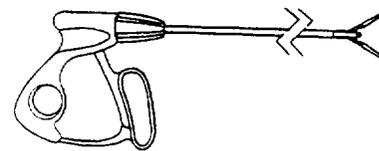
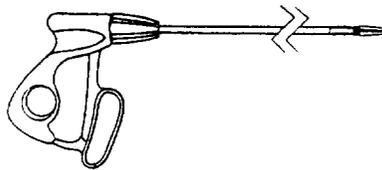
Valleylab recommends that insulated metal cannulas not be used with laparoscopic instrumentation. Compromised cannula insulation or cannula configuration may allow inadvertent contact between the electrode and metal components of these cannulas. This may result in burns to the patient or surgical team due to capacitive coupling of RF current or insulation breakdown.

When using laparoscopic instrumentation with uninsulated metal cannulas, the potential exists for burns to occur at the patient/cannula interface due to capacitive coupling of RF current. This is most likely to occur in instances where the electrosurgical generator is activated for extended periods of time at high power levels.

Do not activate electrosurgery and irrigation simultaneously. Doing so may cause the irrigation bottle caps to become electrically conductive and burn surgical personnel.

Simultaneously activating suction/irrigation and electrosurgical current may result in increased arcing at the electrode tip and/or burns to adjacent tissue.

Records Processed under FOIA Request # 2015-6754; Released by CDRH on 09-02-2015



Conductive fluids (e.g., blood or saline) in direct contact with an active electrode or in close proximity to any active accessory may carry electrical current and cause unintended burns to the patient. This can happen as a result of either direct coupling with the active electrode or capacitive coupling between the active electrode and the external surface of the electrode insulation. Therefore, to prevent unintended burns in the presence of conductive fluids:

- Always keep the external surface of the active electrode away from adjacent tissue while activating the electrosurgical generator.
- Clear irrigation fluid from the electrode and activate suction prior to activating the electrosurgical handset.

### Caution

Inspect accessories and cords (especially reusable accessories and cords) for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

Do not reuse or resterilize accessories labeled "disposable" or "single use only."

### Important

This instrument is for use ONLY in 5 mm cannulas or in larger cannulas with appropriate 5 mm adapters.

**If the Regrasp indicator illuminates and a tone sounds while sealing:**

RF current is automatically discontinued. You should:

- Release the footswitch pedal.
- Open the jaws and inspect the tissue for a successful seal. Repeat the procedure if necessary.

Possible Regrasp alarm triggers include:

**Pooled fluids around the tip** – Minimize fluids. Inspect the tissue for a successful seal and repeat the procedure if necessary.

**Thin tissue** – Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure, or repeat the procedure by closing the handle without latching it in the locked position.

You may also choose to continue the procedure using traditional bipolar current. Set the Bipolar power level on the front panel of the generator; refer to the *LigaSure Vessel Sealing Generator User's Guide* for instructions. Grasp the tissue in the jaws but do not latch the handle in the locked position. Step on the blue pedal of the vessel sealing footswitch. Release the pedal when done.

### After Surgery

Discard the handset after use.

### During Surgery

#### For tissue manipulation and dissection:

To grasp tissue or other structures, place the jaws around the object and gently pull the handle towards the handset body until the jaws close ①. Hold the handle in place to maintain the position of the jaws.

To dissect, gently pull the handle towards the handset body until the jaws close ②. Place the jaws into the structure and release the handle until the jaws are open ③.

#### To rotate the electrode:

Turn the gray rotation knob until the jaws are in the desired position.

#### For sealing vessels and tissue:

- Place the vessel or tissue in the center of the jaws. Do not grasp beyond the electrode surface.
- Close the handle until it clicks and latches in place.
- Activate the instrument by stepping on the purple pedal of the vessel sealing footswitch. A tone sounds to indicate that the vessel is being sealed. When vessel sealing is complete, you will hear two short end tones and the RF output is disabled.
- Release the foot pedal.
- Release the handle by squeezing it until it unlocks.
- Inspect the vessel or tissue to ensure proper sealing.
- If necessary, reapply by overlapping on the proximal edge of the seal.

Sterility is guaranteed unless the package is opened or damaged. Do not resterilize.

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

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# DRAFT

**LigaSure™  
Instrument Sterilizer Case**

**Unit Label**

174/75

REF CAT. **LS0100**

**NONSTERILE**



# LigaSure™ Instrument Sterilizer Case

# DRAFT



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Made in USA

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Exp Date 2003-05

Label P/N

MS  
176

VERSATILE  
STRONG  
PERMANENT  
PREDICTABLE  
CONTRAST

Surgical cases aren't  
always predictable...

but occlusion should be.



It's not always predictable...

but occlusion should be.

For more information, visit

[www.ligasure.com](http://www.ligasure.com)

or call 1-800-451-7777

**LigaSure**<sup>®</sup>

176-777

**An added degree of confidence in virtually  
any surgical procedure.**

# LigaSure Vessel Sealing



Figure 1: LigaSure Vessel Sealing System components.

Figure 2: LigaSure Vessel Sealing System components.

Figure 3: LigaSure Vessel Sealing System components.

*LigaSure Vessel Sealing System*  
The LigaSure Vessel Sealing System is a minimally invasive surgical approach for the treatment of hemorrhoids. The system consists of a LigaSure Vessel Sealing System (LVSS) and a LigaSure Vessel Sealing System (LVSS) handle. The LVSS is a self-contained, self-heating device that uses radiofrequency energy to seal blood vessels. The LVSS handle is used to manipulate the LVSS during the procedure. The LVSS is used to seal the hemorrhoidal artery, which is the blood vessel that supplies the hemorrhoid. This results in the hemorrhoid becoming ischemic and eventually necrotic, leading to its resolution.

*Indications for Use*  
The LigaSure Vessel Sealing System is indicated for the treatment of hemorrhoids. It is used to seal the hemorrhoidal artery, which is the blood vessel that supplies the hemorrhoid. This results in the hemorrhoid becoming ischemic and eventually necrotic, leading to its resolution.

*Contraindications*  
The LigaSure Vessel Sealing System is contraindicated for use in patients with known or suspected bleeding disorders, patients with active infection at the site of use, and patients with known or suspected malignancy at the site of use.

Handle a range of vessel sizes and tissue bundles.

Minimize collateral tissue damage with advanced vessel sealing every time.

Permanently seal vessels and tissues for up to 10 seconds.

Add movements with a soft foot to help you work in tight spaces.

For more information, visit [www.strongbridge.com](http://www.strongbridge.com).

© 2010 Strongbridge Medical Technologies, Inc.

Strongbridge Medical Technologies, Inc. 179

**No other occlusion method offers LigaSure Vessel Sealing's combination of versatility, strength, safety and speed.**

Replace this photo

will be placed here.

Replace this photo

will be placed here.



Compared to everything from sutures, clips, and staples to energy-based occlusion systems, LigaSure Vessel Sealing provides surgeons with the widest range of possibilities while significantly reducing risks. The patented system uses a unique combination of energy and pressure precisely confined to only the targeted tissue. It fuses vessel walls to create a permanent seal

**Work equally well on a range of vessel sizes and tissue bundles.**

- *Skeletonized vessels or tissue bundles*
- *Seal vessels from 1mm to 7mm*
- *Ideal for open and lap procedures*
- *Faster and more efficient than other methods*

**Keep collateral damage to an absolute minimum.**

- *Highly precise tissue targeting*
- *Automatic shut-off when seal is completed*
- *Correct pressure is set automatically*



Vessel Name



Vessel Name



Vessel Name



Vessel Name



Vessel Name



Vessel Name



Vessel Name

180 181



**Complete a successful procedure as quickly as possible.**

- *Average seal completed in 5 seconds*
- *Can reduce an average one hour procedure by up to 00 minutes*
- *No suturing, stapling, clamping, cutting or tying*

**See...and hear...the difference.**

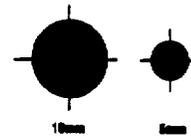
- *Where visualization is possible, translucent seal gives you visual assurance of completion*
- *Audible verification always confirms seal and tells you the system is off*

**Proven strong, reliable, permanent.**

- *Proven burst strength of 3x physiologic blood pressure*
- *Strength is the same, regardless of vessel size*

**Get into confined spaces conveniently.**

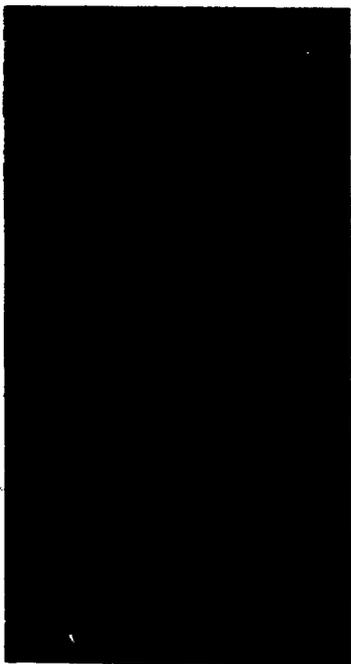
- *Better access and less invasive than other methods*
- *5 mm lap instrument*
- *Ideal for delicate situations*



SAFE  
182

**Reduce risks by leaving nothing behind.**

- *No clips, clamps, sutures or staples*
- *Reduces risks*
- *Reduces costs*



ISE



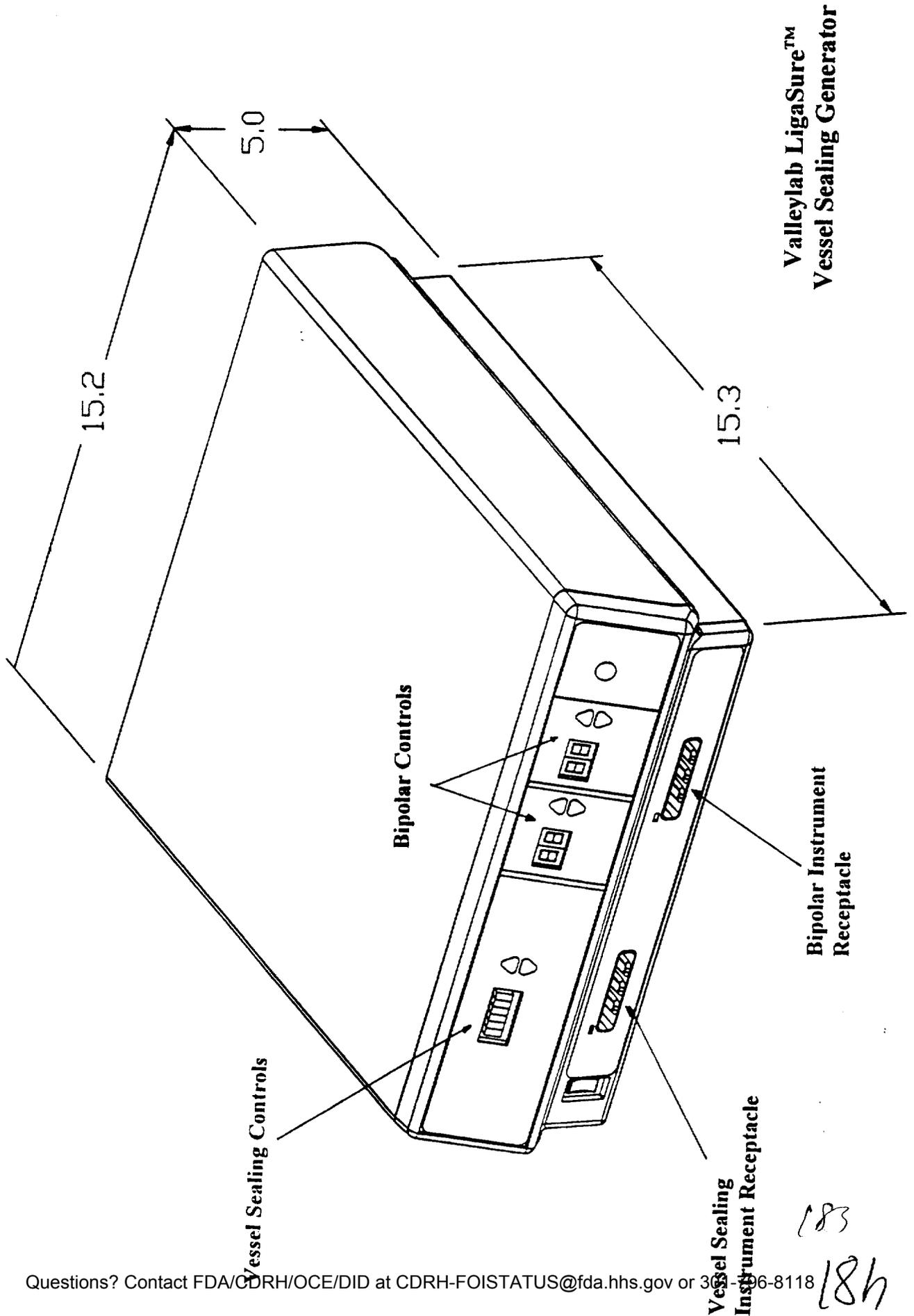
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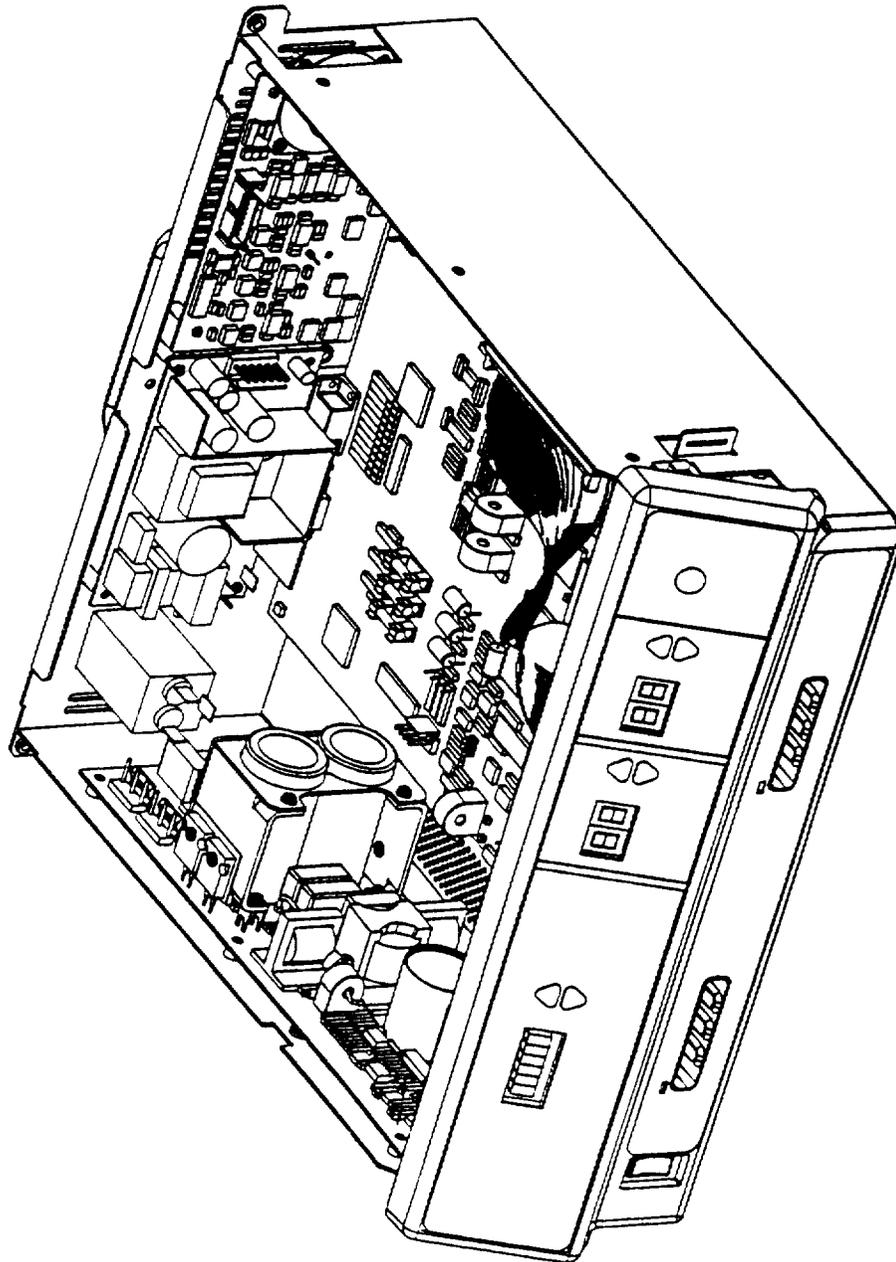
To see how good LigaSure Vessel Sealing really is, you have to try it on your kind of cases. Just call your VALLEYLAB sales representative for an evaluation. Or call customer service 1-800-255-8522 for our clinical information package.

**LigaSure**  
VESSEL SEALING

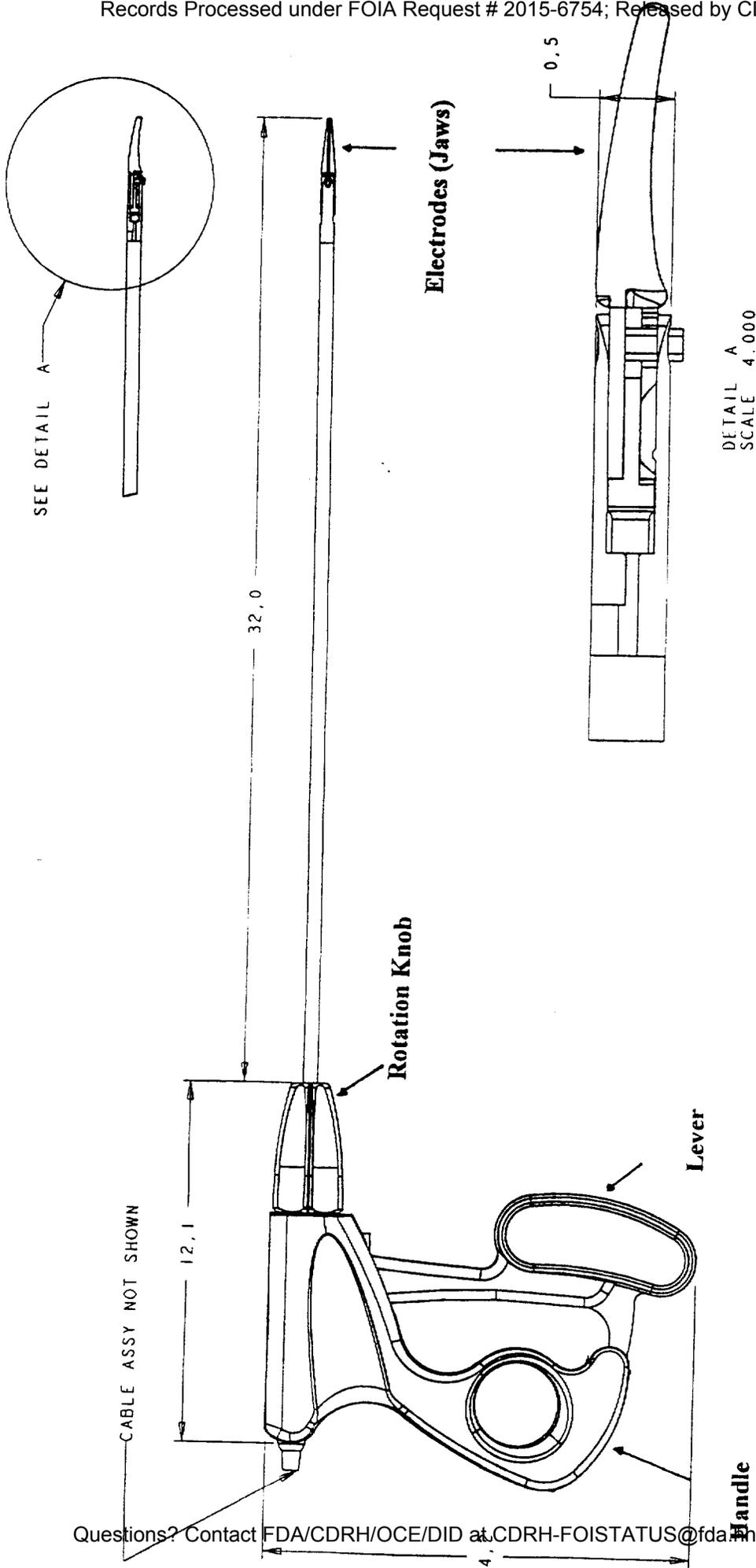
182  
183



**Valleylab LigaSure™  
Vessel Sealing Generator**



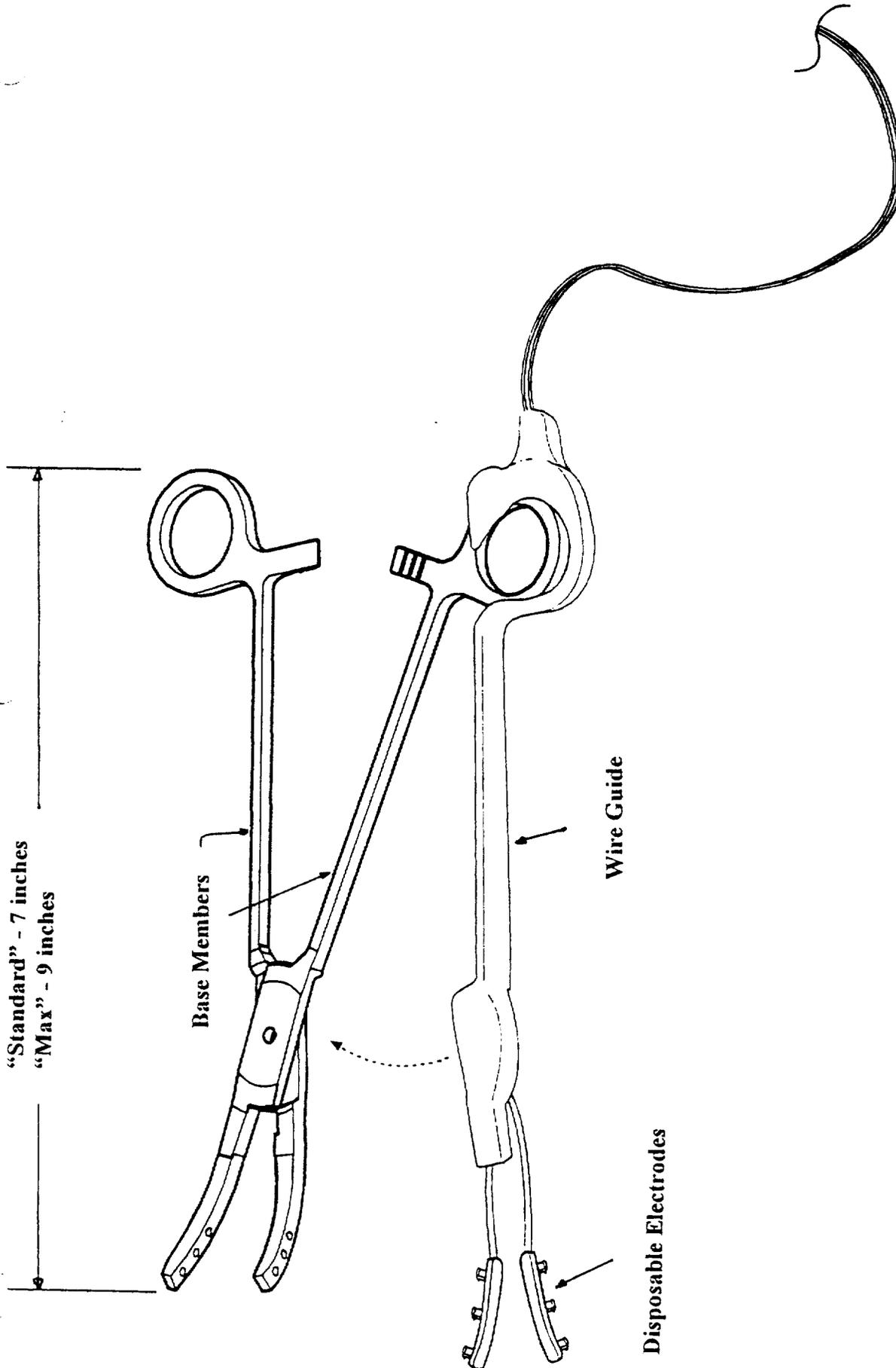
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**Valleylab LigaSure™  
Laparoscopic Instrument**

ALL DIMENSIONS ARE IN CM

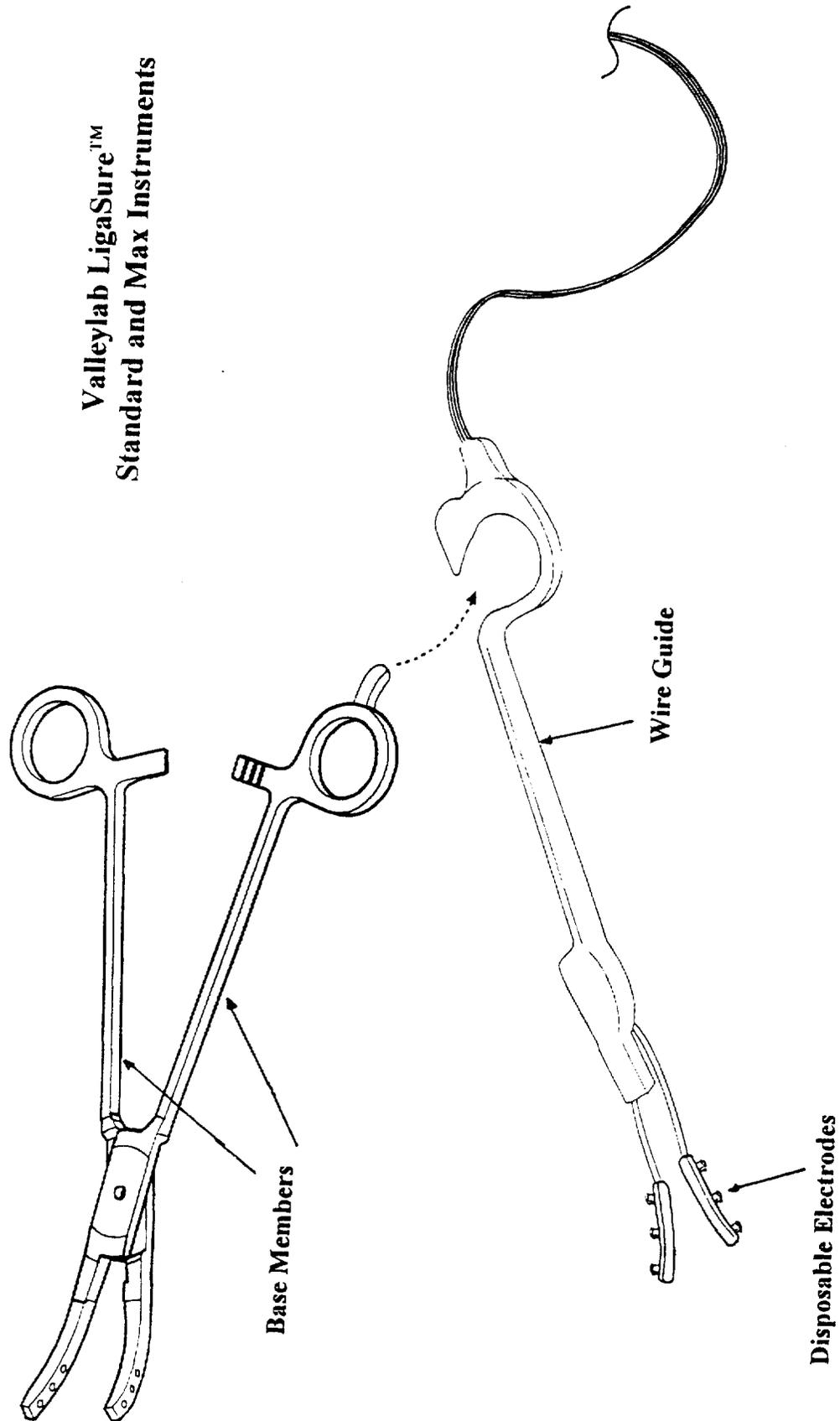
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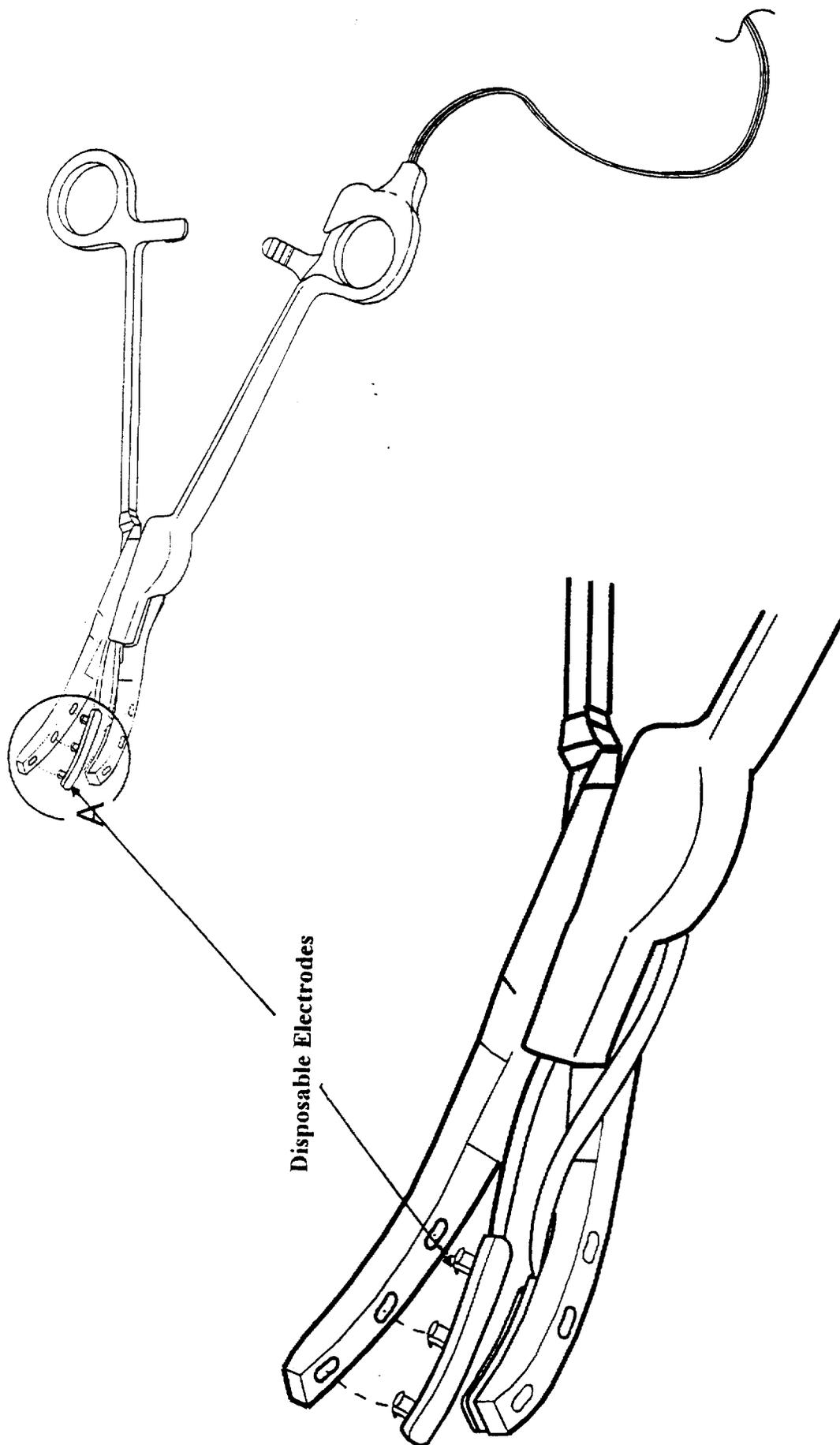
Valleylab LigaSure™  
Standard and Max Instruments

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**Valleylab LigaSure™  
Standard and Max Instruments**



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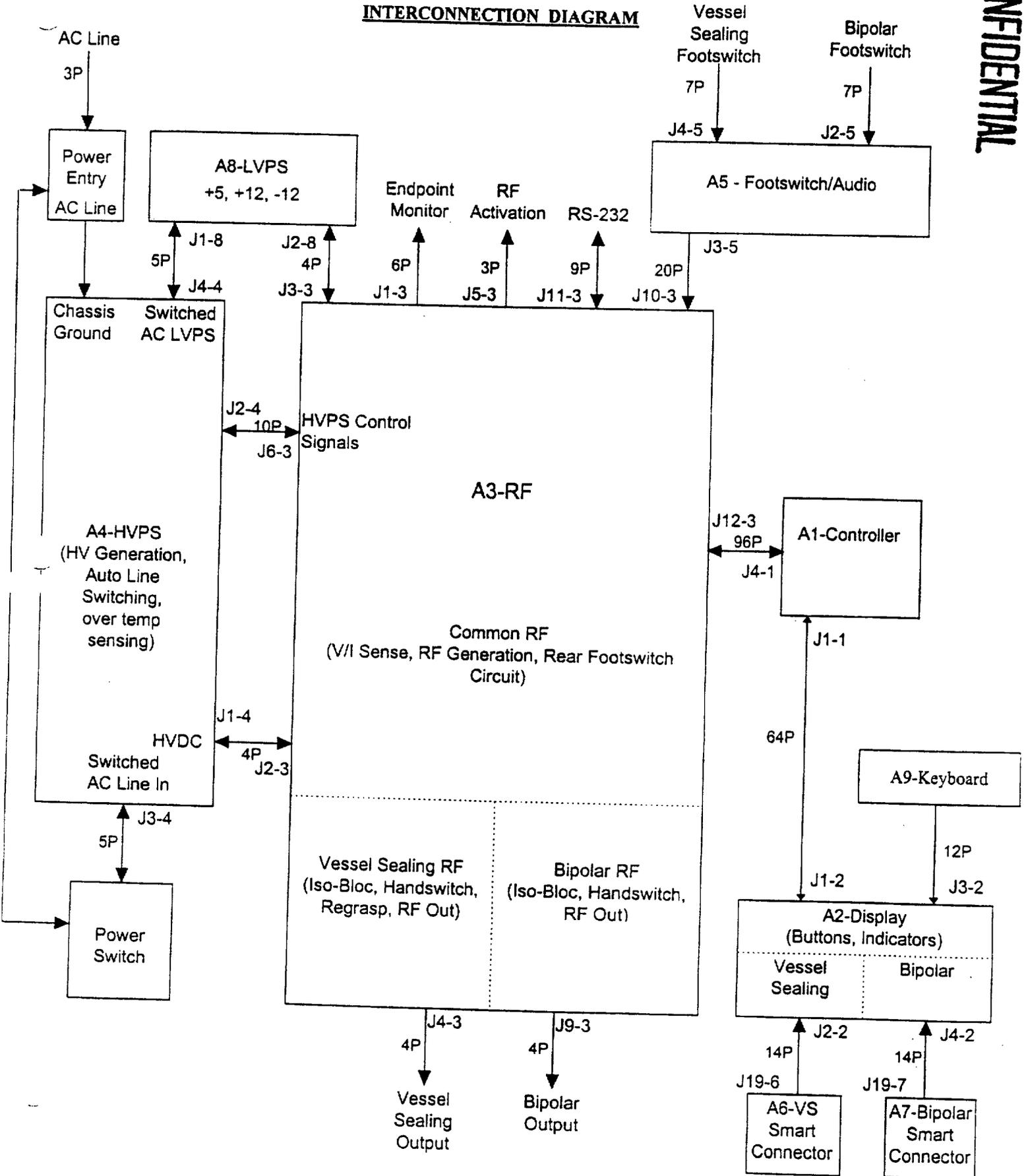


DETAIL A

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**INTERCONNECTION DIAGRAM**



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**BIOCOMPATIBILITY MATERIALS PROFH™ FOR PATIENT CONTACT MATERIALS  
LIGASURE™ VESSEL SEALIN SYSTEM INSTRUMENTS**

Component	Generic Name	Trade Name	Biocompatibility Testing
<b>Open Instruments:</b>			
Reusable Base Members	AISI Stainless Steel *	N/A	*
Disposable Electrode	AISI Stainless Steel*	N/A	*
Electrode Insulation			Systemic Injection Intracutaneous Toxicity Cytotoxicity Sensitization Hemolysis (Testing Complete)
Flex Relief			Testing Ongoing per ISO 10993-1
Wire Guide	or		Testing Ongoing per ISO 10993-1
<b>Laparoscopic Instrument</b>			
Electrodes (Jaws) and Inner and outer nose	Stainless Steel	N/A	Systemic Injection Intracutaneous Toxicity Cytotoxicity Sensitization Hemolysis (Testing Complete)

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Component	Generic Name	Trade Name	Biocompatibility Test
<b>Laparoscopic Instrument</b> Insulator (Inner and outer)			Systemic Injection Intracutaneous Toxicity Cytotoxicity Sensitization Hemolysis (Testing Complete)
Spacer Stake			Testing Ongoing per ISO 10993-1
Electrode Coating			Systemic Injection Intracutaneous Toxicity Cytotoxicity Sensitization Hemolysis (Testing Complete)
Yoke/Rod Overmold			Testing Ongoing per ISO 10993-1
Pushrod and outer Tube	Stainless Steel	N/A	Systemic Injection Intracutaneous Toxicity Cytotoxicity Sensitization Hemolysis (Testing Complete)
Heatshrink Insulation outer tube			Testing Ongoing per ISO 10993-1

Unless otherwise noted, all materials have been tested in accordance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1 - Guidance on Selection of Tests, Device Category "External Communicating Device, Blood Path-Indirect, Contact duration A". Materials marked with an "\*" are currently used in marketed Valleylab products as follows:

- 1) Stainless Steel - currently used in Valleylab Forceps, legally marketed devices, which are preamendment devices and K853143, 10/16/85
- 2) Stainless Steel - currently used in Valleylab CUSA Ultrasonic Handpieces which received FDA clearance under 510(k)

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**VALLEYLAB®**

**PERFORMANCE AND SAFETY TEST REPORT**

**LigaSure™ SYSTEM**

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**I. Summary**

The following report details the results of the testing performed on the LigaSure™ Generator. These tests concentrate on the safety related requirements of AAMI F18/1993 and IEC 601-1 and IEC 601-2-2. The LigaSure™ 510K test protocols contain specific instructions for conducting these tests.

**II Definitions**

The definitions for this document are as follows:

High Line	264 VAC
Low Line	90 VAC (104 VAC is the lowest required by AAME HF 18 and IEC)
Nominal Line	120VAC.
MacroBipolar	Macro bipolar output of the generator
Bipolar	Bipolar output of the generator
Seal	Vessel Seal output of the generator
Operational Modes	MacroBipolar, Bipolar and Seal

**III Testing Results**

**A. RF Output Testing (AAMI HF18/1993 and IEC 601-2-2 § 50.2)**

The RF output power testing was conducted at the high and low line voltage inputs and at the required operating temperature extremes. The operation of the generator at 90 VAC (low line) and 264 VAC (high line) passes HF18 4.3.1 which specifies that the unit shall suffer no damage at voltage levels of 95 VAC and 135 VAC. LigaSure™ Generator serial # 4 was used for the RF output testing.

**1. Power vs. Load Impedance Testing (AAME HF18/1993 § 5.4.1.2)**

All operational modes were tested to verify that Power vs Load curves were within +/- 20% of an average curve for variations in line voltage and temperature. All curves passed at 90/264 VAC line input. Seal, Macro Bipolar, and Bipolar modes passed at 104 VAC, which is the minimum required by HF18. All curves passed at the required operating temperatures of 10°C and 40°C. The resulting power curves are shown in Appendix A of this report.

**2. Open Circuit Voltage Test (AAMI HF18/1993 § 5.4.1.4.)**

All operational modes were measured at the temperature limits to verify that the peak to peak voltage would be within +0%/-30% of the published values. Measurements were performed at nominal line voltage of 120 VAC.

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Test results were recorded as follows:

Mode	25° C	10° C	40° C	Specification Range P-P Voltage
	P-P Voltage	P-P Voltage	P-P Voltage	
Bipolar	320V	320V	317V	233 < 333V
Macro Bipolar	713V	713V	715V	535 < 766V
Seal	566V	560V	563V	402 < 575V

**3. Minimum Power Output Test (AAMI HF18/1993 § 4.2.4.4.3)**

The minimum output power was measured in each mode to verify that the power delivered by the Generator in test is not greater than 5% of the maximum output power, or 10 watts, whichever is smaller over a series of load impedances. The data was taken at an ambient temperature of 25°C, and a nominal line voltage of 120 VAC. In the Seal mode, the front panel setting defines seal intensity; the minimum output setting produces no output power; therefore, meeting the aforementioned standard. In the Macro Bipolar and Bipolar modes the aforementioned standards were met, the results are shown in Appendix B.

**4. Power Output vs. Setting Test (AAMI HF 18/1993 § 5.4.1.3)**

The power output was plotted vs the power settings at a specified load of 100 ohms at an ambient temperature of 25°C and a nominal line voltage of 120 VAC. The AAMI requirements indicate that output power must increase linearly with an increase in power setting. In the Seal mode, the front panel setting controls seal intensity and does not follow a linear power output. For the Bipolar and Macro bipolar modes compliance curves are shown in Appendix C.

**B. Cross Coupling Tests (AAMI HF18/1993 § 4.2.4.1.3)**

This test verified that at 25°C and nominal line voltage of 120VAC, no more than 150 ma is delivered to any unused output. The specified modes (Seal, Macro Bipolar, and Bipolar) were tested at maximum power output settings as the worst case mode for RF energy coupling. LigaSure™ Generator serial # 4 was used for the RF output testing.

Test results were recorded as follows:

Activated	Inactivated	Limits
Seal	Macro/Bipolar	
Unloaded	.9 mA	150 mA
100 Ohm Load	2.25 mA	150 mA

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Macro Bipolar	Seal	
Unloaded	1.2 mA	150 mA
100 Ohm Load	2.25 mA	150 mA

Bipolar	Seal	
Unloaded	5.5 mA	150 mA
100 Ohm Load	.58 mA	150 mA

**C. Low Frequency Leakage Tests (AAMI HF18/1993 § 4.2.9, IEC 601-1 § 19.4)**

All the low frequency leakage measurements passed the specified requirements at a nominal line input of 120 VAC and at the high line input of 264 VAC. The detailed results are shown below for each measurement type. LigaSure™ Generator serial # 4 was used for these tests.

Test results were recorded as follows:

**1. Earth Leakage/Chassis Leakage**

120 VAC	Normal Polarity	Limit	Reverse Polarity	Limit
Ground Closed	2.6 ua	< 100 ua	2.5 ua	< 100 µa
Ground Open	47 ua	< 500 ua	47.1 ua	< 500 µa

264 VAC	Normal Polarity	Limit	Reverse Polarity	Limit
Ground Closed	2.2 µa	< 100 ua	2.2 ua	< 100 µa
Ground Open	107.8 µa	< 500 ua	1.3.2 ua	< 500 µa

**2. Patient Source Current**

Normal Polarity (264 VAC)

Patient Electrode	Seal A	Seal B	Bipolar A	Bipolar B	Limit
Ground Closed	3.5 ua	.44 ua	1.1 ua	.22 ua	< 10 µa
Ground Open	3.1 ua	2.4 ua	1.1 ua	.23 ua	< 50 µa

Reversed Polarity (264 VAC)

Patient Electrode	Seal A	Seal B	Bipolar A	Bipolar B	Limit
Ground Closed	1.3 ua	.45 ua	1.1 ua	.22 ua	< 10 µa
Ground Open	1.2 ua	2.5 ua	1.1 ua	.23 ua	< 50 µa

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## Normal Polarity (120 VAC)

Patient Electrode	Seal A	Seal B	Bipolar A	Bipolar B	Limit
Ground Closed	1.3 ua	.45 ua	1.1 ua	.22 ua	< 10 $\mu$ a
Ground Open	1.2 ua	2.4 ua	1.1 ua	.24 ua	< 50 $\mu$ a

## Reversed Polarity (120 VAC)

Patient Electrode	Seal A	Seal B	Bipolar A	Bipolar B	Limit
Ground Closed	1.3 ua	.44 ua	1.1 ua	.22 ua	< 10 $\mu$ a
Ground Open	1.2 ua	2.4 ua	2.8 ua	.22 ua	< 50 $\mu$ a

**3. Patient Sink Current**

	Test Results	Limit
All outputs in parallel, 120V	0 $\mu$ a	$\leq$ 10 $\mu$ a
All outputs in parallel, 264 V	10 $\mu$ a	$\leq$ 50 $\mu$ a

**D. Audio Test (AAMI HF18/1993 § 4.2.7.3, IEC 601-2-2 § 101.2)**

The IEC Standard indicates that the Generator volume level should be adjustable to a maximum volume of at least 65 dB and a minimum volume of not less than 45 dB. The Alarm volume level (not adjustable) should be at least 65 dB. The test Generator passed the above requirements. LigaSure™ Generator serial # 3 was used for these tests.

**E. High Frequency Leakage Tests (IEC 601-2-2 § 19.101)**

High frequency leakage tests were performed as defined in IEC 601-2-2, figure 105. LigaSure™ Generator serial # 3 was used for these tests.

The test results were recorded as follows:

Mode	Left Electrode Leakage	Right Electrode Leakage	IEC Specification Calculated Maximum
Seal	20 mA	30 mA	$\leq$ 86.6 mA
Macro Bipolar	73 mA	65 mA	$\leq$ 86.6 mA
Bipolar	32 mA	29 mA	$\leq$ 86.6 mA

**F. Output Accuracy Tests ((AAMI HF18/1993 § 4.3.3)**

The output accuracy of the generator over extended keying times is within +/- 15% over the starting output (power and current). The test generator was keyed in Seal, Macro

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Bipolar and Bipolar modes for 3 minutes into a 100 Ohm load. LigaSure™ Generator serial # 4 was used for these tests.

The test results were recorded follows:

Seal	Start	Finish	% Change
Current	1.23 A(rms)	1.23 A(rms)	0%
Power	151.3 watts	151.3 watts	0%

MacroBipolar	Start	Finish	% Change
Current	.684 A(rms)	.684 A(rms)	0%
Power	46.8 watts	46.8 watts	0%

Bipolar	Start	Finish	% Change
Current	.685 A(rms)	.684 A(rms)	.1%
Power	46.9 watts	46.8 watts	.2%

**G. Storage Temperature Tests (AAMI HF18/1993 § 4.3.4, IEC 601-1 § 10.1)**

The test generator was subjected to 16 Hours of temperatures ranging from -40°C to 65°C with a varying humidity level of 10 to 96% (non-condensing). The unit was fully functional and performed according to specifications after being exposed to the aforementioned requirements. LigaSure™ Generator serial # 4 was used for this test.

**H. Input Current Tests (AAMI HF18/1993 § 5.4.1.1, IEC 601-1 § 7.1)**

Test requirements indicate that the input current of the generator should not deviate more than 10% over its specified value, in this case 5A for the Seal Mode and 3A for Macro Bipolar and Bipolar modes. LigaSure™ Generator serial # 4 was used for these tests.

Test result were recorded as follows.

**Bipolar**

	85 VAC	104 VAC	120 VAC	127 VAC	240 VAC	264 VAC
Idle	.169A(rms)	.160A(rms)	.159A(rms)	.160A(rms)	.126A(rms)	.125A(rms)
100 Ohms	.71 A(rms)	.63 A(rms)	.59 A(rms)	.59 A(rms)	.33 A(rms)	.31 A(rms)
500 Ohms	.71 A(rms)	.63 A(rms)	.60 A(rms)	.59 A(rms)	.33 A(rms)	.32 A(rms)
1000 Ohms	.66 A(rms)	.56 A(rms)	.52 A(rms)	.50 A(rms)	.33 A(rms)	.32 A(rms)

**CONFIDENTIAL****Seal**

	85 VAC	104 VAC	120 VAC	127 VAC	240 VAC	264 VAC
Idle	.169A(rms)	.160A(rms)	.159A(rms)	.160A(rms)	.126A(rms)	.125A(rms)
100 Ohms	2.4 A(rms)	3.0	2.9	2.7	1.46	1.34
500 Ohms	1.62A(rms)	1.88A(rms)	1.84A(rms)	1.75A(rms)	.98 A(rms)	.95 A(rms)
1000 Ohms	1.4 A(rms)	1.63A(rms)	1.52A(rms)	1.43A(rms)	.81 A(rms)	.75 A(rms)

**I. Energy Storage Tests (IEC 601-1 § 15.b.c)**

In both nominal and high line conditions, the standard requires that the voltage present on the exposed AC connector should be dissipated within 500 ms from the removal of power. The plot shown in Appendix D indicates a dissipation time of 136 ms for both 110 VAC and 264 VAC. The plot also shows that the voltage on the electrolytic capacitors in the High Voltage power supply were 6.35 VDC after 15 sec, which is less than the IEC requirement of 60V. LigaSure™ Generator serial # 3 was used for these tests.

**J. Chassis to Ground Impedance (IEC 601-1 § 18.f)**

The chassis to ground impedance was measured from the RF board ground to the ground lug and from chassis to the ground lug. In both cases the readings were below the IEC requirement of 0.1 Ohms. The measured impedance from the RF board to ground was .035 Ohms and from the chassis to ground was .038 Ohms.

LigaSure™ Generator serial # 2 was used for these tests.

**K. Dielectric Withstand Tests (IEC 601-1 § 20.1 A-f, 20.2 B-e)**

The test generator was subjected to a high potential voltage of 4200 VAC. This voltage was applied to all the patient connected outputs and ground for a period of 1 minute and 1500 VAC applied to the AC input connector for a period of 1 minute. No arcing between components was observed and the generator performed to specifications after completion of these tests.

LigaSure™ Generator serial # 2 was used for these tests.

**L Enclosure/Chassis Strength Test (IEC 601-1 § 16.0 a,b,c,e and 21.0 a,b)**

The LigaSure™ Generator was designed to conform to the aforementioned standard and testing will be conducted to verify compliance.

**M. Handle Test (IEC 601-1 § 21.0.c)**

The LigaSure™ Generator was designed to conform to the aforementioned standard and testing will be conducted to verify compliance.

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**CONFIDENTIAL****N. Stability Test (IEC 601 § 24.1)**

The generator did not tip over when subjected to a 10° tilt on the front, back, right and left sides. LigaSure™ Generator serial # 3 was used for this test.

**O. Drop Test (IEC 601-1 § 21.6, AAMI HF18/1993 § 4.3.6)**

The LigaSure™ Generator was designed to conform to the aforementioned Standard and testing will be conducted to verify compliance.

**P. Splash Test (AAMI HF18/1993 § 4.2.1.1)**

The test generator was subjected to the splash test as defined in IEC 601-2-2 § 44 and then subjected to a high potential test as described in section K for dielectric withstand test. After these tests the generator was completely functional and performed to specifications. LigaSure™ Generator serial # 3 was used for this test.

**Q. Life Cycle Test (IEC 601-2-2 § 42.4)**

The test Generator was cycled for two hours an ambient temperature of 25°C and at a 50% power duty cycle (15 seconds on, 15 seconds off). The Generator was set in the Seal mode at maximum power. No failures were noted.

LigaSure™ Generator serial # 4 was used for this test.

**R. Open/Short Test (IEC 601-2-2 § 52.101)**

The test generator was activated 10 times in each operational mode, at full power, into both a short and open load for 5 seconds on and 15 seconds off. No damage occurred to the generator. LigaSure™ Generator serial # 4 was used for this test.

**S. Handswitch Impedance Test (IEC 601-2-2 § 56.11.bb)**

This test verifies that the generator will not activate if any of the activation switches are connected by an impedance greater than 1000 Ohms. The test results for the Seal and Bipolar switches are shown below. LigaSure™ Generator serial # 4 was used for these tests.

Test results were recorded as follows:

Mode	Seal Activation Impedance (Ohms)	Bipolar Activation Impedance (Ohms)
Seal Handswitch	806	796
Bipolar Handswitch	805	796

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**T. Power Interruption Tests (IEC 601-2-2 § 51.101)**

The power interruption tests were run on LigaSure™ Generator serial # 4 at 85, 110, and 264 VAC line voltage with the unit both activated and at idle. In all cases, the generator reverted to stand-by and no hazardous outputs were observed.

**U. Defibrillator Discharge (AAMI HF18/1993 § 4.2.8.3, IEC 601-2-2 § 51.102)**

The test generator was subjected to voltages in excess of the defibrillator voltages specified in AAMI HF18/1993 § 4.2.8.3. The generator was fully functional and performed to specifications. LigaSure™ Generator serial # 3 was used for this test.

**V. Output Disable Time Test (AAMI HF18/1993 § 4.2.4.1.1)**

The handswitch output control was used to verify that the output of the generator will shut off within 200 ms of the release of the activation button. The plot of the results is shown in Appendix E. The unit meet the aforementioned standards. LigaSure™ Generator serial # 4 was used for this test.

**W. Electrical Construction (AAMI HF18/1993 § 4.2.2.1.4 ; UL544 Reference 2.2)**

The LigaSure™ Generator was designed to conform to the aforementioned standards and testing will be conducted by an independent testing laboratory to verify compliance.

**X. Electromagnetic Compatibility (IEC 601-2-2 § 36)**

The LigaSure™ Generator was designed to conform to the aforementioned standard and testing will be conducted by TUV to verify compliance.

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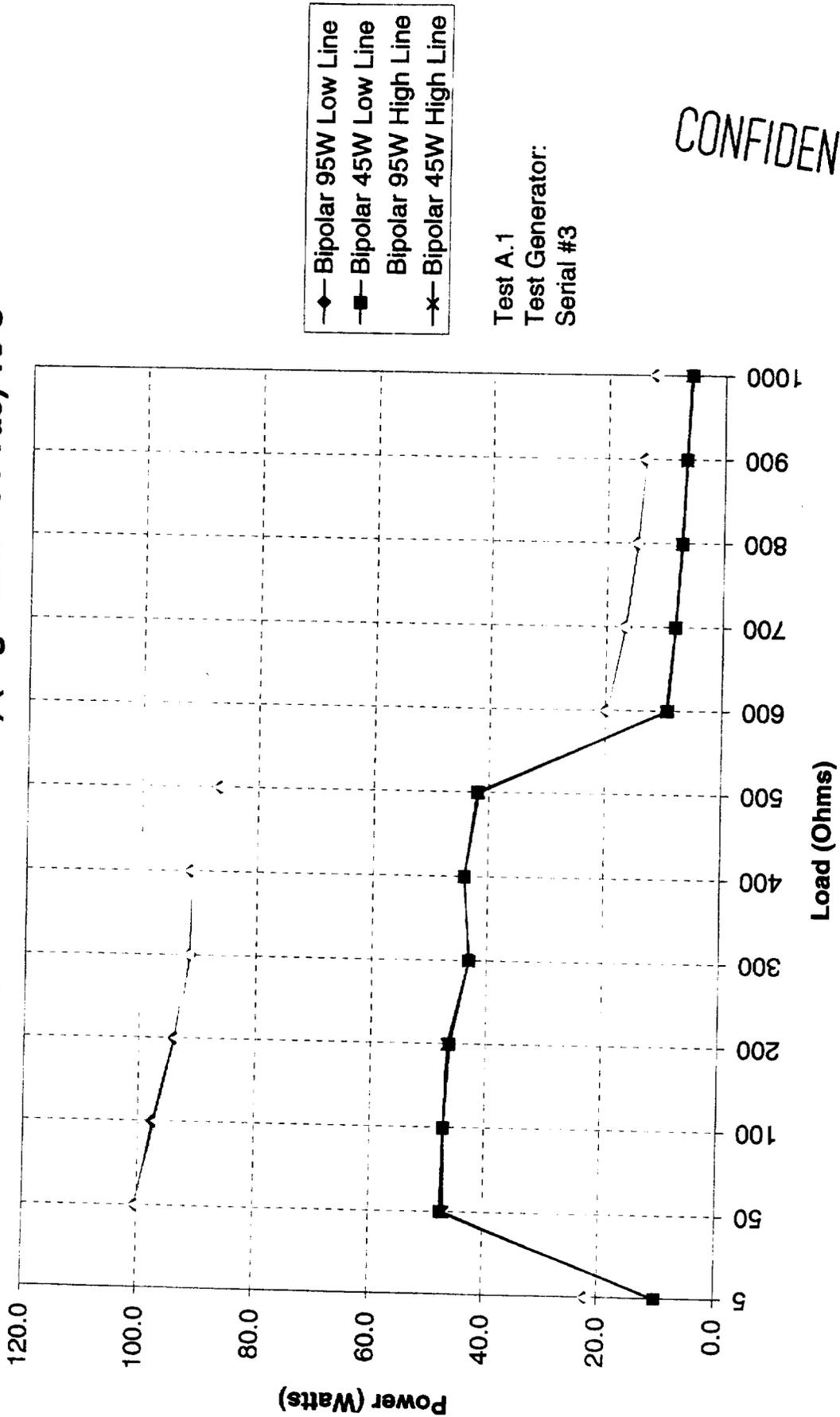
**APPENDIX A**

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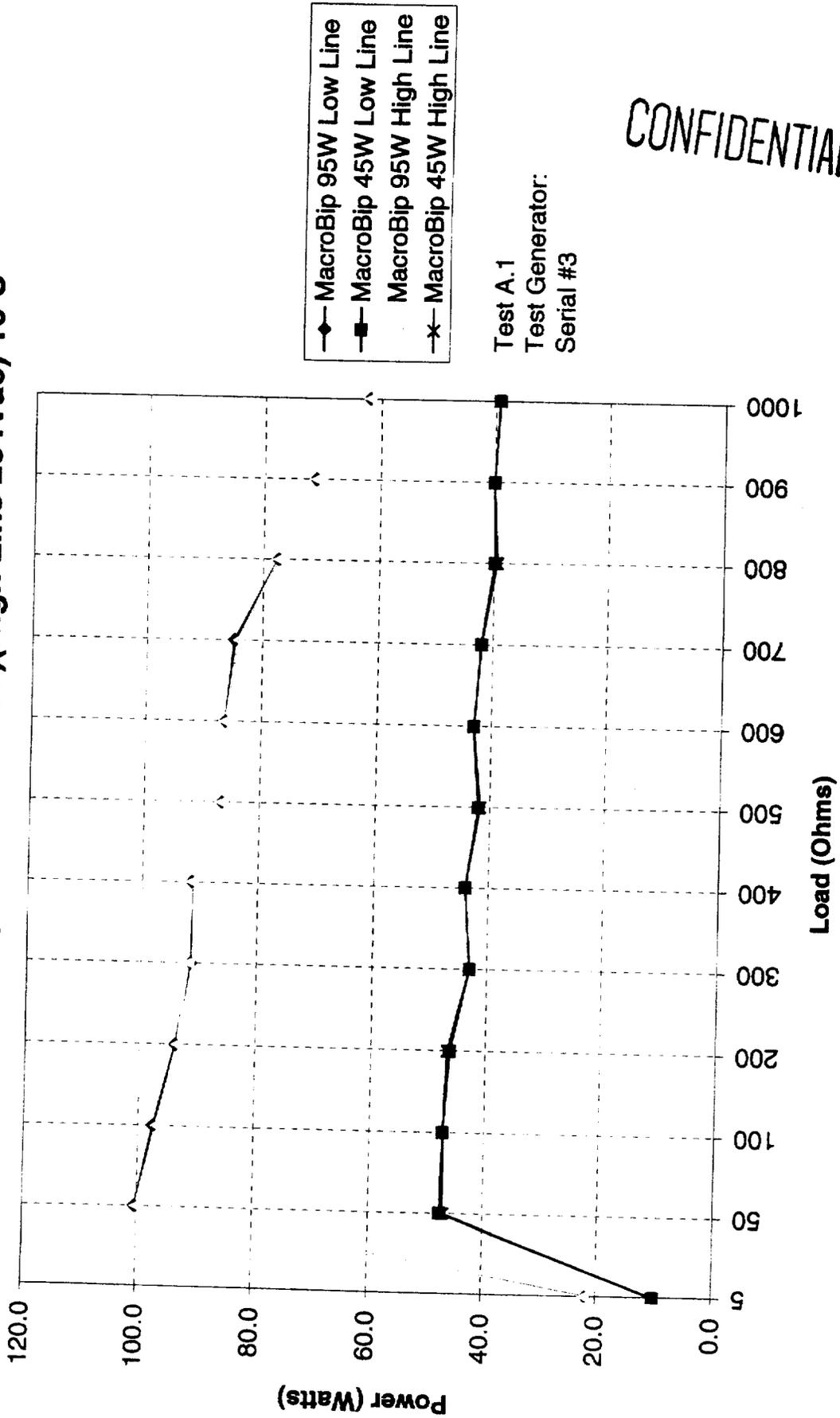
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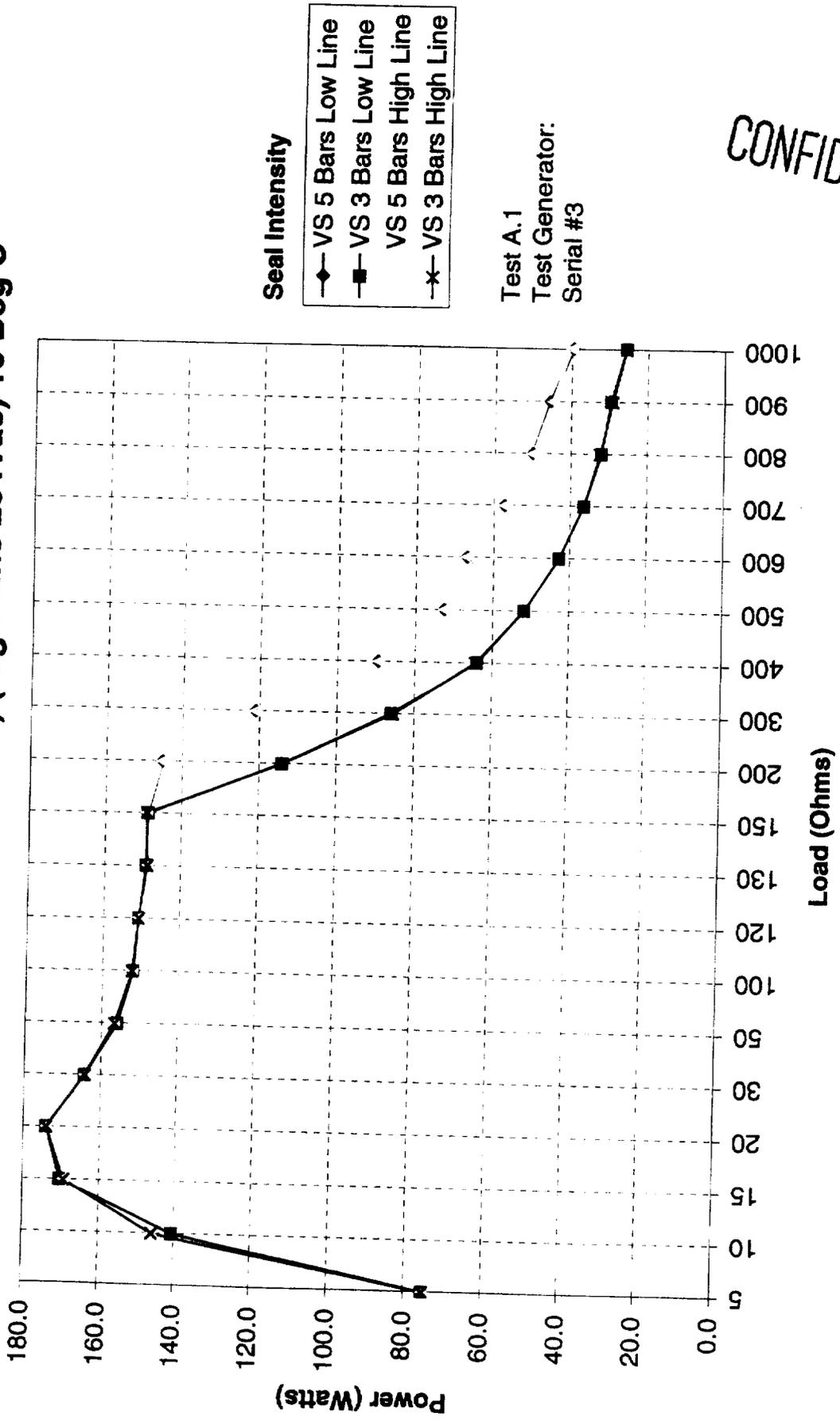
Power vs Impedance  
MacroBipolar(Low Line 90Vac)(High Line 264Vac) 10 C



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### Power vs Impedance Vessel Seal (Low Line 90Vac) (High Line 264Vac) 10 Deg C



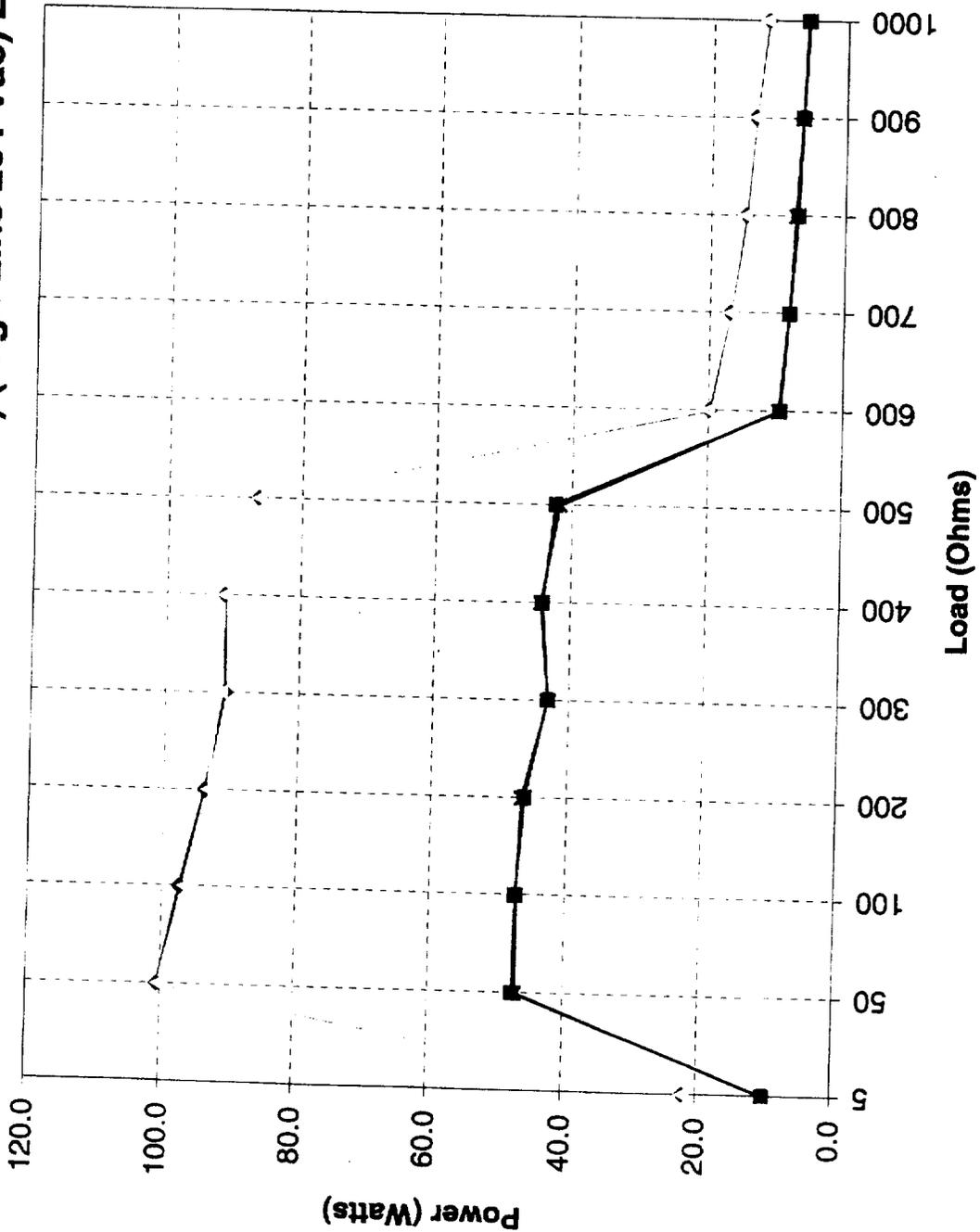
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Power vs Impedance  
Bipolar (Low Line 90 Vac) (High Line 264 Vac) 25 C

- ◆ Bipolar 95W Low Line
- Bipolar 45W Low Line
- ◆ Bipolar 95W High Line
- × Bipolar 45W High Line

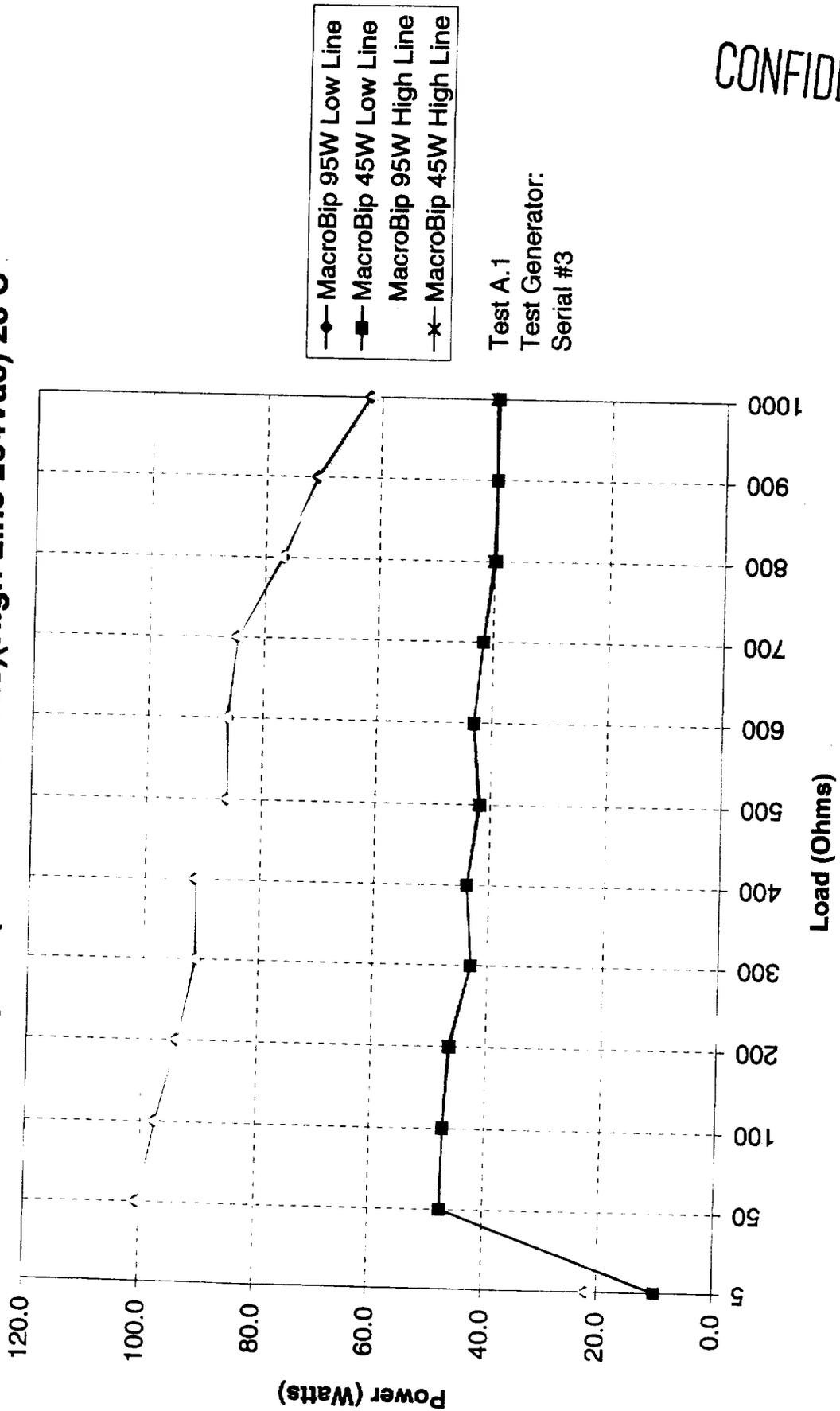
Test A.1  
Test Generator:  
Serial #3



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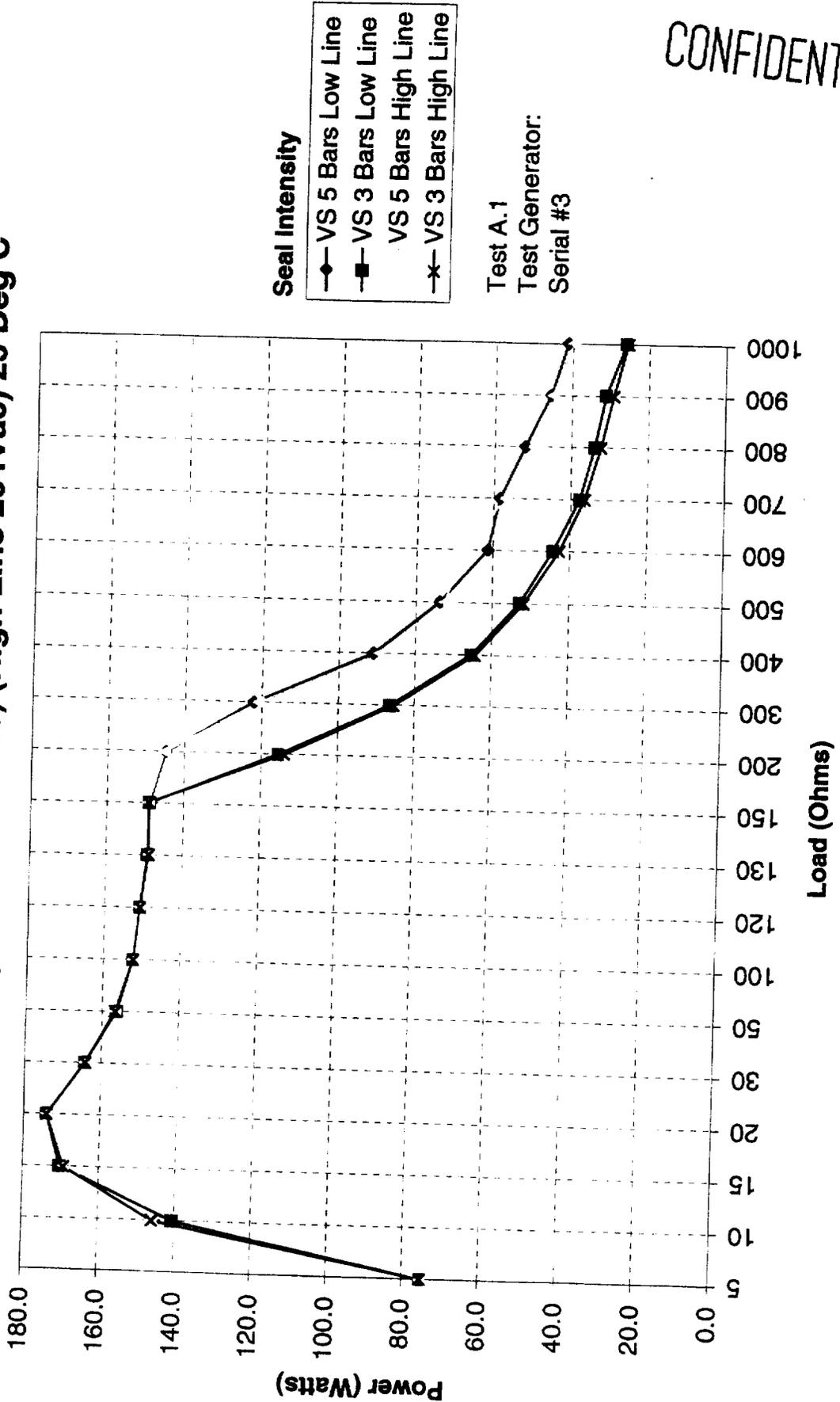
Power vs Impedance  
MacroBipolar(Low Line 90Vac)(High Line 264Vac) 25 C



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Power vs Impedance  
Vessel Seal (Low Line 90Vac) (High Line 264Vac) 25 Deg C



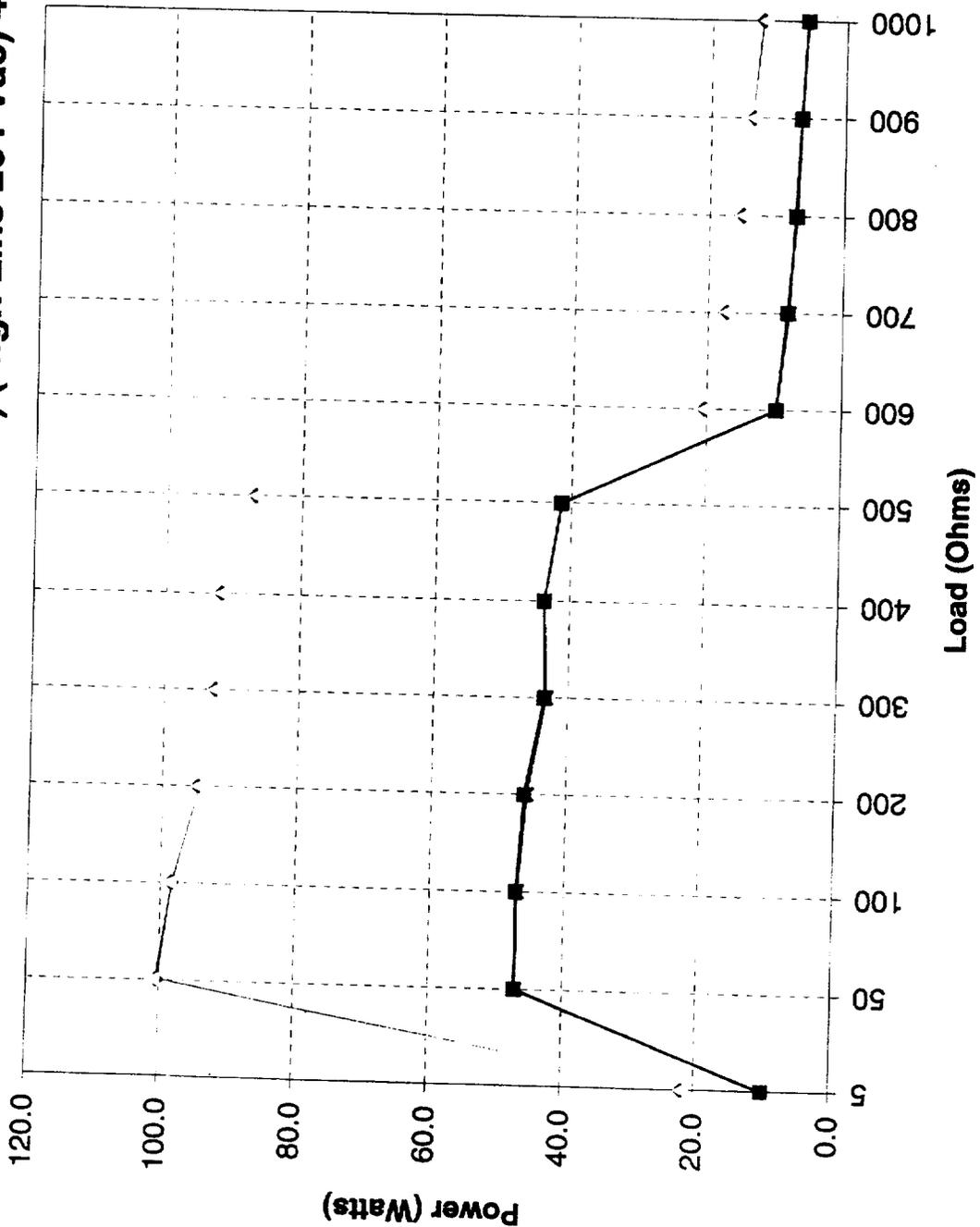
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**Power vs Impedance  
Bipolar (Low Line 90 Vac) (High Line 264 Vac) 40 C**

- ◆ Bipolar 95W Low Line
- Bipolar 45W Low Line
- ◆ Bipolar 95W High Line
- ✕ Bipolar 45W High Line

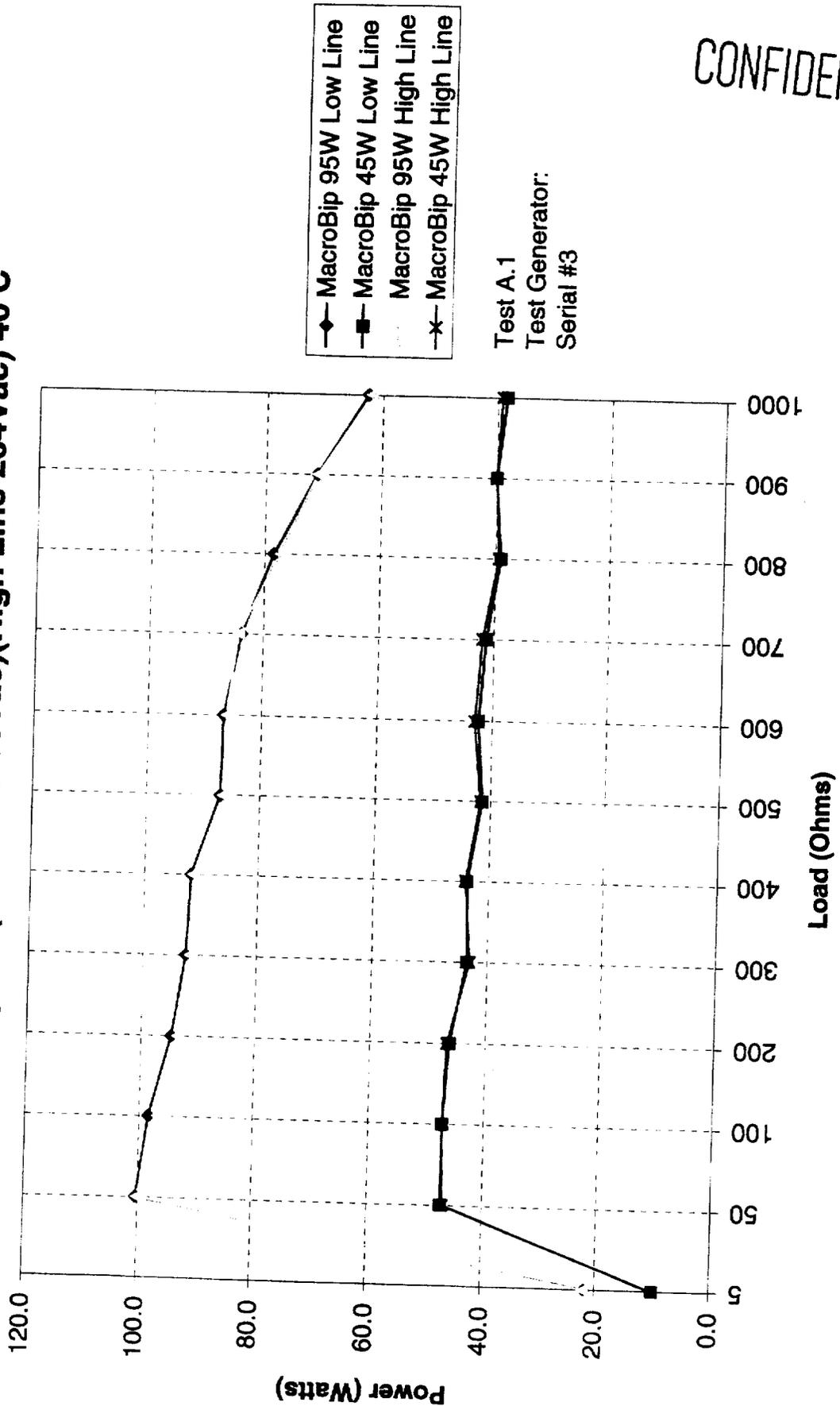
Test A.1  
Test Generator:  
Serial #3



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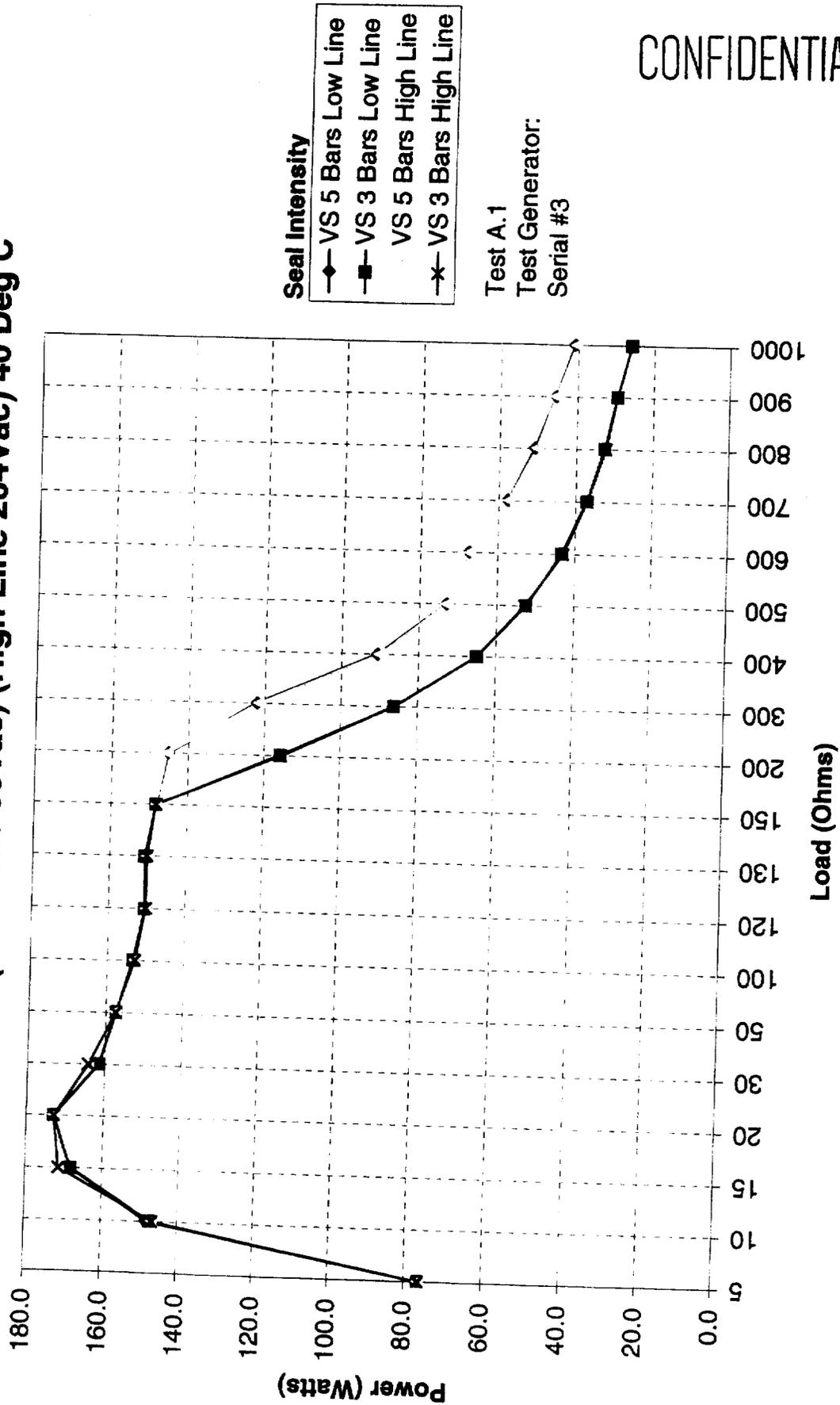
Power vs Impedance  
MacroBipolar(Low Line 90Vac)(High Line 264Vac) 40 C



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Power vs Impedance  
Vessel Seal (Low Line 90Vac) (High Line 264Vac) 40 Deg C



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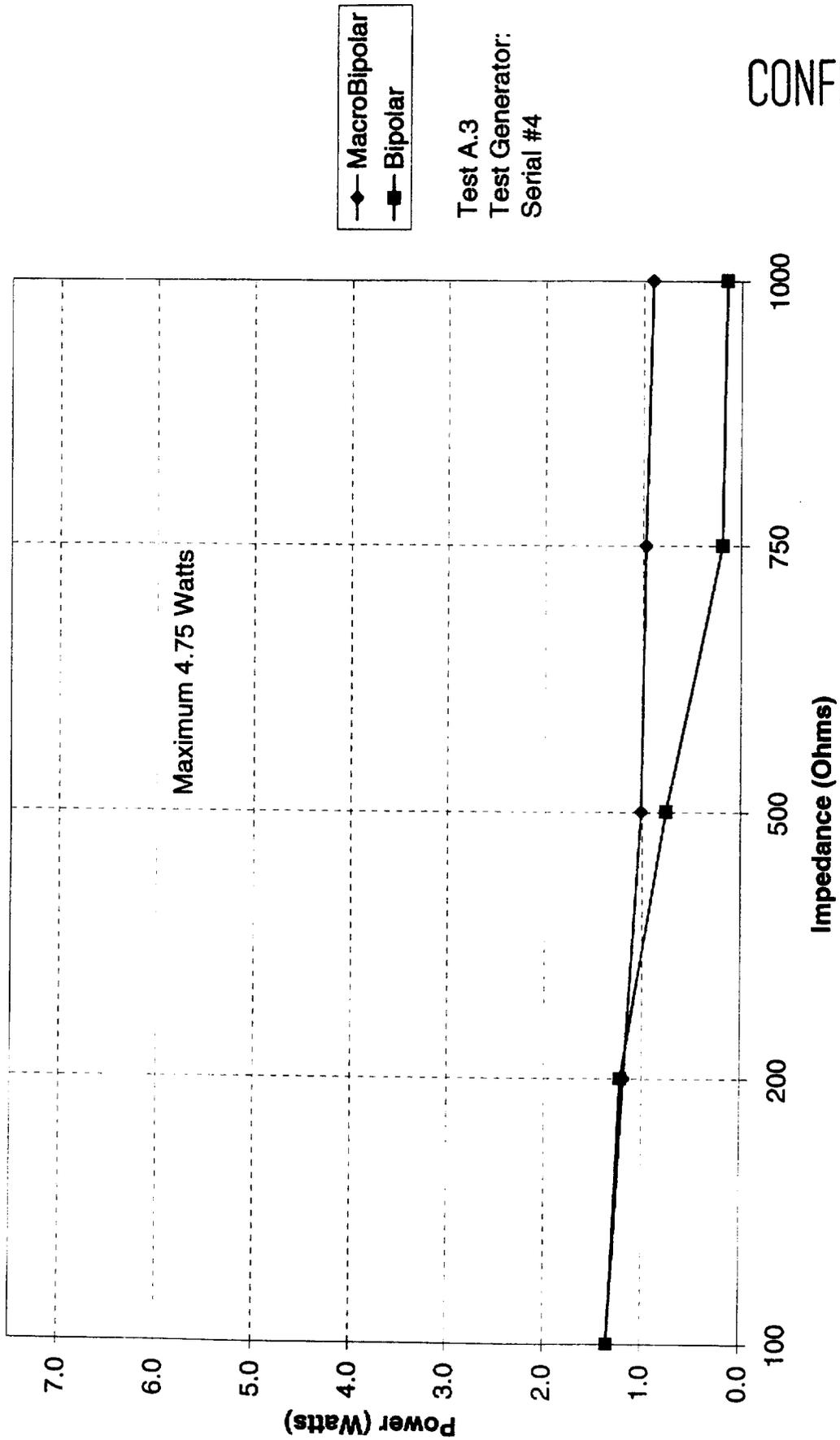
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**APPENDIX B**

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**Minimum Power Setting:  
Macro Bipolar, Bipolar 120Vac, 25c**



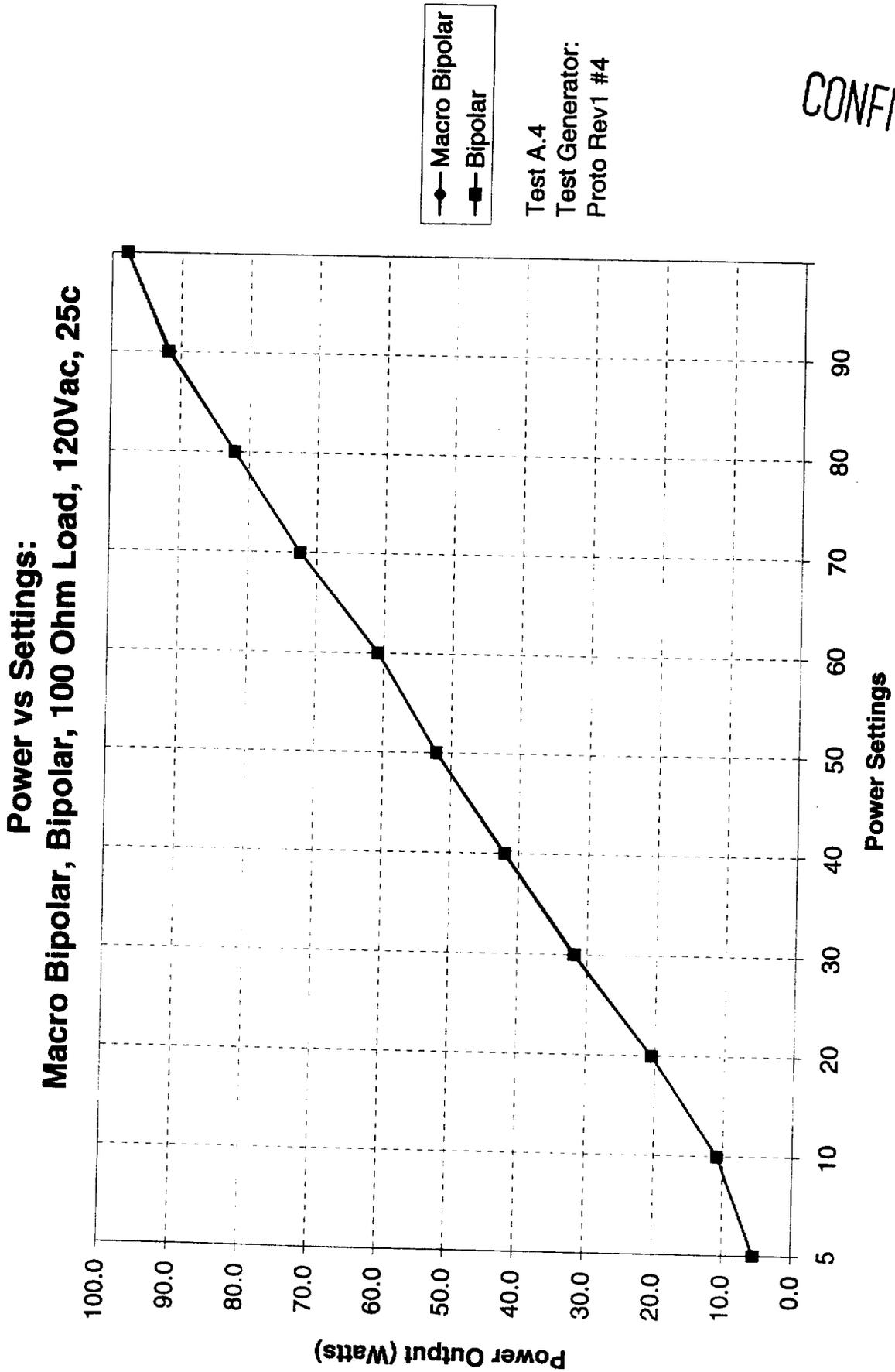
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**APPENDIX C**

213 J/h

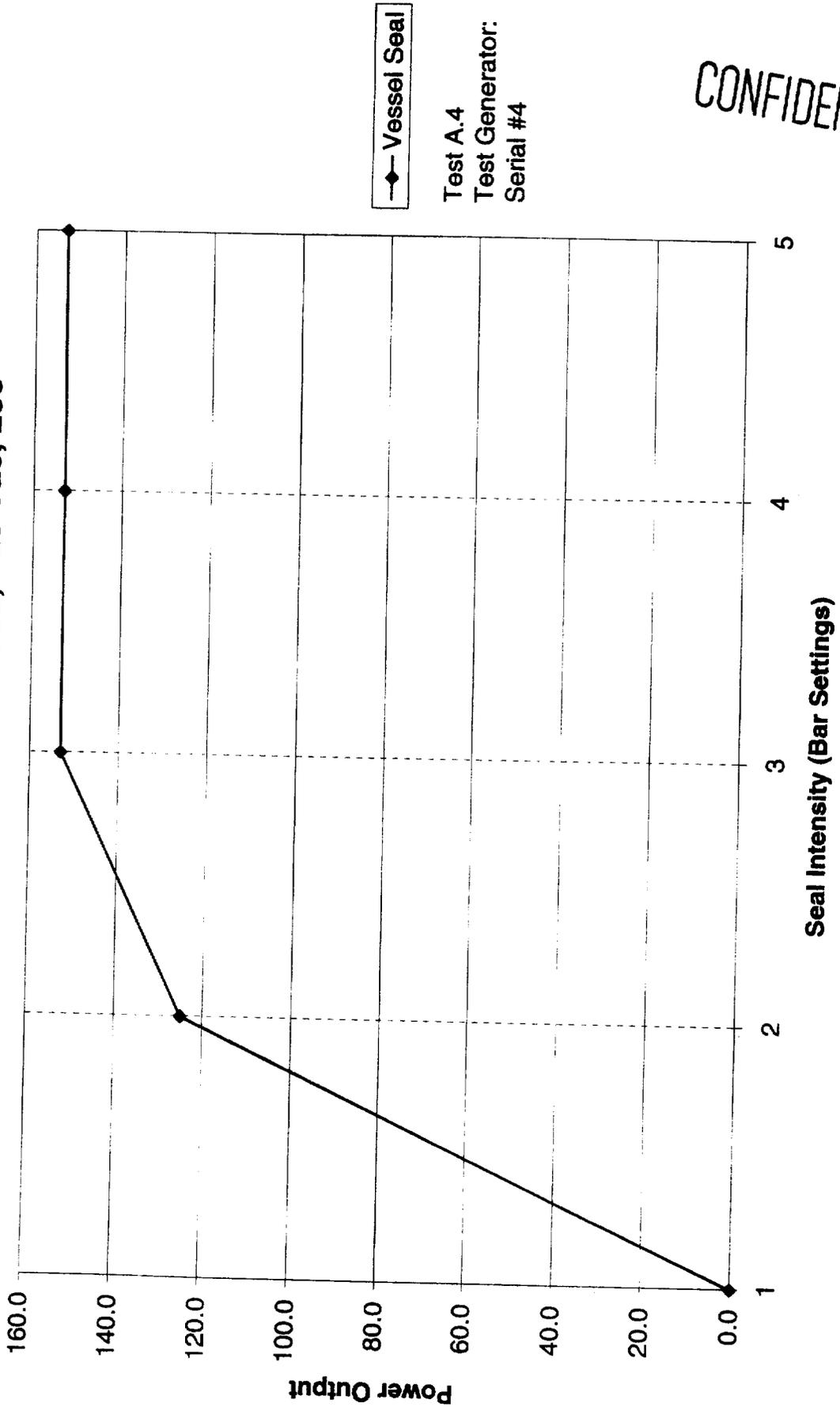
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**Power vs Settings**  
**Vessel Seal, 100 Ohm Load, 120 Vac, 25c**



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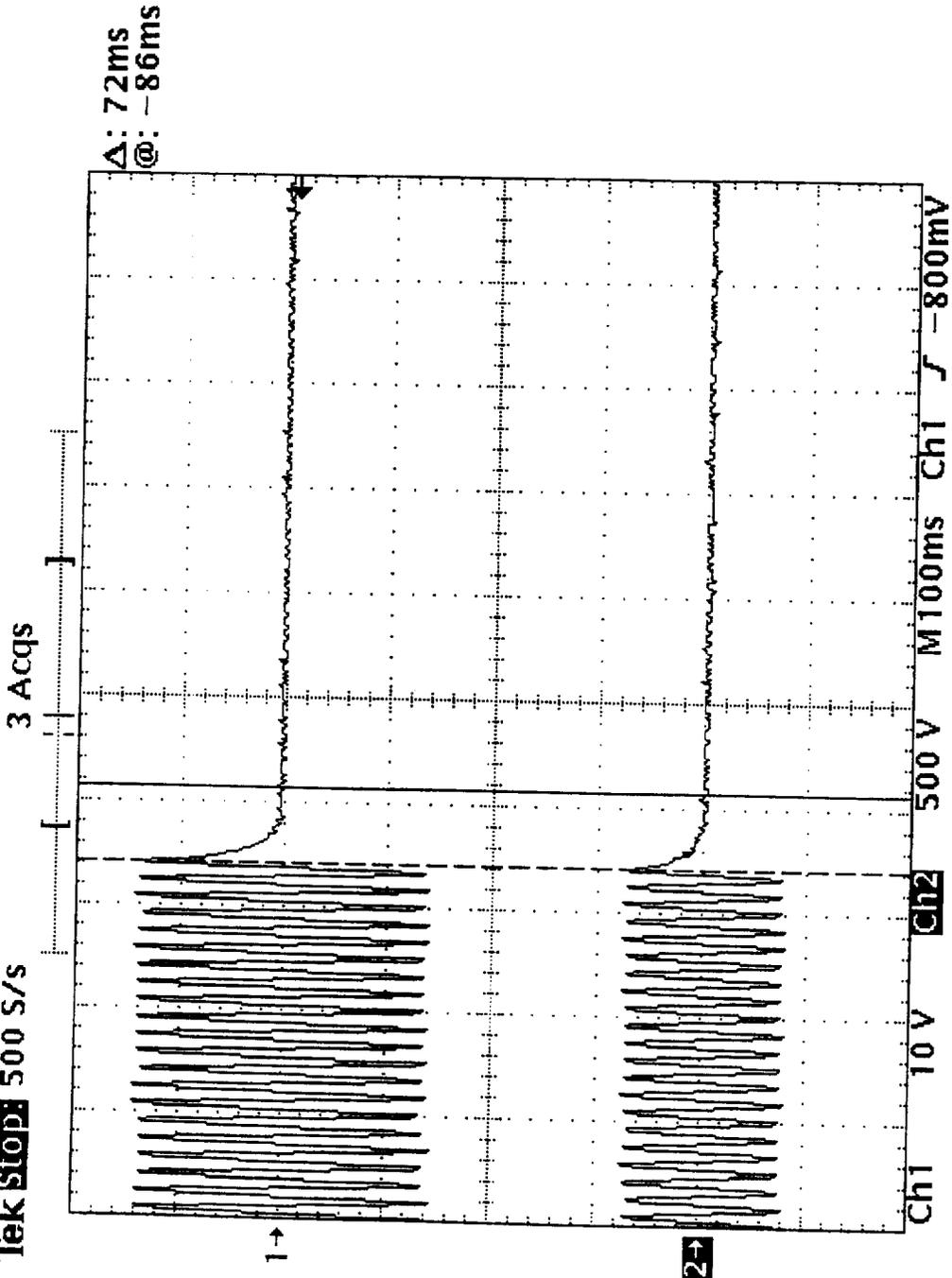
**APPENDIX D**

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510K Test I. Energy Storage Test  
AC Line Voltage 264 vac  
Tek Slope 500 S/S



12 May 1998  
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**APPENDIX E**

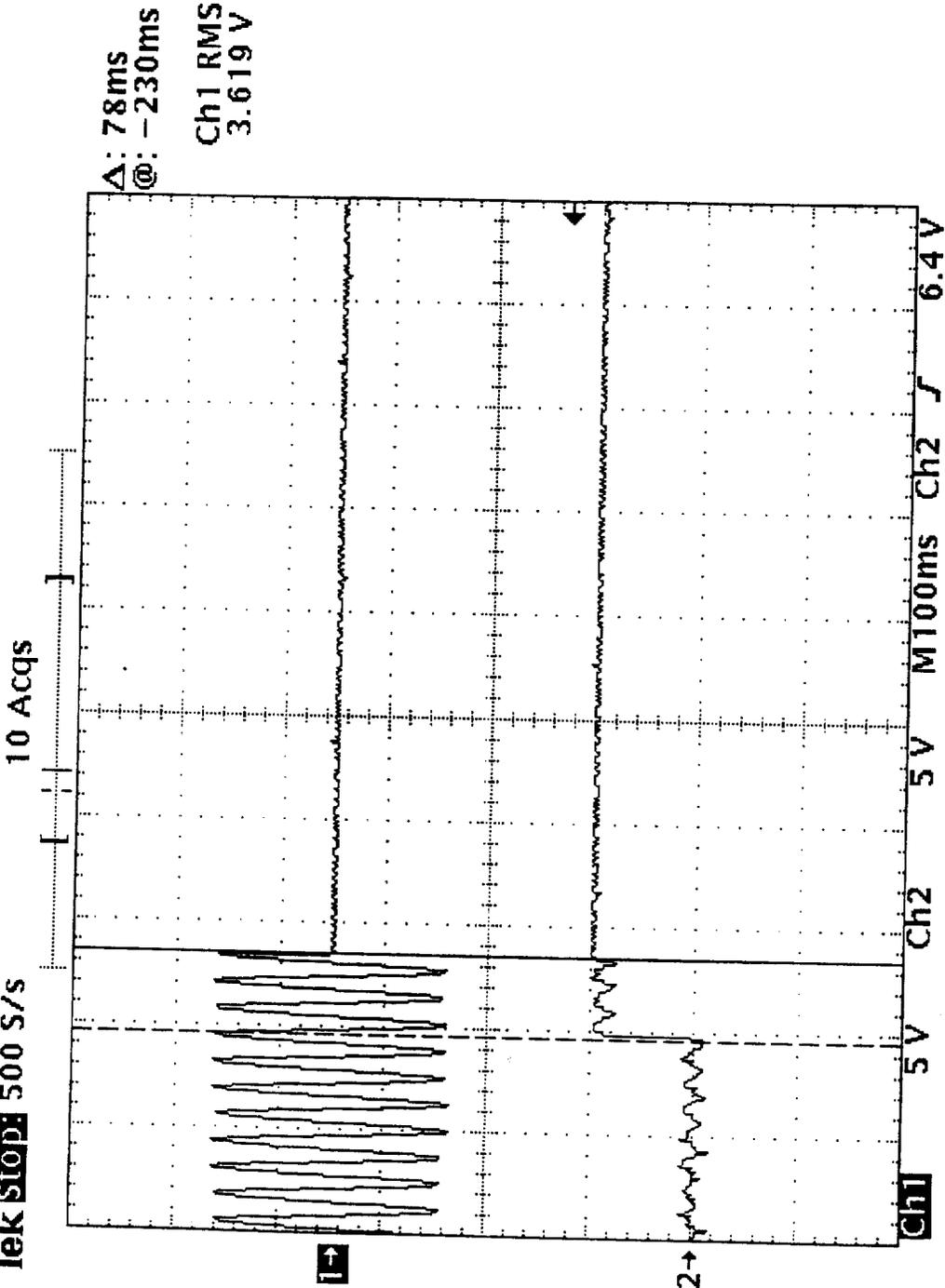
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510K Test V.

Output Disable Time Test

Tek Stop 500 S/s



12 May 1998  
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**VALLEYLAB  
RESEARCH AND DEVELOPMENT - ENGINEERING**

Title: 510K Electrical Test Report For the LigaSure Standard  
and LigaSure Lap Instruments

Issue Date: 05/20/98	Supersedes: N/A	Page: 1 of 6
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Author Sarah Hummel	Signature: <i>Sarah Hummel</i>	Date: 5/22/98
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**SIGNATURES:**

**DATE:**

R&D Engineering / Laparoscopic Engineering Coordinator: Robert Luzzi	
<i>Robert Luzzi</i>	5/22/98
R&D Engineering / Open Engineering Coordinator: Dale Schmalz	
<i>Dale Schmalz</i>	5/22/98
Engineering Specialist: Steve Buysse:	
<i>Steve Buysse</i>	5/22/98
Regulatory: Charles Copperberg	
<i>Charles Copperberg</i>	5/22/98

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**CONFIDENTIAL****PURPOSE:**

510K electrical tests were performed according to the 510K Electrical Tests for the LigaSure Standard and LigaSure Lap Instruments Protocol. The purpose of the tests were to demonstrate the electrical safety of the LigaSure Standard and LigaSure Lap instruments. This report gives the results of the 510K electrical tests.

**MATERIALS:**

- Tektronics oscilloscope with 10x probe, serial number B010445, calibrated on 7/1/97
- Fluke 8920A Voltmeter, serial number 4520012, calibrated on 11/10/97 with Person current transformer
- HP 4277A LCZ Meter, serial number 2228J01105, calibrated on 12/13/97
- Various test leads and alligator clips
- Stopwatch
- Hipot wand with 3/16" ball electrode
- Simpson Model 39 Current Meter
- NH-250 Resistor, 200  $\Omega$
- Instrumentation and generators
  - Force FX® Generator, serial number F6B574A
- 1 Each LigaSure Standard disposable electrode and cord set
  - SLFLB #1 Valleylab Laser Blank
    - Electrode: 25 mm length straight tapered, 3 mm at tip to 5 mm at back
    - Gap: 0.0045 inch - 0.0005 inch
    - 5.2 kg/cm<sup>2</sup> applied pressure at the electrode
  - Prototype LigaSure Standard
    - Electrode: 25 mm length curved tapered, 3 mm at tip to 5 mm at back
    - Cable: 10 feet, 2 conductor, 41 strands of 40 gage wire
- 1 Each LigaSure Lap
  - Prototype LigaSure Lap
    - Handle: Rev 6 #1 (machined)
    - Lever: Rev 6 with cast cover
    - Spring: Rev 6 0.077" thick prototype #1
    - Cable: Rev 5 prototype with ElectroSeal connector, Rev 5 board modified for Rev 6 handle
    - 1st Electrode: #50, straight jaw, sandblasted jaw surface, jaws touch at tip with .005 inch gap at heel in latch position, jaws and noses coated. Rev 5 push rod, Rev 5 one piece tubelock, 50 lbf pushrod force
    - 2nd Electrode: #40, 0.007 inch gap at heel of jaw, 50 lbf pushrod force
    - 3rd Electrode: #41 II - R5, 0.005 inch gap at heel of jaw, 50 lbf pushrod force
- LigaSure Prototype Vessel Sealing Generators
  - ElectroSeal ES-002
  - ElectroSeal ES-004
  - Proto Rev2 #3

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**CONFIDENTIAL****METHOD:**

The following electrical tests were performed on the LigaSure Vessel Sealing System: Generator Parameter Verification, Inductance and Capacitance Measurements, High Frequency Hi-Pot, High Frequency Leakage, and Regrasp Verification.

The algorithm parameters of the LigaSure Vessel Sealing Generator for both the LigaSure Standard and the LigaSure Lap were recorded using a serial port cable to connect the generator to a computer. The program Terminal was run, file e-seal.trm was opened and the command `:ph` was issued to display the generator parameters. All data was recorded in Laboratory Notebook #1300.

Electrical measurements were made to baseline the resistance, inductance and capacitance of each assembled instrument. With the jaws closed, a DVM on the low Ohms scale was used to measure the resistance between each connector at the plug end of the cable. Using a low voltage test signal at 500K Hz provided by an HP 4277A LCZ meter, the capacitance and inductance was measured and recorded in Laboratory Notebook #1300.

Hi-Pot testing was performed with a Force FX generator monitored by a Tektronics oscilloscope. Hipot safety testing was performed in a bipolar manner, as well as a surface wanding/monopolar manner. The bipolar test applied the voltage potential across the bipolar instrument. In the wanding test, one output of the generator was connected to both electrical connectors on the instrument. Then a wand was connected to the other generator output and waved in contact with all coated surfaces. To produce  $285 V_{rms}$ , 1.5 times the maximum voltage of the LigaSure Vessel Sealing Generator, the Force FX was set in the Pure Cut mode at a power setting of 60 Watts for the LigaSure Standard and 90 Watts for the LigaSure Lap. During monopolar testing, the power setting was set at 22 Watts for all instruments. The current to the instrument was monitored with a current transformer (donut) around the lead to the instrument and a Fluke voltmeter.

Regrasp alarm verification tests were performed on the ElectroSeal ES-002 and ES-004 generators with and without the instruments attached. An 8" test lead was connected directly across the generator's output. The generator was activated. The time was measured from activation of the generator to sounding of the Regrasp alarm. This was repeated with an open and short between the LigaSure Standard and LigaSure Lap instrument's jaws. A power verification was also conducted to insure that the ElectroSeal ES-002 and ES-004 generators were delivering the correct amount of current during activation. These tests were performed with 8" lead and with the cable and instrument attached.

The LigaSure Vessel Sealing Generator RF leakage to ground was tested in accordance to IEC 601-2-2 19.101.c. The LigaSure Prototype Vessel Sealing generator Proto Rev2 #3 was used for this testing. A 200 ohm resistor was applied from both the left or right jaw of the hand piece through a current meter to the protective earth terminal on the

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rear of the generator. The generator was activated using the rear Seal footswitch connector and the current meter was read to measure the leakage current.

The generator was calibrated using short leads connections to simulate the method of calibration used by the Final Test area. This calibration method also provides the worst case HF leakage. Leakage current measurements are taken for active and return electrodes at maximum power setting for each mode.

**EVALUATION OF TESTING:**

**Results**

The algorithm parameters of the LigaSure Vessel Sealing Generator for both the LigaSure Standard and the LigaSure Lap were verified and are listed in Table 1 and Table 2.

**Table 1: LigaSure Standard algorithm parameters  
ElectroSeal ES-002**

Zbrk	Pwr	Vmx	Vst	Vmn	Vdc	Vrp	RF_Tm	Cl_Tm	Pmn	Dwl	Poff	Pdes
------	-----	-----	-----	-----	-----	-----	-------	-------	-----	-----	------	------

**Table 2: LigaSure Lap algorithm parameters  
ElectroSeal ES-004**

Zbrk	Pwr	Vmx	Vst	Vmn	Vdc	Vrp	RF_Tm	Cl_Tm	Pmn	Dwl	Poff	Pdes

All instruments, the SLFLB #1 Valleylab Laser Blank, the Prototype LigaSure Standard, and the LigaSure Lap, safely passed both the monopolar and bipolar Hi-Pot tests. For all instruments, no sparks were observed and the current never increased more than 10 mA.

The inductance, capacitance and resistance measurements for the LigaSure Standard SLFLB #1 Valleylab Laser Blank with a 10 foot cable, the Prototype LigaSure Standard and the LigaSure Lap were recorded and are listed in Table 3.

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**CONFIDENTIAL****Table 3: Results of the Inductance, Capacitance and Resistance Measurements**

	Inductance ( $\mu\text{H}$ )	Capacitance ( $\text{pF}$ )	Resistance (ohms)
LigaSure Standard, SLFLB #1 Valleylab Laser Blank	2.419	144.8	1.4
Prototype LigaSure Standard	2.065	159.7	1.3
LigaSure Lap	1.794	321.8	1.2

The current delivered during activation from generators ES-002 and ES-004 and the amount of time for a Regrasp alarm to sound are listed in Table 4. The current dropped an average of 2.3 amps from a 1 ohms resistance to a 50 ohms resistance. The time to Regrasp was an average of 4.1 seconds higher with the cable and instrument attached to the generator rather than the 8" lead.

**Table 4: Results of Power Verification**

		Current with Resistance		Time to Regrasp	
		1 ohm	50 ohm	short circuit	open circuit
		(Amps)	(Amps)	(seconds)	(seconds)
ES-002	short lead	4.01	1.74	1.6	1.0
	with cable and instrument	4.0	1.73	5.4	7.5
ES-004	short lead	4.01	1.71	1.8	2.6
	with cable and instrument	4.01	1.68	5.8	5.0

The leakage current of the LigaSure Vessel Sealing System Generator did not exceed the maximum allowable current of 86 mA. All data is listed in Table 5.

**Table 5: Results of the High Frequency Leakage Test**

Mode	Left Electrode Leakage	Right Electrode Leakage	IEC Specification Calculated Maximum
Seal Mode	20 mA	30 mA	$\leq 86.6$ mA

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### **Conclusions**

The algorithm parameters of the LigaSure Vessel Sealing Generator for both the LigaSure Standard and the LigaSure Lap were verified to be correct and the leakage current was measured to be below the specified limit of 86.8 mA. The inductance, capacitance and resistance measurements for the LigaSure Standard and LigaSure Lap instruments were baselined as was the time to Regrasp. Time to Regrasp, with the cable and instrument, needs to be shorter. The instruments and the generator passed the electrical tests and are safe to use.

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- 1. Product Functional Description - Design Input Document**
- 2. Software Functional description - Software Requirements Document**
- 3. Software Hazard Analysis - LigaSure System Risk Analysis**
- 4. Software Development Process Description**
- 5. Software Quality Assurance Validation**
- 6. Software Validation Testing and Anticipated Results - Software Verification Test Plan**
- 7. Certification Statement**

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**VALLEYLAB®**

**DESIGN INPUT DOCUMENT (DID)**

**REVISION 2**

***Ligasure™* SYSTEM**

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**1.0 INTENDED USE:**

The **LigaSure™** Electrosurgical Generator is intended to act as an energy source for bipolar and vessel sealing instruments in open and laparoscopic surgical procedures.

**2.0 USER/PATIENT/CLINICAL:**

General and gynecological surgeons will be the primary users of the **LigaSure™** Electrosurgical Generator. The OR nursing staff will be the group who set up the Generator prior to use. Initial equipment installation and safety checking will be the responsibility of the Hospital Biomedical Engineering staff. Servicing will be at Valleylab service facilities only. Generator Field Calibration will be allowed to the end user.

The device may be used in any health care setting and on any patient group where general and/or laparoscopic surgery may be indicated.

**3.0 PERFORMANCE CHARACTERISTICS, LIMITS AND TOLERANCES:**

**3.1 RF Waveforms (nominal)**

**Macro bipolar:** 470kHz sinusoid  
**Bipolar:** 470kHz sinusoid  
**Vessel Sealing:** 470kHz sinusoid

**3.2 Output Characteristics (nominal)**

Mode	Open Circuit Voltage @ Max Power (V <sub>rms</sub> )	Short Circuit Current @ Max Power (A <sub>rms</sub> )	Constant Power Range (Ω)	Max Power (W)	Crest Factor
Macro bipolar	250	2.08	22-658	95	1.5
Bipolar	110	2.08	22-512	95	1.5
Vessel Sealing	120	4.00	9.4-96	150	1.5

**3.3 Output Versus Impedance Curves**

Output power versus impedance curves will be generated for each operating mode of the **LigaSure** Generator. The output of a specific **LigaSure™** Generator will match the performance curve to within 5 watts or 15% whichever is greater.

**3.4 Effect Mode operation**

The **LigaSure** Generator effect mode is a closed loop control algorithm implemented in microcontroller firmware. As tissue impedance increases from short circuit to open circuit, the algorithm implements first constant current, then constant power and finally, constant voltage. At low impedance, constant current is

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used to protect output circuitry. At high impedance, constant voltage control limits arcing and EMI.

### 3.5 Vessel Sealing Timing

The vessel sealing process will involve a sequence of two time periods; a heating period, and a cool down period. At the end of this cycle, the RF output will automatically shut off. The entire process will take no more than 10 seconds to complete.

### 3.6 Regrasp

The purpose of the regrasp feature is to detect when the Vessel Sealing forceps tines are shorted and hence no power is being delivered to the tissue. When this condition is detected, the regrasp lamp will flash, a tone will sound twice, and the RF output will be disabled. The regrasp lamp will remain on until the Generator is rekeyed (in any mode). After correcting the shorting condition, the Vessel Sealing process may be initiated by rekeying the Generator.

### 3.7 Output Over Voltage Clamp

The **Ligasure™** Generator will incorporate real-time hardware over voltage clamp on the RF output above the maximum software limit.

### 3.8 Duty Cycle

At maximum power into an 80Ω load, the **Ligasure™** Generator rated worst case activation duty cycle will be 25% defined as 10 seconds on, 30 seconds off for one hour.

### 3.9 Acceptable Mains Voltages and Ranges

The Generator will automatically switch to operate from either a 115 or 230/240 mains voltage. Line fusing will be located within the AC input module.

Voltage	Current	Power
115 Volt line: Regulation Range: 90 - 135 VAC Operation Range: 85 - 140 VAC	0.3 A max. Seal: 5.0 A max. Macro: 3.0 A max. Bipolar: 3.0 A max.	Idle: 35 VA Seal: 600 VA Macro :360 VA Bipolar:360 VA
230 Volt line: Regulation Range: 186 - 264 VAC Operation Range: 170 - 264 VAC		

### 3.10 Acceptable Mains Frequencies and Ranges

The Generator will operate at line frequencies of 50 or 60 Hz.

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### 3.11 Alternate or Backup Power Requirements

The Generator will contain a battery for maintaining calibration and statistical values in battery-backed RAM. The Generator will have no other internal backup power systems.

### 3.12 Self-test Requirements, Including Timing, Frequency, and Method

Self tests will be performed at power up. Error codes will be displayed on the front panel displays as numeric error codes. The error code numbers will be identical to the FORCE FX™/FORCE 300™/NS2000 error codes whenever possible. At least the following tests will be performed:

- Checkerboard test on RAM devices
- CRC on battery-backed RAM
- CRC on ROM
- Display tests
- LED and lamp tests
- Button input test
- Digital to analog converter test
- Dosage error testing

### 3.13 Diagnostic Feedback Required

The dosage error function as described in section 3.12, will be tested at power up.

### 3.14 Functional Verification Requirements

A functional verification will be recommended to be performed once a year.

## 4.0 SAFETY:

### 4.1 Low Frequency Leakage (50/60 Hz) source current

Enclosure source current, ground open < 300  $\mu$ A

Patient connected source current  
(Patient connected leakage specified with all patient leads and outputs tied together.)

Normal polarity, intact chassis ground: < 10 $\mu$ A  
Normal polarity, ground open: < 50 $\mu$ A  
Reverse polarity, ground open: < 50 $\mu$ A  
Sink current, at high line, all inputs: < 20 $\mu$ A

(Reference IEC 601-1 Sub-clauses 19 and AAMI HF18 Sub-clause 4.2.9)  
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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#### 4.2 High Frequency Leakage

The Generator will meet IEC standards for bipolar Generators by producing less than 86mA of RF leakage as outlined in IEC 601-2-2 (2ed) Sub-clause 19.101 c.

#### 4.3 Dielectric Withstand

The Generator will meet the following dielectric withstand values

Patient - Chassis	4200 VAC
Patient - AC Mains	4200 VAC
Footswitch - Chassis	500 VAC
Footswitch - AC Mains	2000 VAC
AC Mains - Chassis	2000 VAC

(Reference IEC 601-2-2 (3ed) Sub-clause 20)

#### 4.4 Catastrophic Failure Conditions and Consequences

The Generator will monitor key operating performance specifications and shut down if an out of bounds error condition occurs. The Generator may have random component failure conditions. The precautionary measures for such will be described in the Generator labeling. A Risk Analysis will be conducted to insure that no single fault failure will result in unintended activation (without keying tones present).

#### 4.5 Fail-safe Requirements

The dosage error circuit, to meet IEC requirements, is the primary fail safe system in the Generator. A dosage error alarm will deactivate the Generator, sound three tones, and indicate the appropriate system error code. It will monitor the proper output performance characteristic as a function of Generator set-up and sound an alarm if the Generator is operating out of specified tolerance ranges. (reference IEC 601-2-2 (3ed) Sub-clause 51.5).

#### 4.6 Surface Characteristics

The chassis and cover will be metal with water based paint. Rough edges, sharp corners and edges which may cause injury or damage will be avoided or covered. (Reference IEC 601-1 Sub-clause 23).

#### 5.0 HAZARD/RISK ANALYSIS:

The following is an initial list of potential hazards related to the **Ligasure™** Generator. This list should serve as a starting point for the hazard analysis completed as part of the development process and described in RL-006.

- Continuous RF power or long Vessel Sealing cycle
- Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA or 301-796-8118

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- Self or inadvertent activation (includes Vessel Sealing cycle)
- High RF energy
- High RF leakage
- Insulation failure on instrument or cord
- Energy out wrong output jack
- Hot instrument tip
- Failure to turn off when keying stops
- Cycle too short
- Output power low
- Cut vein instead of seal
- No seal - too loose grip by instrument
- Continuous regrasps
- Human error
- Insulation failure on power cord
- Grounding breaks
- Loose mains wire
- Power supplies remain energized a long time after power down
- RF transformer - short primary or secondary to ground
- Loss of 60 Hz isolation
- Blocking capacitors short
- Ripple induced by hardware or software
- Overheated parts
- Reversed tantalum or electrolytic capacitor
- Lack of training
- Lack of labeling
- No output
- High noise on AC
- High range RF noise
- Sharp edges - inside or out
- Case is too hot

## 6.0 TOXICITY AND BIOCOMPATIBILITY:

The Generator shall be made of standard materials used in previous Generators. Since the Generator is not a patient contact device, toxicity and biocompatibility testing is not required.

## 7.0 ELECTROMAGNETIC COMPATIBILITY (EMC):

The **Ligasure™** Generator will be designed to operate without interference when placed in close proximity to a **FORCE FX™**, **FORCE 300™**, **FORCE EZ**, **FORCE 2**, **FORCE 40 series**, or **VESTA Generator**.

The **Ligasure™** Generator will meet the following EMC related requirements:

- ESD Immunity (Reference IEC 601-1-2 Sub-clause 36.202.1 and IEC 1000-4-2) 237

- Radiated Immunity - 7 V/m per Valleylab requirement which is greater than IEC requirements (Reference IEC 601-1-2 Sub-clause 36.202.2 and IEC 1000-4-3)
- Electrical Fast Transient/Burst (Reference IEC 601-1-2 Sub-clause 36.202.3.1 and IEC 1000-4-4)
- Surge Immunity (Reference IEC 601-1-2 Sub-clause 36.202.3.2 and IEC 1000-4-5)
- Emissions (Reference IEC 601-1-2 Sub-clause 36.201.1, IEC 601-2-2 (2ed) Sub-clause 36, and CISPR 11)

## 8.0 ACCESSORY/AUXILIARY DEVICES COMPATIBILITY:

The Generator will be released simultaneously with the open and laparoscopic vessel sealing instruments that are each being developed under their own project numbers. These instruments will have smart connectors that are compatible with the receptacles on the front of the Generator. The codes on the instrument connector will tell the Generator that a vessel sealing instrument is present and allow the vessel sealing output to be accessed.

Two new footswitches will be released with this Generator. One will be a dual pedal footswitch with gray and blue pedals. This footswitch will control the generation of the Macrobipolar and Bipolar signals out of the bipolar side output connector. The other will be a two pedal footswitch that will have one conventional blue and one circular mauve "GEM" type pedal for controlling the generation of the Bipolar and Vessel Sealing signals out of the vessel sealing side output connector. A remote endpoint monitor will be released prior to or with this Generator. This endpoint monitor allows for the remote display of the current level being delivered during Macrobipolar and Bipolar operation. The endpoint monitor will connect to a 15 pin miniature sub-D connector identical to that used in the Force FX located at the rear of the Generator.

The **LigaSure™** Generator will have mounting feet which allow for mounting on the existing standard Valleylab carts (the Force 40 cart: E8008, or the Force 2 cart: E8006). This foot pattern will also make it compatible with the new universal cart now under development.

A smart code instrument connector will be present on the Bipolar/Macro Bipolar output of the Generator.

A single adapter will be shipped with each Generator which allows a standard bipolar instrument cord (such as the E0509, E0512, or E0018) to be plugged into the Generator. The smart code for the adapter will allow standard bipolar waveforms only (Bipolar and Macrobipolar). The adapter will allow customers to use their existing footswitching and/or handswitching bipolar instruments.

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## 9.0 DESCRIPTION OF INTENDED USE ENVIRONMENT:

### 9.1 Operating Conditions

Ambient temperature: +10 to +40 °C  
Relative humidity: 15 to 90 % (non-condensing)  
Atmospheric pressure: 700 to 1060 millibars

(Reference IEC 601-1 Sub-clause 10.2.1, AAMI HF18 Sub-clause 4.3.5, and OE Test Protocol)

### 9.2 Liquid Spillage

The **LigaSure™** Generator will be constructed so that liquid spillage in normal use does not wet electrical insulation or other components which when wetted are likely to affect adversely the safety of the equipment. (Reference IEC 601-2-2 (2ed) Sub-clause 44.6 and AAMI HF18 Sub-clause 4.2.1.1)

### 9.3 Shock and Vibration

The **LigaSure™** Generator will comply with shock and vibration requirements as outlined in IEC 601-1 Amend. 1 Sub-clause 21.6, AAMI HF18 Sub-clause 4.3.6, and the VALLEYLAB Environmental Validation Protocol.

### 9.4 Voltage Transients (Emergency Generator Mains Transfer)

The **LigaSure™** Generator will operate in a safe manner when the transfer is made between line AC and an emergency Generator voltage source. (Reference IEC 601-2-2 (2ed) Sub-clause 51.101 and AAMI HF18 Sub-clause 4.2.2)

### 9.5 Location

The **LigaSure™** Generator may be used in any health care setting where general and/or laparoscopic surgery may be indicated. The Generator will be designed so that it can be stacked above or below the VESTA Generator, or other Generators of similar size. It is intended to fit existing VALLEYLAB carts (see section 8) or in an overhead platform.

## 10.0 HUMAN FACTORS AND USER INTERFACE:

### 10.1 Front Panel

The front panel will be designed for ease of use. It should allow visibility when the Generator is mounted either on a cart or on an overhead platform. The front panel will be separated into two distinct sections; Bipolar and Vessel Sealing. The Generator labeling will use International symbols. The international model will have only these symbols on the front panel. In the domestic model, the symbols will also be accompanied by English terms.

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### 10.1.1 Power Setting Control

Power setting control will be achieved via up/down buttons. Separate up/down buttons will be provided for each of the three modes: Macrobipolar, Bipolar, and Vessel Sealing. The UP button, when pressed, will increment the desired power setting up to the maximum power for Bipolar and maximum sealing intensity for Vessel Sealing. The DOWN button will decrement the desired power setting down to the minimum power for Bipolar and minimum sealing intensity for Vessel Sealing. The UP/DOWN buttons for Bipolar and Vessel Sealing will have a gray background and a triangular shape. Within the triangles will be a hollow triangle of an accent color. The accent color for Bipolar will be blue. The accent color for Vessel Sealing will be mauve/violet. The UP/DOWN buttons for Macrobipolar will be white with gray accent triangles.

The list of possible Bipolar and Vessel Sealing settings are shown in the tables below.

#### Macrobipolar & Bipolar

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25  
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 45 50 55 60 65 70 75  
80 85 90 95

When an UP or DOWN button is pressed and held, the power display will change slowly at first, then quickly until the button is released or the maximum or minimum power is reached. When maximum or minimum power is reached, an audio tone will be sounded in lieu of further power changes. Simultaneous adjustment of power settings will be allowed in Macrobipolar and Bipolar only. No changes will be allowed in the vessel sealing power during activation. When the Ligasure Generator is activated, only a single step change in the CUT/COAG power setting will be allowed per UP/DOWN button depression.

#### Vessel Sealing (Sealing Intensity Levels)

Idle, Level 1, Level 2, Level 3, Level 4, Level 5

These six Vessel Sealing intensity levels will be represented on the front panel via a six segment bar graph display. **Numbers will not be displayed**

### 10.1.2 RF Indicators

Three RF indicators will be provided for Macrobipolar, Bipolar, and Vessel Sealing. The appropriate indicator bar will illuminate whenever an RF output is active. All three indicators will be blue when illuminated.

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### 10.1.3 Power Displays

The power settings for Macro bipolar and Bipolar will be displayed using independent seven segment green numerical displays indicating the desired power setting in watts. The range of power settings for Macro bipolar and Bipolar will be 1 to 95W which will require two digit displays. The Vessel Sealing display will consist of a bar graph with six bars. A single yellow bar will indicate that no output (Idle) is selected and that the system is on Stand-by. A green bar represents the sealing intensity level. Sequential green bars (left to right) will be displayed for each increment of sealing intensity until the maximum intensity (Level 5) is reached with all five green bars being illuminated. The Generator will power up with all power and vessel sealing intensity levels set to the minimum allowed for their respective modes. The two Bipolar power settings and the Vessel Sealing intensity setting will be visible whenever the Generator is turned on with the exception that if a device not requiring the Vessel Sealing mode is plugged into the output receptacle on the Vessel Sealing side, the Vessel Sealing power display will go blank.

### 10.1.4 Handset Lamps

Bicolor red/green handset lamps will indicate when an acceptable handpiece has been inserted into an RF output receptacle. There will be two handset lamps, one above each of the RF output receptacles. The handset lamps will remain blank until a smart connector plug is inserted into one of the RF output receptacles. When this occurs, the handset lamp above that output will illuminate green if the smart connector code is acceptable for that output, and red if the code is not acceptable. The RF output will be disabled until an acceptable smart connector code is recognized. In other words, a green handset lamp means the output is enabled and a red or blank handset lamp means the output is disabled.

### 10.1.5 Regrasp Lamp

A single color yellow/orange regrasp lamp will be placed above the RF output receptacle in the Vessel Sealing section of the front panel. The regrasp lamp will illuminate when the vessel sealing bipolar forceps tines are shorted.

### 10.1.6 Memory Button

A memory button will be provided. The function of this button will be to restore the power settings to the last settings prior to when the Generator AC power was last shut off.

### 10.1.7 RF Output Receptacles

There will be two RF output receptacles, one in the Bipolar section and one in the Vessel Sealing section of the front panel. Macro bipolar and Bipolar modes will be available from either output and will be handswitchable or footswitchable. The Vessel Sealing mode will only be available from the output in the Vessel Sealing section and will be handswitchable or footswitchable. Only one of the two outputs may be active at any given time (no simultaneous keying). Both output receptacles

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

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will employ a new, custom keyed, "smart connector" capable of sensing if an acceptable device has been inserted. The Vessel Sealing output receptacle will have color coded labeling adjacent to it to match color coding of Vessel Sealing instrument connectors.

### 10.1.8 Power Switch

A power switch will be located on the front panel to power the Generator on and off. Pressing the switch in the "1" position will power the Generator on and pressing the switch in the "0" position will power the Generator off.

## 10.2 Rear panel

### 10.2.1 AC Line Receptacle

An AC line receptacle will be mounted on the rear panel of the Generator for connection of the line cord.

### 10.2.2 Volume Control Potentiometer

A volume control potentiometer will be located on the rear panel. The volume control potentiometer will control the volume of the activation tones. Alarm tone volumes will not be adjustable.

### 10.2.3 Option Panel

An option panel will be mounted on the rear panel which covers the serial port connector, the expansion port, and an RF activation connector. The option panel will be designed such that a tool is required for removal.

### 10.2.4 Serial Port Connector

A nine pin connector will be provided which contains an RS-232 compatible serial port. The serial port will be electrically isolated from the **LigaSure™** Generator to protect the Generator from external equipment that is improperly connected. This port may be used for calibration of the unit and receiving diagnostic information. The connector will contain the following signals.

Isolated Transmit - The serial data output transmit line.

Isolated Receive - The serial data input receive line.

Isolated Ground - The reference for both transmit and receive.

### 10.2.5 RF Activation Connector

A miniature phone jack will be provided on the rear panel to indicate to other devices connected to the Generator, that the RF is active.

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### 10.2.6 Grounding Lug

An equipotential grounding lug will be provided on the rear panel.

### 10.2.7 Endpoint Monitor Connection

The expansion port will allow for the connection of a portable endpoint monitoring device.

### 10.2.8 Rear Panel Footswitch Connectors

Two footswitch connectors will be provided on the rear panel, one for each of the two RF output receptacles. The footswitch connector for the Bipolar section will be a new design 7 pin connector for use with a new design two pedal footswitch. The two footpedals will be used for activating Macrobipolar and Bipolar out of the output receptacle in the Bipolar section. The footswitch connector for the Vessel Sealing section will be a new design 7-pin connector. This will allow use of a new two pedal footswitch used to activate either Vessel Sealing, Macrobipolar, or Bipolar. These Foot pedals will be designed so that customers cannot physically interchange them. These Foot pedals will be exclusive to the LigaSure™ System.

## 10.3 Controls and Indicators Accessible To Service Personnel

### 10.3.1 ESU Calibration

There will be no calibration potentiometers for Generator adjustments. Calibration will be done using external loads and instruments (the unit will not require internal measurements and adjustments for calibration). Internal firmware calibration defaults will be used to minimize the time required to perform calibration during manufacturing.

### 10.3.2 Serial Port Calibration

The Generator will support calibration via the serial port.

## 10.4 Audio Requirements

Activation tones will be adjustable from a minimum of  $48 \pm 3$  dBA to a maximum of  $68 \pm 3$  dBA. Alarm tones will be  $68 \pm 3$  dBA at a frequency of 985 Hz. The Alarm tone will not be adjustable. The Macrobipolar activation tone frequency will be 520 Hz nominal. The Bipolar activation tone will be 660 Hz nominal. The Vessel Sealing activation tone will be 440 Hz nominal. This continuous audible tone will indicate the presence of RF power changing to a discontinuous on/off signal when the seal is complete. A fourth audio frequency of 780 Hz will be used to indicate when the vessel sealing bipolar forceps tines are shorted. This tone will be accompanied by the illumination of the regrasp lamp. (Reference IEC 601-2-2 (2ed) Sub-clauses 101.1 and 101.2 and AAMI HF18 Sub-clause 4.2.7.3, 4.2.7.4, and 4.2.7.5)

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## 10.5 Visual Requirements

Activation of Macrobipolar, Bipolar, or Vessel Sealing, will be indicated visually by the illumination of the corresponding indicator bar. Alarm conditions will be displayed on the Generator front panel displays as numeric error codes. A regrasp lamp will be lit whenever the Generator senses that the Vessel Sealing Forceps are shorted together. Bipolar and Vessel Sealing handset lamps placed above the RF output receptacles will illuminate red whenever an incorrect handset is inserted. RF output is disabled from the corresponding output until an acceptable handpiece or cord is inserted. The values shown in the power displays will be readable from a distance of 15 feet from the front panel. The text and graphics will be readable from 3 feet (arms length).

## 10.6 Ergonomic Requirements

The Generator will have an angled front panel for the displays and controls. The receptacle area will contain accessory connectors which meet IEC 601 spacing specifications. All control and display colors will meet IEC 601-2-2 and AAMI HF18 specifications. All controls will be labeled clearly, in international symbols. Each button will provide a mechanical (tactile) feedback when pressed. A carrying handle will be provided on the rear panel.

## 11.0 PHYSICAL/CHEMICAL CHARACTERISTICS:

### 11.1 Size and Weight

Depth - 15.0 in. (38.1 cm)  
Width - 14.0 in. (35.6 cm)  
Height - 5.0 in. (12.7 cm) not including feet  
Weight - Less than 15 Lbs.

### 11.2 Transportation

The packaging for the **Ligasure™** Generator will be non-sterile and will be compatible with seaborne shipping container packaging and handling, as well as domestic and international UPS and Federal Express shipping and handling.

### 11.3 Mounting Requirements

The **Ligasure** Generator will have mounting feet which allow for mounting on the existing standard VALLEYLAB carts (the Force 40 cart: E8008, or the Force 2 cart: E8006, Universal Cart). The **Ligasure™** Generator will also be designed so that it can be mounted to an overhead platform.

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#### 11.4 Surface Characteristics

The chassis and cover will be metal with water based paint. Rough edges, sharp corners and edges which may cause injury or damage will be avoided or covered. (Reference IEC 601-1 Sub-clause 23)

#### 11.5 Electrical Connection Requirements

An AC line receptacle will be mounted on the rear panel for connection of the line cord. The domestic version of the Generator will be shipped with a hospital grade line cord and the appropriate fuses. The international version of the Generator will be shipped with a 230 volt line cord and the appropriate fuses. A cable strain relief mechanism will be provided on the AC line cord. (Reference IEC 601-1 Sub-clause 57.4 and AAMI HF18 Sub-clause 4.2.5.5) The line cords shipped with the unit will be 5 meters long.

#### 11.6 Color Constraints and Requirements

The Generator will use approved VALLEYLAB pantone colors for chassis and cover. All indicators and displays will comply with the color specifications outlined in IEC 601-2-2 (2ed) Sub-clause 6.7 and AAMI HF18 Sub-clauses 4.2.7.2.

#### 11.7 Cooling

The Generator will be designed for natural convection cooling only.

#### 12.0 LABELING/PACKAGING:

##### 12.1 Labeling on Product

Product labeling will meet the standards and approvals listed in section 19, Voluntary Standards.

##### 12.2 Operation and Service Manuals

An English language service manual will be provided with each Generator. This service manual will provide minimum information about the installation and periodic safety checking required for the unit. It will not provide detailed servicing information since the labeling will indicate the unit may only be serviced by VALLEYLAB personnel.

The domestic model will also be shipped with an English operators (user) manual. The user manual will be translated into German, Spanish, French, and Italian for full CE/MDD marking. An international order for a Generator will include the Generator itself, and the correct user manual. In this manner each country can receive the unit and user manual it needs and no other.

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### 12.3 Symbols or Foreign Language Requirements

The Generator labeling will use International symbols. The international model will have only these symbols on the front panel. In the domestic model, the symbols will also be accompanied by English terms.

### 12.4 Training Materials

Training materials will be developed concurrently with product release.

### 12.5 Serial Number Label

A serial number label will be mounted on the rear panel. The Generator serial code will indicate AP and year of manufacture.

### 12.6 Safety Agency Approvals Label

A label will appear on the rear panel with the listing marks for the various safety agencies that the Generator is approved with. This will include the UL, cUL, TUV, and CE marks.

### 12.7 Packaging requirements

Each Generator will be shipped in its own package. The package will meet the needs outlined in section 13. Within that package will be the following:

- Generator (1)
- Service manual in 3 ring binder (1)
- Power cord (1)
- Adapter [see section 8.0] (1)
- The Generator will also include an English user manual in a 3 ring binder (1)
- Footswitches will be included in a System order
- Foreign language user manuals will be ordered separately.

### 12.8 Warranty

The unit will have a one year warranty similar to that of the Force FX.

### 13.0 STORAGE AND SHIPMENT REQUIREMENTS:

#### 13.1 Transport and Storage Conditions

Ambient temperature: -34 to +70 °C  
Relative humidity: 0 to 95% (non-condensing)  
Atmospheric pressure: 500 to 1060 millibars

(Reference IEC 601-1 Amend. 2 Sub-clause 10.1, AAMI HF18 Sub-clause 4.3.4, and OE Environmental Validation Protocol)

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### 13.2 Shock and Vibration

The Generator will be enclosed in a specially designed shipping package. The Generator within this package will survive the ISTA procedure 2A Preshipment Test Procedure as well as requirements outlined in the GP-094 ADDN 35 Test Procedure.

### 13.3 Storage Duration

The Generator can be stored indefinitely. The following statement should appear in the Service Manual: if the Generator is stored for over one year, the memory battery must be replaced and the Generator recalibrated.

### 13.4 Equilibration Time

If the Generator has been stored at a temperature outside of its specified operating temperature range it should be allowed to reach room temperature before being used. This time will be a minimum of one hour.

### 14.0 MANUFACTURING PROCESSES:

The Generator will be assembled using conventional processes already in use by VALLEYLAB. Several of the printed circuit boards will be mixed surface mount and through hole technology like that used in our microcontroller boards. These boards will be manufactured and tested by an outside vendor. The other PCB's will be assembled using our existing VALLEYLAB process. Mechanical assembly, final assembly, final test, and packaging will also use existing facilities and processes.

### 15.0 STERILIZATION AND REPROCESSING:

This product will be sold and used as non-sterile.

### 16.0 RELIABILITY:

The Generator will be designed to have a reliability comparable to that of the Force FX.

### 17.0 PRODUCT CARE, MAINTENANCE, AND SERVICE CONSIDERATIONS:

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### 17.1 Cleaning

The Generator shall be suitable for cleaning with a damp cloth and a mild cleaning solution or disinfectant.

### 17.2 Product Maintenance Requirements

It will be recommended that the Generator be inspected by qualified service personnel once a year.

### 17.3 Product Service

This product will not be serviceable by the customer. Service will be by authorized VALLEYLAB personnel only. Generator Field Calibration will be allowed to the end user.

### 18.0 STATUTORY AND REGULATORY REQUIREMENTS:

The Generator is classified as class 2 by the FDA. VALLEYLAB will submit a 510(k) to the FDA to provide for domestic release.

Two models of this device will be produced; a domestic model with English on the front panel labeling, and an international model with front panel symbols (no English).

The Generator will be designed to meet UL, cUL, TUV, and ASA test agency requirements, and will be submitted to these agencies prior to product launch. It will also meet IEC requirements and will be CE/MDD marked.

### 19.0 VOLUNTARY STANDARDS:

The following is a list of all applicable standards which have been referenced throughout this document:

- IEC 601-1 Medical electrical equipment - 2nd Ed. 1988 plus amendments 1 and 2
- IEC 601-1-2 Medical electrical equipment, Collateral Standard: Electromagnetic compatibility - Requirements and tests - 1st Ed. 1993-04
- IEC 601-2-2 Medical electrical equipment, Particular requirements for the safety of high frequency surgical equipment - 2nd Ed. 1991-09
- IEC 601-2-2 Medical electrical equipment, Particular requirements for the safety of high frequency surgical equipment - 3rd Ed. 1996-04 (draft)
- IEC 1000-4-1 Part 4: Testing and measurement techniques - Section 1: Overview of immunity tests. Basic EMC Publication. - 1st Ed. 1992
- IEC 1000-4-2 Part 4: Testing and measurement techniques - Section 2: Electrostatic discharge immunity test. Basic EMC Publication. - 1st Ed. 1995-01
- IEC 1000-4-3 Part 4: Testing and measurement techniques - Section 3: Radiated, radio-frequency, electromagnetic field immunity test.- 1st Ed. 1995-02
- IEC 1000-4-4 Part 4: Testing and measurement techniques - Section 4: Electrical fast transient/burst immunity test. Basic EMC publication - 1st Ed. 1995-01

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- IEC 1000-4-5 Part 4: Testing and measurement techniques - Section 5: Surge immunity tests. - 1st Ed. 1995
- ANSI/AAMI HF18 Electrosurgical devices - 1993
- CISPR 11 Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment - 2nd Ed. 1990-09
- UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety - 1st Ed. August 31, 1994
- ISTA procedure 2A Preshipment Test Procedure - April 1996

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**VALLEYLAB®**

**SOFTWARE REQUIREMENTS DOCUMENT**

**Revision 2**

**LigaSure SYSTEM**

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Software Requirements Document

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**SOFTWARE DEVELOPMENT PROCESS DESCRIPTION**

**LigaSure SYSTEM**

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## 1. Software Development Process

The software development process for the LigaSure system is partitioned as follows:

- Design Input Document
- Hazard Analysis
- Software Requirements Document
- Software Design
- Software Coding
- Code Reviews and Critical Module Testing
- System Integration and Validation Testing
- Certification and Acceptance
- Control and Maintenance

## 2. Design Input Document

The Design Input Document translates the customer requirements into the technical product specifications used for designing the software system.

## 3. Hazard Analysis

The Hazard Analysis is performed prior to development of the software design to assure that all hazards are addressed and that the appropriate hazard mitigation will be designed into the software system. A design review is held on the Hazard Analysis.

The Hazard Analysis is used in the development of the Software Requirements Document, the Software Test Plan and Procedure and to determine critical software functions.

## 4. Software Requirements Document

The Software Requirements Document is developed with input from the Design Input Document and the Hazard Analysis. This document contains all the details a software developer will need to create the software design.

## 5. Software Design

The software design is based on inputs from the Design Input Document, the Hazard Analysis and the Software Requirements Document. This phase is the act of designing the architecture, interfaces and algorithms of the software system. The Software Design depicts the hierarchical organization of the software, the interfaces between modules, and a description of what each module will do. This information is used to create a Software Design Document which will document the software system after coding and testing is complete.

## 6. Software Coding

Software coding is the process of creating or modifying the source code for software modules. It is an iterative process started after the initial Software Design is complete. Source code is written following good coding and documentation guidelines.

## 7. Code Reviews and Critical Module Testing

After a software routine is completed, it will be tested based on the following definitions:

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## **7.1 Code Reviews**

A code review is a visual inspection of the source code that verifies that no obvious anomalies exist and that the documentation and coding are correct and conform to good coding practices. All routines will have a code review.

## **7.2 Critical Module Testing**

Critical modules will receive extra testing attention due to their critical nature. The test method is determined by the test developer and may include but is not limited to black box, white box, path, emulation or simulation testing.

## **8. System Integration and Validation Testing**

System Integration and Validation Testing is the process of verifying software compliance with the requirements and verifying software correctness and consistency from a system level black box perspective. This testing is performed according to a written procedure based on the Design Input Document, the Software Requirements document and the Hazard Analysis.

## **9. Certification and Acceptance**

A certification statement is created at the end of this project stating that the software development process and supportive testing demonstrate that the functional software and system requirements were met.

## **10. Control and Maintenance**

### **10.1 Software Release**

The following is a list of documents that will be included with the Engineering Documentation System:

- Software Specification
- Hazard Analysis
- Source Code
- Software Test Plan
- Software Test Procedure
- Software Test Report
- Software Design Documentation
- Software Module Testing Documentation
- Compiled Output
- All tools, programs or computer structures required for complete compilation of the software environment.

### **10.2 Version Control**

The software will be developed using some form of version control to record and identify iterations of the software throughout the development process.

### **10.3 Anomaly Tracking**

The software will be developed using some form of anomaly tracking to record software anomalies and track their resolution.

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**SOFTWARE QUALITY ASSURANCE VALIDATION**

**LigaSure SYSTEM**

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## 1. Testing Tasks

The software verification and validation process consists of the following tasks:

1. Review preliminary Design Input Document
2. Review preliminary Software Requirements Document
3. Review preliminary Software Design
4. Perform Hazard Analysis
5. Perform Code Reviews
6. Develop Software System Integration and Validation Testing protocol
7. Perform testing per written protocol
8. Write System Integration and Validation Testing Report
9. Certify System

Task 1 through 4 have been completed. Tasks 6 through 9 will be completed before commercialization of the LigaSure Electrosurgical Generator. The following is a summary of the software test plan.

## 2. Testing Approach

The goal of the testing is to assure the unit is safe and meets its functional requirements. An outline of the testing plan is as follows:

### 2.1 Module Testing

A code review is a visual inspection of the source code that verifies that no obvious anomalies exist and that the documentation and coding are correct and conform to good coding practices. All routines will have a code review.

Critical modules will receive extra testing attention due to their critical nature. The test method is determined by the test developer and may include but is not limited to black box, white box, path, emulation or simulation testing.

### 2.2 Functional Based Testing

The system shall be tested against the Design Input Document, the Software Requirements Specification and the Hazard Analysis using a written protocol. A written report will document the testing results.

### 2.3 Hazard Based Testing

Each item identified as a software mitigation in the Hazard Analysis will be tested to assure that the hazard has been appropriately managed by the system.

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Software Verification Test Plan Rev 2

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**SOFTWARE VERIFICATION TEST PLAN**

**Revision 2**

**LigaSure SYSTEM**

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**Valleylab Ligasure™ Vessel Sealing System  
Software Certification Statement**

**Date:** May 30, 1998

The software development process defined in the Valleylab software development procedures was adhered to in the development of the software for the Valleylab Ligasure™ Vessel Sealing System. Testing to demonstrate that safety and efficacy requirements will be met will be completed before commercial distribution.



R. A. Scherschel  
Mgr. Reliability Engr.

5/30/98  
Date



R. Wham  
Sr. Engineer

5/30/98  
Date

**Valleylab LigaSure™ Vessel Sealing System**  
**Software Certification Statement**  
**Date: 5/29/98**

The software development process defined in the Valleylab software development procedures was adhered to in the development of the software for the Valleylab LigaSure™ Vessel Sealing System. Testing to demonstrate that safety and efficacy requirements will be met will be completed before commercial distribution of the device.



May 29, 1998

R.A. Scherschel  
Mgr. Reliability Engineering



May 29, 1998

R. Wham  
Sr. Engineer

**INTERIM REPORT**

**VALLEYLAB, INC.**

**STEVE BUYSSE**

**Study Objectives:**                    **Demonstrate Lumen Fusion**  
**Measure Lateral Thermal Damage from Fusion Site**

**Materials and Methods:**            **Vascular bundles were submitted in 10% buffered formalin. Every attempt was done to orient the vessels in a longitudinal plane. The vessels were processed for paraffin embedding and sectioning. Serial sections were placed on microscopic slides (n = 8-72/embedded specimen) and stained with hematoxylin and eosin stains and Weigert van Giesonn's elastin stain. The slides were reviewed and evaluated for 1) presence or absence of luminal fusion, 2) measureable histologic markers of thermal damage and 3) section orientation. Measurements of thermal damage were made using a calibrated ocular micrometer mounted in a Zeiss Axiophot Microscope using transmission polarizing optics.**

**Results:** **Eleven arteries and veins were longitudinally oriented and evaluable for fusion. Eight arteries and veins were appropriately sectioned to allow measurement of lateral spread of thermal damage. The boundary of partial birefringence loss and no loss in hematoxylin and eosin stained sections was the chosen quantifiable marker for thermal damage. This was measured from the point of luminal fusion in the fusion site. This is a relative measurement of thermal damage not a measurement of ultimate lethal thermal injury which is necrosis detectable at 3-4 days in surviving animals.**

**All vessels except one vein were fused with the fusion persisting through the whole fusion site. Thrombus was found in the upstream lumens of some arteries and veins with thrombus intermixed with venous valves in some cases. In one specimen, lymphatic channels were also fused with dilatation by accumulated fluid in the upstream lumen.**

**The fusion sites were generally uniform with intima to intima fusion in both arteries and veins. The internal elastic lamina was broken in some arterial fusion sites. The medial walls and the adventitia were uniformly thin in the fusion site. The walls of the one vein that did not fuse showed less severe thermal damage and were not thin. There was some molding of the wall at the site edge and thrombus was present in the narrowed, but not fused lumen.**

**In both arteries and veins, the fusion edges were molded and, not infrequently, water vapour vacuoles were present in the media just at the fusion site. No mural rupture with retraction of portions of the media into the vessel lumens were present in these fusions. No char or mural rupture due to arcing was seen. Compared to previous specimens formed during the development of this device, the fusion sites were very consistent in conformation.**

**The blood vessels in Sample 95-101 were not identified therefore could not be correlated to the designations 95-97, Gen#4 or to 98-101 Gen#2. The vessels were sectioned transversely and all were fused.**

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**Table**  
**In Vivo Dog Blood Vessel Fusion**

<b>Experimental # Histology #</b>	<b>Vessel Type</b>	<b>Fusion Present</b>	<b>Lateral Thermal Damage (mm)</b>
Sample 37, G5-LV550-R5	Splenic Bundle		
98VL 68A	Vein	Yes	0.6
98VL 68A	Artery	Yes	2.6
98VL 68B	Vein	Yes	1.2
Sample 42 LDS 50R5	Splenic		
98VL 69A	Artery (small)	Yes	1.9
98VL 69A	Artery (large)	Yes	2.7
98VL 69B	Vein	Yes	Not Measurable
98VL 69C	Artery	Yes	1.9
Sample 5: Seal 48 Heavy Fixed: Gap			
98VL 70	Artery	Yes	1.7
Sample 26 Fact 18	Mesentery		
98VL 71	Vein	Yes	Not Measurable
Sample 36 Fact 27, Histo #2	Splenic Bundle		
98VL 72 A	Vein	No	Not Measurable
98VL 72 B	Nerve		
98VL 72C	Artery	Yes	5

## MEMORANDUM

**TO:** Charlie Copperberg  
**FROM:** Steve Buysse *Buysse*  
**DATE:** 5/29/98  
**SUBJECT:** 510k bench tissue test results

### **PURPOSE:**

This memorandum summarizes the methods and results of the 510k bench tissue testing. The tests were performed according to the approved protocol "510k Tissue Tests for the LigaSure Standard and LigaSure Lap Instruments". The purpose of the 510k tissue tests were to demonstrate that the sealing capability of the LigaSure Standard™ and LigaSure Lap™ instruments are safe, effective and equivalent to other energy based products.

### **METHOD:**

Porcine kidneys with attached arteries were obtained from Longmont Packing. Dissection was performed to isolate the renal arteries. All vessels were categorized into three groups: small - <2.0 mm, medium - 2.0 to 4.0 mm and large - > 4.0 mm. Size was determined by placing the vessel flat over a finger and measuring the width of the vessel. Each instrument was used to seal 30 vessels, 10 for each vessel size category. The seals were performed in a random manner, alternating instruments and vessel size.

The instruments were operated according to manufacturer's instructions with a single activation of energy. The LigaSure Standard and LigaSure Lap instruments were operated with the LigaSure Prototype Vessel Sealing Generator. The Cabot Seitzinger Tripolar 10 mm and 5 mm Handset were used with Valleylab's Force 2 Generator. Ethicon's UltraCision Harmonic Scalpel generator was used with the LCS tip.

All seals were tested to their maximum burst strength using a syringe pump to pump water into the vessel at a rate of 50 ml/hr. The burst strength was recorded in mmHg using a pressure transducer.

### **RESULTS**

All data was analyzed by SynchroStat Systems Corporation, an ASQ certified statistician. Analysis results are presented as the probability of a seal having a burst strength greater than 360 mmHg. Also listed is the percent of the data collected that had burst strengths above 360 mmHg. The probabilities were determined using Statistical Analysis System (SAS), a Gaussian theory probability test/hypothesis test. Table 1 lists the results by instrument, Table 2 list the results by instrument and vessel category.

Table 1: Burst Strength results - sorted by instrument

Instrument	Sample Size	Probability of a seal above 360 mmHg	Percent of data above 360 mmHg
LigaSure Standard	30	0.9194	100
LigaSure Lap	41	0.8678	93
UltraCision	30	0.4929	33
Cabot Seitzinger	30	0.8128	90
Tripolar 10 mm			
Cabot Seitzinger	30	0.4562	47
Tripolar 5 mm			

**Table 2: Burst Strength results - sorted by instrument and vessel size category**

Instrument	Vessel Size category	Sample Size	Mean Burst Pressure (mmHg)	Standard Deviation	Probability of a seal above 360 mmHg	Percent of data above 360 mmHg
LigaSure Standard	large	13	1423	803.3	0.9072	100
LigaSure Lap	large	21	1006	770.4	0.7990	86
UltraCision	large	11	21	47.69	0.0000	0
Cabot Seitzinger	large	16	467	482.0	0.5884	56
Tripolar 10mm						
Cabot Seitzinger	large	10	227	254.6	0.3000	40
Tripolar 5 mm						
LigaSure Standard	medium	10	1434	547.3	0.9752	100
LigaSure Lap	medium	10	1069	448.6	0.9431	100
UltraCision	medium	9	225	194.2	0.2444	33
Cabot Seitzinger	medium	10	1424	983.9	0.8603	100
Tripolar 10mm						
Cabot Seitzinger	medium	10	444	198	0.6642	60
Tripolar 5 mm						
LigaSure Standard	small	10	843	291.5	0.9214	100
LigaSure Lap	small	10	1062	318.0	0.9864	100
UltraCision	small	10	825	699.1	0.7471	70
Cabot Seitzinger	small	10	943	246.4	0.9912	100
Tripolar 10mm						
Cabot Seitzinger	small	10	394	268	0.4463	40
Tripolar 5 mm						

The LigaSure Standard prototype instrument had an overall probability of producing burst strengths above 360 mmHg of 0.9194. The probability rose to 0.9752 and 0.9514 for medium and small vessels respectively. The LigaSure Lap had an overall probability of 0.8678 of producing burst strengths above 360 mmHg. This probability rose to 0.9431 for medium vessels and 0.9864 for small vessels. The Cabot Seitzinger Tripolar's 10 mm probability was 0.8128 overall and decreased to 0.5884 for large vessels. UltraCision's probability of burst strengths above 360 mmHg was only 0.4929 with zero probability on large vessels and a 0.2444 probability on medium sized vessels.

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**Table 3: 510K tissue test results sorted by instrument and vessel size category-small, medium, large**

Instrument	Data	Vessel Category			All
		Large	Medium	Small	
LigaSure Standard	Sample Size	13	10	10	33
	Average of Burst Pressure	1423	1434	843	1251
	StdDev of Burst Pressure	803.3	547.3	291.5	651.6
	Min of Burst Pressure	474	665	397	397
	Max of Burst Pressure	3392	2514	1391	3392
	Average of Vessel Size	5.7	3.0	1.8	3.7
	Average of Application Time	5.2	4.1	3.4	4.3
LigaSure Lap	Average of Thermal Spread	3.1	1.8	1.1	2.1
	Sample Size	21	10	10	33
	Average of Burst Pressure	1006	1069	1062	1036
	StdDev of Burst Pressure	770.4	448.6	318.0	596.5
	Min of Burst Pressure	0	541	472	149
	Max of Burst Pressure	3313	2012	1724	3402
	Average of Vessel Size	5.2	2.9	1.5	3.4
UltraCision	Average of Application Time	6.7	4.6	4.5	5.2
	Average of Thermal Spread	1.8	1.6	1.0	1.5
	Sample Size	11	9	10	30
	Average of Burst Pressure	21	226	825	351
	StdDev of Burst Pressure	47.7	194.2	699.1	535.3
	Min of Burst Pressure	130	554	2270	2270
	Max of Burst Pressure	0	0	0	0
Cabot Seitzinger Tripolar 5 mm	Average of Vessel Size	5.0	2.7	1.5	3.2
	Average of Application Time	12.9	9.3	6.8	9.8
	Average of Thermal Spread	2.6	2.0	1.3	2.0
	Sample Size	10	10	10	30
	Average of Burst Pressure	227	444	394	355
	StdDev of Burst Pressure	254.6	198.1	267.8	252.0
	Min of Burst Pressure	0	33	116	0
Cabot Seitzinger Tripolar 10mm	Max of Burst Pressure	712	659	940	940
	Average of Vessel Size	5.1	3.1	1.7	3.3
	Average of Application Time	4.5	3.4	2.6	3.5
	Average of Thermal Spread	3.1	2.4	1.4	2.3
	Sample Size	16	10	10	36
	Average of Burst Pressure	468	1424	944	866
	StdDev of Burst Pressure	482.0	983.9	246.4	726.2
Cabot Seitzinger Tripolar 10mm	Min of Burst Pressure	1578	3396	1283	3396
	Max of Burst Pressure	0	585	415	0
	Average of Vessel Size	5.8	3.2	1.7	3.9
	Average of Application Time	7.2	5.6	4.0	5.9
	Average of Thermal Spread	3.7	2.9	1.7	3.0

The LigaSure Standard and LigaSure Lap both had average burst strengths above 1000 mmHg. The Cabot Seitzinger Tripolar 10 mm, Cabot Seitzinger Tripolar 5 mm and the UltraCision had average burst strengths of 866 , 355 and 351 mmHg respectively.

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The LigaSure Standard did not have any burst strengths below 360 mmHg while the LigaSure Lap had only 3 burst strengths below 360 mmHg. Two of these values were above 300 mmHg, the third value had a 0 mmHg burst strength. The Cabot Seitzinger Tripolar 10 mm had 7 seals below 360 mmHg with 4 seals having a burst strength of 0 mmHg. The Cabot Seitzinger Tripolar 5 mm had 16 seals below 360 mmHg with 4 seals having a burst strength of 0 mmHg. The UltraCision had 12 seals with 0 mmHg burst strength for 20 seals below 360 mmHg.

The LigaSure Standard and LigaSure Lap maintained high burst strengths of 1423 and 1006 mmHg respectively for large vessels. However the burst strength of large vessels for the Cabot Seitzinger Tripolar 10 mm and 5 mm, dropped to 468 and 277 mmHg respectively and the UltraCision dropped to 21 mmHg.

### **Conclusions**

The LigaSure Standard had an average burst strength of 1251 mmHg, 30% higher than the Cabot Seitzinger Tripolar 10 mm and 72% higher than the Cabot Seitzinger Tripolar 5 mm and the UltraCision. The average burst strength of the LigaSure Lap was 1035 mmHg, 16% higher than the Cabot Seitzinger Tripolar 10 mm and 66% higher than the Cabot Seitzinger Tripolar 5 mm and the UltraCision. The probabilities that the LigaSure Standard and LigaSure Lap will produce a seal with a burst strength of 360 mmHg or higher is 0.9194 and 0.8678 respectively.

The LigaSure Standard and LigaSure Lap instruments effectively seal vessels up to 7.0mm in size producing seals exceeding burst strengths of 360 mmHg. Both instruments have higher average burst strengths and higher probable burst strengths than the Cabot Seitzinger Tripolar 10 mm, the Cabot Seitzinger Tripolar 5 mm and the UltraCision verifying that the LigaSure Standard and LigaSure Lap are more than equivalent

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**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION  
VALLEYLAB LIGASURE™ VESSEL SEALING SYSTEM**

**I. Submitter Information**

Valleylab Inc  
a division of United States Surgical Corporation  
5920 Longbow Drive  
Boulder, Colorado 80301  
Contact: Charles M. Copperberg  
Telephone No.: 303-530-6343

Date Summary Prepared: 05/27/98

**II. Name of Device**

Proprietary Name: LigaSure™ Vessel Sealing System including the LigaSure™ Vessel Sealing Generator and LigaSure™ Open and Laparoscopic Instruments

Common or Usual Name: Bipolar Electrosurgical Generator with bipolar electrosurgical open and laparoscopic instruments

Classification Name: CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories and 21 CFR 884.4120 Gynecologic Electrocautery and Accessories

**III. Predicate Devices**

The LigaSure™ Vessel Sealing Generator is a bipolar generator which is substantially equivalent to the following Valleylab electrosurgical generators: Force FX (K944602), Force 300 (K953195) and NS2000 (K946177).

The LigaSure™ Open and Laparoscopic Instruments are substantially equivalent to the Cabot Seitzinger Tripolar Forceps, the Cabot Bipolar Cutting Forceps (K932293 and K946109) and the Storz Bipolar Forceps (K960009). All of these devices perform the coagulation of tissue via bipolar RF energy applied through the electrodes of the devices.

**IV. Device Description**

The LigaSure™ Vessel Sealing Generator is an isolated, microprocessor based, bipolar only electrosurgical generator which incorporates three bipolar modes; standard, macro and vessel sealing. The generator will accept standard bipolar devices. In addition, the generator will also accept dedicated LigaSure™ Open and Laparoscopic Instruments for use in vessel sealing.

The LigaSure™ Open instruments are reusable forceps type devices with "snap-in" single use, disposable electrodes which are placed in the jaws of the devices. The LigaSure™ laparoscopic

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instrument is a sterile, single use device for use in grasping and vessel sealing in laparoscopic procedures. The device outer diameter is 5 mm and the working length is approximately 32 cms.

The system creates vessel ligation by the application of bipolar electrosurgical RF energy (coagulation/desiccation) to vessel tissue or vascular bundles interposed between the electrodes of the device.

#### **V. Intended Use**

The LigaSure™ Vessel Sealing System is intended for use in general, laparoscopic, and gynecologic procedures where ligation of vessels is desired and as an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

Indications for use for this type of ligation include general, laparoscopic and gynecological procedures such as urological, cardiovascular, thoracic, plastic and reconstructive, bowel resections, hysterectomies (LAVH and abdominal) choleystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

#### **VI. Summary of Technological Characteristics**

The LigaSure™ Vessel Sealing generator and instruments have the same basic technological characteristics as the predicate devices noted above. The LigaSure™ generator provides bipolar RF energy to bipolar devices for coagulation/desiccation of vessels.

#### **VII. Performance Data**

Preclinical laboratory (acute and chronic studies) and performance testing were performed to ensure the devices functioned as intended and met design specification. Sufficient data was obtained to show the LigaSure™ Vessel Sealing system was equivalent to or better than the predicate devices and meet safety and effectiveness criteria.

**Generator Comparison Chart**  
**LigaSure™ Vessel Sealing Generator**

	LS-1000	LS-2000	LS-3000	LS-2000
Output Configuration	Isolated	Isolated	Isolated	Isolated
Bipolar Modes	Standard Bipolar Macro Bipolar Vessel Sealing	Low Bipolar Standard Bipolar Macro Bipolar	Standard Bipolar	Low Bipolar Macro (High) Bipolar
Operating Range Line Voltage	85-140 (110V) 170-264 (220V)	85-140 (110V) 170-264 (220V)	85-140 (110V) 170-280 (220V)	85-140 (110V) 170-264 (220V)
AC Line Current	Bipolar/Macro - 3.0A max Vessel Sealing - 5.0A max	Bipolar - 2.0A max	Bipolar - 2.0A max	Bipolar - 2.0A max
Maximum Power	Bipolar/Macro - 95 Vessel Sealing - 150	Monopolar Cut - 300 Monopolar Coag - 120 Bipolar - 70	Monopolar Cut - 300 Monopolar Coag - 120 Bipolar - 70	Bipolar only - 70
Bipolar Waveform	470 Khz Sinusoidal	470 Khz Sinusoidal	470 Khz Sinusoidal	470 Khz Sinusoidal
Automatic control of output power	Yes - Vessel Sealing and Bipolar modes	Yes - All Bipolar modes and Monopolar cut	Yes - All Bipolar and Monopolar cut modes and low Coag modes.	Yes
Dosage Error Limit	Yes	Yes	Yes	Yes
Foot Switch Operated	Yes	Yes	Yes	Yes

GenComp.Doc

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Records processed under FOIA Request # 2015-6754, Released by CDRH on 09-09-2015

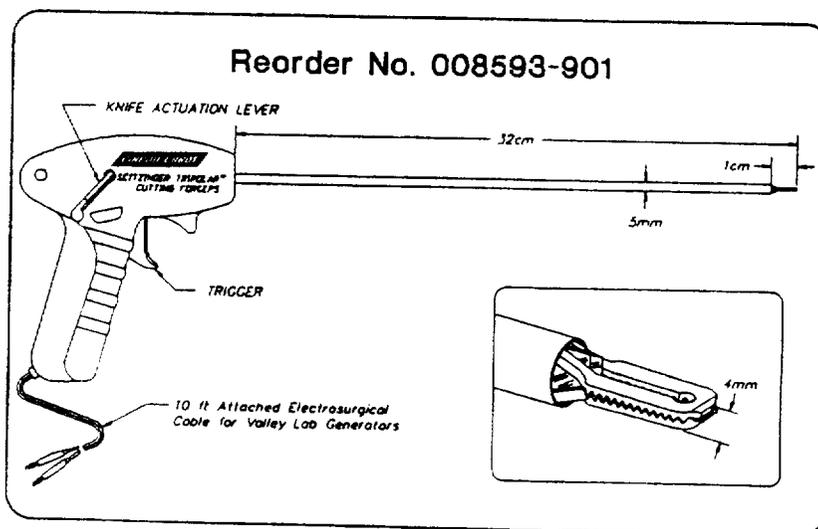
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## 5mm SEITZINGER TRIPOLAR™ CUTTING FORCEPS

### Instructions for Use



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## INDICATIONS FOR USE

The SEITZINGER TRIPOLAR™ CUTTING FORCEPS is used during operative laparoscopic procedures for bipolar coagulation of tissue followed by mechanical cutting of the tissue. See operators manual of your laparoscope for specific indications for use of operative laparoscopy. Typical indications for laparoscopic bipolar coagulation followed by cutting include: Laparoscopic Assisted Vaginal Hysterectomy (LAVH)<sup>1</sup>, Oophorectomy<sup>2,3</sup>, Laparoscopic myomectomy, Uterosacral nerve ablation, Colectomy, Nissen fundoplication, Adhesiolysis, Appendectomy<sup>4,5</sup>, Laparoscopic supra cervical hysterectomy<sup>6</sup>, Laparoscopic cholecystectomy<sup>7</sup>, Salpingectomy<sup>8</sup>. SEE LIST OF REFERENCES ON BACK PAGE.

## CAUTIONS

Federal law restricts this device to sale by or on order of a physician. This device should not be used without proper training.

The efficacy of the SEITZINGER TRIPOLAR™ CUTTING FORCEPS for the indication of contraceptive tubal coagulation (permanent female sterilization) has not been evaluated and is unknown.

The design of the SEITZINGER TRIPOLAR™ CUTTING FORCEPS is significantly different from bipolar designs that are marketed for the indication of contraceptive tubal coagulation. The design differences may affect the efficacy of the procedure and failure rates may not be comparable.

Do not depress the knife actuation levers unless cutting is desired. This instrument contains a surgically sharp knife blade. Actuation of either lever will expose the knife blade.

This instrument can deliver an electrical shock or burn when connected to active electro-surgical unit.

Do not extend the knife blade during electro-surgical coagulation.

## PRECAUTIONS

Laparoscopic Surgical Procedures with the SEITZINGER TRIPOLAR™ CUTTING FORCEPS should be performed only by persons with adequate training and preparation.

Know the specific instrument being used. Each instrument is different in the nuances of motion and feel. Such knowledge is essential to avoid hazards to the patient, the operator and the instrument.

Visually examine the shipping carton and instrument for signs of shipping damage. Any breakage or other apparent damage should be noted, the evidence retained, the carrier or shipping agency notified.

If these instruments or any accessories are damaged, do not use them. The damaged instruments and/or accessories should be returned to Cabot Medical for replacement.

Use the SEITZINGER TRIPOLAR™ CUTTING FORCEPS with a bipolar electro-surgical generator. The SEITZINGER TRIPOLAR™ CUTTING FORCEPS may be used with bipolar generators at up to 40 watts of electro-surgical power.

Published medical literature indicates the use of a cut wave form enhances surgical performance and safety when utilizing a bipolar modality<sup>a,b,c,d</sup>.

Consult the operating manual for light sources, electro-surgical units, and other ancillary devices for appropriate instructions and cautions prior to their use with these instruments. When endoscopic instruments and accessories from different manufacturers are used together, verify that any electrical isolation or grounding is not violated. Before using, inspect all electrical connections.

All personnel should fully understand the naand use of radio frequency (RF) currents before performing electro-surgical procedures. This understanding is essential to avoid shock and burn hazards to both patient and operator and damage to instruments.

If the operating physician feels a higher than normal electrosurgical unit power setting might be required during any electrosurgical procedure, STOP. Do not increase the power setting until all instrument, connections, cables, and patient contacts have been re-checked and appear fault-free. Increase power settings only in small increments, checking resulting change after each increase.

**>> DO NOT EXCEED 40 WATTS<<**

Use surgical glove designated by their manufacturer for electrosurgical procedures. The use of other gloves can result in burns or shocks.

**BEFORE USING THE SEITZINGER TRIPOLAR™ CUTTING FORCEPS CONFIRM THAT:**

The cable connector to the SEITZINGER TRIPOLAR™ CUTTING FORCEPS is connected to the appropriate output of the electrosurgical bipolar generator.

All electrical connections are tight, clean, and dry.

The bipolar electrosurgical generator is set at the desired power level and is ready for operation.

**TYPICAL INSTRUCTIONS FOR USE:**

Under direct vision, a secondary 5mm trocar and cannula is inserted into the peritoneal cavity. The trocar is removed from the cannula and the SEITZINGER TRIPOLAR™ CUTTING FORCEPS is placed through the cannula into the peritoneal cavity. To open the forceps jaws the operator squeezes the trigger with the fingers and the thumb placed comfortably on the hand grip. The tissue to be coagulated is grasped between the opened forcep jaws. **DO NOT GRASP TISSUE BEYOND SERRATED TEETH.** The jaws are closed over the tissue by relaxing pressure on the trigger. Before activating the electrosurgical generator, the physician must ensure that the desired tissue is grasped between the jaws and the forceps are only in contact with the tissue to be coagulated.

Activate the bipolar electrosurgical generator by depressing the foot pedal. After the proper amount of coagulation has occurred, the electrosurgical generator is deactivated by removing pressure from the foot pedal.

NOTE: With the bipolar technique, coagulation is limited to a small area surrounding the forceps jaws. If coagulation over a large area is desired, the operator must re-grasp the structure and repeat the above procedure. The amount of coagulation is self limiting. As the structure is coagulated, its resistance to the flow of electrosurgical high frequency current increases to the point where the current flow becomes ineffective for further coagulation, and therefore, limits the amount of tissue destruction.

After coagulation of the tissue, the tissue between the jaws may be cut using the integral blade of the forceps. The knife blade is actuated by advancing the blade through the coagulated tissue using your thumb. Only the coagulated tissue within the forceps tongs may be cut.

Retract the cutting blade and release the forceps tongs from the coagulated tissue. If further tissue coagulation is desired repeat the procedure as described above.

Following completion of the surgery remove the SEITZINGER TRIPOLAR™ CUTTING FORCEPS from the cannula and dispose

**>>DO NOT REUSE<<**

<sup>a</sup> Valleylab, Inc., Force 1B, Force2, Force 4B Electrosurgical Generators Instruction Manual.

<sup>b</sup> Nduka, Charles C., et al. Cause and Prevention of Electrosurgical Injuries in Laparoscopy, Journal of American Collage of Surgeons, Aug. 1994, v.179.

<sup>c</sup> Tucker, Robert D., et al., Bipolar Electrosurgical Sphincterotomy, Gastrointestinal Endoscopy, vol.38, no.2, 1992.

<sup>d</sup> Soderstrom. R.M., Electrical Safety in Laparoscopy, Endoscopy in Gynecology, AAGL, 1978.

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- <sup>8</sup> Nezhat F, Winer WK, Nezhat C: Salpingectomy via laparoscopy: A new surgical approach. *J Laparoendosc Surg.* 1991;1:91-95.

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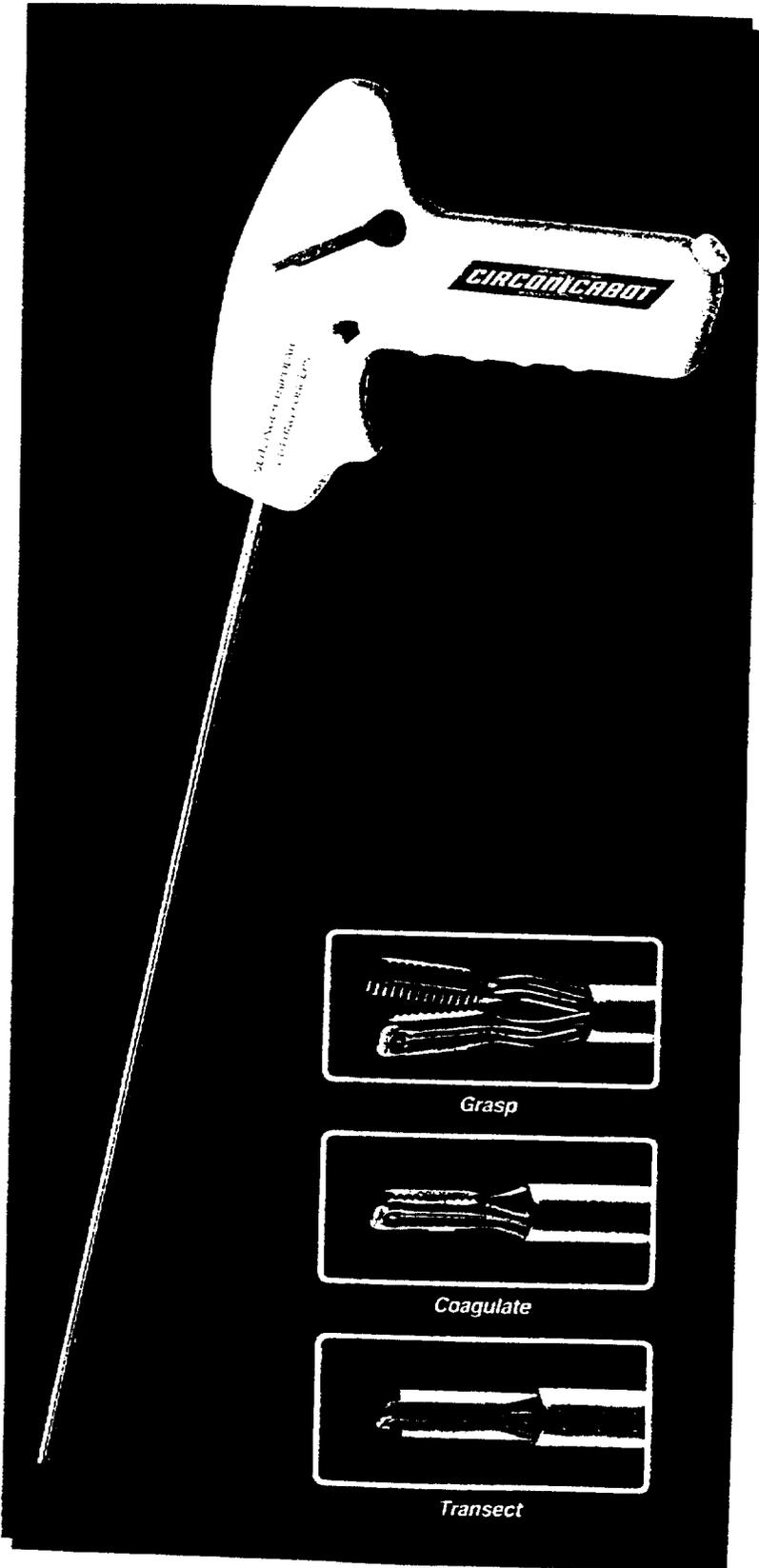
TRIPOLAR™ is a registered trademark of Circon Corporation.

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■ Laparoscopy

# 5 mm Seitzinger Tripolar<sup>®</sup> Cutting Forceps



## Bipolar Safe, Surgically Efficient, Cost Effective

- **Now Available in 5 mm**
  - Smaller incision
  - Reduced risk of incisional hernia
- **Multifunctional Instrument**
  - Grasp, coagulate, and transect with a single instrument
  - No instrument exchange needed, decreasing surgical time
- **Bipolar Modality**
  - Increases patient safety by eliminating problems associated with monopolar
- **Cost Effective**
  - Eliminates the need for costly linear stapling devices in some procedures
  - Reduces O.R. and anesthesia time, decreasing related costs



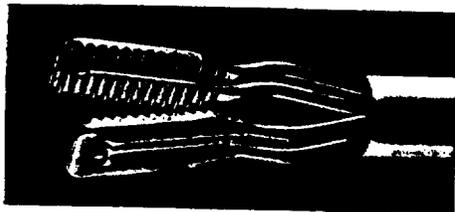
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29h

# 5 mm Seitzinger Tripolar® Cutting Forceps

One Instrument, One Insertion, Multiple Functions!

**Grasp**



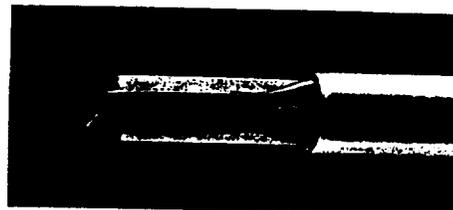
Trigger-activated forceps jaws hold tissue firmly under tension.

**Coagulate**



Bipolar current safely coagulates the tissue.

**Transect**



Thumb lever activates a guillotine blade for repeated precise cuts.

■ **5 mm Diameter for Increased Precision and Control**

The Seitzinger Tripolar Cutting Forceps is one of the most revolutionary endoscopic instruments to date. This technology enables the surgeon to perform such advanced laparoscopic procedures as LAVH and Nissen fundoplication faster, safer, and less expensively than ever before. Now it's available with a 5 mm diameter for delicate tissue.

■ **Surgical Efficiency**

The Seitzinger Tripolar Cutting Forceps combines surgical efficiency, the safety of bipolar electrocautery, and cost effectiveness in a single, multifunctional instrument reducing procedure time, patient anesthesia time, and O.R. time. And, the use of bipolar current eliminates the problem of capacitive coupling as well as the need for grounding pads.

■ **Ideally Suited for Many Procedures**

The 5 mm instrument is simple, effective, and ideally suited for LAVH, myomectomy, adhesiolysis, uterosacral nerve ablation, oophorectomy, Nissen fundoplication, and colectomy.

For more information call (800) 325-7107

■ **Faster, Safer, and More Cost Effective Than Linear Stapling**

In some procedures the Seitzinger Tripolar Cutting Forceps eliminates the need to continually change staple cartridges as well as minimizes the risk of bleeding and the high disposable cost associated with the linear stapling technique. In appropriate cases the unique design of the Seitzinger Tripolar Cutting Forceps will result in improved surgical efficiency, increased patient safety, and cost effectiveness that is not available in linear stapling.

**SEITZINGER 5 MM TRIPOLAR CUTTING FORCEPS SPECIFICATIONS**

<b>Catalog No.:</b>	<b>008593-901</b>
<b>Cannula Outside Diameter:</b>	<b>5 mm</b>
<b>Working Length:</b>	<b>32 cm</b>

**ORDERING INFORMATION**

Catalog No.	Description
008593-901*	Seitzinger Tripolar® Cutting Forceps, 5 mm, 32 cm (5/pkg)
006689-901*	Seitzinger Tripolar® Cutting Forceps, 10 mm, 32 cm (5/pkg)
006689-903*	Seitzinger Tripolar® Cutting Forceps with Rotation, 10 mm, 32 cm (5/pkg)
008140-901*	Seitzinger Tripolar® Cutting Forceps for Open Procedures, 10 mm, 15 cm (5/pkg)
006679-901	Storz / Wolf / Martin Cable Connectors
006680-901	Electro-Gyne Cable Connectors

\* Supplied sterile, single-use, disposable.

CIRCON CABOT

3037 Mount Pleasant Street • Racine, WI 53404-1594 USA  
 (800) 325-7107 or (414) 639-7205 • Fax: (414) 981-4038

CIRCON ACMI  
 300 Stillwater Avenue  
 Stamford, CT 06902-3695  
 USA

Fax: (203) 328-8618  
 Ph: (800) 325-7107  
 (203) 357-8300

CIRCON GmbH  
 Fax: +49 89 612 90766  
 Ph: +49 89 612 9070

CIRCON SA  
 Fax: +33 1 691 10020  
 Ph: +33 1 691 12150

CIRCON CANADA INC.  
 Fax: (203) 328-8618  
 Ph: (800) 325-7107  
 (203) 357-8300

**CIRCON CABOT**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV

279  
 345

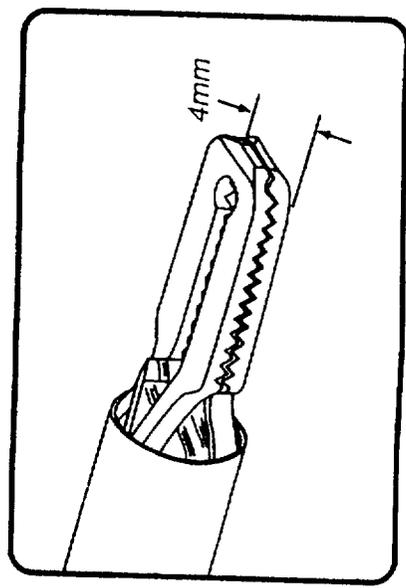
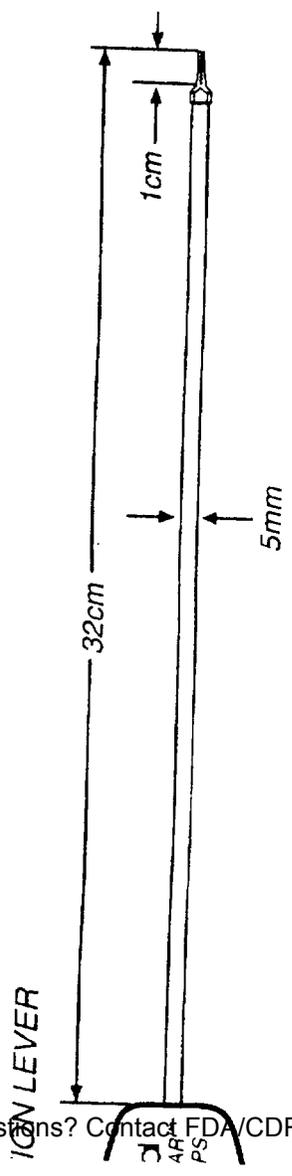
# 5mm SEITZ TRIPOLAR™

LOT NO. 310086L

**INSTRUCTIONS:**

- \* UNDER DIRECT VISION, OPEN FORCEPS JAWS BY SQUEEZING TRIGGER ON HAND GRIP.
- \* PLACE THE ANATOMICAL STRUCTURE TO BE COAGULATED BETWEEN THE OPENED FORCEPS JAWS. DO NOT GRASP TISSUE BEYOND SERRATED TEETH.
- \* CLOSE JAWS OVER TISSUE BY RELAXING PRESSURE ON TRIGGER.
- \* ENSURE FORCEPS JAWS ARE IN CONTACT ONLY WITH THE ANATOMICAL STRUCTURE TO BE COAGULATED.
- \* ACTIVATE ELECTROSURGICAL UNIT AS SPECIFIED BY MANUFACTURER RECOMMENDATION.
- \* AFTER PROPER AMOUNT OF COAGULATION, TISSUE CUTTING IS ACCOMPLISHED BY DEPRESSING KNIFE ACTUATION LEVER.

Reorder No. 008593-901



Attached Electrosurgical  
for Valley Lab Generators

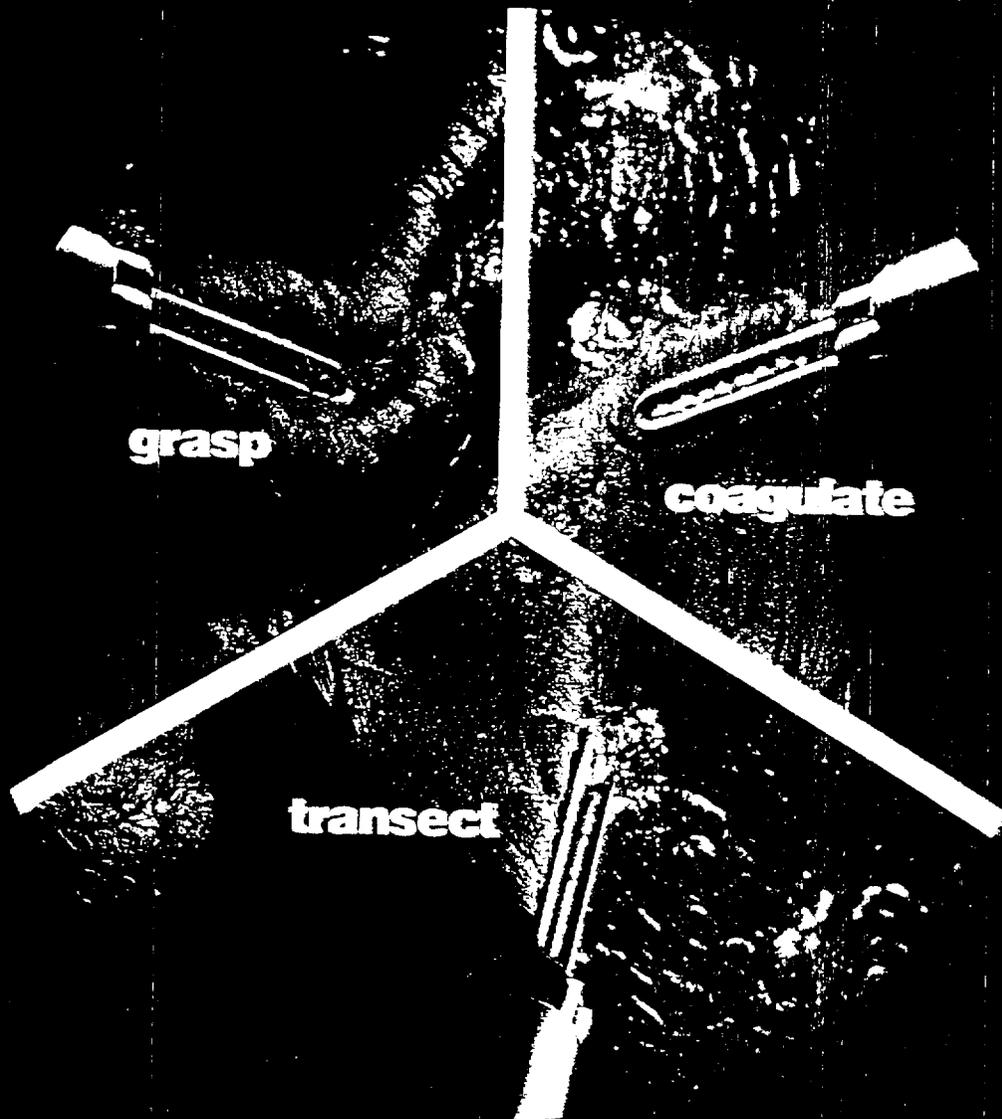
**CAUTION:** This instrument contains a surgically sharp knife blade. Actuation of either lever

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cabot medical

# *Uniquely* **TRIPOLAR™**

**Surgically Efficient  
Bipolar Safe  
Reduced Cost per Procedure**



**One instrument, one insertion, multiple functions!**

*Seitzinger*  
***Tripolar™ Cutting Forceps***

Optional rotating jaws provide improved control and comfort. Easy grip rotation adjustment wheel (on handle) provides for rotation of the distal end.

Thumb lever allows for smooth blade activation with same hand.

Ergonomically designed pistol grip provides stability and comfort. Broad trigger and wide thumb levers on both sides of handle allow for smooth, precise operation with either hand.



Finger-activated trigger opens and closes forceps jaws. Self-adjusting blade stop allows maximum blade extension within opening of jaws.

Extra-long 10-foot cable provides easy attachment to electrocautery generator.



Bipolar cable connects to generator for electrocautery coagulation. Fits Valleylab (shown to left), Aspen, Bard, Codman, Burcher.

# Performing laparoscopic surgery just got easier, faster, and cheaper.

The Seitzinger Tripolar™ Cutting Forceps presents a dramatic advancement in the endoscopy field. This new product was designed to improve the safety and efficiency of procedures, reduce the per-procedure cost and make the most complicated procedures easier to perform.

The Seitzinger Tripolar™ Cutting Forceps atraumatically grasps and holds the tissue during bipolar electro-surgical coagulation. The forceps jaws then hold the tissue firmly under tension allowing the guillotine blade to make precise cuts. And the optional rotating jaws provide for increased surgeon control and comfort. The instrument is simple, effective and ideally suited for complex and costly LAVH procedures, reducing the per-procedure cost by as much as \$700 in disposables when compared to stapling methods.

*(Data on file at Cabot Medical.)*

## No Need to Change Instruments

With the Seitzinger Tripolar™ Cutting Forceps, you can perform multiple functions with a single instrument — in a single insertion. Spend less time inserting and withdrawing instruments. Reduce your procedure time, patient anesthesia time and O.R. time.

## Eliminate the Cost and Concern of Staples

This easy-grasp-coagulate-transect method provides a cost-effective alternative to stapling/cutting. You will dramatically reduce procedure time, eliminate the cost of staple cartridges and eliminate concerns about misfired staples and possible staple migration.

## Improve Patient Safety With Bipolar Current

The Seitzinger Tripolar™ Cutting Forceps uses bipolar current to safely coagulate tissue. This proven method eliminates the problem of capacitive coupling. Bipolar replaces monopolar and associated grounding pads for improved patient safety.

## One Instrument for Multiple Procedures

Use this uniquely designed instrument for a variety of advanced laparoscopic procedures including:

- LAVH
- uterosacral nerve ablation
- adhesiolysis
- Nissen fundoplication
- oophorectomy
- colectomy
- myomectomy

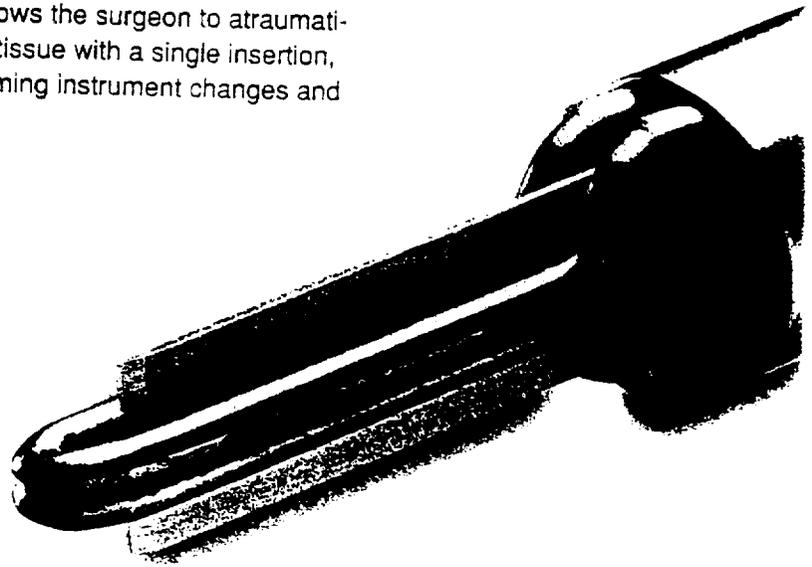
*Seitzinger*  
**Tripolar™ Cutting Forceps**



*Seitzinger*  
*Tripolar<sup>TM</sup> Cutting Forceps*

- Grasp, coagulate, and transect**
- ... one instrument**
- ... one insertion**
- ... multiple functions**

With the Seitzinger Tripolar<sup>TM</sup> Cutting Forceps, Cabot Medical introduces one of the most exciting endoscopic instruments to date. This multiple-function instrument allows the surgeon to atraumatically grasp, coagulate and transect tissue with a single insertion, eliminating the need for time-consuming instrument changes and costly staple cartridges.



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U.S. Food and Drug Administration

# DETAILED INFORMATION

**Device Classification Name:** UNIT, ELECTROSURGICAL, ENDOSCOPIC (WITH OR WITHOUT ACCESSORIES)  
**Regulation Number:** 876.4300  
**510(k) Number:** K946109  
**Device Name:** CABOT MEDICAL REUSABLE BIPOLAR CUTTING FORCEPS  
**Applicant:** CABOT MEDICAL CORP.  
 2021 CABOT BOULEVARD WEST  
 LANGHORNE, PA 19047  
**Contact:** TODD J POLK  
**Product Code:** KNS  
**Date Received:** 12/14/94  
**Decision Date:** 11/21/95  
**Decision:** Substantially Equivalent  
**Classification Advisory Committee:** Gastroenterology  
**Review Advisory Committee:** Obstetrics/Gynecology  
**Statement/Summary/Purged Indicator:** Summary/purged 510(k)  
**Summary/Approval Letter:** SUMMARY

Return For Another Search

CDRH Home Page

FDA HOME PAGE

COMMENTS

(Database Updated April 6, 1998)



Cabot Medical Bipolar Cutting Forceps

Summary of Safety and Effectiveness

JUL 27 1994

K932293

1. Name and Address of Applicant  
Cabot Medical Corporation  
2021 Cabot Boulevard West  
Langhorne, PA 19047  
TEL (215) 752-8300  
Contact: Todd J. Polk  
Vice President - Regulatory Affairs

2. Device Name and Classification

CFR Reference Number and Final Classification  
Unit, Electrosurgical, Endoscopic 876.4300

Classification Name and Panel Classification Number:  
Unit, Electrosurgical, Endoscopic 78KNS

Common/Usual Name:  
Bipolar Forceps

Trade/Proprietary Name:  
Cabot Medical *Bipolar Cutting Forceps*

FDA Classification  
Class II

3. Identification of Predicate Devices

Laparoscopic bipolar electrosurgical coagulation of the fallopian tube was first described by Rioux in 1974 (Rioux J-E, Cloutier D: A new bipolar instrument for laparoscopic tubal sterilization. Am J Obstet Gynecol 119:737, 1974). In a book published in 1976 (Rioux J-E, Cloutier D: Bipolar Electrosurgery for Laparoscopic Sterilization. In: Sciarra JJ, Drougemueller W, Speidel JJ. Advances in Female Sterilization Techniques. Hagerstown, Harper & Row, 1976). Rioux further described the clinical experience of the then available laparoscopic bipolar forceps (the Rioux, Corson [Cameron-Miller], Kleppinger [Richard Wolf Corporation] and Eder Bipolar Forceps). Corson reported his experience on the use of his Bipolar Cutting Forceps for tubal sterilization in 1976 (Corson SL: Two new laparoscopic instruments: Bipolar sterilizing forceps and uterine manipulator. Am J Obstet Gynecol 124:434-436, 1976). Kleppinger described use of his bipolar forceps for other uses in 1977 (Kleppinger RK: Ancillary uses of bipolar forceps. J Repro Med 18:254, 1977).

The Cabot Medical Bipolar Cutting Forceps is substantially equivalent to the following laparoscopic bipolar instruments which were available or were found to be substantially equivalent to devices marketed prior to May 28, 1976: 1) Cameron Miller Corson Bipolar Forceps, 2) Richard Wolf Corporation Kleppinger Bipolar Forceps, 3) Karl Storz Endoscopy-America, Inc. Bipolar Grasping Forceps, Insulated and 4) the Eder Instrument Company, Inc. Micro-Coagulation Forceps for a Bi-Polar Technique, 5mm.

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Cabot Medical Bipolar Cutting Forceps  
Summary of Safety and Effectiveness

4. Device Description:

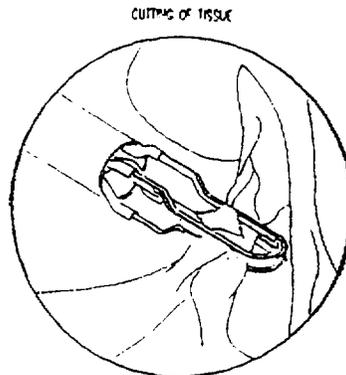
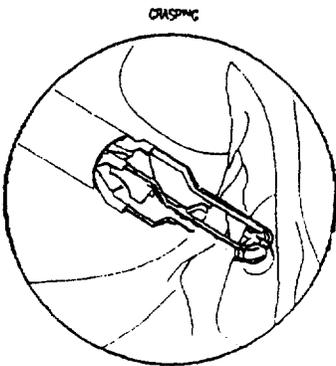
The *Cabot Medical Bipolar Cutting Forceps* are used for endoscopic electrosurgical procedures for coagulation and cutting of tissue. Tissue coagulation is limited to the tissue interposed between the forceps tongs. No patient return plate is required and the current spreads radially around the forceps tongs and not axially through the tissue to the return plate. The Cabot Medical Bipolar Cutting forceps includes an integral cutting blade located between the forceps tongs. The cutting blade is actuated following coagulation for transection of the coagulated tissue.

Illustration of Cabot Medical Bipolar Cutting Forceps

BIPOLAR CUTTING  
FORCEPS



Illustrations of Cabot Medical Bipolar Cutting Forceps  
Tongs and Cutting Blade Configuration



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Cabot Medical Bipolar Cutting Forceps  
Summary of Safety and Effectiveness

5. Indication for Use

The *Cabot Medical Bipolar Cutting Forceps* are used for endoscopic electrosurgical procedures for coagulation and cutting of tissue. Tissue coagulation is limited to the tissue interposed between the forceps tongs. No patient return plate is required and the current spreads radially around the forceps tongs and not axially through the tissue to the return plate. The *Cabot Medical Bipolar Cutting forceps* includes an integral cutting blade located between the forceps tongs. The cutting blade is actuated following coagulation for transection of the coagulated tissue.

Clinical Evaluation of the Device

To ensure that the devices can be used as intended, an investigation was conducted on laboratory animals (pigs). For the investigation a physician experienced in electrosurgical bipolar techniques used the *Cabot Medical Bipolar Cutting Forceps* in the manner described the labeling to coagulate and cut the following tissues: bowel, large intestine, mesentery, liver, spleen and blood vessels. The study concluded that the bipolar cutting forceps were adequate for their intended use and the generator provided sufficient radio frequency power for the intended use.

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**LigaSure™ Vessel Sealing Instruments - Product Comparison Chart**

Characteristic	LigaSure Instrument	Cabot	Cabot
Reusable	Yes - Standard and Max Devices No - Laparoscopic	No	No
Use - Open Procedures	Yes - Standard and Max devices	Yes - 15 cm device	No
Use - Laparoscopic Procedures	Yes - Laparoscopic device	Yes - 32 cm device	Yes
Bipolar coagulation of tissue	Yes	Yes	Yes
Functional Capabilities	Grasping, Coagulation and Dissection	Grasping, Coagulation and Cutting	Grasping Coagulation and cutting
Max. Burst Pressures	LigaSure Standard - 1251 mmHg LigaSure Lap - 1035 mmHg	Cabot 5 mm - 355 mmHg Cabot 10 mm - 866 mmHg	Not available
Procedures - Intended Uses	urologic cardiovascular thoracic plastic & reconstructive bowel resections hysterectomies (both LAVH and abdominal) Cholesystectomies (Laparoscopic) Gall Bladder Adhesiolysis Nissen Fundoplication Oophorectomies	LAVH Oophorectomies Myomectomies Colectomy Nissen Fundoplication Cholesystectomies (Laparoscopic) Adhesiolysis hysterectomies Salpingectomy	ENT procedures Neurosurgery Plastic and reconstructive

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K 960009

MAR - 6 1996

**510(k) Summary of Safety and Effectiveness**

The following information is submitted in accordance with 21 CFR 807.92:

**Submitted by:**

*Audrey Swearingen*

Audrey G. Swearingen  
Storz Instrument Company  
3365 Tree Court Industrial Blvd.  
St. Louis, MO 63122  
314/225-5051

*Revised 510 (k) Summary  
4/5/96 / 2/16/96*

**Contact Person:**

Audrey G. Swearingen  
Regulatory Affairs Associate

**Date Prepared:**

February 12, 1996

**Proprietary Name:**

Storz S2050 series Bipolar Forceps

**Common/Usual Name:**

Bipolar coagulation forceps

**Classification Name:**

Electrosurgical Device, Cutting and Coagulation, and Accessories;  
79(GEI)

**Device Description:** Storz S2050 series of bipolar forceps consists of twenty-one reusable devices for use with Storz DAISY™, Protege®, and PREMIERE® Microsurgical Systems, and Storz S2080 Bipolar Coagulator. All forceps are of the same basic design with differences in tip configurations and handle dimensions. The patient contact portion of the S2050 series of forceps is composed of stainless steel. Some models have a nylon insulation on the handle region of the forceps.

**Intended Use:** The Storz S2050 series of bipolar forceps are used to control bleeding during surgical procedures, using high frequency electric current. Several of the forceps are designed for ophthalmic procedures specifically, while others are marketed for ENT procedures, neurosurgery, and/or plastic and reconstructive surgery. The forceps function by pinching tissue between the forcep tips, and allowing electric current to pass through it. The affected tissue is coagulated, and bleeding is arrested.

**Predicate Devices:** The Kirwan Bipolar Forceps (Kirwan Surgical Products, Inc.); and the Mentor O&O WET-FIELD Bipolar Forceps (Mentor O&O, Inc.).

**Predicate Comparison:** A table comparing the Storz S2050 series Bipolar Forceps to predicate devices, demonstrating substantial equivalence, is attached.

STORZ  
3365 Tree Court Industrial Blvd.  
St. Louis, MO 63122-6694  
(314) 225-5051  
Telex 981491 STORZ ST

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

*282  
108*

Storz S2050 Bipolar Forceps Substantial Equivalence Comparison

Manufacturer	Storz Instrument Company	Kirwan Surgical Products, Inc.	Mentor O & O, Inc.
Device	Storz Bipolar Forceps	Kirwan Bipolar Forceps	Mentor WET-FIELD™ Bipolar Forceps
Model(s)	S2050-XX series	Complete list of model numbers unknown	22-12XX series
Intended Use	Vessel coagulation during surgery	Vessel coagulation during surgery	Vessel coagulation during surgery
Patient-Contact Material Composition	410 and 17-7 Stainless steel	Stainless steel; material of "non-stick" models unknown	Unknown
System(s) for which Device is Designed	Storz DAISY®, Protec®, and PREMIERE® Microsurgical Systems; and S2080 Bipolar Coagulator	No specific system known	Mentor WET-FIELD II™ Coagulator
Connector type	Two-pin male connector	Two-pin male connector	Two-pin male connector
Reusable/Single Use?	Reusable	Reusable	Reusable
Provided Sterile?	No	No	No

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AUG 28 1998

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION  
VALLEYLAB LIGASURE™ VESSEL SEALING SYSTEM****I. Submitter Information**

Valleylab Inc  
a division of United States Surgical Corporation  
5920 Longbow Drive  
Boulder, Colorado 80301  
Contact: Charles M. Copperberg  
Telephone No.: 303-530-6343

K981916

Date Summary Prepared: 08/27/98

**II. Name of Device**

Proprietary Name: LigaSure™ Vessel Sealing System including the LigaSure™ Vessel Sealing Generator and LigaSure™ Open and Laparoscopic Instruments

Common or Usual Name: Bipolar Electrosurgical Generator with bipolar electrosurgical open and laparoscopic instruments

Classification Name: CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories and 21 CFR 884.4120 Gynecologic Electrocautery and Accessories

**III. Predicate Devices**

The LigaSure™ Vessel Sealing Generator is a bipolar generator which is substantially equivalent to the following Valleylab electrosurgical generators: Force FX (K944602), Force 300 (K953195) and NS2000 (K946177).

The LigaSure™ Open and Laparoscopic Instruments are substantially equivalent to the Cabot Seitzinger Tripolar Forceps, the Cabot Bipolar Cutting Forceps (K932293 and K946109) and the Storz Bipolar Forceps (K960009). All of these devices perform the coagulation of tissue via bipolar RF energy applied through the electrodes of the devices.

**IV. Device Description**

The LigaSure™ Vessel Sealing Generator is an isolated, microprocessor based, bipolar only electrosurgical generator which incorporates three bipolar modes; standard, macro and vessel sealing. The generator will accept standard bipolar devices. In addition, the generator will also accept dedicated LigaSure™ Open and Laparoscopic Instruments for use in vessel sealing.

The LigaSure™ Open instruments are reusable forceps type devices with "snap-in" single use, disposable electrodes which are placed in the jaws of the devices. The LigaSure™ laparoscopic

Records Processed under FOIA Request # 2015-6754; Released by CDRH on 09-02-2015

instrument is a sterile, single use device for use in grasping and vessel sealing in laparoscopic procedures. The device outer diameter is 5 mm and the working length is approximately 32 cms.

The system creates vessel ligation by the application of bipolar electrosurgical RF energy (coagulation/desiccation) to vessel tissue or vascular bundles interposed between the electrodes of the device.

#### **V. Intended Use**

The LigaSure™ Vessel Sealing System is intended for use in general, laparoscopic, and gynecologic procedures where ligation of vessels is desired and as an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

Indications for use for this type of ligation include general, laparoscopic and gynecological procedures such as urological, thoracic, plastic and reconstructive, bowel resections, hysterectomies (LAVH and abdominal) cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

#### **VI. Summary of Technological Characteristics**

The LigaSure™ Vessel Sealing generator and instruments have the same basic technological characteristics as the predicate devices noted above. The LigaSure™ generator provides bipolar RF energy to bipolar devices for coagulation/desiccation of vessels.

#### **VII. Performance Data**

Preclinical laboratory (acute and chronic studies) and performance testing were performed to ensure the devices functioned as intended and met design specification. Sufficient data was obtained to show the LigaSure™ Vessel Sealing system was equivalent to or better than the predicate devices and meet safety and effectiveness criteria.

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AUG 28 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Charles Copperberg  
Senior Regulatory Affairs Associate  
ValleyLab, Inc.  
5920 Longbow Drive  
Boulder, Colorado 80301

Re: K981916  
Trade Name: Ligasure Vessel Sealing System  
Regulatory Class: II  
Product Code: GEI  
Dated: May 29, 1998  
Received: June 1, 1998

Dear Mr. Cooperberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

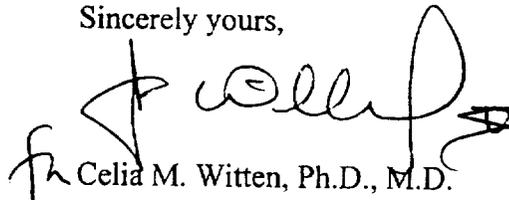
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Page 2 - Mr. Charles Copperberg

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and includes a large loop at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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510(k) Number (if known): K981916

Device Name: Valleylab LigaSure™ Vessel Sealing System

Indications For Use:

The LigaSure™ Vessel Sealing System includes a bipolar electro-surgical generator and dedicated bipolar electro-surgical instruments intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation (seal) by the application of bipolar electro-surgical RF energy (coagulation) to vessels interposed between the jaws of the device.

The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general, (including urologic, thoracic, plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 2.1 CFR 801.109)

OR

Over-The-Counter Use

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K981916



Memorandum

Date: 8/28/98  
 From: Document/Mail Center (HFZ-401)  
 Subject: Premarket Notification Number(s): **K981916/A1**  
 To: Division Director: **BU - 10GRD**

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.]

Additional information requires a new 510(k) however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE (K30) LETTER ON THE LAN.]

Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(k)].

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement or 510(k) statement).

*Hard Copy of faxed info. already reviewed*

**This information should be returned to the DMC within 10 working days from the date of this memorandum.**

Reviewed by: MRO Jaw 9/4/98  
 Date: 9/2/98

K981916/A1



5920 Longbow Drive  
Boulder, CO 80301-3299 USA  
Tel 800 255 8522

August 27, 1998

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

RECEIVED

28 AUG 58 10 36

FDA/CDRH/ODE/DMC

Re: K981916 510(k) Submission  
Valleylab LigaSure™ Vessel Sealing System

Attention: Neil Ogden, FDA/ODE/DGRD

Mr. Ogden;

Enclosed you will find two (2) copies of the data sent to you via fax on 8/27/98 concerning the above referenced 510(k) submission.

Should you need additional information or have any further questions, please give me a call at 303-530-6343.

Sincerely,

Charles M. Copperberg  
Senior Regulatory Affairs Associate  
Valleylab Inc

AK-10

300 2

K981916/A1



5920 Longbow Drive  
Boulder, CO 80301-3299 USA  
Tel 800 255 8522

RECEIVED  
28 Aug 98 10 36  
FDA/CDRH/OCE/DMD

August 27, 1998

Neil Ogden  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
Office of Device Evaluation/DGRD  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Re: 510(k) Submission K981916 LigaSure Vessel Sealing System

Mr. Ogden:

Subsequent to our discussions of August 26th and 27th, I am submitting the following modifications to the above referenced 510(k) submission:

1. Section G, Intended Use, has been modified to remove the cardiovascular indication. (Paragraph 2, line 1). A copy of the modified page is included under Attachment # 1 to this letter. In addition, the "Indications for Use" statement, page 21 of the 510(k) and the Summary of Safety and Effectiveness have also been changed to reflect this modification. These documents are also included in Attachment # 1.
2. The labeling for the products has been modified to include the following statement in the warnings sections:

"The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulations for sterilization procedures. Do not use this system for these procedures"

Copies of representative labeling including this statement can be found in Attachment # 2.

3. The proposed/draft advertisement included in the original 510(k) submission was provided only as an example of how the information may be presented. It was prepared in the early stages of the project when specific claims had not yet been identified or substantiated. Based on our discussions I have deleted those claims which are not substantiated by test data. The draft advertisement with the deletions can be found in Attachment # 3. These are as follows:

A Division of United States Surgical Corporation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

301 3

- Page 3 - "Speed" The reference to sealing with an average of 5 seconds will be eliminated.
- Page 5 - "Skeletonized vessels" refers to vessels that have had the surrounding tissue removed. Examples of vessel sizes may be provided which will have the specific vessel name and its associated (approximate) diameter. No vessels will be shown that are larger than 7 mm.
- Page 6 - The statement containing the average completed seal time of 5 seconds will be eliminated as will the statement indicating an average reduction in procedural time.
- Page 7 - The phrase "Reduces Costs" will be eliminated.

Any substantiation of claims such as these will be the subject of future submissions.

Please let me know if you have any additional questions on the 510(k) submission or on the modifications noted above. I will also be sending you a hard copy of this information. Thank you for your attention and assistance.

Sincerely,

  
Charles Copperberg  
Senior Regulatory Affairs Associate

# ATTACHMENT # 1

33



Class II, 21 CFR 878.4400, **Electrosurgical Cutting and Coagulation Device and Accessories, Panel 79, General and Plastic Surgery** for the devices used in general surgery, and,

Class II, 21 CFR 884.4120, **Gynecologic Electrocautery and Accessories**, for the electrosurgical actives used in gynecological procedures.

**D. Conformance with Section 514 Performance Standards**

Performance standards have not yet been promulgated for this device classification, therefore, Section 514, Performance Standards, of the Food Drug and Cosmetic Act, as amended, does not apply.

**E. Product Labeling**

Labeling for the LigaSure™ Vessel Sealing System includes product identification, cautions to the operator, warnings, contraindications, medical claims as well as instructions for use. Product labeling for the LigaSure™ system is provided in Attachment # 1. This attachment also includes an outline of the contents of the Service Manual which will be completed prior to market introduction.

**F. Advertising**

Attachment # 2 to this submission contains a copy of proposed/draft advertising literature for the LigaSure™ Vessel Sealing system. The information contained in this literature is supported by preclinical and bench testing. Reference Section L, "Safety and Performance" in this submission.

**G. Intended Use**

The LigaSure™ Vessel Sealing System includes a bipolar electrosurgical generator and dedicated bipolar electrosurgical instruments. The system is intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. This system offers an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting and/or coagulation are required.

The indications for use include general, (including urologic, thoracic plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

304 6

510(k) Number (if known): K981916

Device Name: Valleylab LigaSure™ Vessel Sealing System

Indications For Use:

The LigaSure™ Vessel Sealing System includes a bipolar electro-surgical generator and dedicated bipolar electro-surgical instruments intended for use in general, laparoscopic and gynecologic procedures where ligation of vessels is desired. The system creates a vessel ligation (seal) by the application of bipolar electro-surgical RF energy (coagulation) to vessels interposed between the jaws of the device.

The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

The indications for use include general, (including urologic, thoracic plastic and reconstructive), laparoscopic and gynecological procedures where ligation of vessels is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 2.1 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

305 n

**SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION  
VALLEYLAB LIGASURE™ VESSEL SEALING SYSTEM**

**I. Submitter Information**

Valleylab Inc  
a division of United States Surgical Corporation  
5920 Longbow Drive  
Boulder, Colorado 80301  
Contact: Charles M. Copperberg  
Telephone No.: 303-530-6343

Date Summary Prepared: 08/27/98

**II. Name of Device**

Proprietary Name: LigaSure™ Vessel Sealing System including the LigaSure™ Vessel Sealing Generator and LigaSure™ Open and Laparoscopic Instruments

Common or Usual Name: Bipolar Electrosurgical Generator with bipolar electrosurgical open and laparoscopic instruments

Classification Name: CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories and 21 CFR 884.4120 Gynecologic Electrocautery and Accessories

**III. Predicate Devices**

The LigaSure™ Vessel Sealing Generator is a bipolar generator which is substantially equivalent to the following Valleylab electrosurgical generators: Force FX (K944602), Force 300 (K953195) and NS2000 (K946177).

The LigaSure™ Open and Laparoscopic Instruments are substantially equivalent to the Cabot Seitzinger Tripolar Forceps, the Cabot Bipolar Cutting Forceps (K932293 and K946109) and the Storz Bipolar Forceps (K960009). All of these devices perform the coagulation of tissue via bipolar RF energy applied through the electrodes of the devices.

**IV. Device Description**

The LigaSure™ Vessel Sealing Generator is an isolated, microprocessor based, bipolar only electrosurgical generator which incorporates three bipolar modes; standard, macro and vessel sealing. The generator will accept standard bipolar devices. In addition, the generator will also accept dedicated LigaSure™ Open and Laparoscopic Instruments for use in vessel sealing.

The LigaSure™ Open instruments are reusable forceps type devices with "snap-in" single use, disposable electrodes which are placed in the jaws of the devices. The LigaSure™ laparoscopic



instrument is a sterile, single use device for use in grasping and vessel sealing in laparoscopic procedures. The device outer diameter is 5 mm and the working length is approximately 32 cms.

The system creates vessel ligation by the application of bipolar electrosurgical RF energy (coagulation/desiccation) to vessel tissue or vascular bundles interposed between the electrodes of the device.

#### **V. Intended Use**

The LigaSure™ Vessel Sealing System is intended for use in general, laparoscopic, and gynecologic procedures where ligation of vessels is desired and as an alternative to mechanical clamping (clips or staples) or suturing. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired.

Indications for use for this type of ligation include general, laparoscopic and gynecological procedures such as urological, thoracic, plastic and reconstructive, bowel resections, hysterectomies (LAVH and abdominal) cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels up to 7 mm. and bundles as large as will fit in the jaws of the instruments.

#### **VI. Summary of Technological Characteristics**

The LigaSure™ Vessel Sealing generator and instruments have the same basic technological characteristics as the predicate devices noted above. The LigaSure™ generator provides bipolar RF energy to bipolar devices for coagulation/desiccation of vessels.

#### **VII. Performance Data**

Preclinical laboratory (acute and chronic studies) and performance testing were performed to ensure the devices functioned as intended and met design specification. Sufficient data was obtained to show the LigaSure™ Vessel Sealing system was equivalent to or better than the predicate devices and meet safety and effectiveness criteria.

307<sup>2</sup> a

## **ATTACHMENT # 2**

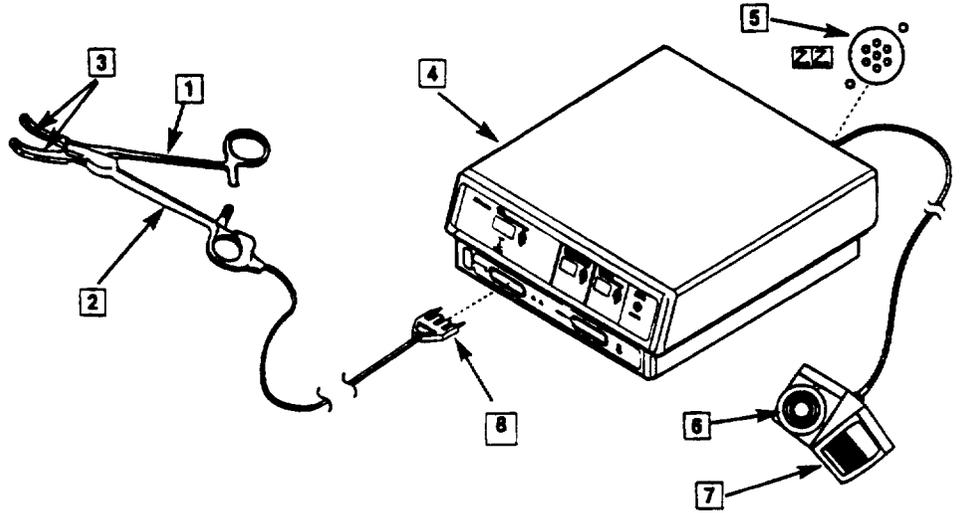
**LigaSure™ System  
Vessel Sealing Electrode/Cord  
Assembly**

for use with LigaSure Vessel Sealing Handsets

**REF** LS2071 for use with LS2070 LigaSure Standard Handset, 7 in.

**CAT** LS3091 for use with LS3090 LigaSure Max Handset, 9 in.

Sterile, Single Use



- 1 Reusable LigaSure Handset
- 2 Electrode Wire Guide
- 3 Snap-in Electrodes
- 4 LigaSure Generator
- 5 Vessel Sealing Footswitch receptacle
- 6 Vessel Sealing Footswitch
- 7 Standard Bipolar Footswitch
- 8 Smart Connector

**DRAFT**



**Prior to surgery, read all instructions and precautions provided with the electrode, handset, and electro-surgical generator to be used.**

**Warnings**

This device has been specifically designed for sealing vessels and tissue in open surgical procedures only.

The LS2070 and LS3090 LigaSure Handsets are intended for use ONLY with the Valleylab LigaSure Vessel Sealing System. Use of these handsets with other Valleylab generators or with generators produced by other manufacturers could result in injury to the patient or surgical team or cause damage to the instrument.

The LS2070 LigaSure Handset can only be used with LS2071 Electrodes. The LS3090 LigaSure Handset can only be used with LS3091 Electrodes. Use of these handsets with any other electrodes or use of these electrodes with any other handset could result in injury to the patient or surgical team or cause damage to the instrument.

The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulations for sterilization procedures. Do not use this system for these procedures.

Before installing or removing the electrodes, ensure that the handset is not connected to the electro-surgical generator, and the generator is OFF or in Standby mode.

Do not wrap accessory cords around metal objects; doing so may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

**Fire Hazard.** Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electro-surgical accessories that are activated or hot from use can cause a fire. When not using active accessories, place them in a holster or in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

**Electric Shock Hazard.** Do not connect wet accessories to the generator.

**Caution**

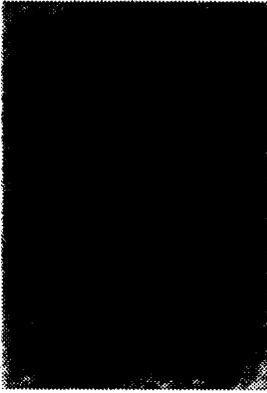
Inspect accessories and cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

*amcopperberg  
8/27/98*



**STERILE**

*309*



# Patient and Operating Room Safety

**DRAFT**

The safe and effective use of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been used safely in numerous procedures. Before starting any surgical procedure, the surgeon should be trained in the particular technique and surgical procedure to be performed, should be familiar with the medical literature related to the procedure and potential complications, and should be familiar with the risks versus the benefits of utilizing electrosurgery in the procedure.

## General

**Warning:** Accidental and unintended burn injury has occurred during procedures in small surgical fields and on small appendages. Catastrophic results have been reported in the context of neonatal and pediatric circumcisions.<sup>1</sup> In those cases of confirmed thermal injury during neonatal and pediatric circumcisions, the mechanism of injury appears to have been associated with contact between a metal clamp (such as a Gomco clamp or a Kocher clamp) in the surgical field and the active electrode, which greatly increased current flow.<sup>2</sup> (See *Contact with Metal Objects* later in this section for further information on the dangers of contact with metal instruments.)

It has also been reported that properly trained physicians use electrosurgery safely in the performance of circumcisions, and that pediatric urologists use electrosurgery with surgical procedures performed on the genitals of male neonates. In performing such procedures, it is reported that many physicians use the electrosurgical generator in a coagulation mode to achieve hemostasis of bleeders, however "buzzing" hemostats clamped to bleeders may increase the risk of thermal injury.

**Warning:** Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.

**Warning:** If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activations of ICDs.

*CM Appenberg*  
*8/27/88*

**Warning:** The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulations for sterilization procedures. Do not use this system for these procedures.

**Warning:** Valleylab recommends against the use of laparoscopic surgery on pregnant patients.

**Warning:** Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

1 The American National Standard for Electrosurgical Devices (ANSI/AAMI HF 18-1993) provides: "Electrosurgery should not be used to perform circumcisions."

2 Information on the safe use and thermal hazards associated with the use of high frequency electricity (electrosurgical machines) in health care facilities appears in NFPA 99, Annex 2, reference in the JCAHO Accreditation Manual for Hospitals.

*12*

**Warning: Hazardous Electrical Output** — This equipment is for use only by trained, licensed physicians.

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3 U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). *Control of Smoke from Laser/Electric Surgical Procedures*. HAZARD CONTROLS, Publication No. 96-128, September, 1996.

# **ATTACHMENT # 3**

3/3  
K

**Valleylab**  
Instructions / Read Manual

**Surgical cases aren't  
always predictable...  
but occlusion should be.**

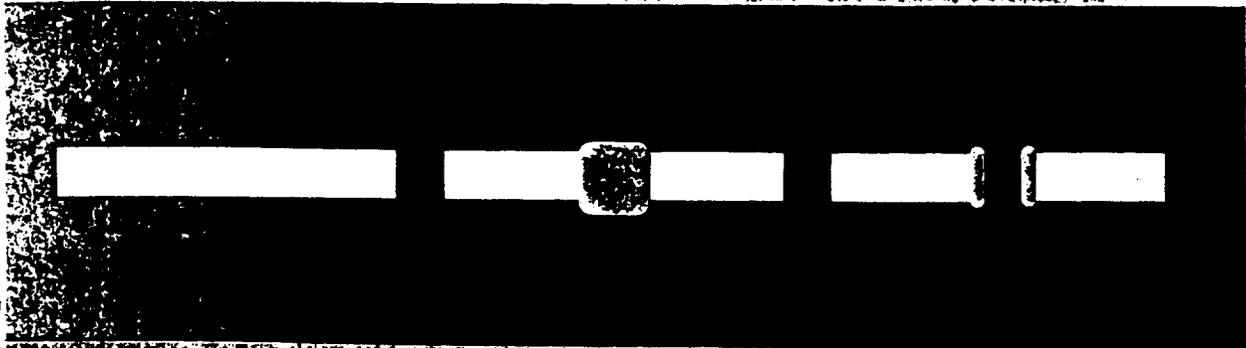


**LigaSure**

BY  
110

**An added degree of confidence in virtually  
any surgical procedure.**

# LigaSure Vessel Sealing



caption will be placed here for the  
first medical illustration

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middle medical illustration

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third medical illustration

LigaSure Vessel Sealing  
provides fast, reliable seals  
for a wide range of open  
and laparoscopic procedures,  
including:

- > Abdominal hysterectomies
- > Vaginal hysterectomies
- > Lap Assisted Vaginal  
hysterectomies
- > Salpingo Oophorectomies
- > Small Bowel Resections
- > Large Bowel Resections
- > Distal Anterior Resections

Can use LigaSure Vessel  
Sealing on a wide range of  
vessel sizes (arteries, veins, lymphatics)  
and create a permanent seal  
even in high pressure  
physiological conditions.

3/5/11

**Handle a range of vessel sizes and tissue bundles.**

**Minimize collateral tissue damage with on-target vessel sealing every time.**

CM Cypres -  
8/27/17

**Added reassurance with a seal you can see and a signal you can hear.**

**Ensure burst strength up to three times the patient's physiologic blood pressure.**

**Get in and out with minimal invasiveness wherever you need access.**

**No sutures, staples, clips or clamps to leave behind.**

**No other occlusion method offers LigaSure Vessel Sealing's  
combination of versatility, strength, safety and speed.**

8/17 19



Compared to everything from sutures, clips, and staples to energy-based occlusion systems, LigaSure Vessel Sealing provides surgeons with the widest range of possibilities while significantly reducing risks. The patented system uses a unique combination of energy and pressure precisely confined to only the targeted tissue. It fuses vessel walls to create a permanent seal

**Work equally well on a range of vessel sizes and tissue bundles.**

- *Skeletonized vessels or tissue bundles*
- *Seal vessels from 1mm to 7mm*
- *Ideal for open and lap procedures*
- *Faster and more efficient than other methods*



Vessel Size



Vessel Size



Vessel Size



Vessel Size



Vessel Size



Vessel Size



Vessel Size

**Keep collateral damage to an absolute minimum.**

- *Highly precise tissue targeting*
- *Automatic shut-off when seal is completed*
- *Correct pressure is set automatically*

318  
A



**Complete a successful procedure  
as quickly as possible.**

*CM Copperberg  
8/27/98*

**See...and hear...the difference.**

- *Where visualization is possible, translucent seal gives you visual assurance of completion*
- *Audible verification always confirms seal and tells you the system is off*

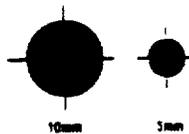
**Proven strong, reliable,  
permanent.**

- *Proven burst strength of 3x physiologic blood pressure*
- *Strength is the same, regardless of vessel size*

- *No suturing, stapling, clamping, cutting or tying*

**Get into confined spaces  
conveniently.**

- *Better access and less invasive than other methods*
- *5 mm lap instrument*
- *Ideal for delicate situations*



**Reduce risks by leaving  
nothing behind.**

- *No clips, clamps, sutures or staples*
- *Reduces risks*

*CM Copperberg {  
8/27/98*



To see how good LigaSure Vessel Sealing really is, you have to try it on your kind of cases. Just call your VALLEYLAB sales representative for an evaluation. Or call customer service 1-800-255-8522 for our clinical information package.

**LigaSure™**  
VESSEL SEALING

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