Report 06008
Electrosurgical vessel sealing systems
UK market survey
March 2006
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Electrosurgical vessel sealing systems

UK market survey

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## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary</td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td>How it works</td>
<td>3</td>
</tr>
<tr>
<td>Purchasing considerations</td>
<td>4</td>
</tr>
<tr>
<td>Clinical considerations</td>
<td>4</td>
</tr>
<tr>
<td>Guide to the product pages</td>
<td>5</td>
</tr>
<tr>
<td>BOWA Arc350</td>
<td>6</td>
</tr>
<tr>
<td>ESU generator</td>
<td>6</td>
</tr>
<tr>
<td>Instruments for vessel sealing</td>
<td>7</td>
</tr>
<tr>
<td>Laparoscopic instruments</td>
<td>7</td>
</tr>
<tr>
<td>Open instruments</td>
<td>8</td>
</tr>
<tr>
<td>Manufacturer recommended surgical procedures</td>
<td>9</td>
</tr>
<tr>
<td>Servicing</td>
<td>10</td>
</tr>
<tr>
<td>Monopolar safety features</td>
<td>10</td>
</tr>
<tr>
<td>Manufacturing standards</td>
<td>10</td>
</tr>
<tr>
<td>Manufacturer’s comments</td>
<td>10</td>
</tr>
<tr>
<td>ERBE VIO 300D BiClamp</td>
<td>11</td>
</tr>
<tr>
<td>ESU generator</td>
<td>11</td>
</tr>
<tr>
<td>Instruments for vessel sealing</td>
<td>12</td>
</tr>
<tr>
<td>Laparoscopic instruments</td>
<td>12</td>
</tr>
<tr>
<td>Open instruments</td>
<td>13</td>
</tr>
<tr>
<td>Manufacturer recommended surgical procedures</td>
<td>15</td>
</tr>
<tr>
<td>Servicing</td>
<td>16</td>
</tr>
<tr>
<td>Monopolar safety features</td>
<td>16</td>
</tr>
<tr>
<td>Manufacturing standards</td>
<td>16</td>
</tr>
<tr>
<td>Manufacturer’s comments</td>
<td>16</td>
</tr>
<tr>
<td>Gyrus PK Vessel Sealing Instruments</td>
<td>17</td>
</tr>
<tr>
<td>ESU generator</td>
<td>17</td>
</tr>
<tr>
<td>Instruments for vessel sealing</td>
<td>18</td>
</tr>
<tr>
<td>Open instruments</td>
<td>18</td>
</tr>
<tr>
<td>Manufacturer recommended surgical procedures</td>
<td>19</td>
</tr>
<tr>
<td>Servicing</td>
<td>20</td>
</tr>
<tr>
<td>Manufacturing standards</td>
<td>20</td>
</tr>
<tr>
<td>Manufacturer’s comments</td>
<td>20</td>
</tr>
<tr>
<td>Martin Maxium - SealSafe and EndoSeal</td>
<td>21</td>
</tr>
<tr>
<td>ESU generator</td>
<td>21</td>
</tr>
<tr>
<td>Instruments for vessel sealing</td>
<td>22</td>
</tr>
<tr>
<td>Laparoscopic instruments</td>
<td>22</td>
</tr>
<tr>
<td>Open instruments</td>
<td>23</td>
</tr>
<tr>
<td>Manufacturer recommended surgical procedures</td>
<td>24</td>
</tr>
</tbody>
</table>
## Contents

Servicing ........................................ 25  
Monopolar safety features ................. 25  
Manufacturing standards ................. 25  
Manufacturer’s comments ............... 25  

Valleylab LigaSureTM ......................... 26  
ESU generator ............................... 26  
Instruments for Vessel Sealing .......... 27  
Laparoscopic instruments ............... 27  
Open instruments ......................... 28  
Manufacturer recommended surgical procedures 30  
Servicing ..................................... 31  
Manufacturing standards ............... 31  
Manufacturer’s comments ............... 31  

References ..................................... 32  

Acknowledgements ......................... 33  

Appendix ....................................... 34  
How good is the seal ? .................... 34  
Manufacturing standards for medical devices 35  
A brief guide to the Medical Devices Directive 35
Electrosurgical vessel sealing is a specialist system developed by manufacturers for minimal access and open surgery. This technology can facilitate a range of minimal access surgical procedures, helping to meet government objectives of reduced length of stay for patients in hospital.

Each of these devices comprises an electrosurgical unit (ESU) with a high power and low voltage bipolar mode and specialist instruments that combine tissue compression with tissue heating to produce haemostasis in arteries, veins or a bundle of tissue.

This comparative report provides information to help staff identify the range of products available and the issues that can influence the suitability of products. It is divided into two sections. The first introduces some of the technical, clinical and procurement issues. The second section comprises product pages for each system, using information and images supplied by the manufacturers and UK suppliers.

Five devices are included in this report. Prospective purchasers are encouraged to read the detailed information in this report before selecting devices for local assessment.

- **BOWA Arc 350** is a general purpose ESU which can be configured for use with a range of modular instruments: **LIGATOR** for laparoscopic sealing (2 options) and **TissueSeal** for open surgery sealing (6). All the instruments are reusable but the open instruments require single use electrodes.

- **ERBE VIO 300D** is a general purpose ESU which is software upgradeable to permit the use of vessel sealing surgical instruments: **LAP Biclamp** (4 options) for laparoscopic sealing and **Biclamp** (5) for open surgery. All are reusable.

- **Gyrus PK System SuperPulse** generator is a versatile bipolar ESU generator that can be used with their **SEAL** range of vessel sealing instruments for open surgery (3 options). All instruments are single patient use.

- **Martin Maxium** general purpose ESU generator can use **SealSafe** technology and specialist instruments for vessel sealing: **marLap** (2 options) for laparoscopic surgery and **marClamp** (7) for open surgery. All are reusable.

- **Valleylab LigaSure** is a bipolar generator with two outputs, one for normal bipolar cutting and coagulation and the other for vessel sealing. Specialist instruments for laparoscopy (3 options) and open surgery (6) are available. Three instrument models incorporate a mechanical cutting device. Most are single patient use.
Electrosurgery (surgical diathermy) vessel sealing systems can offer an effective alternative method for sealing blood vessels and tissue bundles up to 7mm in diameter replacing established surgical techniques such as suturing, surgical clips and staples. Other energy sources have also been developed for sealing tissue and vessels, such as ultrasonic coagulating shears, but these are not included in this market survey.

Suturing is the traditional technique for sealing vessels in open surgery, but where access is limited, clips and staples are now becoming popular. However, all of these methods involve leaving foreign body material inside the patient.

Surgeons have also used haemostats to clamp tissue or vessels during open surgery and then touched the metal clamp with a monopolar electrode and activated the ESU, known as ‘buzzing the haemostat’. Although this can be a quick technique in open surgery it has a poor safety record. Accidental ‘diathermy burns’ to the surgeon or attending staff, alternative site burns for the patient, patient electrode (plate) burns and heating of adjacent tissues are known problems.

For these reasons the use of bipolar mode is strongly encouraged as the current only passes between the prongs of the forceps. However, for most ESUs the bipolar mode is not appropriately configured for completely heating and coagulating larger vessels. The primary advantage of bipolar electrosurgery is that the current path is very localised, so the surgical team can safely use two bipolar ESUs simultaneously on one patient.

Vessel sealing using bipolar electrosurgery is a development pioneered by the Ligasure system. More recently other manufacturers have developed devices capable of achieving a similar surgical outcome. Three systems use general purpose ESUs with specific modes designed for specialist vessel sealing instruments. The others are based on specialist bipolar ESUs.

This report enables direct comparison between five systems available in the UK. The data and images have been supplied by the manufacturers and UK suppliers. No vessel sealing system in this report has been evaluated, either technically or clinically. If the ESU has been technically evaluated previously the report number is given.

Other recent evaluation reports [1,2,3,4] can also provide background information, a glossary and an introduction to the electrosurgical technique and technical issues related to ESUs.
Introduction

How it works

Electrosurgical vessel sealing systems are bipolar electrosurgical generators [1] with a range of specially designed applicators or instruments that are intended to produce haemostasis in arteries, veins and tissue bundles.

All instruments clamp the vessel, or tissue bundle, and deliver a high frequency electrical current to achieve heating within the tissue. The prongs should remain relatively cool so the instrument does not tear the tissue when the clamp is released.

The combination of temperature and pressure shrinks and denatures collagen and other cellular proteins in an irreversible process. The structure of collagen changes as its bonds become broken and it forms a gel-like substance that acts as a glue between vessel walls. To achieve this effect the tissue needs to be heated to between 70°C and 95°C, sufficient for collagen and elastin in the tissue to convert into gelatin [1]. As the gelatin cools under compression it becomes an effective seal, which can withstand considerable pressures (see Appendix). Tissue and vessels can appear flexible, transparent and plastic-like when fusion is complete.

Although control of the tissue temperature is an important success factor for these devices none of the instruments incorporates temperature sensor within the instrument tip. All devices continuously measure an electrical property of the tissue, the impedance (or resistance) to electrical current, as an indicator of tissue state. As heating lowers the water content within tissue it also reduces the ability of the tissue to conduct an electrical current, so the impedance rises.

The essential elements of these systems include:

- physical pressure from a bipolar surgical instrument
- generator capable of high current and low voltage, to avoid sparking
- monitoring changes in tissue impedance during heating
- microprocessor-control to achieve a reproducible electrosurgical effect
- automatic ‘power off’ and/or an audible and visual alarm when the system assesses that the optimum seal has been achieved.

Vessel sealing devices incorporate impedance monitoring circuitry and use complex microprocessor based algorithms that measure the impedance of the tissue structure and use this information to control the current. Some systems use pulsed electrosurgical current to enable intermittent measurement of tissue impedance and achieve more moderate heating. These features are designed to deliver electrical current until the tissue impedance indicates that the vessel or tissue bundle is likely to have a permanent seal. Most systems automatically switch the output current off when this has been achieved, others provide an audible alarm alerting the surgeon to stop activation. Although the first approach appears to take the control from the surgeon it can achieve consistent surgical results. The surgeon can always repeat ESU activation, if required.
Automatic control can mean that the current flows only as long as is necessary and avoids overheating, limits ‘tissue charring’ and reduces the chances of the instrument ‘sticking’ to the tissue. Surface properties of the clamp are also claimed to reduce these problems, so some manufacturers use instruments with tines that are ribbed, or have a non-stick or thermally sensitive coating.

Bipolar mode is generally considered safer than monopolar electrosurgery. The current and heat is concentrated in the tissue between the clamp tines so there is usually reduced ‘thermal spread’ (heating of adjacent tissues) compared with monopolar techniques. Some laparoscopic vessel sealing instruments incorporate a cutting device, so excision may be quickly achieved by only one instrument both sealing and cutting each vessel feeding the organ or tissue mass.

**Purchasing considerations**

Factors that should be considered include:

- local or national policies, which may encourage the use of reusable instruments (to minimise waste and overall cost) or single use surgical instruments (to reduce risk of cross infection). Some manufacturers have produced documents that justify the increased cost of single-use technology.
- number of surgical procedures needing this particular feature. A high demand may make purchase of a dedicated vessel sealing generator cost effective.
- estimation of lifetime cost (e.g. 10 years) which includes the cost of generator, surgical instruments, cleaning and maintenance compared with the existing method and equipment.
- estimation of changes in patient care cost, especially if minimal access, day surgery is being considered.
- complication rates for current methods and the new surgical procedure, including the costs associated with readmission and extended length of stay, corrective action and litigation.

**Clinical considerations**

Factors important for the surgical performance of electrosurgical vessel sealing devices include:

- temperature of the outer surface of the tines which can become heated by contact with the hot tissue during activation. Inadvertent warming above 49°C can cause irreversible cellular damage. Accidental contact with tissue, such as loops of bowel, may lead to significant post operative complications. Thermal spread data provided by manufacturers does not indicate the maximum
temperature attained at the thermal margins and usually refers to tissue
damage to the vessel / tissue bundle either side of the clasped tines.
• reliability of the seal under all post operative situations; for example the burst
pressure for arteries should exceed the peak arterial pressure observed during
hypertension, which may go above 220 mmHg (see Appendix).
• reduction in the procedure time can only achieve significant financial savings if
the reduction in total theatre time (preparation, surgery and post-operative
recovery) is sufficient to enable extra case(s) to be added to the session.

Guide to the product pages

The summary provides an overview of relevant features of the vessel sealing
generator and associated surgical instruments. The ESU is then described in more
detail and includes: an image, details of any relevant technical evaluation report,
cost and the contact details for the supplier.

Subsequent pages summarise key features and the cost of the specialist
instruments available for vessel sealing. There are separate lists suitable for
laparoscopy and open surgery. A comparative look-up table enables identification of
those instruments appropriate for a range of surgical procedures, and is based on
the manufacturer’s recommendations.

The final page provides the ESU service cost information, details of manufacturing
standards used in the design of the generator (see Manufacturing standards), and
an overview of the safety features incorporated in the ESU. Each Manufacturer’s
comments section provides an opportunity for the supplier or manufacturer to
directly comment on the information provided in this report.
BOWA Arc350

Summary

- General purpose ESU with an optional vessel sealing module requiring BOWA LIGATOR and BOWA TissueSeal instruments
- Max vessel sealing power: 100W
- Max bipolar power: 120W (coagulation) 150W (cut)
- Output sockets: 2 monopolar, 2 bipolar and 2 pin sockets (8mm)
- Output automatically switches off when vessel sealing is complete
- 2 laparoscopic and 6 open vessel sealing instruments are available
- Reusable laparoscopic instruments with a non-stick coating
- Reusable open surgery instruments with single use electrode tips
- Capability for vessel sealing can not be retro-fitted on the BOWA generator
- Suitable for bipolar vessel sealing surgical procedures in both open and laparoscopic operations

ESU generator

The BOWA Arc350 is a general purpose ESU incorporating monopolar and bipolar technology, and was reviewed previously [4]. BOWA LIGATOR BOWA Non-Stick CUT and BOWA TissueSeal instruments can be connected to the ESU if it incorporates the bipolar contact high current coagulation mode, which cannot be retro-fitted. Surgeons may select a continuous RF current waveform (blend = 0) or one of nine different pulsed modes (blend = 1-9). When the BOWA algorithm estimates that a good seal has been achieved the ESU will automatically switch the power off to the vessel sealing instruments and produce an audible tone. The footswitch must be pressed again to restart the sealing current.

Detail: Maximum monopolar power: 300W Class IIB. CF type. Weight: 14kg
Dimensions: 180(H) 430(W) 400(D) mm
Fundamental frequency: 330kHz

Price (ex VAT) £9500.00
Supplier: Avail Medical
Address: 8 Ninian Park
Tame Valley
Dosthill
Tamworth
Staffordshire
B775ES
Telephone: 01827 288883
Fax: 01827 288334
Website: availmedical@aol.com
Email: availmedical@aol.com
Manufacturer: BOWA
Manufactured in: Germany
Instruments for vessel sealing

Laparoscopic instruments

**BOWA LIGATOR 770-036: £750.00**
Modular laparoscopic reusable surgical instrument system with interchangeable jaw inserts, incorporating a non-stick coating.
Seals vessels and tissue bundles.
Shaft diameter: 5mm
Shaft length: 360mm
Shaft rotation: *information not supplied*
Reusable (autoclavable at 134°C).

**LIGATOR insert 771-036: £350.00**
Jaw angle: straight, ribbed (top left)
Seal width: *information not supplied*
Average thermal spread: *not supplied*
Reusable (autoclavable at 134°C).

**LIGATOR insert 772-036: £350.00**
Jaw angle: Maryland Curve.(top right)
Seal width: *information not supplied*
Average thermal spread: *not supplied*
Reusable (autoclavable at 134°C).
Open instruments

BOWA TissueSeal
Modular surgical instrument system with reusable handles of different lengths and disposable tips. Handle can lock in position to achieve consistent sealing forces. Seals vessels and tissue bundles.

**TissueSeal 760-019: £750.00**
Length: 190mm
Seal width: *information not supplied*
Average thermal spread: *not supplied*
Reusable (autoclavable at 134° C).

**TissueSeal 760-023: £775.00**
Length: 230mm
Seal width: *information not supplied*
Average thermal spread: *not supplied*
Reusable (autoclavable at 134° C).

**TissueSeal 760-028: £825.00**
Length: 280mm
Seal width: *information not supplied*
Average thermal spread: *not supplied*
Reusable (autoclavable at 134° C).

**Electrode tips 830-000: £350.00 (5 sets)**
Jaw angle: straight (top left)
Seal width: *information not supplied*
Average thermal spread: *not supplied*
Single patient use.

**Electrode tips 830-010: £350.00 (5 sets)**
Jaw angle: 30 degrees (top right).
Seal width: *information not supplied*
Average thermal spread: *not supplied*
Single patient use.
## Manufacturer recommended surgical procedures

<table>
<thead>
<tr>
<th>Surgical procedure</th>
<th>Laparoscopic instruments</th>
<th>Open instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LIGATOR 771-036</td>
<td>TissueSeal 760-019 straight</td>
</tr>
<tr>
<td>General surgery / Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemorrhoidectomy</td>
<td>● ●</td>
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</tr>
<tr>
<td>Gastrectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Adrenalectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver resection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Axillary dissection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Splenectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Adhesiolysis</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Gastric bypass</td>
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</tr>
<tr>
<td>Appendectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Nissen fundoplication</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Thyroidectomy</td>
<td></td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Parotidectomy</td>
<td></td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Colon resection</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Whipple</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td><strong>Gynaecology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal hysterectomy (open)</td>
<td></td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Vaginal hysterectomy (VH)</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Laparoscopic assisted VH</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Salpingo oophorectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td><strong>Urology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radical prostatectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Cystectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
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<td>Nephrectomy</td>
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Servicing

Maintenance check is recommended once per year (parts not included)

Return to base service (inc. loaner unit and carriage costs for both units): £145.00
On-site examination (including loaner unit): £350.00

Fully comprehensive maintenance agreement (inc. parts and loaner unit): £1,050.00

Monopolar safety features

Contact Quality Monitoring (CQM) and Plate Attachment Monitoring (PAM).

Manufacturing standards


Notified body (for CE marking): TUV       Code: CE0123

Manufacturer’s comments

Comments have been received from the manufacturer and, where appropriate, their suggested changes have been incorporated into the report.
ESU generator

The ERBE VIO 300D is a general purpose ESU# providing monopolar and bipolar modes [3], with a BiClamp upgrade**. The BiClamp instruments are connected to the ESU via the MF (multi-functional) receptacle. This allows instrument detection and the ESU automatically configures the appropriate default power setting for the instrument. Output sockets are interchangeable by a qualified technician, allowing the surgeon to choose several MF monopolar and bipolar sockets. BiClamp instruments are intended for coagulation and cannot produce an incision. The ESU will automatically switch the power off to the BiClamp instrument when a good seal is deemed to have been achieved. An audible tone signals ESU activation and a ‘beep’ signals completion.

**Detail:** Maximum monopolar power: 300W. Class IIB. F type. Weight: 9.5kg. Dimensions: 165(H) 410(W) 380(D) mm. Fundamental frequency: 350kHz.

<table>
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<th>Price (ex VAT)</th>
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</tr>
<tr>
<td>Address</td>
<td>The Antler Complex</td>
</tr>
<tr>
<td></td>
<td>2 Bruncliffe Way</td>
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<td></td>
<td>Morley</td>
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<td>Leeds</td>
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<td>LS27 0JG</td>
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<tr>
<td>Telephone</td>
<td>01827 288883</td>
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<tr>
<td>Fax</td>
<td>01827 288334</td>
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<tr>
<td>Website</td>
<td><a href="http://www.erbeuk.com">www.erbeuk.com</a></td>
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<tr>
<td>Email</td>
<td><a href="mailto:sales@erbeuk.com">sales@erbeuk.com</a></td>
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<td>Germany</td>
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Summary

- General purpose ESU with optional incorporated vessel sealing technology called ‘BiClamp’
- Max vessel sealing power: 300W
- Max bipolar power: 120W
- Output sockets are interchangeable
- LCD display for ease of use
- Output automatically switches off when vessel sealing is complete
- 4 laparoscopic and 4 open BiClamp instruments are available
- Automatic instrument detection for BiClamp devices
- The basic VIO unit is software upgradeable to incorporate the BiClamp vessel sealing technology at a cost of £3460.00**
- Suitable for bipolar vessel sealing surgical procedures in both open and laparoscopic operations
Instruments for vessel sealing

Laparoscopic instruments

**LAP BiClamp Maryland, ribbed: £1574.00**
Seals vessels and tissue bundles up to and including 7mm in diameter.
Shaft diameter: 5mm
Shaft length: 340mm
Shaft rotation: 360 degrees
Jaw angle: Maryland Curve, 7 degrees
Seal width: 2.5mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134° C - 138° C).

**LAP BiClamp Maryland, smooth: £1574.00**
Seals vessels and tissue bundles up to and including 7mm in diameter.
Shaft diameter: 5mm
Shaft length: 340mm
Shaft rotation: 360 degrees
Jaw angle: Maryland Curve, 7 degrees
Seal width: 2.5mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134° C - 138° C).

**LAP BiClamp Fenestrated, ribbed: £1574.00**
Seals vessels and tissue bundles up to and including 7mm in diameter.
Shaft diameter: 5mm
Shaft length: 340mm
Shaft rotation: 360 degrees
Jaw angle: Straight
Seal width: 4.6mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134° C - 138° C).
LAP BiClamp Fenestrated, smooth: £1574.00
Seals vessels and tissue bundles up to and including 7mm in diameter.
Shaft diameter: 5mm
Shaft length: 340mm
Shaft rotation: 360 degrees
Jaw angle: Straight
Seal width: 4.6mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134° C - 138° C).

Open instruments

BiClamp 150: £535.00
Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 150mm
Jaw angle: 23 degrees
Seal width: 0.5/3.4 mm x 18 mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134° C - 138° C).

BiClamp 200 C: £494.00
Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 200mm
Jaw angle: 18 degrees
Seal width: 4.2/6 mm x 25 mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134° C - 138° C).
**BiClamp 210: £582.00**
Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 210mm
Jaw angle: 25 degrees
Seal width: 5,5/5,6 mm x 35 mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134°C - 138°C).

**BiClamp 260: £559.00**
Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 260mm
Jaw angle: 18 degrees
Seal width: 1/3,9 mm x 15,5 mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134°C - 138°C).

**BiClamp 270: £542.00**
Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 270mm
Jaw angle: 18 degrees
Seal width: 4,2/6 mm x 25 mm
Average thermal spread: 2mm
Re-usable 50 times (autoclavable at 2 bar 134°C - 138°C).
## Manufacturer recommended surgical procedures

<table>
<thead>
<tr>
<th>Surgical procedure</th>
<th>Laparoscopic</th>
<th>Open instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LAP BiClamp</td>
<td>BiClamp 150</td>
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<tr>
<td></td>
<td>Maryland ribbed</td>
<td>200</td>
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<td></td>
<td>Maryland smooth</td>
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<td></td>
<td>fenestrated ribbed</td>
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<td></td>
<td>fenestrated smooth</td>
<td>270</td>
</tr>
</tbody>
</table>

### General surgery / Other

- **Hemorrhoidectomy**
- **Gastrectomy**
- **Adrenalectomy**
- **Liver resection**
- **Axillary dissection**
- **Colectomy**
- **Splenectomy**
- **Adhesiolysis**
- **Gastric bypass**
- **Appendectomy**
- **Nissen fundoplication**
- **Thyroidectomy**
- **Parotidectomy**
- **Colon resection**
- **Whipple**

### Gynaecology

- **Abdominal hysterectomy (open)**
- **Vaginal hysterectomy (VH)**
- **Laparoscopic assisted VH**
- **Salpingo oophorectomy**

### Urology

- **Radical prostatectomy**
- **Cystectomy**
- **Nephrectomy**
Servicing

**Non Contract Price:** Rate/hour service (on site) £68.25 Rate /hour travel £66.15

**Contract Price:** Standard annual service £790.00. Total care annual service £1185
Both contract options include a loaner unit (above prices exclude VAT)

Monopolar safety features

Contact Quality Monitoring (CQM) and Plate Attachment Monitoring (PAM)

Manufacturing standards


**Notified body (for CE marking):** DEKRA  
**Code:** CE0124

Manufacturer’s comments

Comments have been received from the manufacturer and, where appropriate, their suggested changes have been incorporated into the report.
ESU generator

Gyrus PK Super Pulse generator is a dedicated bipolar ESU. This unit has not been previously evaluated by CEP. The generator has two output modes, Vapour Pulse Coagulation (VPC) for bipolar coagulation and vessel sealing (PKS SEAL) and Plasma Kinetic (PK) tissue cutting for bipolar cutting, including laparoscopic cutting. Individual PKS instruments are identified by the generator and the relevant default power setting is displayed, offering the user the option of accepting it or selecting an alternative power setting. Pulsed output allows cooling between energy pulses, to reduce thermal spread and tissue sticking. Unlike most vessel sealing devices the output power is not automatically switched off. The ESU provides an audible and visual impedance indicator and a signal when the desired tissue effect endpoint is reached. The surgeon must release the footswitch to deactivate surgical current.

Detail: Class IIB. BF type. Weight: 8kg
Dimensions: 135(H) 410(W) 410(D) mm
Fundamental frequency: 340-450kHz

Summary

- Dedicated bipolar ESU incorporating vessel sealing technology ‘PKS SEAL’
- Max vessel sealing power: 90W
- Default bipolar power: 60W (coagulation mode)
- Output sockets: 2 bipolar
- LED display
- Audible and visual impedance indicator to determine tissue seal end point
- 3 PKS SEAL open forceps are available
- Automatic instrument detection for Gyrus PK SEAL instruments
- No monopolar output
- Suitable for bipolar vessel sealing surgical procedures in open operations

Price (ex VAT) £11,717.00
Supplier: Gyrus International Ltd
Address: 410 Wharfedale Rd
Winnersh Triangle
Wokingham, Berks
RG41 5RA
Telephone: 01189 219700
Fax: 01189 219800
Website: www.gyrusplc.com
Email: sales@gyrusintl.com
Manufacturer Gyrus Medical Ltd
Manufactured in: UK
Instruments for vessel sealing

Open instruments

PKS SEAL Open Forceps Curved: £1023.00 (5 / case)
Seals vessels and tissue bundles up to and including 7mm in diameter. Coagulate, grasp and retract.
Instrument length: 247mm
Jaw angle: 18.5 degrees
Seal width: 3.2 - 4.4mm.
Average thermal spread: 0.4 - 2.3mm*
Single patient use.

PKS SEAL Open Forceps Straight: £1091.00 (5 / case)
Seals vessels and tissue bundles up to and including 7mm in diameter. Coagulate, grasp and retract.
Instrument length: 247mm
Jaw angle: Straight
Seal width: 3.2 - 4.4mm
Average thermal spread: 0.4 - 2.3mm*
Single patient use.

PKS SEAL Open Forceps Angled: £1514.00 (5 / case)
Seals vessels and tissue bundles up to and including 7mm in diameter. Coagulate, grasp and retract.
Instrument length: 210mm
Jaw angle: 69 degrees
Seal width: 3.2 - 4.5mm
Average thermal spread: 0.4 - 2.3mm*
Single patient use.

* thermal spread depends on vessel size
### Manufacturer recommended surgical procedures

<table>
<thead>
<tr>
<th>Surgical procedure</th>
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<th>Open instruments</th>
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</thead>
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<td>PKS SEAL Open/Curved</td>
<td>PKS SEAL Open/Straight</td>
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<td><strong>General surgery / Other</strong></td>
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<tr>
<td>Hemorrhoidectomy</td>
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<tr>
<td>Gastrectomy</td>
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<tr>
<td>Adrenalectomy</td>
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<td>Axillary dissection</td>
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<td>Laparoscopic assisted VH</td>
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<tr>
<td>Nephrectomy</td>
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</table>
Servicing

Currently UK Gyrus does not offer any annual maintenance contracts. If a generator requires servicing it should be returned to Gyrus, Cardiff and a replacement will be sent to the hospital.

Manufacturing standards


Notified body (for CE marking): TUV       Code: CE0123

Manufacturer’s comments

The Gyrus Medical PK Technology a highly versatile bipolar system, consisting of a PK Generator and PK Instruments, designed as a system.

Unlike competitive systems which use an algorithm to determine desiccation endpoint, the PK Technology utilizes constant voltage and variable current to provide real time dynamic monitoring of tissue impedance.

The PK Technology can be used across medical specialties for a wide variety of surgical procedures to optimize performance and maximize clinical results which include, true bipolar cutting, simultaneous cutting and coagulation, vapor pulse coagulation, enhanced vessel sealing, minimal thermal spread, virtually no sticking. In addition to the PK Open Forceps, vessel sealing can also be performed with teh PK Cutting Forceps and PK Lyons Dissecting Forceps. New developments being offered in the future include PlasmaCision (PK PlasmaSeal Forceps ) a technology offering rapid simultaneous sealing and cutting.

PK Technology provides surgeons with unique RF energy to seal, transect, coagulate, dissect and mobilize. PK fast starts in bloody fields, maximizes coagulation within the tissue, reduces or eliminates sticking, low thermal margin and can seal large vessels.
Martin Maxium - SealSafe and EndoSeal

Summary

- General purpose ESU with incorporated vessel sealing technology ‘SealSafe’ and ‘EndoSeal’ technology
- Max SealSafe power: 320W
- Max EndoSeal power: 100W
- Max power: 120W bipolar
- Output sockets: 2 monopolar and 2 bipolar
- LCD display and Quick Step Control for ease of use
- Output automatically switches off when vessel sealing is complete
- 2 laparoscopic and 7 open instruments are available
- Suitable for bipolar vessel sealing surgical procedures in both open and laparoscopic operations

ESU generator

The Martin Maxium is a general purpose ESU generator and was reviewed previously [4]. Open vessel sealing procedures use the the SealSafe mode (320W max) on the ESU with the marClamp range of instruments. Laparoscopic procedures require marLap instruments and the ESU mode is set to EndoSeal (100W max), which is specifically designed for laparoscopic procedures. Vessel sealing is initiated by pressing the footswitch. Output power is automatically switched off when the algorithm deems that a good seal has been achieved. The unit also supports a range of bipolar and monopolar modes, including auto start and auto stop bipolar coagulation modes, and a bipolar cutting scissors system. The system is totally configurable through a simple user interface.

Detail: Maximum monopolar power: 400W Class IIB. CF type. Weight: 8.3kg Dimensions: 182(H) 390(W) 435(D) mm Fundamental frequency: 300-600kHz

Price (ex VAT) £ price on application
Supplier: KLS Martin ##
Address: Ludwigstaler Strabe 132
Postfach 60
78501 Tuttlingen
Germany
Telephone: +49 7461 706321
Fax: +49 7461 706205
Website: www.klsmartin.com
Email: sandra.braunbart@klsmartin.com
Manufacturer Martin
Manufactured in: Germany

## details of UK supplier not available at time of publication please contact the manufacturer.
Instruments for vessel sealing

Laparoscopic instruments

**marLap Maryland: Price on request**
Ribbed curved electrodes for grasping and coagulating.
Shaft diameter: 5mm
Shaft length: 340mm
Shaft rotation: 360 degrees
Jaw angle: Curved
Seal width: _information not supplied_
Average thermal spread: _not supplied_
Reusable instrument (autoclavable at 2 bar 134° C - more than 100 times).

**marLap Clamp: Price on request**
Fenestrated and ribbed electrodes for grasping and coagulating. Seals vessels and tissue bundles.
Shaft diameter: 5mm
Shaft length: 340mm
Shaft rotation: 360 degrees
Jaw angle: Straight.
Seal width: _information not supplied_
Average thermal spread: _not supplied_
Reusable instrument (autoclavable at 2 bar 134° C - more than 100 times).
Open instruments

marClamp Curved: Price on request
Seals vessels and tissue bundles and
incorporates a ratchet and ceramic spacers to
securely clamp the tissue. To be used with
standard Martin bipolar cables.
Instrument length options include: 160mm (d)
180mm (e), 230mm (f) and 280mm (g)
Jaw angle: Curved
Seal width: information not supplied
Average thermal spread: not supplied
Reusable instrument (autoclavable at 2 bar
134°C - more than 100 times).

marClamp Straight: Price on request
Seals vessels and tissue bundles and
incorporates a ratchet and ceramic spacers to
securely clamp the tissue. To be used with
standard Martin bipolar cables.
Instrument length options include: 180mm (a),
230mm (b) and 280mm (c)
Jaw angle: Straight
Seal width: information not supplied
Average thermal spread: not supplied
Reusable instrument (autoclavable at 2 bar
134°C - more than 100 times).

marClamp curved instrument
180mm length

marClamp straight instruments
marClamp curved instruments
### Manufacturer recommended surgical procedures

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</table>
Servicing

2 year warranty. After the warranty period has ended the supplier has a range of service contracts available. Further details available from the manufacturer.

Monopolar safety features

Contact Quality Monitoring (CQM) and Plate Attachment Monitoring (PAM) which the manufacturer calls Patient Control System (PCS).

Manufacturing standards


Notified body (for CE marking): DQS Code: CE 0297

Manufacturer’s comments

Other features of the ESU include:

- 100 user defined programs
- May be connected to an Argon Beamer
- 14 cutting and 27 coagulation currents
- Program favourites for fast program selection
- Generator can be updated and upgraded
- Service interface to read out data (error-code memory)
- Software upgrades and updates possible
- Different versions for different types of accessories
- Endo-Currents, Duo-Spray and Micro-Currents available
- Night-View design for endoscopic applications
- Automatic identification of the neutral electrode
- Dynamic and arc controlled output control
- Monopolar power range from 100mW to 400W
- 4 Working channels
- Reusable accessories
- Large colour display
ESU generator

The Valleylab LigaSure™ is a specially designed bipolar ESU for vessel sealing. The ESU senses the instrument and automatically selects the appropriate default settings. Power output may be adjusted by up to five increments but the seal time is not adjustable. Tissue impedance data is used to control the output voltage and over a controlled time period to achieve a consistent surgical effect. When a good seal is detected the ESU output stops automatically and a beep informs the surgeon. Three potential alert conditions are indicated by a two tone beep and an orange visual indicator to alert the surgeon to an unsuitable seal. After solving the problem the procedure may be repeated. The ESU generator also provides two other bipolar modes, a macro bipolar producing high peak voltages for bipolar cutting and a normal bipolar mode for coagulation.

**Detail:**
- Class IIB. CF type.
- Weight: 5.9 kg
- Dimensions: 127(H) 386(W) 406(D) mm
- Fundamental frequency: 473 kHz

**Summary**

- Dedicated bipolar ESU, vessel-sealing unit
- Max vessel sealing power: 150W
- Max power: 95W macro bipolar
- Max power: 95W bipolar
- Output sockets: 1 bipolar (blue) and 1 LigaSure™ seal socket (purple)
- LED display
- Output automatically switches off when vessel sealing is complete
- 3 laparoscopic and 6 open instruments are available
- Automatic instrument detection for LigaSure™ devices
- Suitable for bipolar vessel sealing surgical procedures in both open and laparoscopic operations

**Price (ex VAT)**

£12875.00

**Supplier:** TycoHealthcare UK
**Address:**
154 Fareham Road
Gosport
Hampshire
Chalgrove
PO13 0AS

**Telephone:**
01329 224115
**Fax:**
01329 224260
**Website:**
www.ligasure.com
**Email:**
uksales@emea.
tycohealthcare.com

**Manufacturer:**
Valleylab Inc.
**Manufactured in:**
USA
Instruments for Vessel Sealing

Laparoscopic instruments

**LigaSure™ V: £2009.00 (6 / case)**
Seals vessels and tissue bundles up to and including 7mm in diameter. Dissects, grasps, seals and divides.
Shaft diameter: 5mm
Shaft length: 370mm
Shaft rotation: 179 degrees
Jaw angle: Straight
Seal width: 4.63mm (2 * 2.2mm)
Average thermal spread: 1.5mm
Single patient use.

**LigaSure™ Atlas: £1475.00 (6 / case)**
Seals vessels and tissue bundles up to and including 7mm in diameter without dissection. Dissects, grasps, seals and divides.
Shaft diameter: 10mm
Shaft length: 370mm
Shaft rotation: <359 degrees
Jaw angle: Straight
Seal width: 6mm (2 * 3mm)
Average thermal spread: 2mm
Single patient use.

**LigaSure™ Lap: £982.00 (6 / case)**
Seals vessels and tissue bundles up to and including 7mm in diameter without. Intended for fine dissection in confined spaces.
Shaft diameter: 5mm
Shaft length: 320mm
Shaft rotation: continuous
Jaw angle: Maryland curve 15 degrees
Seal width: 2 - 4mm
Average thermal spread: 2mm
Single patient use.
Open instruments

**LigaSure™ Atlas 20cm: £1475.00 (6 / case)**
Seals vessels and divides tissue bundles up to 7mm in diameter. Dissects, grasps, seals and divides.
Shaft diameter: 10mm
Shaft length: 200mm
Shaft rotation: <359 degrees
Jaw angle: Straight
Seal width: 6mm (2 * 3mm)
Average thermal spread: 2mm
Single patient use.

**LigaSure™ Precise: £1475.00 (6 / case)**
Permanently seals vessels and tissue bundles up to 7mm in diameter. Replaces suture used for ligation. Can be used for blunt dissection when ESU not activated.
Instrument length: 165mm
Shaft rotation: *not applicable*
Jaw angle: 15 degrees
Seal width: 1 - 3mm
Average thermal spread: 1mm.
Single patient use.

**LigaSure™ Std: Hand piece £ 488.00**
**Electrodes £1246.00 for 12**
Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 180mm
Shaft length: 320mm
Jaw opening: 3mm
Jaw angle: 30 degrees
Seal width: 2.5 - 5mm
Average thermal spread: 2mm
Reusable hand piece (autoclavable - unlimited number of times) with single patient use snap-in electrodes.
LigaSure™ Max: Hand piece £488.00
Electrodes £1246.00 for 12
Designed for improved access during gynaecological procedures. Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 230mm
Jaw angle: 30 degrees
Seal width: 3 - 5mm
Average thermal spread: 2mm
Reusable hand piece (autoclavable - unlimited number of times) with single patient use snap-in electrodes.

LigaSure™ Axs: Hand piece £658.00
Electrodes £1639.00 for 12
Curved jaw for improved access during deep pelvic procedures. Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 266.7mm
Jaw angle: 60 degrees
Seal width: 3 - 4mm
Average thermal spread: 2mm
Reusable hand piece (autoclavable - unlimited number of times) with single patient use snap-in electrodes.

LigaSure™ Xtd: Hand piece £546.00
Electrodes £1443.00 for 12
Longer length for improved access during deep pelvic procedures. Seals vessels and tissue bundles up to and including 7mm in diameter.
Instrument length: 280mm
Jaw angle: 30 degrees
Seal width: 2.5 - 5mm
Average thermal spread: 2mm
Reusable hand piece (autoclavable - unlimited number of times) with single patient use snap-in electrodes.
# Manufacturer recommended surgical procedures

<table>
<thead>
<tr>
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<tr>
<td></td>
<td>LigaSure™ V</td>
<td>LigaSure™ Atlas</td>
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<tr>
<td></td>
<td>LigaSure™ Lap</td>
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<tr>
<td>Liver resection</td>
<td>● ● ● ● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Axillary dissection</td>
<td></td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Colectomy</td>
<td>● ● ● ● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Splenectomy</td>
<td>● ● ● ● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Adhesiolysis</td>
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<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Gastric bypass</td>
<td>● ● ● ● ●</td>
<td>● ● ● ● ● ●</td>
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<tr>
<td>Appendectomy</td>
<td></td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Nissen fundoplication</td>
<td>● ●</td>
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</tr>
<tr>
<td>Thyroidectomy</td>
<td></td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Parotidectomy</td>
<td></td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Colon resection</td>
<td>● ● ● ● ●</td>
<td>● ● ● ● ● ●</td>
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<tr>
<td>Whipple</td>
<td>● ● ● ● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Gynaecology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal hysterectomy (open)</td>
<td>● ● ● ● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Vaginal hysterectomy (VH)</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Laparoscopic assisted VH</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Salpingo oophorectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Urology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radical prostatectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Cystectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
<tr>
<td>Nephrectomy</td>
<td>● ●</td>
<td>● ● ● ● ● ●</td>
</tr>
</tbody>
</table>
Servicing

**Option (a)** fully comprehensive contract £1500 per annum this includes all parts, labour, travel for breakdowns, 2 Pre-Planned Maintenance (PPM) visits and unlimited use of loaner device. **Option (b)** Pre-Planned Maintenance contract £700 per annum this includes 2 PPM visits for up to 3 ESU to be tested on the same day and unlimited use of loaner device. Parts are charged extra and under a breakdown, labour and travel are charged, but at a reduced rate (see below).

Service charges with PPM contract: labour/travel £60 per hour, mileage £0.38 /mile. Service charges without contract: labour/travel £85 per hour, mileage £0.38 /mile.

Manufacturing standards


**Notified body (for CE marking):** BSI  
**Code:** CE0086

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**Manufacturer’s comments**

Key issues when choosing a system is clinical performance and proven reliability.

The clinical performance of the Ligasure™ Vessel Sealing System can be measured by three main criteria; vessel size, burst pressure and control of lateral thermal spread. The Ligasure™ Vessel Sealing System will, using all the instrumentation identified above, seal vessels up to and including 7 mm, along with muscle bundles. Through the use of controlled energy and mechanical pressure, substantially larger vessels can be sealed compared to standard coagulation/dissection techniques associated with monopolar, bipolar and ultrasonic dissectors which rely on a proximal thrombus as the mechanism of haemostasis. The Ligasure™ seal zones, created by reforming the collagen in the vessel walls/muscle bundles, will withstand an average of 3 times normal systolic pressure (360 mmHg). As the Ligasure™ Vessel Sealing System utilizes a ‘closed loop’ method of energy control, the lateral thermal spread generated in the tissue is less than 2 mm, except for the Ligasure™ V laparoscopic instrument which is less than 1.5 mm and the Precise™ instrument which is less than 1 mm. As Ligasure™ Vessel Sealing measures tissue impedance and turns off the generator when the seal cycle has been completed, alerting surgeon by single beep, the quality and reliability of the seal zone is guaranteed.

Finally the Ligasure™ Vessel Sealing System has completed 567,000 surgical procedures worldwide across all surgical specialties and with over 200 clinical papers. For clinical paper details and video footage of the system in action, please refer to www.ligasure.com.
References


We would like to thank all the suppliers and manufacturers who assisted in the production of this report by providing documentation, information and feedback.

We would also like to thank Mr Neil Warren (Cardiff University), Dr Richard Penketh (University Hospital of Wales) and Mrs Mel King (Medicines and Healthcare products Regulatory Agency) for their advice and proof-reading.
**How good is the seal?**

Burst strength testing can be performed to demonstrate vessel closure integrity of a range of vessel sealing techniques, including sutures, surgical clips and ultrasonic devices as well as RF electrosurgery. Arterial seals that can withstand 300 mmHg (which is considerably greater than usual maximum arterial systolic pressures) may be considered adequate. Lower burst pressures are sufficient for veins.

This section summarises several research studies conducted in different centres. Some researchers were working in conjunction with the device manufacturers. All studies summarised here used porcine vessels to investigate the strength of the vascular seal. This is not a comprehensive literature review but it does illustrate the type of objective information relating to surgical performance that may be available for prospective purchasers to study.

Arterial burst pressures for *in vivo* porcine vessels after sealing with the ERBE VIO system were measured as 748 +/- 168 mmHg, when using the BiClamp instrument (designed for open surgery), and 960 +/- 165 mmHg for the BiClamp laparoscopic device [5]. The vessel diameters ranged between 2 - 7mm and no significant trend with size was observed. During the same sequence of experiments venous burst pressures were reported to range between 154 +/- 52 mmHg using the Biclamp open surgery instrument and 167 +/- 26 mmHg when using the Biclamp laparoscopic applicator.

Presthus et al. [6] used porcine vessels to evaluate the sealing ability of the Gyrus PKS SEAL vessel system. Initially 70 segments of carotid artery between 4-10mm diameter were used as an *in vitro* ‘bench’ model and a 95.5% success at the vessel seal withstanding 300mmHg was achieved. Subsequently during an *in vivo* assessment on femoral, iliac, axillary, carotid and renal arteries (from 2.5 to 7mm in diameter), 95.7% produced seals which withheld a burst pressure of 300mmHg for 10 seconds. The endpoint burst pressure ranged from 565 to 1934 mmHg. Peitrow et al [7] found that porcine renal arteries up to 5mm in diameter were reliably sealed using a Gyrus system and produced mean burst pressures of 291mmHg, but poorer results were obtained with larger vessels. By contrast renal veins between 2 and 12mm in diameter were reliably sealed with mean burst pressures of 288mmHg.

Porcine arteries have also been used to test the burst pressures following use of the Ligasure vessel sealer. This has been reported in a comparative study with coagulating shears, titanium or plastic clips. The mean burst pressures for the Ligasure were found to be 601mmHg for vessels 4-5mm in diameter, 442mmHg for 6-7mm vessels and only 128mmHg for smaller vessels (2-3 mm) [8]. Richter et al [5] obtained higher arterial burst pressures for the Ligasure system and observed them to be 905 +/- 172 mmHg for an applicator designed for open surgery and 810 +/- 111 mmHg for the laparoscopic instrument. The vessels were between 2 to 7mm in diameter.
Manufacturing standards for medical devices

### Table 1: Standards relevant for the design and manufacture of electrosurgery units

<table>
<thead>
<tr>
<th>Manufacturing standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS EN ISO 13485:2003</td>
<td>Quality systems applied to medical devices. Particular requirements for the application of ISO9001</td>
</tr>
<tr>
<td>BS EN ISO 13485:2001</td>
<td></td>
</tr>
<tr>
<td>BS EN ISO 13485:1996</td>
<td></td>
</tr>
<tr>
<td>ISO 13485:2001</td>
<td></td>
</tr>
<tr>
<td>ISO13485:1996</td>
<td></td>
</tr>
<tr>
<td>BS EN 46001:1997</td>
<td>Specification for application of EN ISO 9001 to the manufacturer of medical devices (Withdrawn in 2004)</td>
</tr>
<tr>
<td>EN 55011:1991</td>
<td>Specification for limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment</td>
</tr>
<tr>
<td>BS EN 60601-1:1990</td>
<td>Medical electrical equipment. General requirements for safety.</td>
</tr>
<tr>
<td>IEC 60601-1:1988</td>
<td></td>
</tr>
<tr>
<td>IEC 60601-1-2:1988</td>
<td></td>
</tr>
<tr>
<td>ISO9001:2000</td>
<td></td>
</tr>
<tr>
<td>BS – British Standard</td>
<td></td>
</tr>
<tr>
<td>EN – European harmonised standard</td>
<td></td>
</tr>
<tr>
<td>ISO – International Organisation for Standardisation</td>
<td></td>
</tr>
<tr>
<td>IEC – International Electrotechnical Commission</td>
<td></td>
</tr>
</tbody>
</table>

A brief guide to the Medical Devices Directive

The European Medical Devices Directive (MDD) [9] became mandatory in June 1998 ([http://europa.eu.int/comm/enterprise/medical_devices/index_en.htm](http://europa.eu.int/comm/enterprise/medical_devices/index_en.htm)). The MDD sets out the ‘Essential requirements’ with which a medical device must comply in order to be eligible for CE-marking. These are necessarily written in general terms as they cover all products which fall within the definition of a medical device. The CE mark means that a product can be marketed in any country within the EU; there are no further country-specific requirements.

The European harmonised standards have been developed to provide more specific guidance for manufacturers. It is not necessary to meet the applicable standards in order to be compliant with the ‘Essential requirements’, but it is the simplest method
for a manufacturer to obtain the CE mark. In the UK the British Standards Institute ([www.bsi-global.com](http://www.bsi-global.com)) publishes European Standards with the prefix “BS EN”. The ISO and IEC standards also cover countries beyond the EU borders and may have slightly different requirements to the European standards.

Table 2: Routes for demonstrating conformity with the Medical Devices Directive

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Routes to satisfying the Medical Devices Directive &amp; obtaining CE marking</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIa or IIb</td>
<td>Full Quality Assurance System covering design, production and quality monitoring of the process</td>
</tr>
<tr>
<td>IIa</td>
<td>Declaration of conformity by the manufacturer AND</td>
</tr>
<tr>
<td></td>
<td>Product Verification (e.g. batch testing) OR</td>
</tr>
<tr>
<td></td>
<td>Product Quality Assurance (i.e. how a unit is tested at the end of the production) OR</td>
</tr>
<tr>
<td>IIb</td>
<td>Type testing of the device AND</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>Production Quality Assurance (i.e. how a device is produced)</td>
</tr>
</tbody>
</table>

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health ([www.mhra.gov.uk](http://www.mhra.gov.uk)) and regulates a wide range of products from medicines to medical devices. MHRA is the EU designated Competent Authority for medical devices in the United Kingdom. Medical devices must be assessed by organisations, called “Notified Bodies”, before a CE mark can be applied. The MHRA audits UK Notified Bodies and also inspects UK manufacturers to ensure that companies are complying with the appropriate regulations. Information on all the Notified Bodies within Member States of the European Union can be found at the following web address: [http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies](http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies)