VALUE ANALYSIS BRIEF

LigaSure™ Small Jaw Instrument
LigaSure™ Small Jaw Instrument

- Is an 18.8 cm (7.4 inch) vessel sealer and divider designed to be used in confined surgical spaces where access and visibility are a necessity

- Provides an integrated cutting mechanism independent of sealing leaving the critical cutting decisions in the hands of the surgeon

- May reduce the exchange of instruments compared to mechanical ligation

LigaSure™ technology seals vessels, up to and including 7 mm, lymphatics, pulmonary vasculature and tissue bundles in approximately 2 to 4 seconds using the ForceTriad™ energy platform. “LigaSure™ technology has the highest burst pressure and fastest sealing time and was the highest rated overall” compared to Gyrus PKS™, Harmonic ACE™ and ENSEAL™

LigaSure™ instruments may be associated with:

- Reduced procedure time, blood loss and pain compared to conventional techniques
- Reduced operative time, perioperative blood loss, drainage volume and duration, and incidence of seroma or lymphedema

More than 300 studies have been published about LigaSure™ technology in peer-reviewed journals.

References
LigaSure™ Small Jaw Overview and Features

Overview
The LigaSure™ small jaw instrument, designed for open surgery, offers the ability to selectively cut or grasp tissue and permanently seal vessels up to and including 7 mm in diameter, lymphatics, and tissue bundles without sutures, staples or clips. The LigaSure™ small jaw instrument is compatible with the ForceTriad™ energy platform\(^1\) which can seal vessels and tissue bundles in approximately 2 to 4 seconds.

Specialties
Ear, Nose, and Throat (ENT)
General
Plastic/Reconstructive
Urologic
Thoracic

Order Information
Ordering Code: LF1212
Order Quantity: 6 units/case

Features
Instrument Length: 18.8 cm (7.4 in)
Jaw Angle: 28 degrees
Seal Width: 1-4 mm
Seal Length: 16.5 mm
Cut Length: 14.7 mm
Jaw Texture: Textured surface with ceramic dots
Hand or Foot Activation

\(^1\)Only when using ForceTriad™ software version 3.40 or greater

Learn more about the new U.S. FDA 510(k) clearance for use in ENT procedures at:
http://energysolutions.covidien.com/content/ppv-whats_new
Compared to mechanical ligation techniques, LigaSure™ technology may be associated with:

- Reduced **operative time** in breast\(^1\) and hemorrhoid\(^2\) surgery
- Reduced **blood loss** in breast\(^1\) and hemorrhoid\(^2\) surgery
- Reduced **length of hospital stay** in hemorrhoid\(^2\) surgery
- Reduced **post-operative complications** in breast\(^1\) surgery
- Reduced **post-operative pain** after hemorrhoid\(^2\) surgery

Compared to other energy-based modalities, LigaSure™ technology may be associated with:

- Reduced **operative time** in hemorrhoid surgery compared to Harmonic Scalpel\(^{TM*3}\)
- Reduced **post-operative pain and analgesic requirements** after hemorrhoid surgery compared to Harmonic Scalpel\(^{TM*3}\)

Compared to other energy-based modalities, LigaSure™ technology has been shown to:

- Have the "highest burst pressure and fastest sealing time and was the highest rated overall" compared to Gyrus PKS\(^{TM*}\), Harmonic ACE\(^{TM*}\) and ENSEAL\(^{TM*4}\)
- Have a **lower temperature profile** compared to Harmonic Scalpel\(^{TM*5}\)

**References**

Compared to mechanical ligation techniques, LigaSure™ technology may be associated with:

- Reduced operative time in breast1 and hemorrhoid2 surgery
- Reduced blood loss in breast1 and hemorrhoid2 surgery
- Reduced length of hospital stay in hemorrhoid2 surgery
- Reduced post-operative complications in breast1 surgery
- Reduced post-operative pain after hemorrhoid2 surgery

Compared to other energy-based modalities, LigaSure™ technology may be associated with:

- Reduced operative time in hemorrhoid surgery compared to Harmonic Scalpel™3
- Reduced post-operative pain and analgesic requirements after hemorrhoid surgery compared to Harmonic Scalpel™3

Compared to other energy-based modalities, LigaSure™ technology has been shown to:

- Have the “highest burst pressure and fastest sealing time and was the highest rated overall” compared to Gyrus PKS™, Harmonic ACE™, and ENSEAL™4
- Have a lower temperature profile compared to Harmonic Scalpel™5

References


The LigaSure™ small jaw instrument can potentially replace the following devices within these areas:

**Vessel Sealing Devices**

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Catalog #</th>
<th>Description</th>
<th>Diameter</th>
<th>Length</th>
<th>Hand Activation</th>
<th>Cutting Independent of Sealing</th>
<th>Generator</th>
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<tbody>
<tr>
<td>Ethicon</td>
<td>ETTRIO314H</td>
<td>ENSEAL™ Trio</td>
<td>5 mm</td>
<td>14 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>RF-60 Generator ENSEAL™ RF-60 Generator</td>
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<td>ENSEAL™ Trio</td>
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<td>25 cm</td>
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<td>Yes</td>
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<td>ERBE</td>
<td>20195-230</td>
<td>BiClamp™ 110</td>
<td>5 mm</td>
<td>110 mm</td>
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<td>10140-100 VIO 300 D</td>
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<td>20195-221</td>
<td>BiClamp™ 150 C</td>
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**Other Energy-based Devices**

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<td>Ethicon</td>
<td>FCS-9</td>
<td>Harmonic FOCUS™</td>
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<td>Covidien</td>
<td>012026</td>
<td>AutoSonix™ ULTRA SHEARS Short Instrument</td>
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<td>15.7 cm</td>
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**Mechanical Devices**

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<td>Various Manufacturers</td>
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<td>Clips</td>
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1Energy-based devices are used predominantly for dissection to include ultrasonic, radio frequency (RF), light, thermal, hydromechanical, cryogenic and microwave technologies.
DEPARTMENT OF HEALTH & HUMAN SERVICES

Covidien
% Mr. John Van Hoven
Surgical Solutions
5920 Longbow Drive
Boulder, CO 80301

Re: K113572
Trade/Device Name: LigaSure™ Curved, Small Jaw, Open Sealer / Divider (LF1212)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 29, 2012
Received: August 30, 2012

SEP 0 5 2012

Dear Mr. Van Hoven:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to [http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm) for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to [http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm) for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address [http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic, and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (If known): K113572

Device Name: LigaSure™ Curved, Small Jaw, Open Sealer / Divider (LF1212)

Indications for Use:

The LigaSure™ Curved, Small Jaw, Open Sealer / Divider is a bipolar electrosurgical instrument intended to be used with the ForceTriad™ energy platform. The instrument is indicated for use in open general surgical procedures where ligation and division of vessels (up to 7 mm in diameter), tissue bundles, and lymphatics is performed, such as urologic, thoracic, plastic, and reconstructive; and including such procedures as bowel resections, gall bladder procedures, Nissen fundoplication, adhesiolysis, etc.

The device is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally sensitive structures such as nerves and parathyroid glands.

The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

Prescription Use  ✔ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D)  (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off) Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113572