I am requesting the following instruments be stocked in our facility so that I have consistent access to these devices for my cases:

- LigaSure™ 5 mm blunt tip 20 cm open/sealer/divider (LF1520)
- LigaSure™ 5 mm blunt tip 37 cm laparoscopic/sealer/divider (LF1637)
- LigaSure™ 5 mm blunt tip 44 cm long laparoscopic/sealer/divider (LF1544)

The LigaSure™ 5 mm blunt tip family of instruments:

- Offers a longer cutting length compared to most commercially available 5 mm laparoscopic sealing devices.
- Enables cutting independent of sealing.
- Provides sealing, grasping and access to surgical structures to accommodate a variety of open and laparoscopic procedures.

LigaSure™ technology seals vessels, up to and including 7 mm, lymphatic, pulmonary vasculature* and tissue bundles in 2 to 4 seconds using the ForceTriad™ energy platform.

LigaSure™ instruments have been found to:

- Have the highest burst pressure and fastest sealing time and were highest rated overall compared to Gyrus PK™, Harmonic ACE™, and ENSEAL™.
- Reduce blood loss compared to sutures and clips²,³,⁴
- Reduce procedure time compared to sutures²,³
- Reduce patient length of stay compared to sutures²

More than 300 studies have been published about LigaSure™ technology in peer-reviewed journals. I am confident in using a technology backed by such a significant body of evidence-based research.

Thank you for reviewing this information. Please contact me if you have any questions.

Sincerely,

Additional Comments:


*Only when using the ForceTriad™ Energy Platform.
Product Overview
Performance beyond expectations

LigaSure™ 5 mm Blunt Tip Family of Instruments

Overview
The LigaSure™ 5 mm blunt tip family of instruments (LF1520, LF1637 & LF1544) offers cutting independent of sealing, atraumatic grasping and a longer cutting length compared to other commercially available 5 mm sealing devices. These devices seal vessels, up to and including 7 mm, lymphatic, pulmonary vasculature*, and tissue bundles in 2 to 4 seconds using the ForceTriad™ energy platform.

Specialties:
Colorectal
General Surgery
Gynecology
Urology

Order Information:
LF1520-6 units/case (20 cm shaft length)
LF1637-6 units/case (37 cm shaft length)
LF1544-6 units/case (44 cm shaft length)

<table>
<thead>
<tr>
<th>Description</th>
<th>LF1637</th>
<th>LF1520</th>
<th>LF1544</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaft Length:</td>
<td>37 cm</td>
<td>20 cm</td>
<td>44 cm</td>
</tr>
<tr>
<td>Device Type:</td>
<td></td>
<td>Sterile, single use</td>
<td></td>
</tr>
<tr>
<td>Shaft Diameter:</td>
<td>5 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaw Type:</td>
<td>Blunt, double-action with contoured tips</td>
<td>Blunt, single-action with contoured tip</td>
<td></td>
</tr>
<tr>
<td>Jaw Surface:</td>
<td></td>
<td>Textured with ceramic stops</td>
<td></td>
</tr>
<tr>
<td>Jaw Aperture:</td>
<td>14.5 mm</td>
<td>13.5 mm</td>
<td></td>
</tr>
<tr>
<td>Shaft Rotation:</td>
<td>180 degrees</td>
<td>159 degrees</td>
<td></td>
</tr>
<tr>
<td>Activation Method:</td>
<td></td>
<td>Hand or foot</td>
<td></td>
</tr>
</tbody>
</table>

The LigaSure™ 5 mm blunt tip family of instruments is only compatible with the ForceTriad™ energy platform software version 3.5 and higher.

*Only when using the ForceTriad™ Energy Platform.
Compared to mechanical ligation techniques, LigaSure™ technology has been shown to:

- Significantly reduce operative blood loss in colorectal, gynecologic and urologic surgery\(^1\)-\(^6\)
- Significantly reduce perioperative blood transfusions in gynecologic, urologic and general surgery\(^5\),\(^7\),\(^8\)
- Significantly reduce procedure time in colorectal, gynecologic and urologic surgery\(^1\),\(^2\),\(^3\),\(^4\),\(^6\),\(^9\),\(^10\)
- Significantly reduce length of hospital stay in gynecologic and urologic surgery\(^3\)

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

- Significantly reduce operative blood loss in colorectal and gynecologic surgery\(^11\)-\(^13\)
- Significantly reduce procedure time in colorectal and gynecologic surgery\(^11\),\(^13\)

References

# Cross Reference Chart

## LigaSure™ 5 mm Blunt Tip Portfolio - 20 cm Shaft Length Competitive Comparison

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Cat #</th>
<th>Description</th>
<th>Diameter</th>
<th>Shaft Length</th>
<th>Hand-switching</th>
<th>Sealing Independent of Cutting</th>
<th>Generator</th>
<th>Generator Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covidien</td>
<td>LF1520</td>
<td>LigaSure™ 5 mm</td>
<td>5 mm</td>
<td>20 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>ForceTriad™</td>
<td>ForceTriad™ Energy Platform</td>
</tr>
<tr>
<td>Ethicon</td>
<td>ACE14E</td>
<td>Harmonic ACE™ with ergonomic grip</td>
<td>5 mm</td>
<td>14 cm</td>
<td>Yes</td>
<td>No</td>
<td>GEN04 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>ACE23E</td>
<td>Harmonic ACE™ with ergonomic grip</td>
<td>5 mm</td>
<td>23 cm</td>
<td>Yes</td>
<td>No</td>
<td>GEN04 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>Wave18S</td>
<td>Harmonic WAVE™ with ergonomic grip</td>
<td>5 mm</td>
<td>18 cm</td>
<td>Yes</td>
<td>No</td>
<td>GEN04 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>Focus</td>
<td>Harmonic FOCUS™ Long</td>
<td>5 mm</td>
<td>17 cm</td>
<td>Yes</td>
<td>No</td>
<td>GEN04 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSEAL514H</td>
<td>ENSEAL™ device with standard tip</td>
<td>5 mm</td>
<td>14 cm</td>
<td>Yes</td>
<td>No</td>
<td>RF60 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSEAL514RH</td>
<td>ENSEAL™ device with round tip</td>
<td>5 mm</td>
<td>14 cm</td>
<td>Yes</td>
<td>No</td>
<td>RF60 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSEAL525H</td>
<td>ENSEAL™ device with standard tip</td>
<td>5 mm</td>
<td>25 cm</td>
<td>Yes</td>
<td>No</td>
<td>RF60 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSEAL525RH</td>
<td>ENSEAL™ device with round tip</td>
<td>5 mm</td>
<td>25 cm</td>
<td>Yes</td>
<td>No</td>
<td>RF60 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>ETRIO-314H</td>
<td>ENSEAL™ TRIO device</td>
<td>5 mm</td>
<td>14 cm</td>
<td>Yes</td>
<td>No</td>
<td>RF60 / GEN11</td>
<td>Harmonic / EES Generator</td>
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<tr>
<td>Ethicon</td>
<td>ETRIO-325H</td>
<td>ENSEAL™ TRIO device</td>
<td>5 mm</td>
<td>25 cm</td>
<td>No</td>
<td>No</td>
<td>RF60 / GEN11</td>
<td>Harmonic / EES Generator</td>
</tr>
<tr>
<td>Gyrus</td>
<td>PK</td>
<td>PKS™ Cutting Forceps</td>
<td>10 mm</td>
<td>15 cm</td>
<td>No</td>
<td>No</td>
<td>777000</td>
<td>G400 Generator</td>
</tr>
<tr>
<td>Gyrus Omni</td>
<td>PKS™-Omnit™</td>
<td>PKS™-Omnit™</td>
<td>5 mm</td>
<td>15 cm</td>
<td>No</td>
<td>No</td>
<td>777000</td>
<td>G400 Generator</td>
</tr>
</tbody>
</table>
## Cross Reference Chart

### LigaSure™ 5 mm Blunt Tip Portfolio - 37 cm Shaft Length Competitive Comparison

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Catalog Number</th>
<th>Description</th>
<th>Shaft Diameter</th>
<th>Shaft Length</th>
<th>Hand Switching</th>
<th>Cutting Independent of Sealing</th>
<th>Generator Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covidien</td>
<td>LF1637</td>
<td>LigaSure™ 5 mm Blunt Tip</td>
<td>5 mm</td>
<td>37 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>ForceTriad™ ForceTriad™ Energy Platform</td>
</tr>
<tr>
<td>Ethicon</td>
<td>ACE36E</td>
<td>Harmonic ACE™* Curved Shears</td>
<td>5 mm</td>
<td>36 cm</td>
<td>Yes</td>
<td>No</td>
<td>GENII Ethicon™ Endo-surgery Generator</td>
</tr>
<tr>
<td></td>
<td>NSLG2C35</td>
<td>ENSEAL™* G2 Curved Tissue Sealer</td>
<td>5 mm</td>
<td>35 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>GENII Ethicon™ Endo-surgery Generator</td>
</tr>
<tr>
<td></td>
<td>NSLG2S35</td>
<td>ENSEAL™* G2 Straight Tissue Sealer</td>
<td>5 mm</td>
<td>35 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>GENII Ethicon™ Endo-surgery Generator</td>
</tr>
<tr>
<td></td>
<td>ETRIO-335H</td>
<td>ENSEAL™* TRIO device</td>
<td>5 mm</td>
<td>35 cm</td>
<td>No</td>
<td>No</td>
<td>GENII Ethicon™ Endo-surgery Generator</td>
</tr>
<tr>
<td>Olympus</td>
<td>TB-0535IC, TB-0535PC</td>
<td>THUNDERBEAT™*</td>
<td>5 mm</td>
<td>35 cm</td>
<td>Yes</td>
<td>No</td>
<td>USG-400, ESG-400 USG-400™ Ultrasonic Generator, ESG-400™ Electrosurgical Generator</td>
</tr>
<tr>
<td></td>
<td>HACF0533</td>
<td>Gyrus PKS™* Halo Cutting Forceps</td>
<td>5 mm</td>
<td>33 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>777000 PK™* G400 Workstation</td>
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<tr>
<td></td>
<td>920005PK</td>
<td>Gyrus PKS™* Cutting Forceps</td>
<td>5 mm</td>
<td>33 cm</td>
<td>No</td>
<td>Yes</td>
<td>777000 PK™* G400 Workstation</td>
</tr>
<tr>
<td></td>
<td>970010PC</td>
<td>Gyrus PKS™* Omni™*</td>
<td>5 mm</td>
<td>33 cm</td>
<td>No</td>
<td>Yes</td>
<td>777000 PK™* G400 Workstation</td>
</tr>
<tr>
<td>ConMed</td>
<td>60-9522-001</td>
<td>Altrus™* 5 mm</td>
<td>5 mm</td>
<td>36 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>System 5000™* Altrus™* Thermal Tissue Fusion System Energy Source</td>
</tr>
</tbody>
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### LigaSure™ 5 mm Blunt Tip Portfolio - 44 cm Shaft Length Competitive Comparison

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Cat #</th>
<th>Description</th>
<th>Diameter</th>
<th>Shaft Length</th>
<th>Hand-switching</th>
<th>Sealing Independent of Cutting</th>
<th>Generator Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covidien</td>
<td>LF1544</td>
<td>LigaSure™ 5 mm</td>
<td>5 mm</td>
<td>44 cm</td>
<td>Yes</td>
<td>Yes</td>
<td>ForceTriad™ ForceTriad™ Energy Platform</td>
</tr>
<tr>
<td>Ethicon</td>
<td>ACE45E</td>
<td>Harmonic ACE™* with ergonomic grip</td>
<td>5 mm</td>
<td>45 cm</td>
<td>Yes</td>
<td>No</td>
<td>GEN04 / GEN11 Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>ETRIO-345H</td>
<td>ENSEAL™* TRIO device</td>
<td>5 mm</td>
<td>45 cm</td>
<td>Yes</td>
<td>No</td>
<td>RF60 / GEN11 Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSEAL-545H</td>
<td>ENSEAL™* device with standard tip</td>
<td>5 mm</td>
<td>45 cm</td>
<td>Yes</td>
<td>No</td>
<td>RF60 / GEN11 Harmonic / EES Generator</td>
</tr>
<tr>
<td>Ethicon</td>
<td>NSEAL-545RH</td>
<td>ENSEAL™* device with round tip</td>
<td>5 mm</td>
<td>45 cm</td>
<td>No</td>
<td>No</td>
<td>RF60 / GEN11 Harmonic / EES Generator</td>
</tr>
</tbody>
</table>
Covidien

% Ms. Diane Reed
Senior Regulatory Affairs Product Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K130744
Trade/Device Name: LigaSure™ 5mm Blunt Tip Laparoscopic Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 18, 2013
Received: March 19, 2013

Dear Ms. Reed:

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 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 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.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure
Indications for Use Statement

510(k) Number (if known): K130744

Device Name: LigaSure™ 5 mm Blunt Tip Laparoscopic Sealer/Divider (LF1637)

Indications for Use:

The LF1637 LigaSure 5 mm, Blunt Tip, Laparoscopic Sealer/Divider is a bipolar electrosurgical instrument intended for use with the ForceTriad Energy Platform in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure 5 mm Blunt Tip Laparoscopic Sealer/Divider can be used on vessels and lymphatics up to and including 7 mm, and tissue bundles.

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)

Joshua C., Nipper -S For

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K130744
Subject: Regulatory Status - Covidien releases two new lengths of the LigaSure™ 5 mm Blunt Tip Sealer / Divider (LF1520 and LF1544)

To Whom It May Concern:

Covidien Surgical Solutions recently released the LigaSure™ 5 mm blunt tip sealer/divider instruments LF1520 and LF1544. These devices are a short (20 cm) version and a long version (44 cm) of the existing LF1537, which was released in 2009. These two devices are very similar to the LF1537. The differences between the two new devices and the LF1537 relate only to device shaft length:

- LigaSure Blunt Tip Open/Sealer/Divider (LF1520)-20 cm shaft length
- LigaSure Blunt Tip Laparoscopic/Sealer/Divider (LF1544)-44 cm shaft length

The Regulatory Affairs Department at Covidien Surgical Solutions performs an evaluation of all new or modified devices. This evaluation process based on FDA Guidance document “Deciding When to Submit a 510(k) for a Change to an Existing Device”, dated January 10, 1997, compares new or modified products to Covidien products previously cleared by FDA for marketing in the United States.

Based on this evaluation, it was concluded that the subject devices (LF1520 and LF1544) are modifications to the previously cleared LigaSure 5 mm Blunt Tip Laparoscopic Sealer / Divider, LF1537 (K092879).

As such, the subject devices do not require new premarket submissions since they represent modifications to these predicate devices that do not change the device indications for use or raise new issue of safety or effectiveness other than what was already identified in the previous premarket notification.

Therefore, we attest that the 510(k) premarket notification requirements for the subject devices have been met as a medical device per applicable FDA regulations and these products can be legally marketed in the United States.

Andres Holle
Sr. Director, Regulatory Affairs
Covidien, Endomechanical & Energy Division (EED)
Surgical Solutions Group
Valleylab, a Division of Tyco Healthcare Group LP
% Mr. Philip E. Ake, Senior Regulatory Associate
5920 Longbow Drive
Boulder, CO 80301

Re: K092879
Trade/Device Name: LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 17, 2009
Received: September 18, 2009

Dear Mr. Ake:

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.

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.
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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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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): __________

Device Name: LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider

Indications for Use:

The LigaSure 5mm, Blunt tip, Laparoscopic Sealer-Divider is a bipolar electrosurgical instrument intended for use the Force Triad Generator in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The LigaSure 5mm Blunt tip Laparoscopic Sealer-Divider can be used on vessels and lymphatics up to and including 7 mm and tissue bundles as large as will fit in the jaws of the instrument.