FMsealer Laparoscopic Shears are an intelligent, multifunctional thermal vessel sealing instrument that uses ferromagnetic technology to efficiently seal and divide tissue with minimal lateral thermal spread in laparoscopic and open surgical procedures.

- **Reliable sealing** of vessels up to 7 mm in diameter, including lymphatics
- **Faster dissection times** than competitive instruments through vascular tissue bundles
- **Precise control of heat**, with less lateral thermal spread than competitive instruments
- **No stray electrical current**, no risk of capacitive coupling, safe to use around metal staples and clips

FMsealer Laparoscopic Shears are a component of the **FMX Ferromagnetic Surgical System**.

To watch surgical videos of FMX instruments in action, visit domainsurgical.com/video

To learn how ferromagnetic technology works, visit domainsurgical.com/fmx

© 2016 Domain Surgical, Inc. All rights reserved. LB-054 Rev. B
FMsealer Laparoscopic Shears are an intelligent, multifunctional thermal vessel sealing instrument that uses ferromagnetic technology to efficiently seal and divide tissue with minimal lateral thermal spread in laparoscopic and open surgical procedures.

- Reliable sealing of vessels up to 7 mm in diameter, including lymphatics
- Faster dissection times than competitive instruments through vascular tissue bundles
- Precise control of heat, with less lateral thermal spread than competitive instruments
- No stray electrical current, no risk of capacitive coupling, safe to use around metal staples and clips

FMsealer Laparoscopic Shears are a component of the FMX Ferromagnetic Surgical System.

To watch surgical videos of FMX instruments in action, visit domainsurgical.com/video
To learn how ferromagnetic technology works, visit domainsurgical.com/fmx

For additional information on the advantages and safety considerations of the FMX System, please visit domainsurgical.com.
For patent information, please visit domainsurgical.com/patent. © 2016 Domain Surgical, Inc. All rights reserved. LB-054 Rev. B
The FMSealer sealed vessels with clinically reliable burst pressure consistent with other technologies currently available. The FMSealer compared favorably with the other technologies in speed and efficiency as well as in terms of minimal thermal injury. Ferromagnetic heating can be used to seal vascular tissue bundles, membranes, and small vessels in laparoscopic and open procedures. The FMSealer uses an automated inflation system to pressurize the vessels, with the seal failed. Burst pressure comparisons were performed using FMSealer instruments on porcine arteries ranging between 3 and 7 mm in diameter. Each vessel was sealed, divided, and pressurized in this study. Vessel sealing tests were performed using FMSealer Laparoscopic Shears and LigaSure laparoscopic vessel sealing instruments. After sealing and dissection, each artery was harvested. HE staining and histologic assessment of lateral thermal spread was performed by an independent reviewer. Lateral thermal spread was determined to be the maximum distance thermal injury extends laterally from the edge of the instrument.

### Reliability of Vessel Sealing
- Vessel sealing reliability and burst pressure measurements are comparable to Harmonic ultrasonic and LigaSure bipolar laparoscopic vessel sealing technologies.
- No electrical current passes through the instrument, reducing the risk of capacitive coupling, safe for use around metal implants and clips.

### Burst Pressure Analysis
- Sealing reliability and burst pressure results are shown in the chart below.
- Average burst pressure results in mmHg are shown below.
- n = 476 for LigaSure, n = 10 for FMSealer, n = 10 for Harmonic.
- Average burst pressures: LigaSure = 350 mmHg, FMSealer = 30.0 mmHg, Harmonic = 2.63 mmHg.
- SD = 1.68 mmHg for LigaSure, SD = 2.03 mmHg for FMSealer, SD = 2.43 mmHg for Harmonic.

### Speed and Efficiency
- FMSealer sealing and dividing cycles are faster compared to Harmonic ultrasonic and LigaSure bipolar laparoscopic vessel sealing technologies.
- No additional activation required for tissue division.

### Minimal Thermal Injury
- Pure thermal effect with minimal lateral thermal spread compared to LigaSure bipolar laparoscopic vessel sealing technologies.
- Minimal thermal injury with no evidence of lateral thermal spread.
- Internal data on file.
FMsae1er
Plug
Pulsed audio tone indicating activation of vessel sealing cycle - followed by three short beeps indicating activation.

Ferromagnetic heating can be stray current, safe to use around standard 5 mm trocars.

The FMsealer sealed vessels with clinically reliable burst pressures consistent with other Electrically silent operation, no stray electrical current passes through the patient, no risk of thermal spread was determined to be the maximum distance thermal injury extends laterally from the edge of the instrument.

Seal & Divide Mode:
- Used to seal & divide large vessels
- > 2 mm in diameter*

Seal Only Mode:
- Used to seal & divide tissue bundles, membranes, and small vessels

Chen J, Manwaring PK, Scott RR, Manwaring KH, Glasgow RE. Ferromagnetic Heating for Vessel Sealing and Division: Surgical Innovation. Utility and Comparative Study to Ultrasonic and Bipolar Technologies. 2015.

* Based on surgeon experiences and feedback.

Vessel sealing reliability and burst pressure measurements are comparable to bipolar Harmonic ultrasonic vessel sealing instruments.

Burst pressure comparisons were performed using FMsealer Laparoscopic Shears, LigaSure, and Harmonic laparoscopic vessel sealing instruments. After sealing and dissection, each artery was sealed, divided, and pressurized using an automated inflation system until the seal failed.

Average burst pressure results in mmHg are shown below.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Average Burst Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMsealer</td>
<td>896</td>
</tr>
<tr>
<td>LigaSure</td>
<td>846</td>
</tr>
<tr>
<td>Harmonic</td>
<td>824</td>
</tr>
</tbody>
</table>

SD = 402

Lateral Thermal Spread Analysis

Histologic analysis of comparative seals using a LigaSure laparoscopic vessel sealing instrument with harmonic ultrasonic laparoscopic vessel sealing instruments.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Lateral Thermal Spread (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LigaSure</td>
<td>1.80</td>
</tr>
<tr>
<td>Harmonic</td>
<td>2.03</td>
</tr>
<tr>
<td>FMsealer</td>
<td>1.68</td>
</tr>
</tbody>
</table>

SD = 0.39

Minimal Thermal Injury

Heat transfer is limited in the hands of the surgeon than competitive instruments.

Pulse mode allows for less lateral thermal spread than Ligasure bipolar harmonic ultrasonic laparoscopic vessel sealing instruments.

FMsealer Laparoscopic scissors are actively cooled, preventing heat transfer from Harmonic ultrasonic laparoscopic vessel sealing instruments.

Dual activation modes put full control of thermal effect in the hands of the surgeon.

Patented active cooling system ensures localization of heat in the hands of the surgeon.

The FMX Ferromagnetic Surgical System harnesses state-of-the-art technology to achieve minimal thermal injury. Its surgical instruments are designed to deliver energy to the tissue, continuously monitors and manages the communication throughout the system.

The FMX Generator features a patented active cooling system for use, follow these simple steps:
1. Connect the FMX Power Modules to the FMX Generator.
2. The generator remembers each instrument's previous power setting, making switch overs quick and easy.
3. Simply remove the power module from the back of the FMsealer and snap it into any another FMX instrument. The generator can be easily removed from the back of the FMsealer and the FMsealer is ready for use.
4. Utilizing a single power module, multiple FMX instruments can be connected to the generator, and intelligently manages the communication throughout the system.
The FMsealer sealed vessels with clinically reliable burst pressures consistent with other technologies currently available. The FMsealer compared favorably with the other technologies in speed and efficiency as well as in safety, including thermal spread and injury.

**Sealing/Reliability Analysis**
- Vessel sealing reliability and burst pressure measurements are comparable to LigaSure bipolar laparoscopic vessel sealing systems.
- No drop in electrical current passed through the incision in case of capacitive coupling, safe for use around metal staples and clips.
- The percentage of overall seals that resulted in burst pressures above 240 mmHg, are shown below.†

**Burst Pressure Analysis**
- Vessel sealing and dissection times for use with FMsealer and LigaSure are shown below. Time to complete each 10 cm dissection is shown below.

**Lateral Thermal Spread Analysis**
- Histologic analysis of comparative seals using a LigaSure laparoscopic vessel sealing instrument and FMsealer. The Histologic analysis of comparative seals is shown below.

**Dissection Speed Test**
- Dual activation modes put full control of sealing and dividing cycles in the hands of the surgeon.

**High Power Seal & Divide Mode**
- Used to quickly seal & divide vessels up to 7 mm in diameter.*

**Seal Only Mode**
- Used to seal & divide large vessels greater than 2 mm in diameter.*

**Seal & Divide Mode**
- Continuous audio tone indicating activation of high power energy to simultaneously seal & divide the vessel.

**Pulsed audio tone indicating activation of vessel sealing cycle**
- Followed by three short beeps indicating completion of the cycle. If desired, the button can be activated to divide the sealed vessel.

**FMmax**
- Ensures localization of heat in the jaws and rapid cool down.

**FMmin**
- Electrically silent operation, no audible activation modes.

**Capacity and Benefits**
- The FMsealer sealed vessels with clinically reliable burst pressures consistent with other technologies currently available. The FMsealer compared favorably with the other technologies in speed and efficiency as well as in safety, including thermal spread and injury.

**Compatibility with Instruments**
- Compatible with Laparoscopic Shears, LigaSure, and Harmonic laparoscopic vessel sealing instruments†

**LigaSure**
- n = 376
- n = 10
- 350 mmHg
- 26.8 seconds
- 84%
- 90%

**FMsealer**
- n = 476
- n = 42
- 30.0 mmHg
- 12.4 seconds
- 91%
- 91%

**Harmonic**
- n = 63
- 1.80 mmHg
- 1.68
- 2.03
- 94%
- 94%

**Vessel sealing tests were performed using FMsealer and LigaSure laparoscopic vessel sealing instruments†**

**System for use, follow these simple steps:**
1. Snap the Power Module into the back of the FMsealer.
2. Snap the Power Module into the front panel of the FMX Generator.
3. The generator remembers each instrument's previous power setting, making instrument swap fast and seamless.

**Internal data on file**
- Dual activation modes put full control of sealing and dividing cycles in the hands of the surgeon.
- Faster sealing and dividing cycles than competitive instruments†
- Thermal effect in the hands of the surgeon than Harmonic ultrasonic laparoscopic vessel sealing instruments†
- Temperatures than Harmonic ultrasonic laparoscopic vessel sealing instruments†

**Histologic analysis of comparative seals using a LigaSure laparoscopic vessel sealing instrument (left), Harmonic laparoscopic vessel sealing instrument (middle), and FMsealer Laparoscopic Shears (right).**

**Lateral Thermal Spread**
- Lateral thermal spread was harvested. HE staining and histologic assessment of lateral thermal spread was performed by an independent reviewer. Lateral thermal spread was harvested. HE staining and histologic assessment of lateral thermal spread was performed by an independent reviewer. Lateral thermal spread was harvested. HE staining and histologic assessment of lateral thermal spread was performed by an independent reviewer. Lateral thermal spread was harvested. HE staining and histologic assessment of lateral thermal spread was performed by an independent reviewer.
FMsealer Laparoscopic Shears are an intelligent, multifunctional thermal vessel sealing instrument that uses ferromagnetic technology to efficiently seal and divide tissue with minimal lateral thermal spread in laparoscopic and open surgical procedures.

- Reliable sealing of vessels up to 7 mm in diameter, including lymphatics
- Faster dissection times than competitive instruments through vascular tissue bundles
- Precise control of heat, with less lateral thermal spread than competitive instruments
- No stray electrical current, no risk of capacitive coupling, safe to use around metal staples and clips

FMsealer Laparoscopic Shears are a component of the FMX® Ferromagnetic Surgical System. To watch surgical videos of FMX instruments in action, visit domainsurgical.com/video. To learn how ferromagnetic technology works, visit domainsurgical.com/fmx.

For additional information on the advantages and safety considerations of the FMX System, please visit domainsurgical.com. For patent information, please visit domainsurgical.com/patent. © 2016 Domain Surgical, Inc. All rights reserved. LB-054 Rev. B