SAFETY

FMsealer Laparoscopic Shears provides reliable vessel sealing and minimized thermal impact to healthy tissue without passing electrical current through tissue; eliminating stray current, reducing risk of capacitive coupling, and making it safe to operate near metal staples, clips, and instruments.[2]

RELIABILITY

FMsealer Laparoscopic Shears seals vessels **up to 7 mm** in diameter, including lymphatics, with reliability and performance comparable to industry-leading vessel sealing instruments.[1]

SPEED & EFFICIENCY

50% faster transection of vascular tissue bundles than bipolar and ultrasonic devices.[1] Distinct activation modes have been optimized for different desired tissue interaction.

PRECISION

Precise control of heat with less lateral thermal spread than competitive instruments.[1]

References

1. Validation of a Laparoscopic Ferromagnetic Technology-based Vessel Sealing Device and Comparative Study to Ultrasonic and Bipolar Laparoscopic Devices, Jennwood Chen, MD, Curtis R. Jensen, MS, Preston K. Manwaring, MSEE, PhD, and Robert E. Glasgow, MD, *Surgical Laparoscopy Endoscopy & Percutaneous Techniques*, 2017 Apr;27(2):e12-e17
2. Internal data on file

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Domain® SURGICAL An OmniGuide Company

FMsealer™

Laparoscopic Shears

A multi-functional vessel sealing instrument that combines reliable sealing with predictability and precision.

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FMsealer Laparoscopic Shears are a multi-functional vessel sealing instrument that uses ferromagnetic technology to reliably seal and divide tissue with minimal impact to adjacent healthy tissue.

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

ENHANCED PATIENT SAFETY

Energy-based vessel sealing instruments use a combination of heat, friction, and compression force to seal and divide tissue. Each source of energy presents unique operational and safety considerations.

Bipolar

- Electrical current passes through the tissue clamped between opposing electrodes, creating heat and fusing the tissue together.
- After the vessel is sealed, a mechanical blade is used to divide tissue.
- Bipolar devices produce a high amount of lateral thermal spread, posing risk of injury to adjacent tissue structures, and presenting a risk of stray electrical current, arcing, or sparking.

Ultrasonic

- Heat is created through vibrational friction of the active blade, sealing and dividing the tissue clamped in the jaw.
- Tissue is simultaneously sealed and divided.
- The active jaw of ultrasonic devices emanates heat in all directions. Contacting metal or plastic instruments, staples, or clips while activated can damage the blade, making it unusable.

Ferromagnetic

- Thermal energy is directed from the active jaw to the inactive jaw, uniformly fusing tissue together.
- Both "seal only" and "seal & divide" activation modes are available.
- Ferromagnetic instruments provide reliable vessel sealing[1] and less thermal spread than competitive devices[1], without passing electrical current through tissue; eliminating stray current, reducing risk of capacitive coupling, providing safe operation around metal staples and clips.[2]

RELIABLE VESSEL SEALING

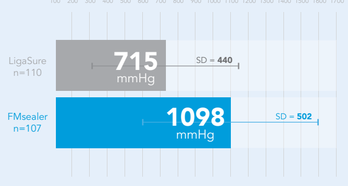
FMsealer Laparoscopic Shears deliver effective vessel sealing with reliability and performance comparable to or better than industry leading vessel sealing instruments, even when sealing larger vessels (> 5 mm in diameter).[1]

Sealing Reliability Study

Porcine arteries measuring 5-7 mm in diameter were sealed in a controlled laboratory setting using LigaSure™ and FMsealer laparoscopic vessel sealing instruments. The percentage of overall seals that resulted in burst pressures above 240 mmHg are shown below.[1]

Burst Pressure Study

Porcine arteries measuring 5-7 mm in diameter were sealed using LigaSure and FMsealer laparoscopic vessel sealing instruments. Each vessel was sealed, divided, and pressurized using an automated inflation system until the seal failed. Average burst pressure results in mmHg are shown below.[1]

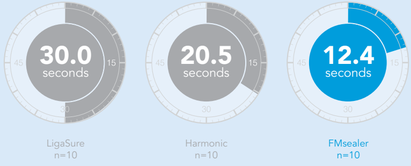


SPEED & EFFICIENCY

FMsealer Laparoscopic Shears provide unmatched speed and efficiency when transecting through vascular tissue bundles.

Transection Speed Test

Speed tests were performed using LigaSure, Harmonic, and FMsealer laparoscopic vessel sealing instruments. A 10 cm section of porcine mesentery was measured and marked prior to transection. Each instrument was used to seal and divide pre-measured segments. Multiple rounds were completed with each instrument, and the average time to complete each 10 cm transection is shown below.[1]



Activation Modes

FMsealer offers multiple power settings and activation modes, each optimized for a different desired tissue interaction.

FM MAX 3

High power seal & divide mode: Used to quickly seal & divide vascular tissue bundles, membranes, and small vessels (< 2mm in diameter*).

FM MIN 2

Seal & divide mode: Used to seal & divide large vessels (> 2 mm in diameter*) with single button activation.

FM MIN 1

Seal only mode: Used to seal large vessels (> 2 mm in diameter*). If desired, vessel can then be divided by activating the **FMmax** button.

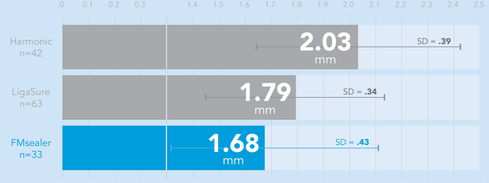
* Based on surgeon experiences and feedback

PRECISION, PREDICTABILITY, & CONTROL

FMsealer Laparoscopic Shears seal and divide tissue with a predictable thermal effect, producing less lateral thermal spread than competitive bipolar and ultrasonic vessel sealing instruments.[1]

Lateral Thermal Spread Study

Porcine arteries measuring 5 mm in diameter were sealed and divided using Harmonic, LigaSure, and FMsealer laparoscopic vessel sealing instruments. After sealing and dividing, 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.



Histologic analysis of comparative seals using a Harmonic (top), LigaSure (middle) and FMsealer (bottom) laparoscopic vessel sealing instruments in porcine arteries. Black lines indicate measurements of thermal damage.