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# ENSEAL™ X1 Tissue Sealers

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Value Analysis Summary



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Reimagining how we heal™

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# The ENSEAL™ X1 Tissue Sealer portfolio

Advanced Bipolar devices intended for use during open or laparoscopic procedures<sup>1</sup>



Secure sealing<sup>2,3\*</sup>



More Efficiency<sup>4-9‡±#</sup>



Ease of use<sup>6,7≤</sup>



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\*In benchtop testing on porcine arteries, average burst pressures exceeded 1000 mmHg. Based on pre-clinical testing on animal models and clinical effect is unknown. †ENSEAL™ Large Jaw has 360° rotation versus Ligasure Impact with only 180° rotation. ‡ENSEAL™ X1 Curved Jaw Tissue Sealer did capture, seal and transect a longer length of tissue per single activation due to a 16% (or 3.4mm) longer jaw (p < 0.001) and a 19% (or 3.5mm) longer cut length (p < 0.001) compared to Ligasure™ Maryland (LF1937). Pre-clinical test data are not necessarily indicative of clinical performance. ±ENSEAL™ X1 Straight Jaw Tissue Sealer can capture, seal and transect a longer length of tissue per single activation due to a 7% (or 1.3mm) longer jaw (p < 0.001), a 17% (or 2.3mm) wider unbiased jaw aperture (p < 0.001) and a 11% (or 1.8mm) longer cut length (p < 0.001) compared to Ligasure™ Blunt Tip (LF1837). †≤88.9% of Surgeons questioned (n=27) rated the ENSEAL™ CURVED as better or the same in terms of ease of use vs. their current Ligasure™ device simulated-use animate porcine lab. All ENSEAL™ X1 devices share a common handle design.

1. As Per Instructions For Use 2. Ethicon Floyd Relaunch Claims Ex-Vivo Sealing. 06/18/2020. Windchill document #PRC094697A (253819-230714) 3. Ethicon ENSEAL™ X1 Large Jaw Marketing Claims.12/12/2022. Windchill document #501171465A (253819-230714) 4. Ethicon, DOC022221, X1 Large Jaw better design and ergonomics vs Impact memo, July 2016, Data on File (119856-230614) 5. Ethicon, SCN008985A, Ergonomic Analysis of the Ligasure™ Impact (ValleyLab), April 2009, Data on File (119856-230614) 6. Ethicon, DOC023555A, Floyd Claims Industrial Design Memo, July 2018, Data on File (119856-230614, 152982-220811) 7. Ethicon, DOC024721A, Floyd Marketing Claims Memo, Jan 2019, Data on File (119856-230614, 152982-220811) 8. Ethicon, PRC079564B, Project Floyd: Claims Metrology Report, June 2018, Data on File (246361-230420, 153299-220819) 9. Ethicon, PRC095763A, Floyd Relaunch Claims Metrology, June 2020, Data on File (246361-230420)



## Secure sealing<sup>1,2\*</sup>

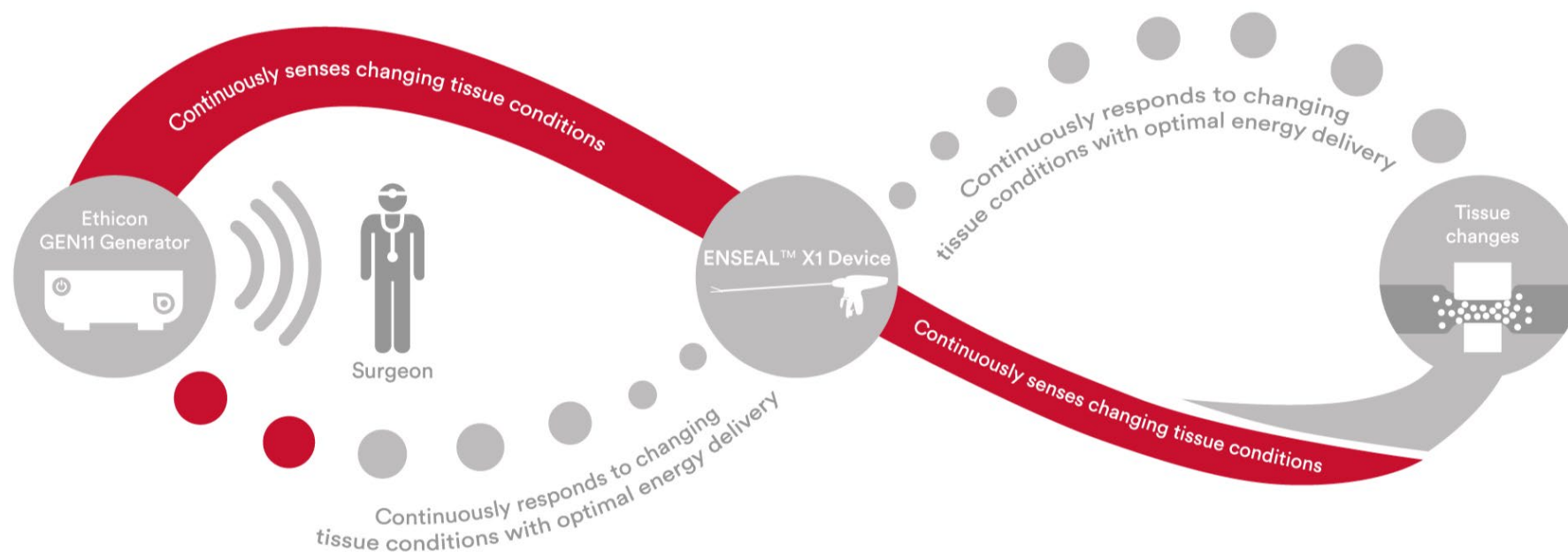
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\*In benchtop testing on porcine arteries, average burst pressures exceeded 1000 mmHg. Based on pre-clinical testing on animal models and clinical effect is unknown  
1. Ethicon Floyd Relaunch Claims Ex-Vivo Sealing. 06/18/2020. Windchill document #PRC094697A (253819-230714) 2. Ethicon ENSEAL™ X1 Large Jaw Marketing Claims.12/12/2022. Windchill document #501171465A (253819-230714)

**ENSEAL™**

# Intelligent energy delivery

Adaptive Tissue Technology **sensed changes** in electrical impedance and responded with an **optimized amount of energy** based on the tissue conditions to deliver **strong and reliable seals** and **minimal thermal damage**.<sup>1-8\*</sup>



\*As shown in multiple internal preclinical and benchtop studies for ENSEAL™ X1 Curved, Straight and Large Jaw. Based on benchtop testing and clinical effect is unknown

# Secure sealing<sup>4,5^A</sup>

Stronger sealing capabilities than LigaSure™ 1,4,5

## ENSEAL™ X1 Curved Jaw Tissue Sealer

Sealed vessels with **22% higher** burst pressures than LigaSure™ Maryland.<sup>1</sup>



## ENSEAL™ X1 Straight Jaw Tissue Sealer

**19% higher** average burst pressure than vessels sealed with LigaSure™ Blunt Tip<sup>2</sup>



## ENSEAL™ X1 Tissue Sealers

- Seal vessels up to and including 7mm and lymphatics<sup>3</sup>
- Vessels sealed with ENSEAL™ X1 Tissue Sealers had an average burst pressure of more than 8x normal systolic blood pressure.<sup>4,5^A</sup>
- Produced minimal thermal spread (mean  $\leq$  2mm)<sup>6,7</sup>

\*In benchtop testing on porcine arteries, vessels sealed with ENSEAL X1 Curved Jaw had a 22% higher average burst pressure than vessels sealed with LigaSure™ Maryland (LF1937). (1055mmHg vs. 862mmHg,  $p < 0.001$ ) <sup>1</sup>Comparison of ENSEAL X1 Curved Jaw to LigaSure™ Maryland (LF1937). Benchtop testing on porcine arteries (1055mmHg vs. 862mmHg,  $p < 0.001$ ) <sup>2</sup>ENSEAL™ X1 Straight Jaw had a 24% higher average burst pressure than vessels sealed with LigaSure™ Maryland Pre-clinical test data are not necessarily indicative of clinical performance <sup>3</sup>Comparison of ENSEAL™ X1 Straight Jaw to LigaSure™ Blunt Tip (LF1837). Benchtop testing on porcine arteries (1023mmHg vs. 863mmHg.  $p < 0.001$ ) Based on benchtop testing and clinical effect is unknown <sup>4</sup>In benchtop testing on porcine arteries, average burst pressures exceeded 1000 mmHg. Based on pre-clinical testing on animal models and clinical effect is unknown <sup>5</sup>ENSEAL™ X1 Curved, Straight and Large Jaw mean thermal spread measured via histology on porcine vessels 7 mm or less in diameter. Curved: 2.03+/-0.61 mm, Straight: 2.05+/-0.68 mm, Large: 1.5+/-0.22 mm. Based on pre-clinical testing on animal models and clinical effect is unknown

1. Ethicon, Floyd Relaunch Claims Ex-Vivo Sealing, June 2020, PRC094697A (145069-200629, 181384-221219) 2. Ethicon, 500805374A, Floyd Straight vs. LigaSure™ Blunt Claims Ex-Vivo Sealing, Oct 2021, Data on File (200488-221218) 3. As Per Instructions For Use (201479-221219) 4. Ethicon Floyd Relaunch Claims Ex-Vivo Sealing. 06/18/2020. Windchill document #PRC094697A (253819-230714) 5. Ethicon ENSEAL™ X1 Large Jaw Marketing Claims.12/12/2022. Windchill document #501171465A (253819-230714) 6. Ethicon Project Brick: ENSEAL X1 Large Jaw (NSLX120L): Design Verification Acute Study in the Pig. 09/25/2020. Windchill document #PSB004387C (253811-230714) 7. Ethicon, 21-0079, Project Floyd: Evaluation of Thermal Spread of Enseal™ Curved and Straight Devices Compared to LigaSure™ Maryland and Blunt Devices in Acute Porcine Vessel Sealing Model, Dec 2021, Data on File (253811-230714)

# Reliable sealing<sup>1,2\*¥</sup>

## ENSEAL™ X1 Tissue Sealers:

100% of vessels sealed in preclinical testing achieved first pass hemostasis<sup>1,2\*¥</sup>



In Vivo Preclinical Testing: Durable Sealing	ENSEAL™ X1 Curved Jaw	ENSEAL™ X1 Straight Jaw
Maintained hemostasis during an elevated blood pressure challenge to simulate a hypertensive crisis (% of seals) <sup>1,2*¥</sup>	<b>100%</b> (112 / 112)	<b>99%</b> (104 / 105)
Remained hemostatic through a 30-day post-operative time frame with no evidence of hemorrhage at the procedure sites or surrounding tissues <sup>3,4≤#</sup>	<b>100%</b> (60 / 60)	<b>100%</b> (62 / 62)

Ex vivo and in vivo preclinical testing included **multiple vessel types and sizes** to account for variation seen across surgical procedures

### Examples of types of vessels and tissues tested

- |                                |                          |
|--------------------------------|--------------------------|
| Gastroepiploic Artery and Vein | Renal Artery and Vein    |
| Gastroepiploic Pedicle         | Carotid Arteries (3-7mm) |
| Pancreatic-Duodenal Pedicle    | Pulmonary Vessels        |
| Short Gastric Pedicle          | Uterine Artery and Vein  |
| Splenic Artery and Vein        | Omentum                  |
| Inferior Mesenteric Artery     | Thyrocervical Arteries   |
| Ovarian Pedicle                | Mesometrium              |

<sup>1</sup>112 of 112 vessels sealed successfully on first pass in an acute porcine model. All seals maintained hemostasis during blood pressure challenge. During blood pressure challenge, systolic blood pressure was increased to at least 200 mmHg for a minimum of 10 minutes to simulate a hypertensive crisis. Pre-clinical test data are not necessarily indicative of clinical performance <sup>¥</sup>In an acute porcine model, 104 of 105 vessels sealed maintained hemostasis during blood pressure challenge. During blood pressure challenge, systolic blood pressure was increased to at least 200 mmHg for a minimum of 10 minutes to simulate a hypertensive crisis. <sup>≤</sup>Based on evaluation of seal durability after 30 (± 2) day survival period and simulated hypertensive crisis in a preclinical chronic porcine model. (n=60 seals) <sup>#</sup>Based on evaluation of seal durability after 30 (± 2) day survival period and simulated hypertensive crisis in a preclinical chronic porcine model. (n=62 seals). Pre-clinical test data are not necessarily indicative of clinical performance



ENSEAL™ X1  
Curved Jaw

LigaSure™  
Maryland

ENSEAL™ X1  
Straight Jaw

LigaSure™  
Blunt Tip

# More Efficiency<sup>1,2\*</sup>¥

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\*ENSEAL™ X1 Curved Jaw Tissue Sealer did capture, seal and transect a longer length of tissue per single activation due to a 16% (or 3.4mm) longer jaw (p < 0.001) and a 19% (or 3.5mm) longer cut length (p < 0.001) compared to LigaSure™ Maryland (LF1937). Pre-clinical test data are not necessarily indicative of clinical performance. †ENSEAL™ X1 Straight Jaw Tissue Sealer can capture, seal and transect a longer length of tissue per single activation due to a 7% (or 1.3mm) longer jaw (p < 0.001), a 17% (or 2.3mm) wider unbiased jaw aperture (p < 0.001) and a 11% (or 1.8mm) longer cut length (p < 0.001) compared to LigaSure™ Blunt Tip (LF1837)

1. Ethicon, PRC079564B, Project Floyd Claims Metrology Report, June 2018, Data on File 153299-220819, 246361-230420 2.. Ethicon, PRC095763A, Floyd Relaunch Claims Metrology, June 2020, Data on File (246361-230420)

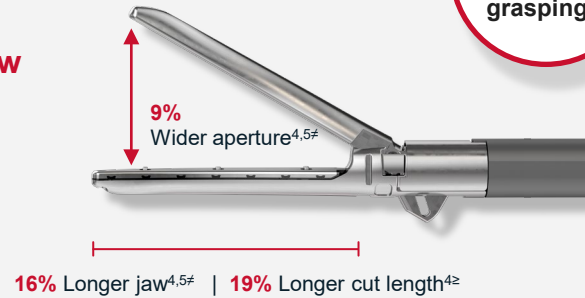
**ENSEAL™**

# More Efficiency<sup>1,5\*±</sup>

Capture more tissue per bite compared to LigaSure™ 4-6#s

## ENSEAL™ X1 Curved Jaw Tissue Sealer

Compared to LigaSure™ Maryland



## ENSEAL™ X1 Straight Jaw Tissue Sealer

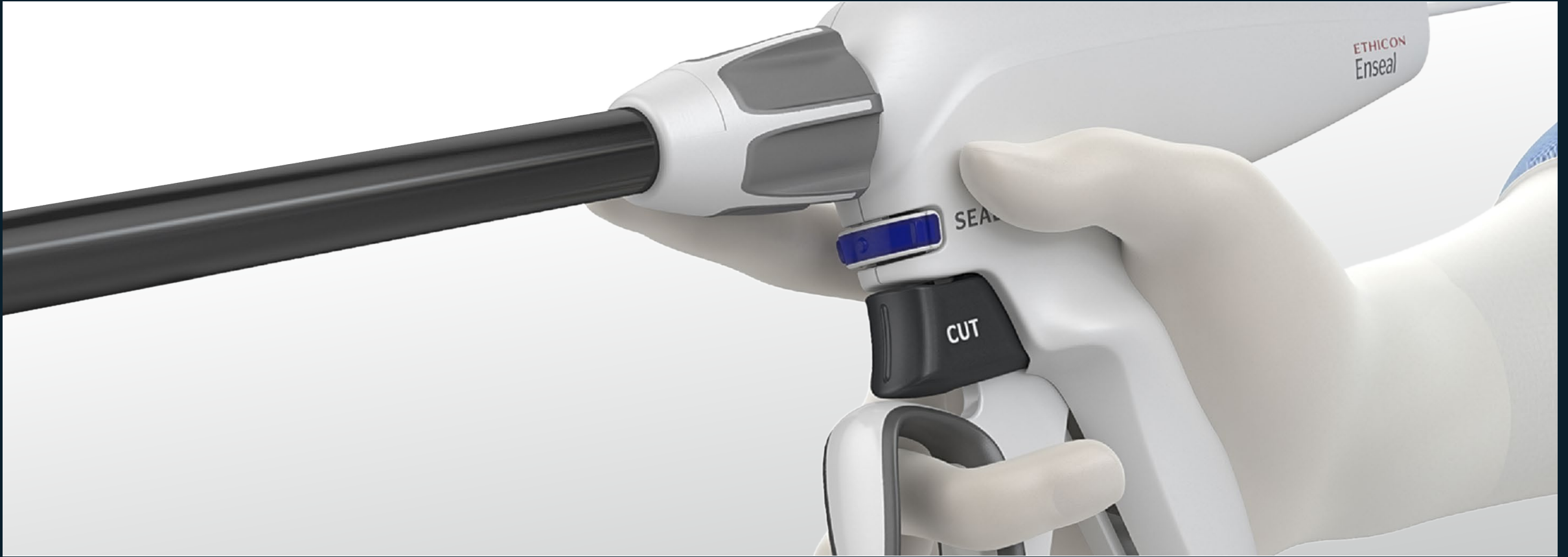
Compared to LigaSure™ Blunt Tip



## ENSEAL™ X1 Tissue Sealers

- 360° continuous shaft rotation to enable access to targeted tissue<sup>2,3</sup>
- Multifunctional instruments designed for grasping and dissecting tissue with separate seal and cut capabilities<sup>3</sup>

±ENSEAL™ X1 Straight Jaw Tissue Sealer can capture, seal and transect a longer length of tissue per single activation due to a 7% (or 1.3mm) longer jaw (p < 0.001), a 17% (or 2.3mm) wider unbiased jaw aperture (p < 0.001) and a 11% (or 1.8mm) longer cut length (p < 0.001) compared to LigaSure™ Blunt Tip (LF1837) \*ENSEAL™ X1 Curved Jaw Tissue Sealer did capture, seal and transect a longer length of tissue per single activation due to a 16% (or 3.4mm) longer jaw (p < 0.001) and a 19% (or 3.5mm) longer cut length (p < 0.001) compared to LigaSure™ Maryland (LF1937). Pre-clinical test data are not necessarily indicative of clinical performance #Based on metrology data, ENSEAL X1 Curved Jaw Tissue Sealer has a 16% (or 3.4mm) longer jaw than LigaSure™ Maryland (LF1937) (p < 0.001) and ENSEAL X1 Curved Jaw Tissue Sealer has a 9% (or 1.15mm) wider jaw aperture than LigaSure™ Maryland (LF1937) (p < 0.001) ≤Based on metrology data, ENSEAL™ X1 Straight Jaw Tissue Sealer has a 6% (or 1.1mm) longer jaw than LigaSure™ Blunt Tip (LF1837) (p < 0.001) ≥Metrology report comparing ENSEAL™ X1 Curved Jaw to LigaSure™ Maryland (LF1937) (p < 0.001) ∂ Grasping force measured as the maximum amount of force required to pull porcine jejunum from the distal tip of device jaws. Comparison of ENSEAL X1 Curved Jaw to LigaSure™ Maryland (LF1937) (p < 0.001) ∞Metrology report comparing Enseal™ X1 Straight Jaw to LigaSure™ Blunt Tip (LF1837) (p < 0.001)



## Ease of use<sup>1,2\*</sup>

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\*88.9% of Surgeons questioned (n=27) rated the ENSEAL™ CURVED as better or the same in terms of ease of use vs. their current LigaSure™ device simulated-use animate porcine lab. All ENSEAL™ X1 devices share a common handle design

1. Ethicon, DOC023555A, Floyd Claims Industrial Design Memo, July 2018, Data on File (152982-220811) 2. Ethicon, DOC024721A, Floyd Marketing Claims Memo, Jan 2019, Data on File (152982-220811)

**ENSEAL™**

# Common user experience across portfolio

ENSEAL™ X1 Tissue Sealers are ergonomically designed<sup>1</sup> with conveniently placed control buttons for less hand movement<sup>1</sup> with silicone-coated jaws to produce minimal sticking<sup>1,2</sup>.



## ENSEAL™ X1 Curved Jaw Tissue Sealer

Curved, tapered tip designed for fine dissection<sup>1,3</sup>



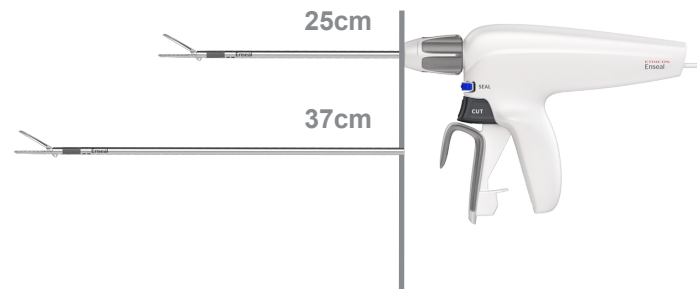
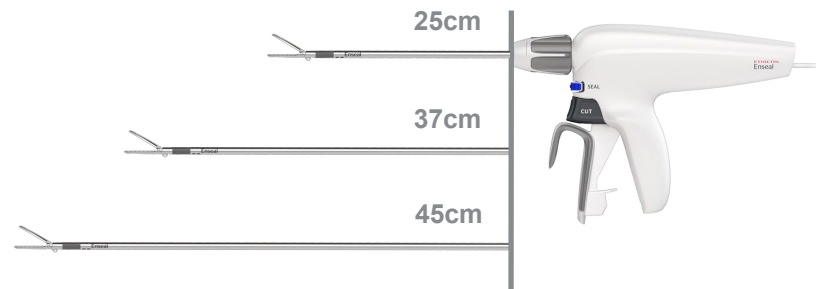
## ENSEAL™ X1 Straight Jaw Tissue Sealer

Blunt jaw with smooth dissecting tip



## ENSEAL™ X1 Large Jaw Tissue Sealer

Large, curved jaw for open procedures<sup>4</sup>



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1. Ethicon, DOC023555A, Floyd Claims Industrial Design Memo, July 2018, Data on File (116498-221219, 152444-230217, 152450-220608) 2. Ethicon, PRC074959A, Brick EB2 Silicone versus No Silicone Testing, Sept 2016, Data on File (152444-230217) 3. Ethicon, DOC024721A, Floyd Marketing Claims Memo, Jan 2019, Data on File (152450-220608) 4. As Per Instructions For Use

# Ease of use<sup>1,2\*</sup>

## Ergonomically Designed<sup>1</sup>

### ENSEAL™ X1 Large Jaw compared to LigaSure™ Impact

- Conveniently placed control buttons are designed for less hand movement.<sup>1</sup>
- Designed to accommodate a wide range of hand sizes<sup>3,4‡</sup>
- Can be operated with one hand<sup>1†</sup>



## Less hand fatigue<sup>5‡</sup>

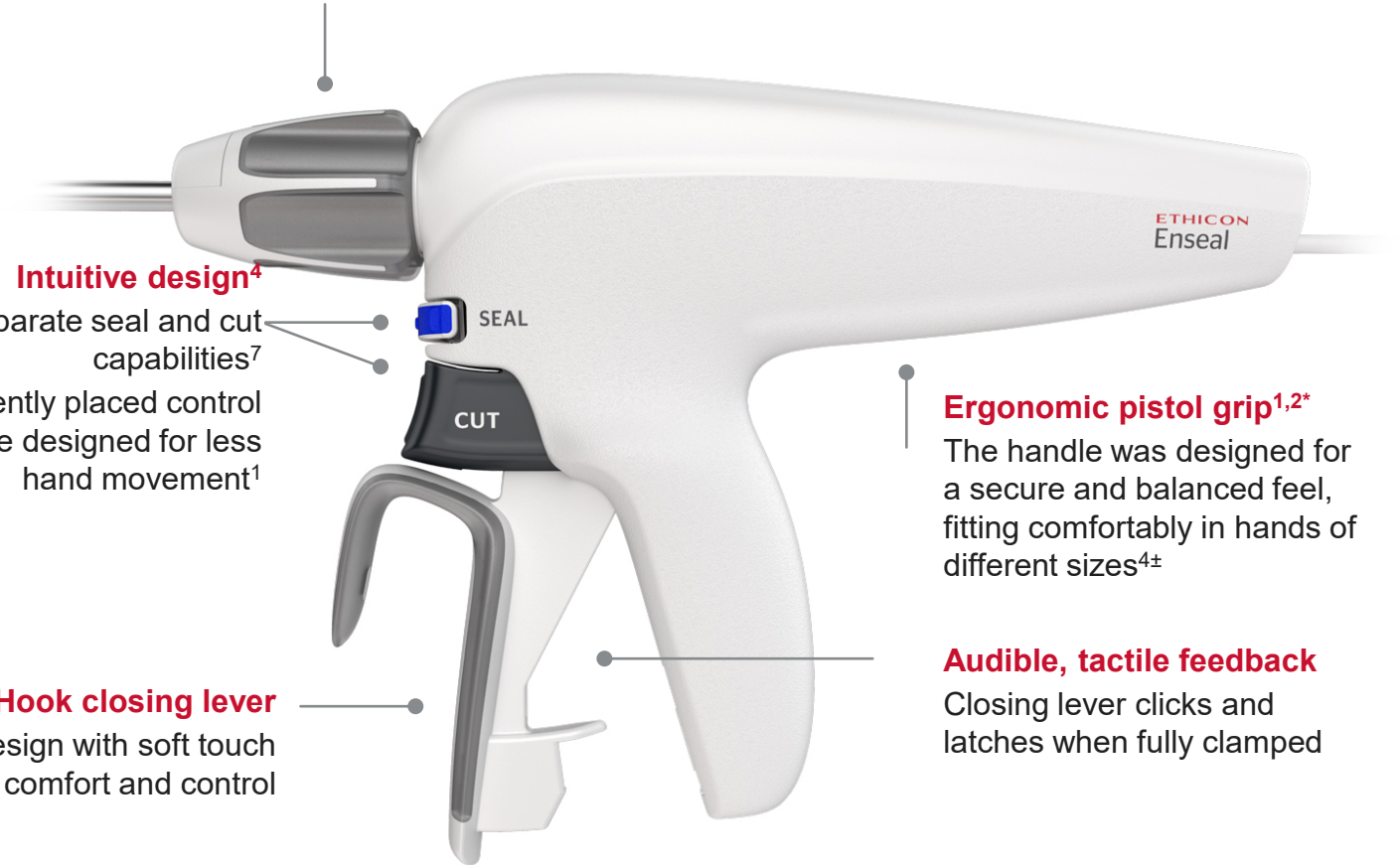
### ENSEAL™ X1 Curved Jaw compared to LigaSure™ Maryland

Required 50% less force to complete a full sealing cycle<sup>5‡</sup>



## 360° continuous shaft rotation

To enable access to targeted tissue<sup>4,7</sup>



## Intuitive design<sup>4</sup>

Separate seal and cut capabilities<sup>7</sup>

Conveniently placed control buttons are designed for less hand movement<sup>1</sup>

## Ergonomic pistol grip<sup>1,2\*</sup>

The handle was designed for a secure and balanced feel, fitting comfortably in hands of different sizes<sup>4‡</sup>

## Hook closing lever

Open design with soft touch grip for comfort and control

## Audible, tactile feedback

Closing lever clicks and latches when fully clamped

\*88.9% of Surgeons questioned (n=27) rated the ENSEAL™ CURVED as better or the same in terms of ease of use vs. their current LigaSure™ device simulated-use animate porcine lab. All ENSEAL™ X1 devices share a common handle design ‡Device controls can be reached by 90% of people: the device controls can be reached by 5%ile female hands to 95% male hands measured grip span to the distal phalange †Force measurements determined by the static effort required for a full seal cycle (a proxy of hand fatigue) for ENSEAL™ X1 Curved Jaw and LigaSure™ Maryland (LF1937) (p<0.001) ‡Per design science anthropometric data comparison to metrology measurements. †All device controls can be reached by 90% of people: the device controls can be reached by 5%ile female hands to 95% male hands measured grip span to the distal phalange

1. Ethicon, DOC023555A, Floyd Claims Industrial Design Memo, July 2018, Data on File (152982-220811, 116498-221219) 2. Ethicon, DOC024721A, Floyd Marketing Claims Memo, Jan 2019, Data on File (152982-220811) 3. Ethicon, DOC022221, X1 Large Jaw - better design and ergonomics vs Impact, July 2016, Data on File (130166-200102) 4. Ethicon, DOC023555A, A Floyd Claims Memo - Industrial Design, July 2018, Data on File (130166-200102, 152441-220803, 155022-220614, 173802-221216) 5. Ethicon, 500708171, ENSEAL™ X1 Force Claims Testing Report, Feb 2022, Data on File (205042-221219) 6. Ethicon, SCN008985A, Ergonomic Analysis of the Ligasure™ Impact (ValleyLab), April 2009, Data on File (119856-230614) 7. As Per Instructions For Use (152441-220803, 201474-221219)



## Device comparisons and indications

# Advanced bipolar device quick comparison

## Curved jaw devices<sup>1</sup>

## Straight jaw devices<sup>1</sup>

## Large jaw devices<sup>1</sup>

	 <b>ENSEAL™ X1 Curved Jaw</b> Tissue Sealer	 <b>LigaSure™ Maryland</b> Tissue Sealer	 <b>ENSEAL™ G2</b> Articulating Tissue Sealer	 <b>ENSEAL™ G2</b> Curved Tissue Sealer	 <b>ENSEAL™ TRIO</b> Tissue Sealer	 <b>ENSEAL™ X1 Straight Jaw</b> Tissue Sealer	 <b>LigaSure™ Blunt Tip</b> Tissue Sealer	 <b>ENSEAL™ G2</b> Straight Tissue Sealer	 <b>ENSEAL™ G1</b> Round Tip Tissue Sealer	 <b>ENSEAL™ X1 Large Jaw</b> Tissue Sealer	 <b>LigaSure™ Impact™</b> Tissue Sealer
Shaft length (cm)	25, 37, 45	23, 37, 44	35, 45	14, 25, 35, 45	14, 25, 35, 45	25, 37	23, 37, 44	14, 25, 35, 45	14, 25, 35, 45	20	18
Jaw length (mm)	24.0	20.6	19.2	19.2	19.2	20.4	19.3	19.8	19.8	38	36
Cut length (mm)	21.8	18.2	16.2	16.2	15.0	18.0	16.3	15.8	15.7	33.5	34
Jaw aperture (mm)	13.4	12.2	13.6	13.6	12.2	13.6	13.1	11.9	12.0	23.4	23
Rotation	360	350	360	360	360	360	180	360	360	360	180
Total articulation span	--	--	110°	--	--	--	--	--	--	--	--

# Alternatives to existing surgical devices

## Product codes

ENSEAL™ X1 Tissue Sealers are compatible with the Ethicon GEN11 Generator and can replace other products on the shelf or provide useful alternatives to existing Ethicon advanced bipolar devices.

Product codes	Device	Shaft length (cm)	Shaft diameter (mm)	ENSEAL X1 product codes
LF1923	LigaSure™ Maryland	23	5	NSLX125C
LF1937		37	5	NSLX137C
LF1944		44	5	NSLX145C
LF1823	LigaSure™ Blunt Tip	23	5	NSLX125S
LF1837		37	5	NSLX137S
LF1844		44	5	NSLX145C
LF6644	LigaSure Advance™	44	5	NSLX145C
LS1037	LigaSure Atlas™	37	10	NSLX137C
LS1520	LigaSure™ Dolphin Tip	20	5	NSLX125C
LS1500		37	5	NSLX137C
LF4418	LigaSure Impact™	18	13.5	NSLX120L
NSLG2C26	ENSEAL™ G2 Curved	25	5	NSLX125C
NSLG2C36		35	5	NSLX137C
NSLG2C46		45	5	NSLX145C
NSLG2C26	ENSEAL™ G2 Straight	25	5	NSLX125S
NSLG2C36		35	5	NSLX137S
NSLG2C46		45	5	NSLX145C
ETRIO325H	ENSEAL™ Trio	25	5	NSLX125C
ETRIO335H		35	5	NSLX137C
ETRIO335H		35	5	NSLX145C
NSEAL525RH	ENSEAL™ Round Tip	25	5	NSLX125S
NSEAL535RH		35	5	NSLX137S
NSEAL545RH		45	5	NSLX145C

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# Indications<sup>1</sup>

## **ENSEAL™ X1 Curved and Straight Jaw Tissue Sealers**

The ENSEAL™ X1 Tissue Sealers are bipolar electro-surgical instruments for use with an electro-surgical generator. They are intended for use during open or laparoscopic surgical procedures to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general, gynecological, urologic, thoracic, and ENT surgical procedures or any procedure where vessel ligation (cutting and sealing), tissue grasping, dissection, and division of vessels, lymphatics, and tissue bundles is performed (e.g. bowel resections, hysterectomies, gall bladder procedures, Nissen Fundoplication, adhesiolysis, and oophorectomies). The devices can be used on vessels up to and including 7 mm and bundles as large as will fit in the jaws of the instruments.

The ENSEAL™ X1 Tissue Sealers have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

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# Indications<sup>1</sup>

## **ENSEAL™ X1 Large Jaw Tissue Sealers**

The ENSEAL™ X1 Large Jaw Tissue Sealer instrument is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. It is a bipolar instrument for use with the Ethicon Generator G11 (GEN11). It is intended for use during open surgery to cut and seal vessels, cut, grasp, and dissect tissue during surgery. Indications for use include open general, gynecologic, urologic, thoracic, and vascular procedures. These procedures include hysterectomies, colectomies, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels (arteries, veins, pulmonary vasculature, lymphatics) up to and including 7 mm and tissue bundles.

The ENSEAL™ X1 Large Jaw Tissue Sealer instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.



# How to order

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**ENSEAL™**

# Ordering information

## How to order

Please contact your local Ethicon Sales representative.

**Learn more at [www.jnjmedtech.com](http://www.jnjmedtech.com)**

Product code	Description	Device image	Shaft length (cm)	Qty
NSLX120L	ENSEAL™ X1 Large Jaw		20	6
NSLX125C	ENSEAL™ X1 Curved Jaw		25	3
NSLX137C			37	3
NSLX145C			45	3
NSLX125S	ENSEAL™ X1 Straight Jaw		25	3
NSLX137S			37	3

ENSEAL™ X1 Curved Jaw and ENSEAL™ X1 Large Jaw are supplied sterile for single-patient use. Both devices are compatible with the Ethicon GEN11 Generator (software version 2016-1 or later versions)