Enseal®

Value Analysis Summary

ENSEAL® X1 Tissue Sealers

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Ethicon Energy Solutions. Healing first.

Contents

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About Ethicon energy

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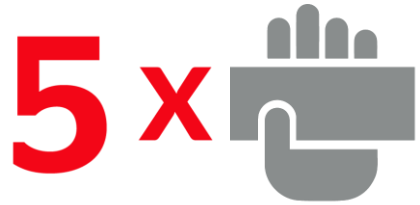
Why Ethicon energy? Healing first.

At Ethicon we understand that surgeons, nurses, and administrators are aiming to deliver…

POSITIVE SURGICAL OUTCOMES

while…

IMPROVING EFFICENCY, OR SAFETY, AND REDUCING COSTS.



Surgical burdens increase complications which can **increase cost by up to five times**[1]

Our focus for Ethicon Energy Solutions is on addressing surgical burdens including:

- ✓ Bleeding
- ✓ Length and cost of operative time

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1. In a study evaluating 1,200 consecutive patients undergoing major surgery, patients without complications had mean in-hospital costs per case of $27,946 while patients with grade IV complications had mean in-hospital costs per case of $159,345. Vonlanthen R, et al. The impact of complications on costs of major surgical procedures: a cost analysis of 1200 patients. *Ann Surg*., 2011;254(6).

How we deliver value

Ethicon energy solutions

That's why Ethicon energy is dedicated to delivering energy solutions for surgeons to help patients heal faster and help protect the OR team from surgical risks.

Less invasive energy

Optimize energy delivery to do less tissue damage,[1] advance outcomes,[2] so that surgeries go according to plan.

Right energy product for the right job

Deliver the most comprehensive product portfolio so surgeons have the right tools for the right energy job in a particular procedure.[3]

Enhance OR safety and efficiency

Work with OR staff to provide training and education they need for optimal product use and help improve OR safety and efficiency.

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1. Based on preclinical studies demonstrating decreased activation times and thermal damage vs. HARMONIC ACE® without Adaptive Tissue Technology (044012-151130). **2.** Based on the large body of clinical evidence comparing advanced energy devices to conventional methods across multiple specialties and procedures. Each listed benefit may not be applicable to every advanced energy device, patient and/or procedure (000953-200929). **3.** Upon review of product catalogs and websites (Advanced Energy, Core Energy, Surgical Smoke Evacuation) for the respective manufacturers: Medtronic, Olympus, Intuitive Surgical, Conmed. Ethicon (2017) (088146-180227).

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ENSEAL® X1 Tissue Sealers

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The ENSEAL® X1 Tissue Sealer portfolio

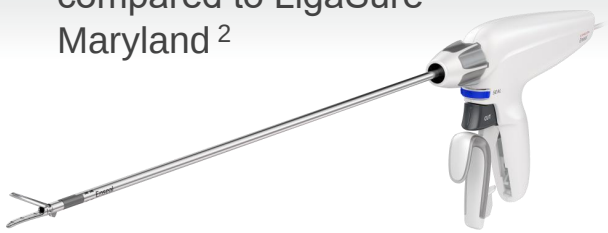
Executive overview

Advanced bipolar devices intended for use during open or laparoscopic procedures.[1]

More efficient

ENSEAL® X1 Curved Jaw

Capture more tissue per bite with a longer jaw and wider jaw aperture compared to LigaSure™ Maryland [2]



ENSEAL® X1 Straight Jaw

Capture more tissue per bite with a longer jaw compared to LigaSure™ Blunt Tip [3]

More secure sealing

ENSEAL® X1 Large Jaw

Better sealing with less bleeding at the distal tip compared to LigaSure Impact™ [4]

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1. ENSEAL® X1 Large Jaw is intended for use in open surgical procedures. **2.** 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) ($p < 0.001$). (145041-200629). **3.** Based on metrology data, ENSEAL® X1 Straight Jaw Tissue Sealer has a 6% (or 1.1mm) longer jaw than LigaSure™ Blunt Tip (LF1837) ($p < 0.001$). (093775-210608). **4.** Preclinical test of distal tip bleeding (ENSEAL® X1 Large Jaw vs. Impact-LF4318) in thick porcine mesentery base ($p=0.001$). (093443-201029).

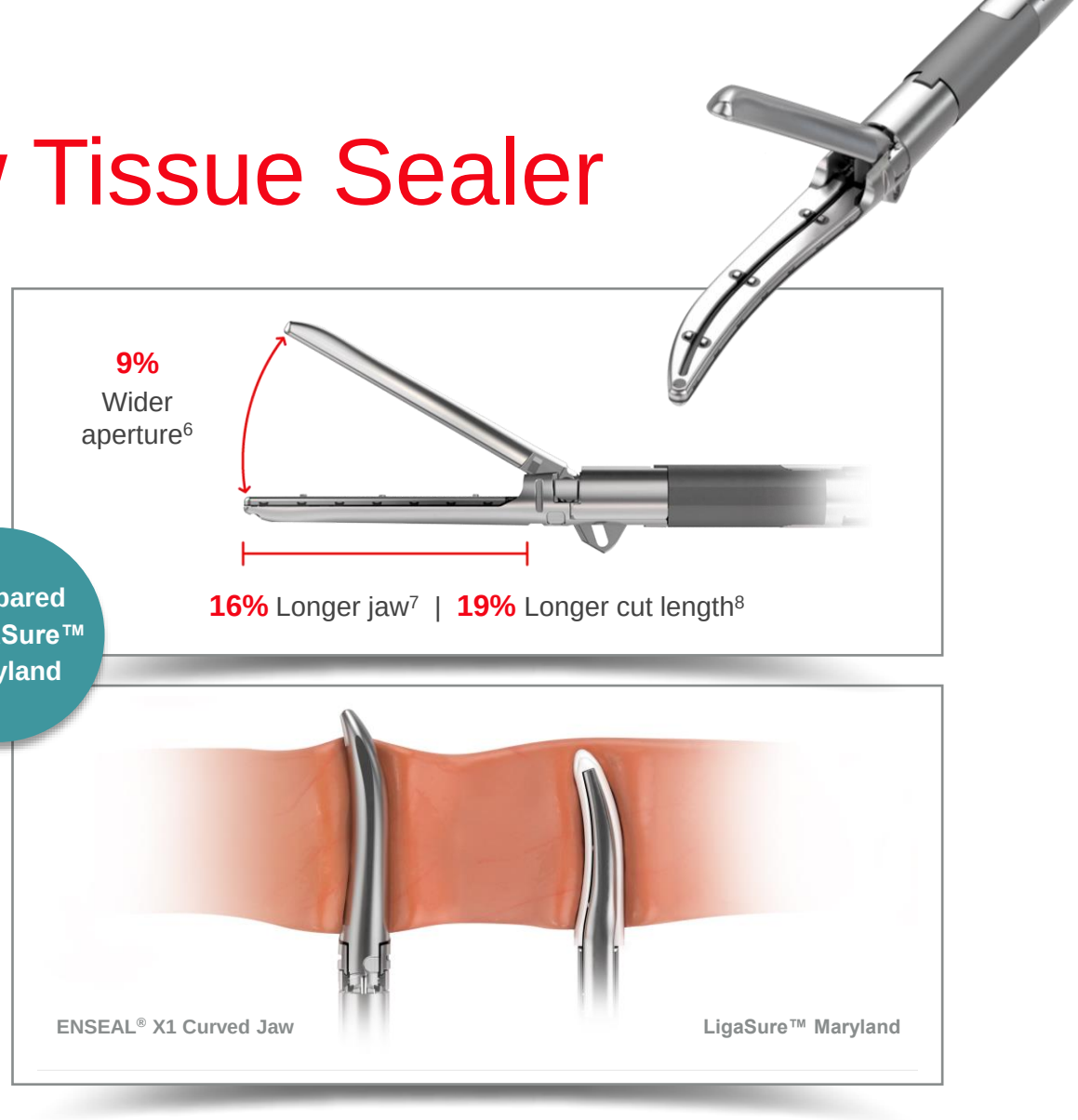
ENSEAL® X1 Curved Jaw Tissue Sealer

Product overview

More efficient

than LigaSure™ Maryland[1]

- Can **capture more tissue** per bite with a longer jaw and wider jaw aperture[2]
- Has a **curved, tapered tip** designed for fine dissection[3]
- More **secure grasping** with 32% stronger distal tip grasping compared to LigaSure Maryland[4]
- 360º **continuous shaft rotation** to enable **easy access** to targeted tissue[5]



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1. ENSEAL X1 Curved Jaw Tissue Sealer can 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). (145163-200630). **2.** 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) ($p < 0.001$). (145041-200629). **3**. (095323-210624). **4.** 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) ($p < 0.001$). (145160-200630). **5.** (093778-210601). **6.** 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) ($p < 0.001$). (145041-200629). **7.** Metrology report comparing ENSEAL® X1 Curved Jaw to LigaSure™ Maryland (LF1937) ($p < 0.001$) (093771-180619) (093769-210528).

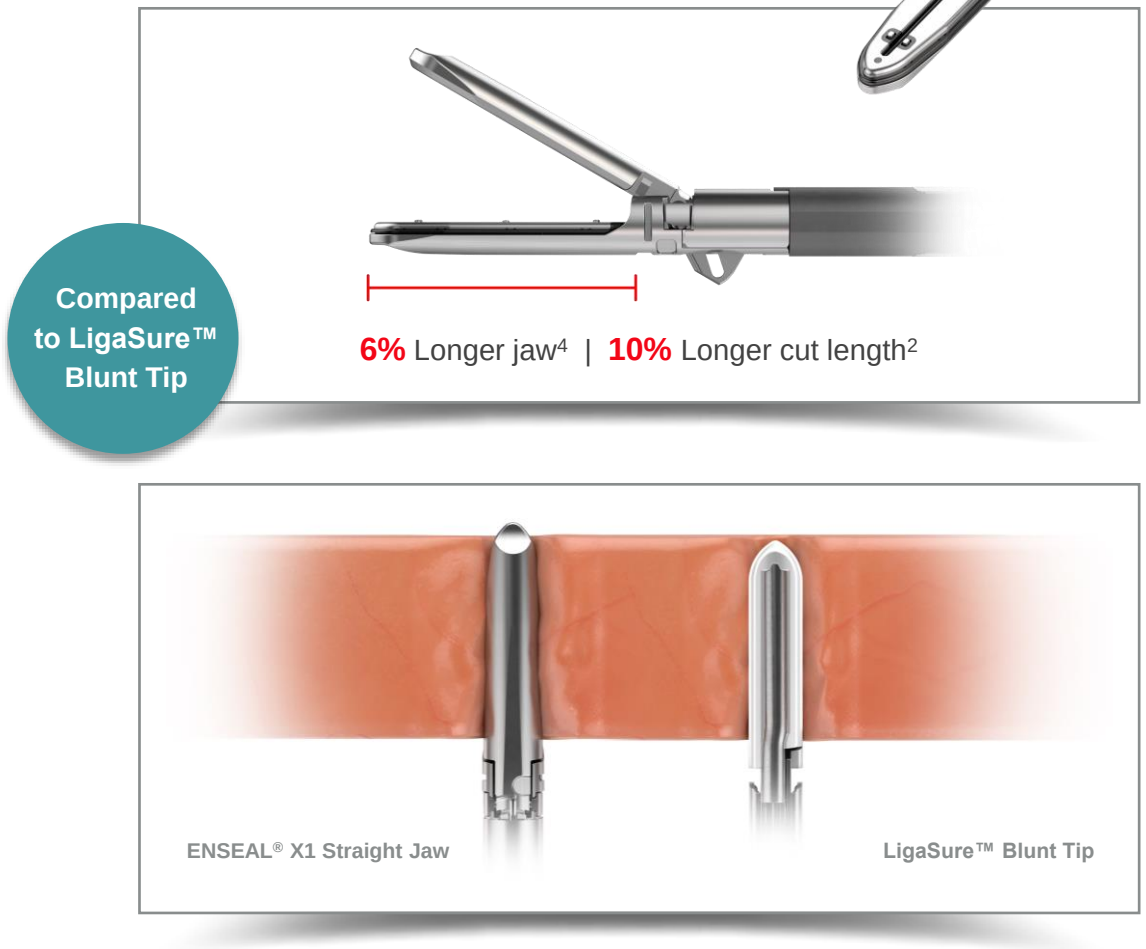
ENSEAL® X1 Straight Jaw Tissue Sealer

Product overview

More efficient

than LigaSure™ Blunt Tip[1]

- Can **capture more tissue** per bite with a longer jaw[1]
- **Transect more tissue** at a time with a 10% longer cut length[2]
- 360º **continuous shaft rotation** to enable **easy access** to targeted tissue[3]



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1. Based on metrology data, ENSEAL® X1 Straight Jaw Tissue Sealer has a 6% (or 1.1mm) longer jaw than LigaSure™ Blunt Tip (LF1837) ($p < 0.001$). (093775-210608). **2.** Metrology report comparing ENSEAL® X1 Straight Jaw to LigaSure™ Blunt Tip (LF1837) ($p < 0.001$). (093768-210608). **3.** (093778-210601). **4.** Metrology report comparing ENSEAL® X1 Straight Jaw to LigaSure™ Blunt Tip (LF1837) ($p < 0.001$) (093770-210608).

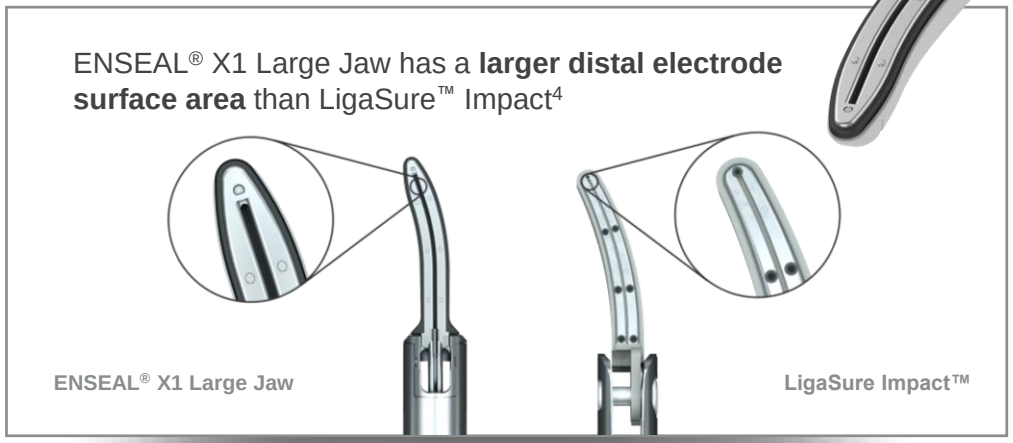
ENSEAL® X1 Large Jaw Tissue Sealer

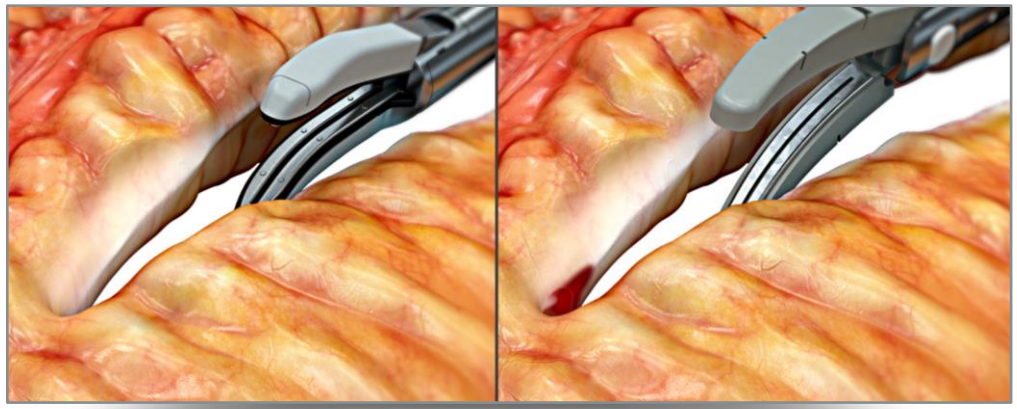
Product overview

More secure sealing

than LigaSure Impact™ [1]

- Enabled **better sealing with 59% less bleeding** at the distal tip[1]
- Had **41% less lateral thermal spread**[2]
- Has a **better design** with convenient controls and 360º rotation[3]





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1. Preclinical test of distal tip bleeding in thick porcine mesentery base; ENSEAL® vs. Impact-LF4318 (p=0.001). (119146-190723). **2.** Preclinical testing on porcine carotids (ENSEAL® vs. Impact-LF4318) that measured mean max lateral thermal damage via histology (p=0.005) (062746-180228). **3.** (093778-210601). **4.** (062722-161103).

Explore the devices yourself

Experience in augmented reality (AR)

ENSEAL® X1 Curved Jaw Tissue Sealer

ENSEAL® X1 Straight Jaw Tissue Sealer

ENSEAL® X1 Large Jaw Tissue Sealer

Scan the QR codes below with your iOS 14 iPhone or iPad camera to visit the website.
Then tap the AR icon for the experience.

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Performance and study data

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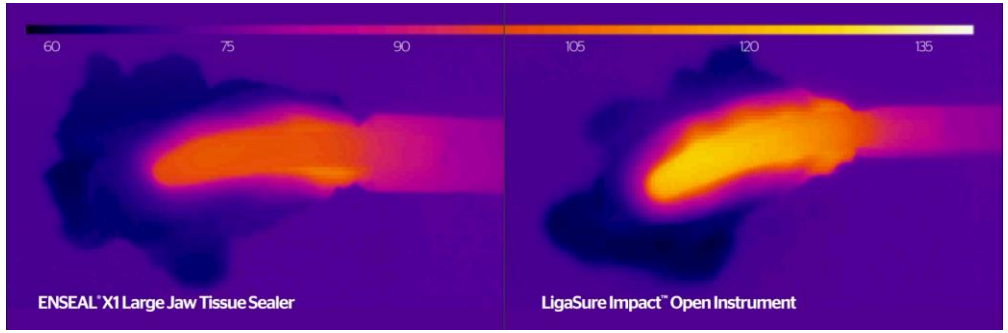
Effective tissue management

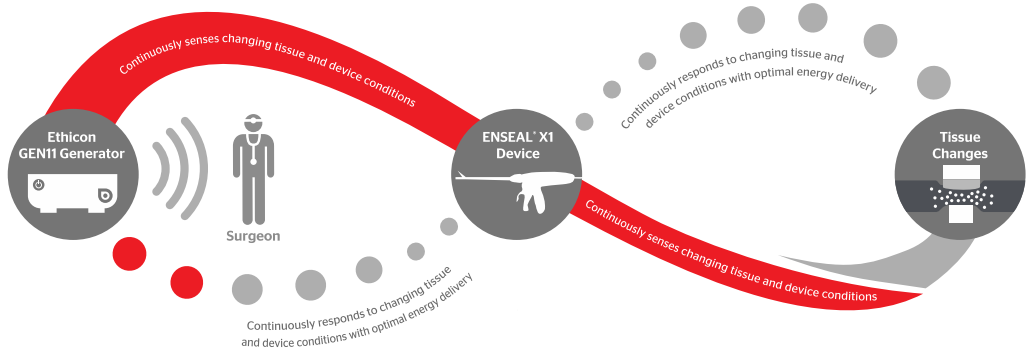
ENSEAL® X1 Tissue Sealers produce minimal lateral thermal spread[1,2]

ENSEAL® X1 Large Jaw had **41% less thermal spread** compared to LigaSure Impact™ [3]

Thermal jaw imaging comparison[4]



The Intelligence of **Adaptive Tissue Technology**



Adaptive Tissue Technology, powered by the Ethicon GEN11 Generator, uses an advanced algorithm for intelligent and efficient energy delivery. In ENSEAL® X1 devices, it continuously:

- **Senses** changes in tissue and device conditions
- **Responds** with the optimized amount of energy
- **Delivers** precision and efficiency[5]

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1. Mean thermal spread measured via histology on porcine carotid arteries. Care should be taken near thermally sensitive tissues. See IFU for complete warnings and precautions. (095310-210202). **2.** Preclinical testing on porcine cartoids that measured mean max lateral thermal damage via histology (mean=1.57mm). (062963-161108). **3.** Preclinical testing on porcine carotids (ENSEAL® vs. Impact-LF4318) that measured mean max lateral thermal damage via histology (p=0.005). (062746-180228). **4.** Thermal imaging of jaws under IR camera. Results may vary. The above image represents the respective devices being used on porcine mesentery after a single activation that lasted approximately eight seconds. **5.** (061415-161010).

Stronger sealing capabilities

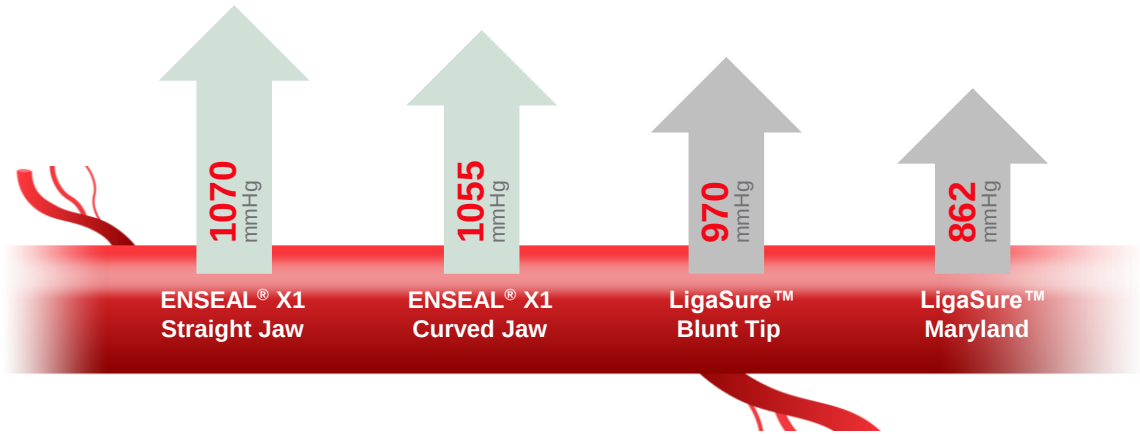
Vessels sealed with ENSEAL® X1 Curved Jaw or ENSEAL® X1 Straight Jaw had higher average burst pressures than vessels sealed with LigaSure™ Maryland[1,2]

Secure sealing[1]:

- Seal vessels up to and including **7mm and lymphatics**[3]
- Average burst pressures of **more than 8x** normal systolic blood pressure[4,5]
- Compared to LigaSure™ Maryland:
  - ENSEAL® X1 Curved Jaw had **22% higher** average burst pressures[1]
  - ENSEAL® X1 Straight Jaw had **24% higher** average burst pressures[2]

Burst pressure comparison[1]

Average minimum burst pressures



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1. Comparison of ENSEAL® X1 Curved Jaw to LigaSure™ Maryland (LF1937). Benchtop testing on porcine arteries (1055mmHg vs. 862mmHg, $p < 0.001$). (145069-200629). **2.** Comparison of ENSEAL® X1 Straight Jaw to LigaSure™ Maryland (LF1937). Benchtop testing on porcine arteries (1077mmHg vs. 862mmHg, $p < 0.001$). (178295-210527). **3.** (093781-210527). **4.** In benchtop testing on porcine arteries, average burst pressure was 1055 mmHg. (145156-200630). **5.** In benchtop testing on porcine arteries, average burst pressure was 1077 mmHg. (094359-210601).

Reliable sealing[1]

Preclinical testing results

	ENSEAL® X1 Curved Jaw	ENSEAL® X1 Straight Jaw
Reliable sealing:		
Achieved hemostasis on the first pass (% of seals) [1,2]	**100%** (112/112)	**100%** (105/105)
Maintained hemostasis during an elevated blood pressure challenge (% of seals) [1,3]	**100%** (112/112)	**99%** (104/105)
Durable sealing:		
Remained hemostatic through 30-day post-operative time frame (% of seals) [4,5]	**100%** (60/60)	**100%** (62/62)

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

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1. 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. (095317-200519). **2.** 105 of 105 vessels sealed successfully on first pass in a acute porcine model. (140887-200520). **3.** 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. (140890-200520). **4.** 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). (143327-200612). **5.** 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). (143334-200612).

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Device comparison

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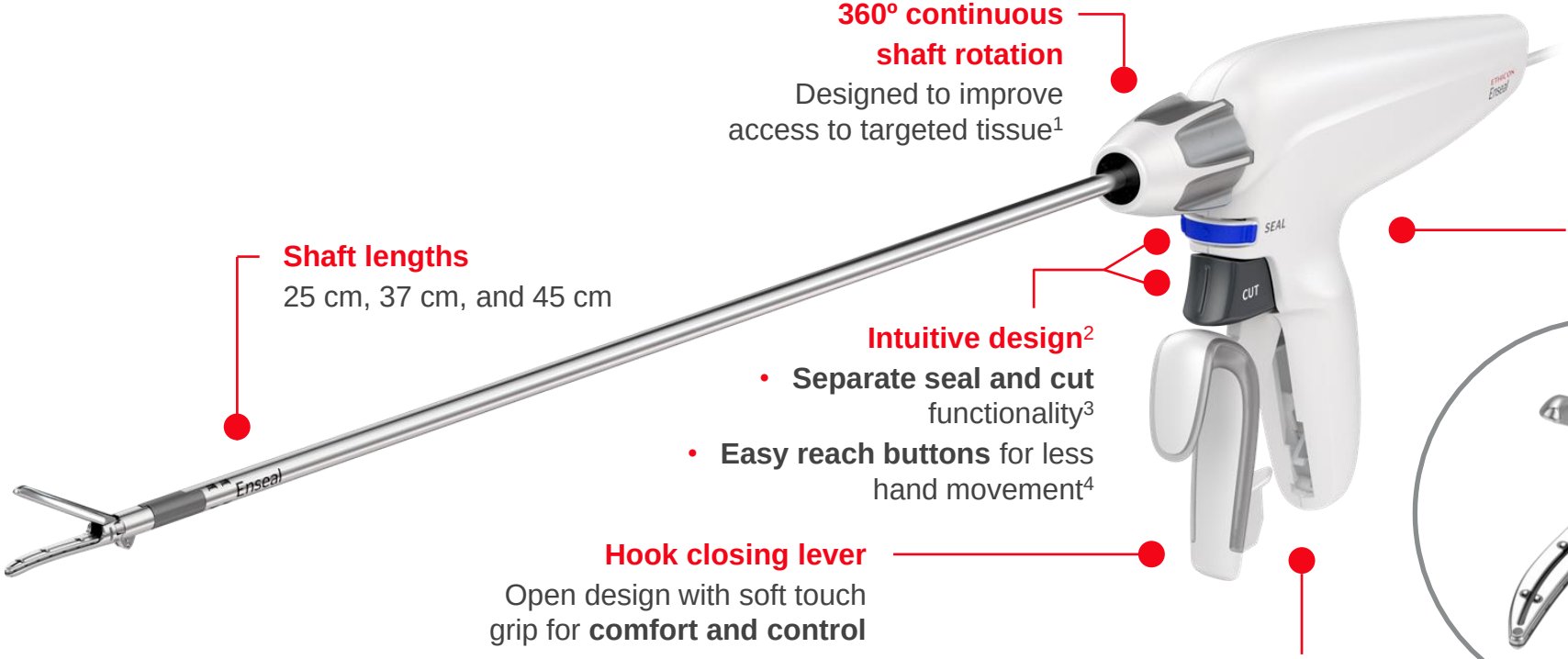
Common user experience across the portfolio

ENSEAL® X1 Curved Jaw Tissue Sealer device features

360º continuous shaft rotation
Designed to improve access to targeted tissue[1]

Shaft lengths
25 cm, 37 cm, and 45 cm

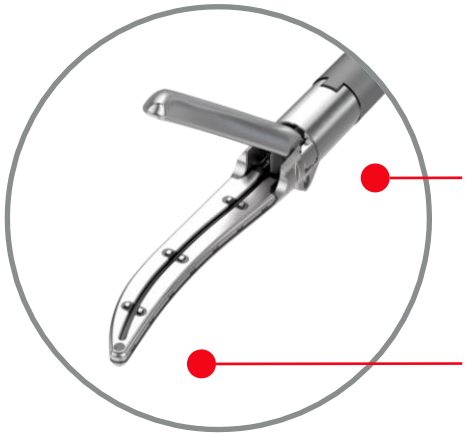


Intuitive design[2]
- **Separate seal and cut** functionality[3]
- **Easy reach buttons** for less hand movement[4]

Ergonomic pistol grip
Provides a **secure and balanced** feel[5]

Hook closing lever
Open design with soft touch grip for **comfort and control**

Audible and tactile feedback
Closing lever clicks and latches when fully clamped



Silicone-coated jaws
Designed to reduce tissue sticking[6]

Curved, tapered jaw
Designed for fine dissection[7]

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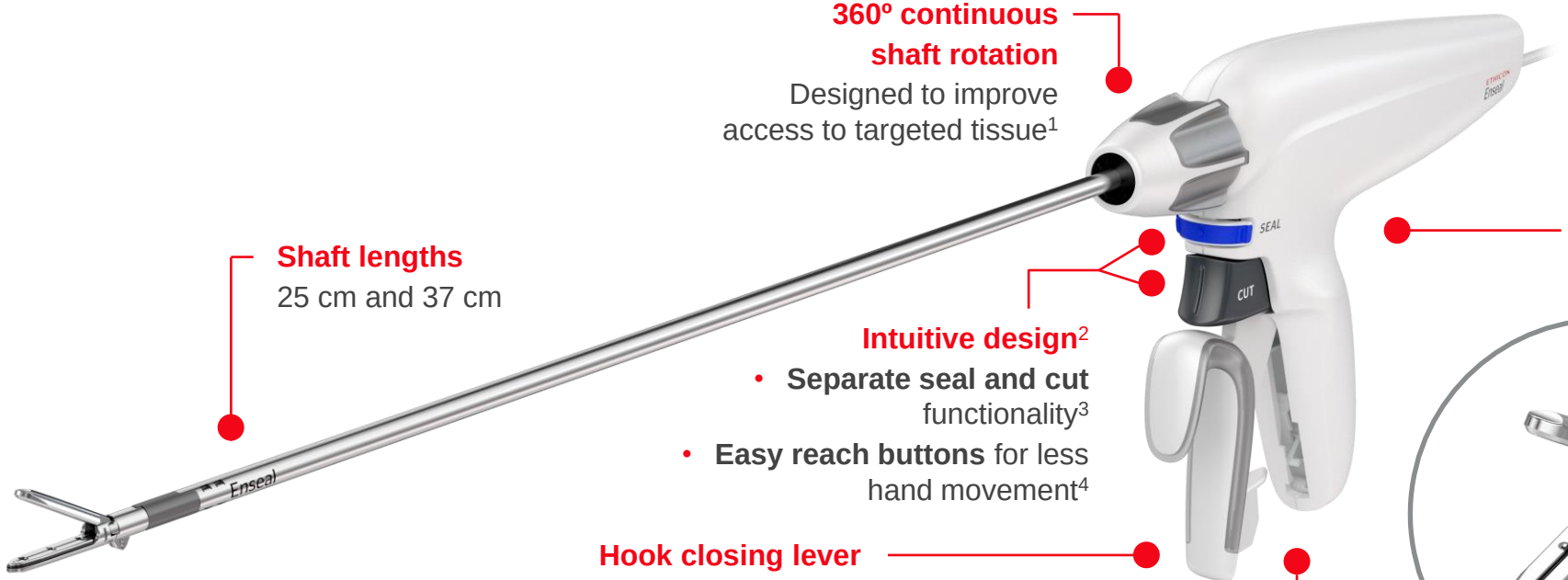
1. (093778-210601). **2.** (095687-210203). **3.** (093782-210528). **4.** (095686-210203). **5.** Per design science anthropometric data comparison to metrology measurements. (095689-210203). **6.** (095690-180724). **7.** (095323-210624).

Common user experience across the portfolio

ENSEAL® X1 Straight Jaw Tissue Sealer device features



360º continuous shaft rotation

Designed to improve access to targeted tissue[1]

Shaft lengths

25 cm and 37 cm

Intuitive design[2]

- **Separate seal and cut** functionality[3]
- **Easy reach buttons** for less hand movement[4]

Hook closing lever

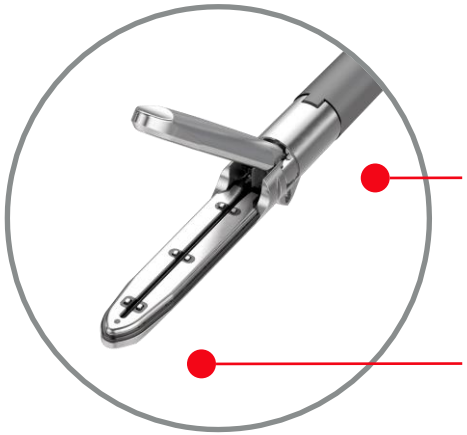
Open design with soft touch grip for **comfort and control**

Audible and tactile feedback

Closing lever clicks and latches when fully clamped

Ergonomic pistol grip

Provides a **secure and balanced** feel[5]



Silicone-coated jaws

Designed to reduce tissue sticking[6]

Blunt jaw

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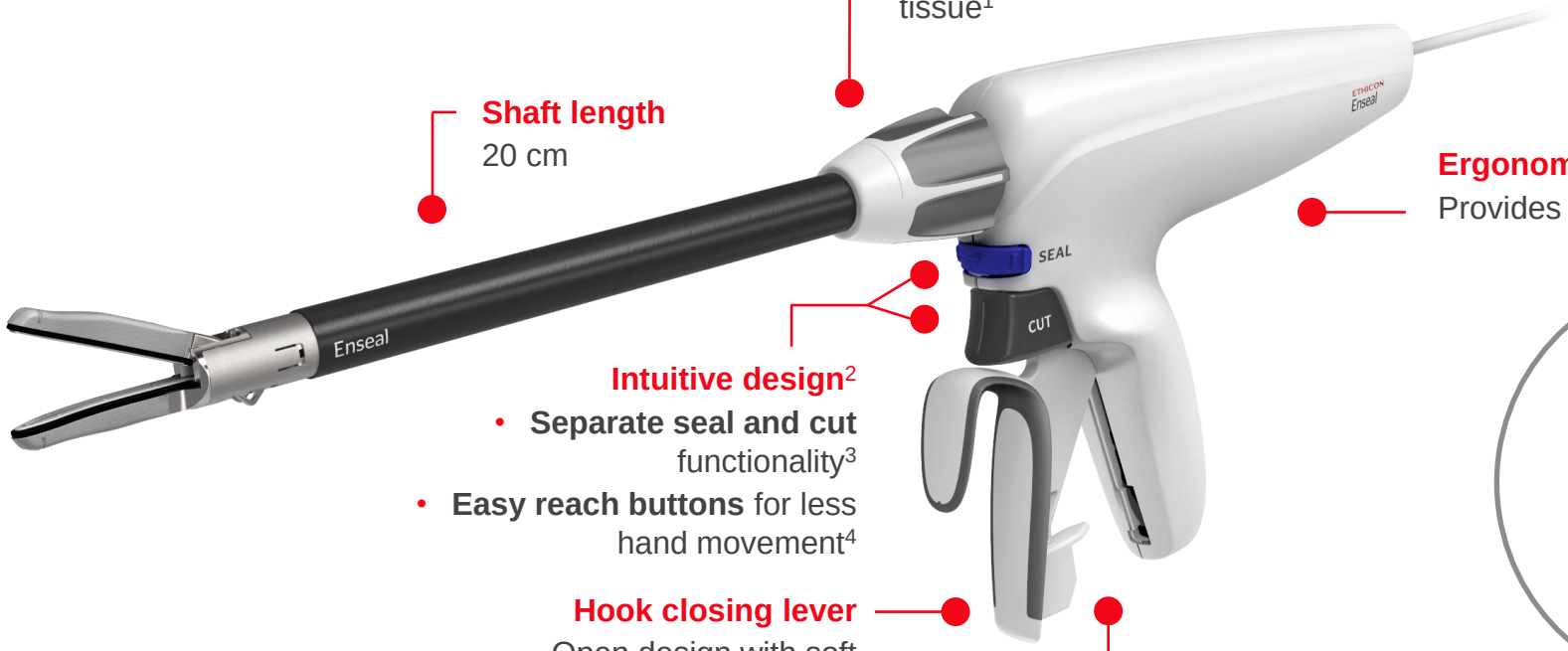
1. (093778-210601). **2.** (095687-210203). **3.** (093782-210528). **4.** (095686-210203). **5.** Per design science anthropometric data comparison to metrology measurements. (095689-210203). **6.** (095690-180724).

Common user experience across the portfolio

ENSEAL® X1 Large Jaw Tissue Sealer device features

360º continuous shaft rotation
Designed to improve access to targeted tissue[1]

Shaft length
20 cm

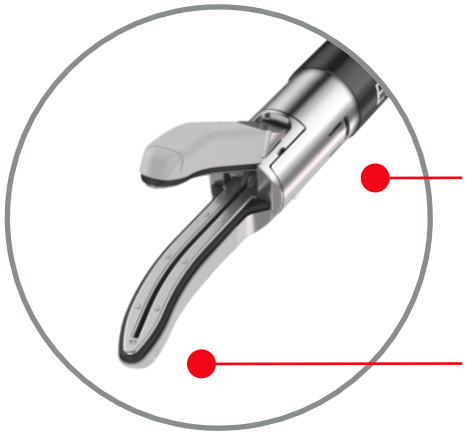


Ergonomic pistol grip
Provides a **secure and balanced** feel[5]

Intuitive design[2]
- **Separate seal and cut** functionality[3]
- **Easy reach buttons** for less hand movement[4]

Hook closing lever
Open design with soft touch grip for comfort and control

Audible and tactile feedback
Closing lever clicks and latches when fully clamped



Silicone-coated jaws
Designed to reduce tissue sticking[6]

Curved jaw

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1. (093778-210601). **2.** (095687-210203). **3.** (093782-210528). **4.** (095686-210203). **5.** Per design science anthropometric data comparison to metrology measurements. (095689-210203). **6.** (095690-180724).

Surgeon feedback

ENSEAL® X1 5mm devices

Among surgeons using ENSEAL® X1 5mm devices in product concept testing:[1]

- **71%** indicated ENSEAL® X1 will make related **surgical tasks easier**
- **67%** thought ENSEAL® X1 will lead to **more efficient** surgeries
- **65%** felt ENSEAL® X1 is a **significant improvement over current devices or techniques** for the same task

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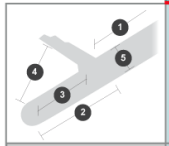
1. Based on surgeon opinion statements in ENSEAL® X1 Concept Aided Product Test, May 2016 (n=24 ENSEAL® and 28 non-ENSEAL® users). Percentages represent the percent top-2-box agreement for each statement listed.

Advanced bipolar devices

Quick comparison

Curved jaw devices[1]

	ENSEAL® X1 Curved Jaw	LigaSure™ Maryland	Thunderbeat	ENSEAL® G2 Articulating	ENSEAL® G2 Curved	ENSEAL® TRIO
		 LF1937				
1 Shaft Length (cm)	**25, 37, 45**	23, 37, 44	20, 35, 45	35, 45	14, 25, 35, 45	14, 25, 35, 45
2 Jaw Length (mm)	**24.0**	20.6	17.4	19.2	19.2	19.2
3 Cut Length (mm)	**21.8**	18.2	17.4	16.2	16.2	15.0
4 Jaw Aperture (mm)	**13.4**	12.2	14.5	13.6	13.6	12.2
5 Total Articulation Span	**N/A**	N/A	N/A	110°	N/A	N/A

Straight jaw devices[1]

ENSEAL® X1 Straight Jaw	LigaSure™ Blunt Tip	ENSEAL® G2 Straight	ENSEAL® G1 Round Tip
	 LF1837		
25, 37	23, 37, 44	14, 25, 35, 45	14, 25, 35, 45
20.4	19.3	19.8	19.8
18.0	16.3	15.8	15.7
13.6	13.1	11.9	12.0
N/A	N/A	N/A	N/A

Large jaw devices[2]

ENSEAL® X1 Large Jaw	LigaSure Impact™
	 LF4418
20	18
38	36
33.5	34
N/A	N/A
N/A	N/A

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1. Data for shaft length from device IFUs. Data for other features reflect average measurements from benchtop metrology report. **2.** Brick -D.V. Verify by Inspection, G10002, etc., ENSEAL® X1 Large Jaw IFU.

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.

DEVICE	PRODUCT CODES	SHAFT LENGTH (CM)	SHAFT DIAMETER (MM)	ENSEAL® X1 PRODUCT CODES
LigaSure™ Maryland	LF1923	23	5	NSLX125C
	LF1937	37	5	NSLX137C
	LF1944	44	5	NSLX145C
LigaSure™ Blunt Tip	LF1823	23	5	NSLX125S
	LF1837	37	5	NSLX137S
	LF1844	44	5	NSLX145C
LigaSure Advance™	LF5544	44	5	NSLX145C
LigaSure Atlas™	LS1037	37	10	NSLX137C
LigaSure™ Dolphin Tip	LS1520	20	5	NSLX125C
	LS1500	37	5	NSLX137C
LigaSure Impact™	LF4418	18	13.5	NSLX120L
THUNDERBEAT®	TB-0520FC	20	5	NSLX125C
	TB-0535FC	35	5	NSLX137C
	TB-0545FC	45	5	NSLX145C
ENSEAL® G2 Curved	NSLG2C25	25	5	NSLX125C
	NSLG2C35	35	5	NSLX137C
	NSLG2C45	45	5	NSLX145C
ENSEAL® G2 Straight	NSLG2S25	25	5	NSLX125S
	NSLG2S35	35	5	NSLX137S
	NSLG2S45	45	5	NSLX145C
ENSEAL® Trio	ETRIO325H	25	5	NSLX125C
	ETRIO335H	35	5	NSLX137C
	ETRIO345H	45	5	NSLX145C
ENSEAL® Round Tip	NSEAL525RH	25	5	NSLX125S
	NSEAL535RH	35	5	NSLX137S
	NSEAL545RH	45	5	NSLX145C

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LigaSure™ data from http://www.medtronic.com/covidien/en-us/products/vessel-sealing.html | THUNDERBEAT data from http://medical.olympusamerica.com/products/thunderbeat-handpieces

Indications

ENSEAL® X1 Curved and Straight Jaw Tissue Sealers

The ENSEAL® X1 Tissue Sealers are bipolar electrosurgical instruments for use with an electrosurgical 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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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

Indications

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.

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Enseal®

How to order

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Ordering information

All ENSEAL® X1 purchase orders are made to Johnson & Johnson Healthcare Care Systems, Inc. (JJHCS)

Electronic ordering options

Note: Placing order electronically avoids minimum order fees for hospitals.

- Johnson & Johnson Gateway
  Visit **jnjgateway.com** or call **1-866-JNJ-GATE**
- Global Healthcare Exchange
  Visit **ghx.com** or call **1-866-YOUR-GHX**
- Electronic Data Interchange
  Call JJHCS Help Line: **1-800-262-2888**

Non-electronic/manual ordering options

Call JJHCS at **1-800-255-2500** (option 1) between 8:30 am and 8:00 pm Eastern time or fax your order to **1-732-562-2212**.

Customer support

For more information or product support, call **1-877-ETHICON** or visit **Ethicon.com/ensealx1lap**. See **Instructions for Use** for complete product details.

DEVICE	PRODUCT CODES	QTY / SALES UNIT	SHAFT LENGTH (CM)	SHAFT DIAMETER (MM)
ENSEAL® X1 Curved Jaw	NSLX125C	3	25	5
ENSEAL® X1 Curved Jaw	NSLX137C	3	37	5
ENSEAL® X1 Curved Jaw	NSLX145C	3	45	5
ENSEAL® X1 Straight Jaw	NSLX125S	3	25	5
ENSEAL® X1 Straight Jaw	NSLX137S	3	37	5
ENSEAL® X1 Large Jaw	NSLX120L	6	20	13

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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).

Ethicon Energy Solutions. Healing first.