Enseal™

# ENSEAL™ X1 Tissue Sealers

# Expect more.[1-3*]


*ENSEAL™ X1 Curved Jaw has a longer jaw, longer cut length and wider jaw aperture compared to LigaSure Maryland (LF1937) ($p < 0.001$). 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, $p < 0.001$).

**References: 1.** Ehticon, Project Floyd: Claims Metrology Report, June 2018, PRC079564B (145171-200630)
**2.** Ethicon, Floyd Relaunch Claims Metrology, June 2020, PRC095763A (145171-200630)
**3.** Ethicon, Floyd Relaunch Claims Ex-Vivo Sealing, June 2020, PRC094697A (145171-200630)

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Shaping the future of surgery

# The ENSEAL™ X1 Tissue Sealers **offer more** than LigaSure™


## More secure[1*]

## More efficient[2,3**]

The ENSEAL™ X1 Tissue Sealers are advanced bipolar devices designed for use in open or laparoscopic surgical procedures.[#] We have and will further redesign our Ethicon Energy Advanced Bipolar Portfolio, to provide secure sealing with more intuitive and simplified steps-for-use.[4,5]

***Preclinical test of distal tip bleeding (ENSEAL® vs. Impact-LF4318) in thick porcine mesentery base (p=0.001). ****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).ures **#**ENSEAL™ X1 Large Jaw is intended for use in open surgical procedures

**REFERENCES: 1.** Ethicon, PSP005173A, Final Report- 2017 Brick Claims: Comparison of Distal Tip Sealing Performance Between ENSEAL™ X1 Large Jaw (NSLX120L) with Algorithm and Ligasure™ Impact (LF4318), Sept 2016, Data on File (154862-201002) **2.** Ethiicon, Project Floyd: Claims Metrology Report, June 2018, PRC079564B (145163-200630) **3.** Ethicon, Floyd Relaunch Claims Metrology, June 2020, PRC095763A (145163-200630) **4.** Ethicon, DOC023555A, A Floyd Claims Memo Industrial Design, July 2018, Data on File (155321-201009) **5.** Ethicon, PRC095915A, Curved Design Validation 2 Completion Report, June 2020, Data on File (155321-201009)

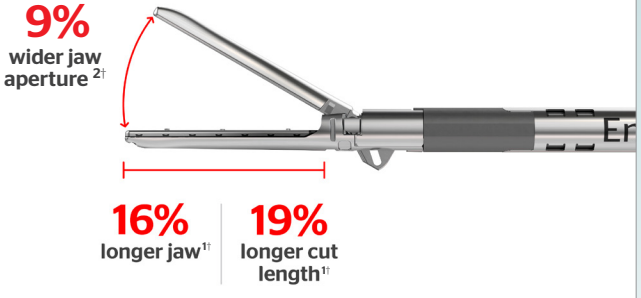
# ENSEAL™ X1
# Curved Jaw

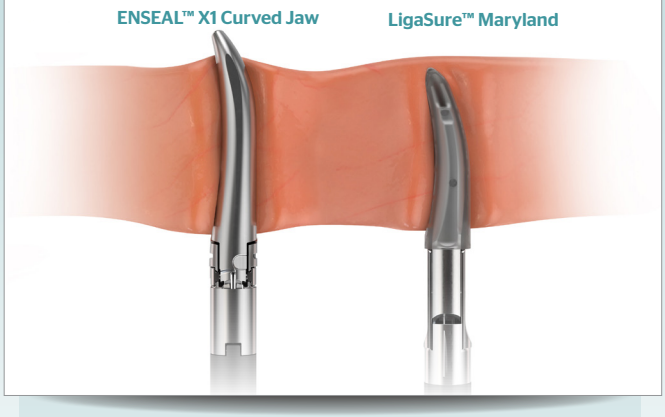
# More efficient
## than LigaSure™ Maryland[1,2*]

**Curved, tapered tip** designed for fine dissection[5,6]

- **Capture more tissue** per bite with a longer jaw and wider jaw aperture[1,2**]
- 32% stronger grasping[3 #]
- **360° shaft rotation** to enable access to targeted tissue[4,5]

**ENSEAL™ X1 Curved Jaw can capture more tissue per bite with a 16% longer jaw and 9% wider jaw aperture compared to LigaSure™ Maryland[1,2**]**




*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). **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) ($p < 0.001$). #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 the jaw aperture of ENSEAL™ X1 Curved Jaw to LigaSure™ Maryland (LF1937) ($p < 0.001$)

**REFERENCES: 1.** Ethicon, Project Floyd: Claims Metrology Report, June 2018, PRC079564B (145163-200630, 145041-200629, 152465-200909 152466-200909) **2.** Ethicon, Floyd Relaunch Claims Metrology, June 2020, PRC095763A (145163-200630, 145041-200629, 145034-200629) **3.** Ethicon, Floyd Relaunch Claims Grasping Force, June 2020, PRC096063A (145160-200630) **4.** As Per Instructions For Use (152441-200909) **5.** Ethicon, DOC023555A, A Floyd Claims Memo - Industrial Design, July 2018, Data on File (152441-200909, 152450-200909) **6.** Ethicon, DOC024721A, Floyd Marketing Claims Memo, Jan 2019, Data on File (152450-200909)

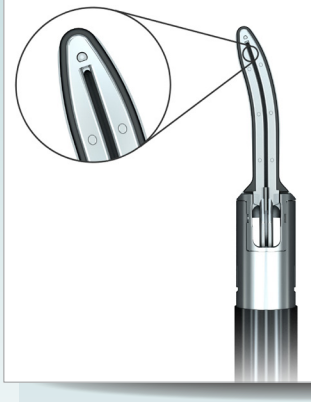
# ENSEAL™ X1
# Large Jaw


# More secure
## than LigaSure Impact™[1]*

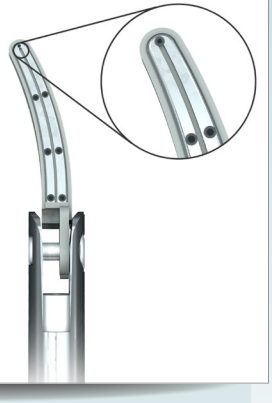
- Had **less bleeding** at the distal tip vs LigaSure Impact™ in thick tissue[2,3]*
- Had **41% less lateral thermal spread** than LigaSure™ Impact[4]**
- The convenient controls of the ENSEAL™ X1 Large Jaw were designed for less hand movement[5]
- Has improved ergonomics which allows a 360° rotation compared to LigaSure Impact™[5]

**ENSEAL™ X1 Large Jaw has a larger distal electrode surface area than LigaSure™ Impact.[6] ENSEAL™ X1 Large Jaw had significantly less bleeding at the distal tip vs LigaSure Impact™ in thick tissue.[2]****

ENSEAL™ X1 Large Jaw



LigaSure Impact™



ENSEAL™ X1 Large Jaw

***Preclinical test of distal tip bleeding (ENSEAL® vs. Impact-LF4318) in thick porcine mesentery base (p=0.001). ****Preclinical testing on porcine carotids (ENSEAL™ vs. Impact-LF4318) that measured mean max lateral thermal damage via histology (p=0.005)

**REFERENCES: 1.** Ethicon, PSP005173A, Final Report- 2017 Brick Claims: Comparison of Distal Tip Sealing Performance Between ENSEAL™ X1 Large Jaw (NSLX120L) with Algorithm and Ligasure™ Impact (LF4318), Sept 2016, Data on File (154862-201002) **2.** Ethicon, PSB004548 Final Report Brick Distal Tip Sealing Algo D, Sept 2016, Data on File (116497-190612) **3.** Ethicon, PSP005819, Final Report- 2017 Brick Claims: COMPARISON OF DISTAL TIP SEALING PERFORMANCE BETWEEN ENSEAL™ X1 LARGE JAW (NSLX120L) AND LIGASURE IMPACT (LF4318), Sept 2017, Data on File. (116497-190612) **4.** Ethicon, PSB004570 Final Report Brick Thermal Damage vs Impact1, April 2018, Data on File (114378-190516) **5.** Ethicon, DOC022221, X1 Large Jaw - better design and ergonomics vs Impact, July 2016, Data on File (130163-200102, 116496-190612) **6.** Ethicon, DOC022209A Brick - Superior Distal Tip Sealing Rationale, Aug 2016, Data on File (124114-190923)

# **Expect more** with ENSEAL™ X1 devices

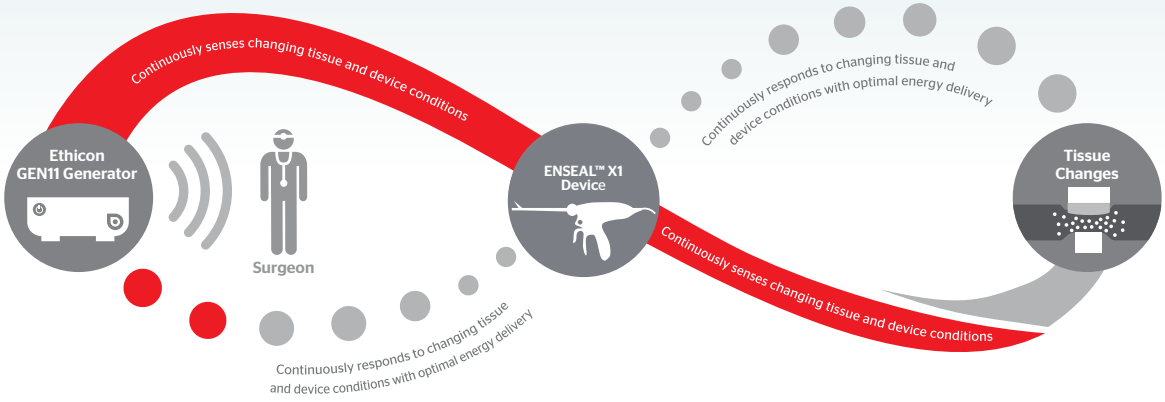
## Intelligent energy delivery

**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 optimal amount of energy

ENSEAL™ X1 Curved Jaw Tissue Sealer produces minimal lateral thermal spread (2.5mm)[1]*

## The Intelligence of **Adaptive Tissue Technology**





## Advancing beyond secure sealing

- **ENSEAL™ X1 Tissue Sealers can seal vessels up to and including 7mm and lymphatics[2]**
- **Vessels sealed with ENSEAL™ X1 Curved Jaw had an average burst pressure of more than 8x normal systolic blood pressure[3]****
- **Silicone coating minimizes tissue sticking[4]#**

***Mean thermal spread measured via histology on porcine carotid arteries. ****In benchtop testing on porcine arteries, average burst pressure was 1055 mmHg.
#Preclinical testing that compared average sticking force (lbf) of ENSEAL X1 Large Jaw end-effector coated with and without non-stick silicone ($p<0.001$).

**REFERENCES: 1.** Ethicon, PSP007612A, Evaluation of ENSEAL™ X1 Tissue Sealer, Curved Jaw, in an Acute Porcine Model, Feb 2020, Data on File (145177-200630) **2.** As Per Instructions For Use (130176-200102) **3.** Ethicon, Floyd Relaunch Claims Ex-Vivo Sealing, June 2020, PRC094697A (145156-200630) **4.** Ethicon, PRC074959A, Brick EB2 Silicone versus No Silicone Testing, Sept 2016, Data on File (123391-190913)

# ENSEAL™ X1 devices feature **ergonomic engineering**


- **Intuitive design**[1] Separate seal and cut functionality[2]
- **Conveniently placed control buttons** are designed for less hand movement[3]
- ENSEAL™ X1 Tissue Sealers have **360° shaft rotation** to enable access to targeted tissue[4,5]

| DESCRIPTION | PRODUCT CODE | SHAFT LENGTH (cm) | SHAFT DIAMETER (mm) | QUANTITY/SALES UNIT |
|---|---|---|---|---|
| ENSEAL™ X1 Curved Jaw | NSLX125C | 25 | 5 | 3 |
| ENSEAL™ X1 Curved Jaw | NSLX137C | 37 | 5 | 3 |
| ENSEAL™ X1 Curved Jaw | NSLX145C | 45 | 5 | 3 |
| ENSEAL™ X1 Large Jaw | NSLX120L | 20 | 13 | 6 |

- 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)

## How to order

Please contact your local Ethicon Sales Representative.

## Customer support

**Visit www.jnjmedicaldevices.com for more information about the ENSEAL™ X1 Tissue Sealers.**

**References: 1.** Ethicon, DOC023555A, A Floyd Claims Memo - Industrial Design, July 2018, Data on File (155022-201006) **2.** (113402-190503) **3.** Ethicon, DOC023555 - Floyd Claims Industrial Design Memo, July 2018, Data on File (116498-190612) **4.** As Per Instructions For Use (152441-200909) **5.** Ethicon, DOC023555A, A Floyd Claims Memo - Industrial Design, July 2018, Data on File (152441-200909)

**Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.**



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