

Caiman[®] Vessel Sealers

Value Analysis Brief



Aesculap Laparoscopy

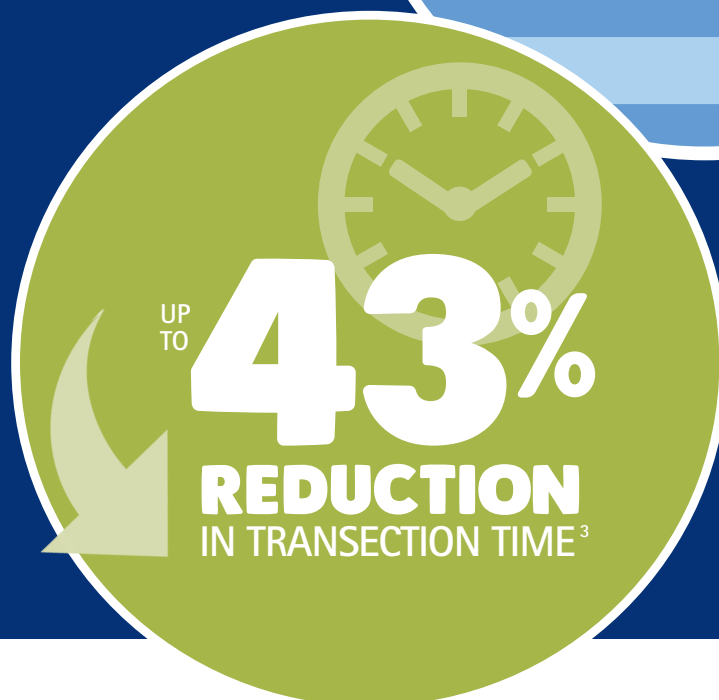
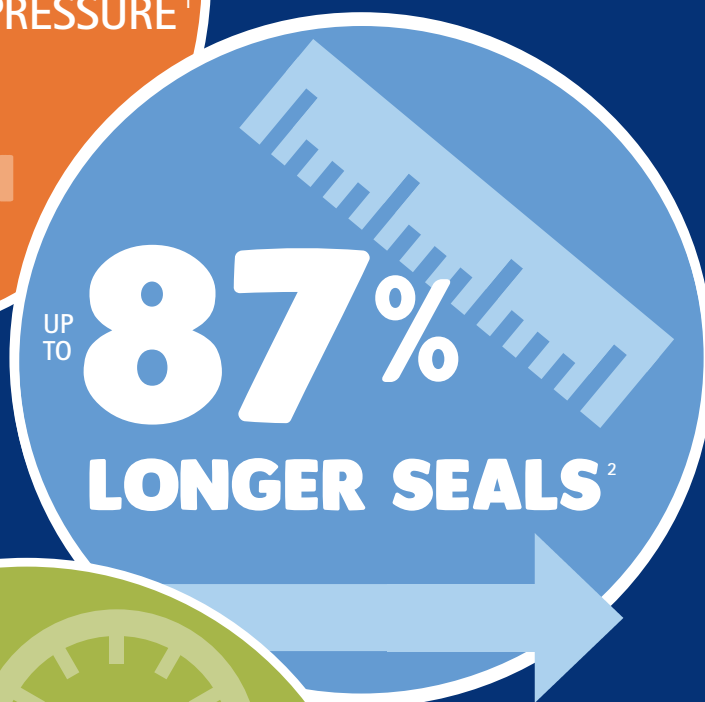
AESCULAP[®]

Caiman[®] Vessel Sealers

Value Analysis Brief

**NOT ALL
ENERGY
IS CREATED
EQUAL.**

The Caiman portfolio features a wide range of vessel sealing and cutting devices in open and laparoscopic surgery for vessels up to and including 7 mm. Uniquely designed jaws optimize procedural efficiency with exceptional transection speed, secure tissue manipulation and minimal thermal spread.



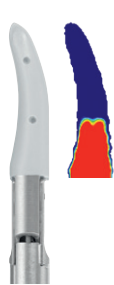
Caiman[®] Vessel Sealers

Value Analysis Brief



Caiman's unique jaw design delivers uniform compression with a clean and consistent seal quality, independent of where the vessel is positioned in the jaws.

- **Strong Uniform Compression** is key to creating a confident seal. Compression force in other devices may decline from proximal to distal end, influencing the sealing quality and causing tissue slippage during jaw closure.



Comparable Product
Maryland (5 mm)



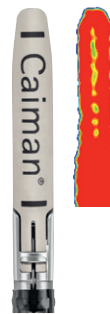
Comparable product
(5 mm)



Comparable product
(10 mm)



Caiman® 5 Maryland
(5 mm)



Caiman® 5
(5 mm)



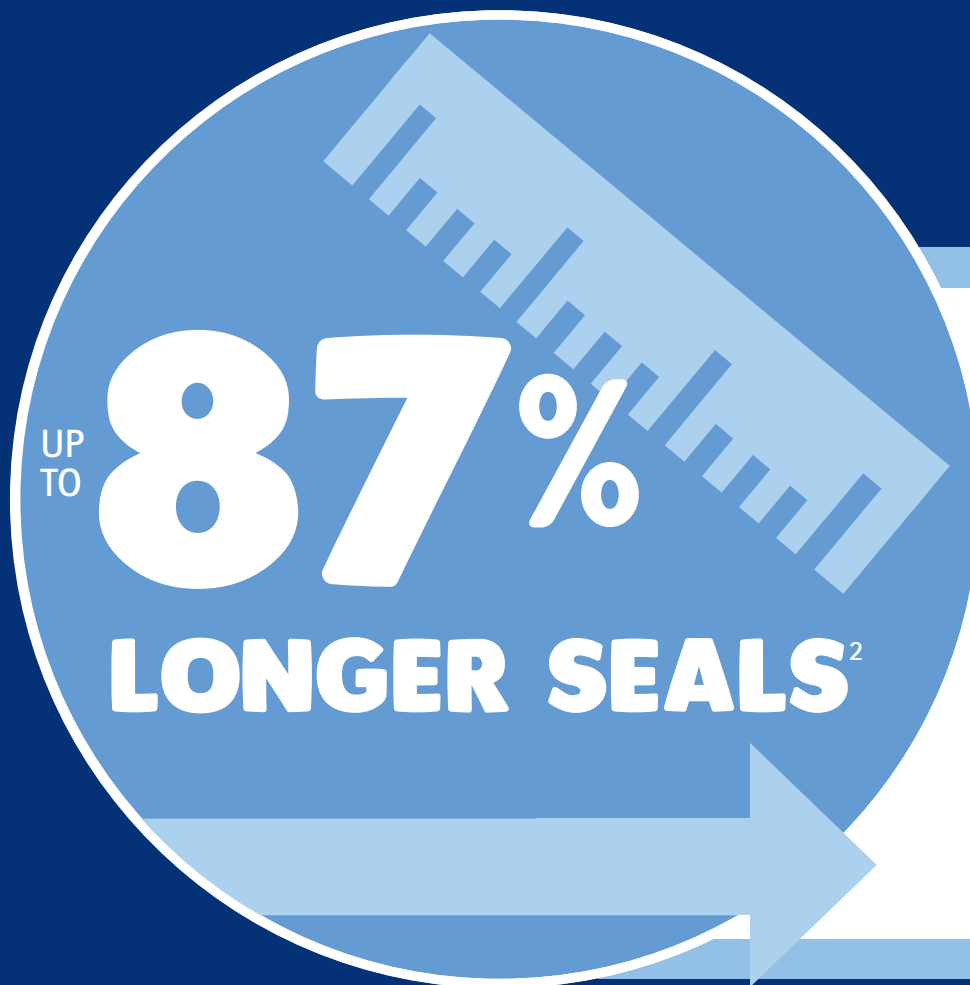
Caiman® 12
(12 mm)

Red represents minimum required pressure (or greater). Blue represents insufficient pressure.

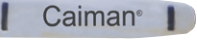







Minimum required pressures based on Aesculap calculated requirements. Graphs of minimum required pressure produced on a synthetic tissue model.




Caiman[®] Vessel Sealers

Value Analysis Brief



Caiman has the longest jaws on the market for any advanced bipolar or ultrasonic device available, allowing for heightened efficiency in laparoscopic and open procedures.

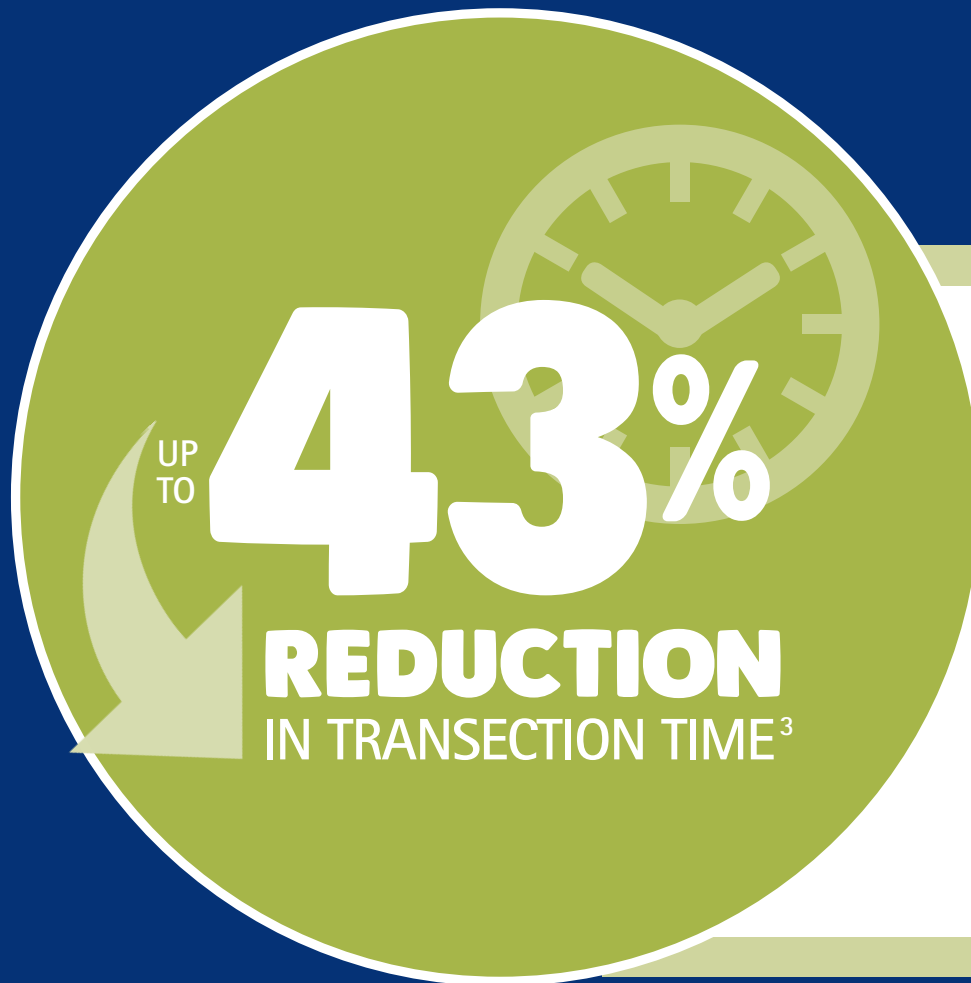
Jaw Length (mm)	Cut Length (mm)	Caiman® 5 Jaw Comparison	
26.5	23.5		Caiman® 5
21.5	20		Caiman® Maryland
20	18		LigaSure® Maryland
19.5	17.8		LigaSure® 5 mm Blunt Tip
20	19		Enseal® G2
14.2	14.2		Harmonic ACE®+
~16	~16		Thunderbeat®
13.7	11.8		HALO PKS™

Jaw Length (mm)	Cut Length (mm)	Caiman® 12 Jaw Comparison	
50	47		Caiman® 12
36	34		LigaSure® Impact
40	37		Enseal® G2 Super Jaw

All images are 1/1 ratio

Caiman® Vessel Sealers

Value Analysis Brief



Caiman's unique hinged jaw paired with the longest jaws on the market helps provide exceptional transection time.

- **Tip-First Closure**

Lower jaw hinge causes the tip of the instrument to close first, capturing tissue and preventing slippage.

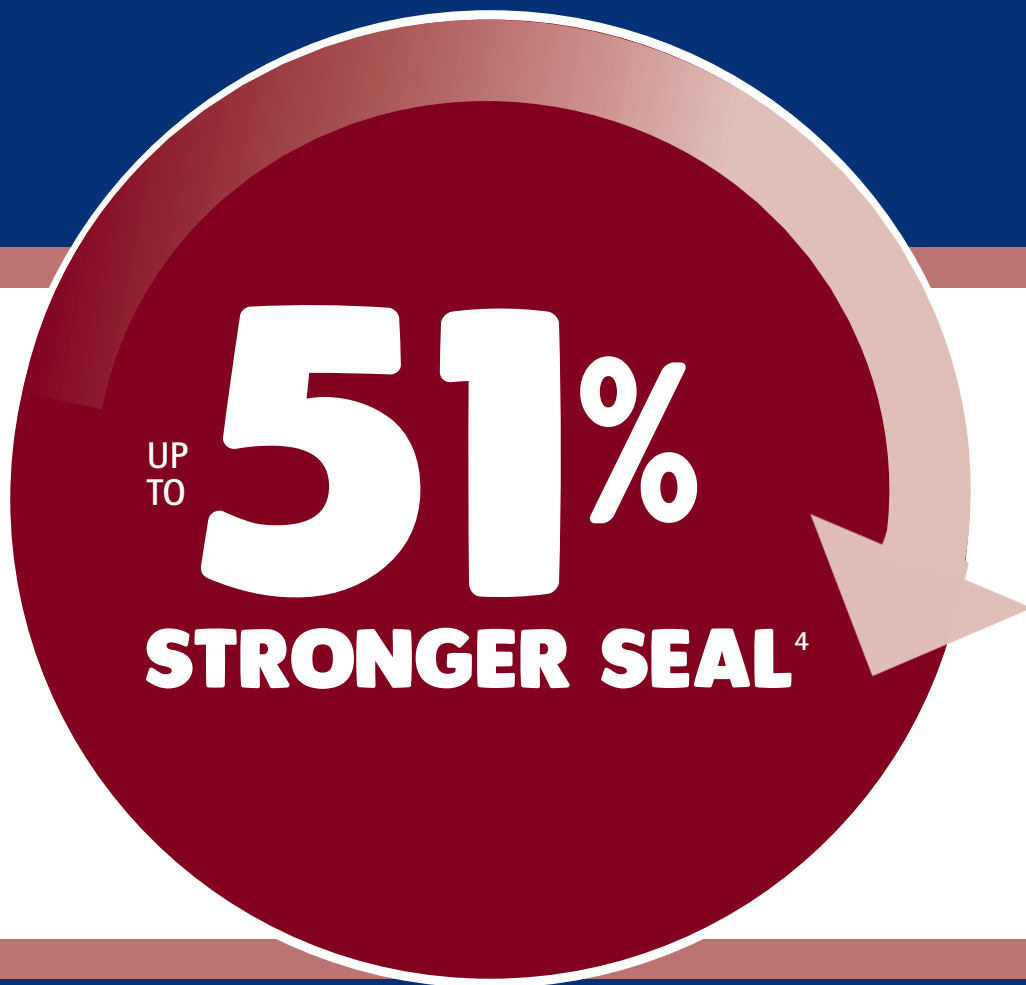
- **Efficient Energy**

Minimizes tissue damage with less thermal spread than other advanced bipolar devices.



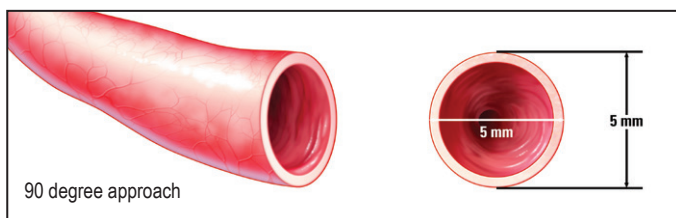
Caiman[®] Vessel Sealers

Value Analysis Brief

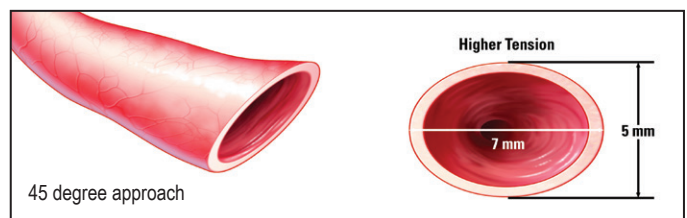


■ Improved Maneuverability

Articulation is offered to improve access to vessels in challenging anatomy. With 80° of articulation, procedures can be completed more efficiently with fewer trocar port changes. Articulation supports perpendicular vessel sealing, which may result in up to 51% greater sealing strength compared to seals created at an angle.⁴



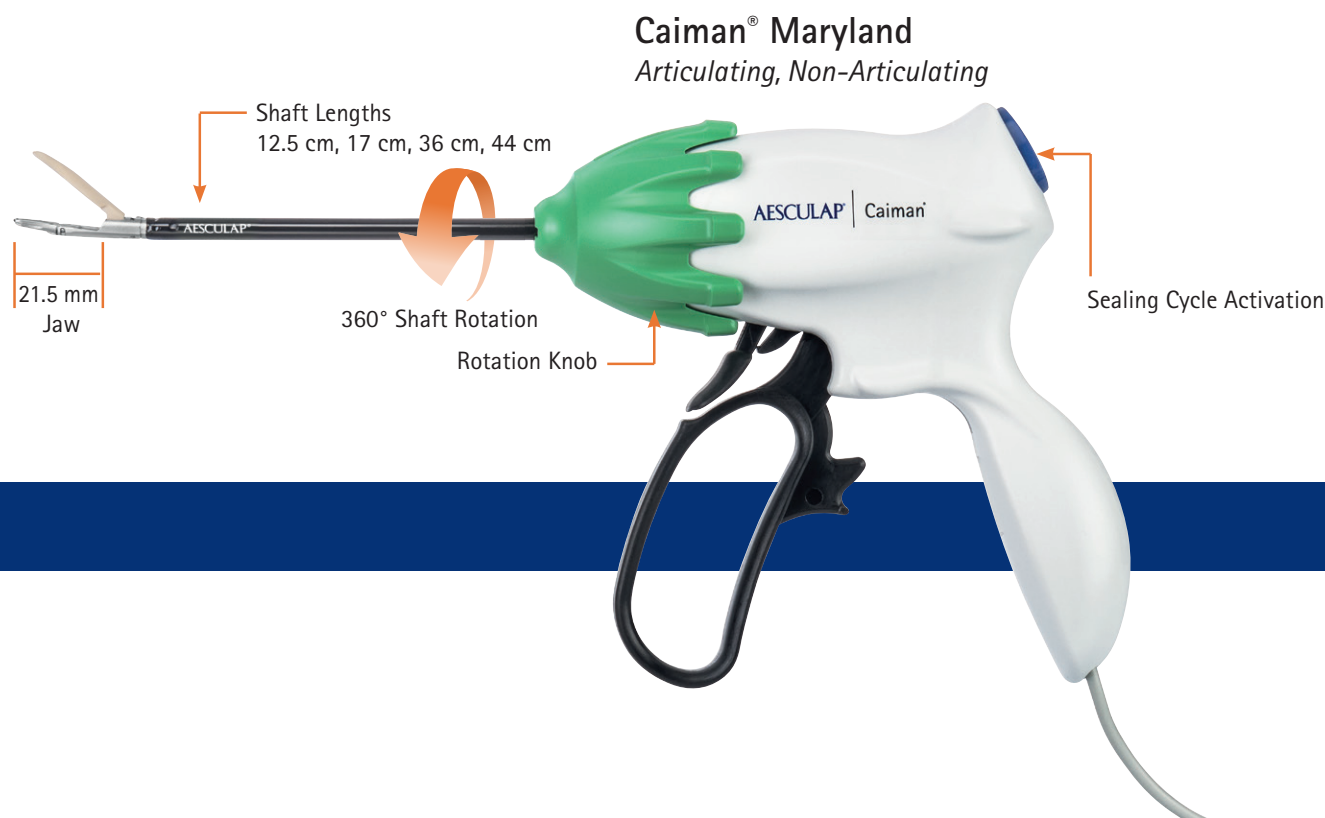
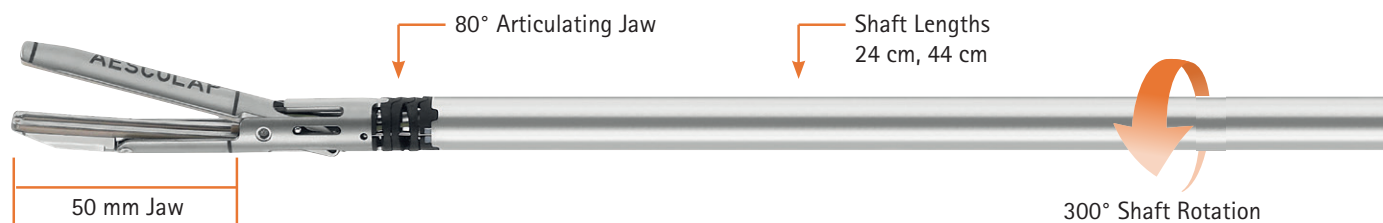
90 degree approach



45 degree approach

Caiman[®] Vessel Sealers

Value Analysis Brief



Caiman® 12

Articulating



Generator

Caiman instruments are utilized with the Lektrafuse® generator to deliver a proprietary algorithm of energy customized for various tissue types and thicknesses. Equipped with two sealing modes, the Lektrafuse generator features a plug and play mechanism and a small footprint for ease of use and handling.





Caiman generators can be consigned or purchased.

Caiman® Vessel Sealers

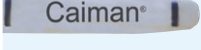




Value Analysis Brief

5 mm Vessel Sealer Cross Reference Chart

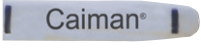


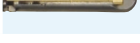

Caiman® 5 – 24 cm Comparison (Open Surgery)

Company		Item No.	Description	Diameter	Shaft Length	Seal Length	Cut Length	Shaft Rotation	Tip First Closure
Aesculap		PL738SU PL739SU	Caiman 5/ Caiman 5 Articulating	5 mm	24 cm	26.5 mm	23.5 mm	360°	Yes
Medtronic		LF1623	LigaSure® 5 mm Blunt Tip	5 mm	23 cm	19.5 mm	17.8 mm	180°	No
Medtronic		LS1520	LigaSure Dolphin Tip	5 mm	20 cm	18 mm	12 mm	179°	No
Ethicon		ETRIO-314H ETRIO-325H	Enseal® TRIO	5 mm	14 cm 25 cm	18 mm	15 mm	360°	No

Caiman 5 – 36 cm Comparison (Laparoscopic Surgery)

Company		Item No.	Description	Diameter	Shaft Length	Seal Length	Cut Length	Shaft Rotation	Tip First Closure
Aesculap		PL740SU PL741SU	Caiman 5/ Caiman 5 Articulating	5 mm	36 cm	26.5 mm	23.5 mm	360°	Yes
Medtronic		LF1637	LigaSure 5 mm Blunt Tip	5 mm	37 cm	19.5 mm	17.8 mm	180°	No
Medtronic		LS1500	LigaSure Dolphin Tip	5 mm	37 cm	18 mm	12 mm	179°	No
Ethicon		NSLG2C35A NSLG2S35A	Enseal G2 Articulating	5 mm	35 cm	20 mm	19 mm	360°	No
Ethicon		ETRIO-335H	Enseal TRIO	5 mm	35 cm	18 mm	15 mm	160°	No

Caiman 5 – 44 cm Comparison (Laparoscopic Surgery)

Company		Item No.	Description	Diameter	Shaft Length	Seal Length	Cut Length	Shaft Rotation	Tip First Closure
Aesculap		PL742SU PL743SU	Caiman 5/ Caiman 5 Articulating	5 mm	44 cm	26.5 mm	23.5 mm	360°	Yes
Medtronic		LF1644	LigaSure 5 mm Blunt Tip	5 mm	44 cm	19.5 mm	17.8 mm	159°	No
Medtronic		LF5544	LigaSure Advance	5 mm	44 cm	18 mm	15.5 mm	340°	No
Ethicon		NSLG2C45A NSLG2S45A	Enseal G2 Articulating	5 mm	45 cm	20 mm	10 mm	360°	No
Ethicon		ETRIO-345H	Enseal TRIO	5 mm	45 cm	18 mm	15 mm	360°	No

LigaSure is a registered trademark of Covidien AG.




EnSeal is a registered trademark of Ethicon Endo-Surgery, Inc.

Products shown actual size




All images are 1/1 ratio

5 mm Vessel Sealer Cross Reference Chart

Caiman® 5 Maryland Comparison (Open Surgery)

Company		Item No.	Description	Diameter	Shaft Length	Seal Length	Cut Length	Shaft Rotation	Tip First Closure
Aesculap		PL774SU PL775SU	Caiman 5 Maryland	5 mm	12.5 cm 17 cm	21.5 mm	20 mm	360°	Yes
Medtronic		LF1723	LigaSure® Maryland	5 mm	23 cm	20 mm	18 mm	350°	No
Ethicon		NSLG2C14 NSLG2S14 NSLG2C25 NSLG2S25	Enseal® G2 Curved/Straight	5 mm	14 cm 25 cm	20 mm	17 mm	360°	No

Caiman 5 Maryland Comparison (Laparoscopic Surgery)


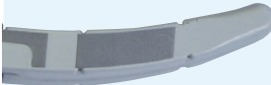


Company		Item No.	Description	Diameter	Shaft Length	Seal Length	Cut Length	Shaft Rotation	Tip First Closure
Aesculap		PL770SU PL771SU PL772SU PL773SU	Caiman 5 Maryland Caiman 5 Maryland Articulating	5 mm	36 cm 44 cm	21.5 mm	20 mm	360°	Yes
Medtronic		LF1737 LF1744	LigaSure Maryland	5 mm	37 cm 44 cm	20 mm	18 mm	350°	No
Ethicon		NSLG2C35 NSLG2S35 NSLG2C45 NSLG2S25	Enseal G2 Curved/Straight	5 mm	35 cm 45 cm	20 mm	17 mm	360°	No

Caiman[®] Vessel Sealers



Value Analysis Brief

12 mm Vessel Sealer Cross Reference Chart

Caiman 12 – 24 cm Comparison (Open Surgery)

Company		Item No.	Description	Diameter	Shaft Length	Seal Length	Cut Length	Shaft Rotation	Tip First Closure
Aesculap		PL730SU	Caiman 12 Articulating	12 mm	24 cm	50 mm	47 mm	300°	Yes
Medtronic		LF4318	LigaSure [®] Impact	13.5 mm (oval)	18 cm	36 mm	34 mm	180°	No
Medtronic		LS1020	LigaSure Atlas	10 mm	20 cm	22 mm	20 mm	359°	No
Ethicon		NSEALX22L	Enseal [®] G2 Super Jaw	12 mm	20 cm	40 mm	37 mm	360°	No

Caiman 12 – 44 cm Comparison (Laparoscopic Surgery)

Company		Item No.	Description	Diameter	Shaft Length	Seal Length	Cut Length	Shaft Rotation	Tip First Closure
Aesculap		PL731SU	Caiman 12 Articulating	12 mm	44 cm	50 mm	47 mm	300°	Yes
Medtronic		LS1037	LigaSure Atlas	10 mm	37 cm	22 mm	22 mm	359°	No

Ordering Information

		Item No.	Shaft diameter	Working length	Quantity per box
Caiman 5 Non Articulating		PL738SU	5 mm	24 cm	6
		PL740SU	5 mm	36 cm	6
		PL742SU	5 mm	44 cm	6
Caiman 5 Non Articulating Maryland		PL774SU	5 mm	12.5 cm	6
		PL775SU	5 mm	17 cm	6
		PL770SU	5 mm	36 cm	6
		PL772SU	5 mm	44 cm	6
Caiman 5 Articulating		PL739SU	5 mm	24 cm	6
		PL741SU	5 mm	36 cm	6
		PL743SU	5 mm	44 cm	6
Caiman 5 Articulating Maryland		PL771SU	5 mm	36 cm	6
		PL773SU	5 mm	44 cm	6
Caiman 12 Articulating		PL730SU	12 mm	24 cm	3
		PL731SU	12 mm	44 cm	3

References

- 1 Data on file; Caiman® 5, Harmonic Ace®+, Harmonic Ace®+7, LigaSure™ Blunt Tip and Enseal® G2 studied via in vivo vessel sealing and ex vivo burst pressure testing on porcine veins (10 per device) and arteries (10 per device) up to 7mm diameter, 2014
- 2 Data on file; Caiman® 5, Harmonic Ace®, LigaSure™ Blunt Tip, Enseal® G2, Thunderbeat® and HALO PKS™ sealing length comparison
- 3 Data on file; Caiman® 5, Harmonic Ace®+, Harmonic Ace®+7, LigaSure™ Blunt Tip and Enseal® G2 studied via in vivo timed transection of porcine colonic mesentery in 15 cm increments (10 per device), 2014
- 4 A. C. Voegelé, PE, D. L. Korvick, VMD, M. Gutierrez, MSHS, J. W. Clymer, PhD, J. F. Amaral, MD; Perpendicular Blood Vessel Seals Are Stronger Than Those Made at an Angle; Journal of Laparoendoscopic & Advanced Surgical Techniques; Vol. 23, No. 0, 2013.

Caiman[®] Vessel Sealers

Value Analysis Brief

Stocking Request Form

I am requesting the following instruments to be evaluated at our facility:

- ☐ PL774SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 12.5 cm length
- ☐ PL775SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 17 cm length
- ☐ PL738SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- ☐ PL740SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL770SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL772SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL742SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL739SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- ☐ PL741SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL743SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL771SU – Caiman Maryland articulating vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL773SU – Caiman Maryland articulating vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL730SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 24 cm length
- ☐ PL731SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 44 cm length

I am requesting Caiman for the following procedures:

Currently, I am using the following energy device(s):

- ☐ LigaSure[®] (Medtronic) ☐ Thunderbeat[®] (Olympus) ☐ Enseal[®] (Ethicon) ☐ Harmonic[®] (Ethicon) ☐ Other _____

I have clinically evaluated Caiman for the procedures, and below are the results compared to what I am currently using:

Key Evaluated Performance Areas	Below Average	Same	Superior
Quality of Seal (consistency, hemostasis)			
Seal & Cutting Length			
Tissue Retention in Jaws			
Other:			
Other:			
Time Saved	<input type="checkbox"/> 0-10 minutes	<input type="checkbox"/> 10-30 minutes	<input type="checkbox"/> 30+ minutes

Signature: _____

Date: _____

Additional Comments:

Evaluation Request Form

I am requesting the following instruments to be evaluated at our facility:

- ☐ PL774SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 12.5 cm length
- ☐ PL775SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 17 cm length
- ☐ PL738SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- ☐ PL740SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL770SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL772SU – Caiman Maryland vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL742SU – Caiman vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL739SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 24 cm length
- ☐ PL741SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL743SU – Caiman articulating vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL771SU – Caiman Maryland articulating vessel sealing/cutting instrument, 5 mm diameter, 36 cm length
- ☐ PL773SU – Caiman Maryland articulating vessel sealing/cutting instrument, 5 mm diameter, 44 cm length
- ☐ PL730SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 24 cm length
- ☐ PL731SU – Caiman articulating vessel sealing/cutting instrument, 12 mm diameter, 44 cm length

I would like to have access to Caiman for the following procedures:

Caiman Technology Offers:

- Tip-First Closure and Hinged Jaw to support tissue retention and uniform compression for delivery of a clean and consistent seal
- Long Jaws for heightened procedural efficiency
 - Seal up to 21.5 mm and cut up to 20 mm of tissue at a time (Caiman Maryland 5 mm devices)
 - Seal up to 26.5 mm and cut up to 23.5 mm of tissue at a time (Caiman 5 mm devices)
 - Seal up to 50 mm and cut up to 47 mm of tissue at a time (Caiman 12 mm devices)
- Articulation to improve access to challenging anatomy

Signature:

Date:

Additional Comments:

Caiman® Vessel Sealers

Value Analysis Brief



K183180

Page 1 of 2

510(k) SUMMARY (as required by 21 CFR 807.92)

Caiman® 5 Maryland

March 11, 2019

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Ms. Jessica Stigliano
610-984-9063 (phone)
610-791-6882 (fax)
jessica.stigliano@Aesculapimplants.com

TRADE NAME: Caiman® 5 Maryland

COMMON NAME: Electrosurgical, Cutting & Coagulation & Accessories

REGULATION NUMBER: 21 CFR 878.4400

PRODUCT CODE: GEI

REVIEW PANEL: General and Plastic Surgery

PRIMARY PREDICATE

K151696 – Caiman Seal and Cut Technology

REFERENCE DEVICE

K130596 – Caiman Seal and Cut Technology

K110824 - Aragon Surgical RF System - 5mm Laparoscopic Instrument

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Caiman® 5 Maryland is substantially equivalent to the primary predicate, Caiman® Seal and Cut Technology (K151696) and reference devices, Caiman® Seal and Cut Technology (K130596) and Aragon Surgical RF System – 5mm Laparoscopic Instrument (K110824).

DEVICE DESCRIPTION

The Caiman® 5 Maryland instruments are seal and cut devices which are provided as sterile, single use devices. These devices are capable of vessel sealing, blunt dissection, grasping and dividing tissue enclosed within its jaws during open and laparoscopic procedures. The devices

are designed to be used with the dedicated Lektrafuse RF Generator and create vessel ligation by the application of bipolar electrical RF energy and tissue division with a cutting blade.

INDICATIONS FOR USE

Instruments 12.5 cm, 17 cm, and 24 cm in length are indicated for open procedures and instruments 36 cm and 44 cm in length are indicated for laparoscopic procedures. The indications for use include general surgical procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resection, and oophorectomy etc., or any procedure where vessel ligation (seal and cut), tissue grasping, and dissection is performed. The devices can be used on vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

Caiman Seal and Cut Technology has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))

The modifications made to the Caiman instruments do not affect the fundamental scientific technology. The modifications made to these devices do not raise any new issues of safety and effectiveness, as confirmed by the testing and validation activities described in the submission.

Caiman[®] Vessel Sealers

Value Analysis Brief



K151696

Page 1 of 2

510(k) SUMMARY (as required by 21 CFR 807.92)

Caiman[®] Seal and Cut Technology

June 22, 2015

COMPANY:

Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT:

Denise R. Adams, RAC
610-984-9076 (phone)
610-791-6882 (fax)

TRADE NAME:

Caiman Seal and Cut Technology

COMMON NAME:

Electrosurgical, Cutting & Coagulation & Accessories

CLASSIFICATION NAME: Electrosurgical Cutting and Coagulation Device and Accessories

REGULATION NUMBER: 21 CFR 878.4400

PRODUCT CODE: GEI

SUBSTANTIAL EQUIVALENCE

Caiman Seal and Cut Technology is substantially equivalent to the Caiman Seal and Cut Technology system cleared via K130596.

DEVICE DESCRIPTION

Caiman Seal and Cut Technology consists of the Lektrafuse RF Generator and the Caiman seal and cut devices which are provided as sterile, single use devices. These devices are capable of vessel sealing, blunt dissection, grasping and dividing tissue enclosed within its jaws during open and laparoscopic procedures. The devices are designed to be used with the dedicated Lektrafuse RF Generator and create vessel ligation by the application of bipolar electrical RF energy and tissue division with a cutting blade. The 5 mm instruments (not the generator) are the subject of this submission.

INDICATIONS FOR USE

Caiman Seal and Cut Technology consists of dedicated bipolar electrosurgical instruments intended for use in general surgery and gynecologic surgical procedures where ligation and division of vessels is desired. The instruments create a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structure (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

Instruments 24 cm in length are indicated for open procedures and instruments 36 cm and 44 cm in length are indicated for laparoscopic procedures. The indications for use include general surgical procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resection, and oophorectomy etc., or any procedure where vessel ligation (seal and cut), tissue grasping, and dissection is performed. The devices can be used on vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

Caiman Seal and Cut Technology has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

TECHNOLOGICAL CHARACTERISTICS (compared to predicates)

The modifications made to the Caiman Seal and Cut Technology system do not affect the fundamental scientific technology. The principal of operation has not changed for these devices. The following modifications made to these devices do not raise any new issues of safety and effectiveness: addition of 5mm articulating instrument, addition of a gasket in the shaft, shaft length, isolator assembly, distal cable connector, an adhesive change. Material changes were made to the dissection clip and heat shrink material.

PERFORMANCE DATA

Bench testing was performed on the modified devices and found them to be substantially equivalent to the predicate devices. The testing included the following tests: Articulation Angle/Torque, Biocompatibility, Cutter Advancement, Cutting Blade Termination, Dissection Distance, Distal Jaw Gap, Flow Rate, Force to Lock and Release Jaw, Instrument Life, Jaw Adhesion, Jaw Force (clamping compression), Jaw Grasp, Tissue Resistance Test, Sealing (length, size & time), Seal Burst Pressure on three different tissue types, Thermal Spread Trocar Compatibility, Visual Arcing and Regrasp.

The Caiman Seal and Cut Technology is in compliance with the following safety standards: IEC 60601-2-2, IEC 60601-1-2, IEC 60601-1: 3rd Edition, and IEC 60601-2-18.

Caiman[®] Vessel Sealers

Value Analysis Brief



K151858

Page 1 of 2

510(k) SUMMARY (as required by 21 CFR 807.92)

Caiman[®] Seal and Cut Technology July 15, 2015

COMPANY: Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Denise R. Adams, RAC
610-984-9076 (phone)
610-791-6882 (fax)

TRADE NAME: Caiman Seal and Cut Technology

COMMON NAME: Electrosurgical, Cutting & Coagulation & Accessories

CLASSIFICATION NAME: Electrosurgical Cutting and Coagulation Device and Accessories

REGULATION NUMBER: 21 CFR 878.4400

PRODUCT CODE: GEI

SUBSTANTIAL EQUIVALENCE

Caiman Seal and Cut Technology is substantially equivalent to the Caiman Seal and Cut Technology System cleared via K140839.

DEVICE DESCRIPTION

Caiman Seal and Cut Technology consists of the Lektrafuse RF Generator and the sterile, single use Caiman devices. These devices are capable of vessel sealing, blunt dissection, grasping and dividing tissue enclosed within its jaws during open and laparoscopic procedures. The devices are designed to be used with the dedicated Lektrafuse RF Generator and create vessel ligation by the application of bipolar electrical RF energy and tissue division with a cutting blade.



INDICATIONS FOR USE

Page 2 of 2

Caiman Seal and Cut Technology consists of dedicated bipolar electrosurgical instruments intended for use in general surgery and gynecologic surgical procedures where ligation and division of vessels is desired. The instruments create a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structure (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

Instruments 24cm in length are indicated for open procedures and instruments 36cm and 44 cm in length are indicated for laparoscopic procedures. The indications for use include general surgical procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resection, and oophorectomy etc., or any procedure where vessel ligation (seal and cut), tissue grasping, and dissection is performed. The devices can be used on vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

Caiman Seal and Cut Technology has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

TECHNOLOGICAL CHARACTERISTICS (compared to predicate)

The modifications made to the Caiman Seal and Cut Technology system do not affect the fundamental scientific technology. The design, materials, and principal of operation have not changed for these devices. The modifications made to these devices do not raise any new issues of safety and effectiveness.

PERFORMANCE DATA

Bench testing was performed on the modified devices and found them to be substantially equivalent to the predicate devices. The Plus Mode performance verification on the Lektrafuse Generator with the Caiman 12mm and Caiman 5mm included the following tests:

1. Seal Burst Pressure on three different tissue types
2. Visual Arcing
3. Jaw Adhesion
4. Thermal Spread

Caiman Seal and Cut Technology is in compliance with the following safety standards:

1. IEC 60601-2-2
2. IEC 60601-1-2
3. IEC 60601-1: 3rd Edition
4. IEC 62304

Indications for Use

510(k) Number (if known)
K140839

Device Name
Caiman Seal and Cut Technology

Indications for Use (Describe)

Caiman Seal and Cut Technology consists of dedicated bipolar electrosurgical instruments intended for use in general surgery and gynecologic surgical procedures where ligation and division of vessels is desired. The instruments create a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structure (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

The Caiman 12 Plus (44cm) and the Caiman 5 are indicated for laparoscopic procedures and the Caiman 12 Plus (24cm) is indicated for open procedures. The indications for use include general surgical procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resection, and oophorectomy etc., or any procedure where vessel ligation (seal and cut), tissue grasping, and dissection is performed. The devices can be used on vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

Caiman Seal and Cut Technology has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

All rights reserved. Technical alterations are possible. This leaflet may be used for no other purposes than offering, buying and selling of our products. No part may be copied or reproduced in any form. In the case of misuse we retain the rights to recall our catalogs and price lists and to take legal actions.

©2019 AESCULAP. ALL RIGHTS RESERVED. PRINTED IN THE USA.
Aesculap is an equal opportunity employer

Aesculap, Inc. | 3773 Corporate Parkway | Center Valley, PA | 18034
Phone 800-282-9000 | Fax 610-791-6886 | www.aesculapusa.com

Aesculap, Inc. – a B. Braun company

DOC1158 Rev D 1.5M 6/19