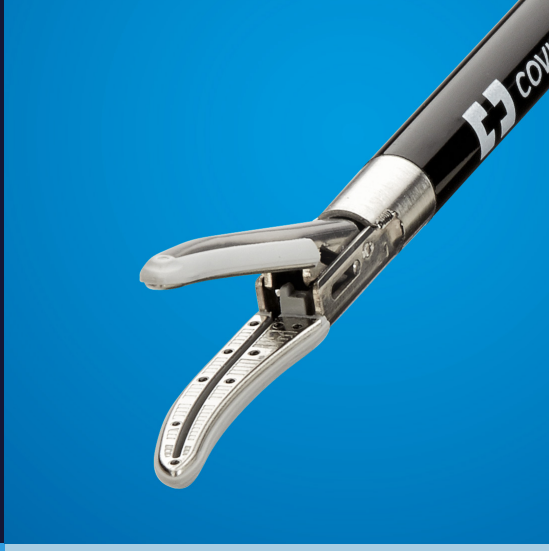
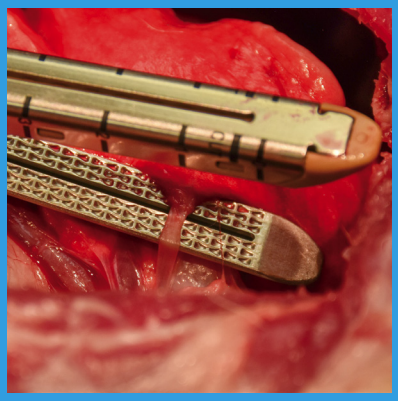
BEST PRACTICES FOR OUR PULMONARY VESSEL SEALER

Optimizing performance of the LigaSure™ Maryland Jaw thoracic device (LF1930T)



What size pulmonary vessel can this device seal?

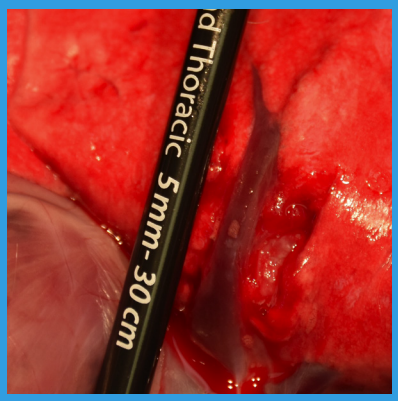
The LF1930T is indicated for use on pulmonary arteries and veins up to and including **7 mm**.[1] It can be considered for use if a surgeon believes that a stapler is not suitable for access to pulmonary vasculature. Additionally, this device is also indicated for sealing and dividing tissue bundles and lymphatics up to and including 7 mm.[1]



How should I estimate the size of vessels?

When estimating size, vessels should be circular, not compressed or flattened. You can use the shaft of the device (~5 mm) for reference.

Note: For initial use, consider sealing vessels less than the size of the shaft of the device until you are familiar with the application of energy-based vessel sealing.



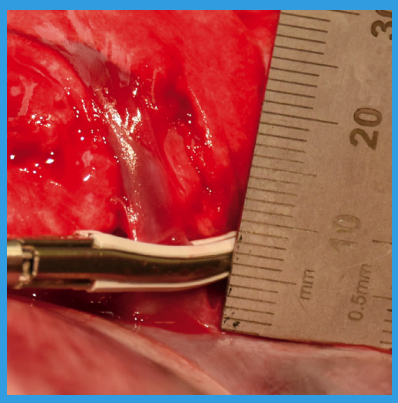
Shaft parallel to vessel

What is the thermal spread for this device?

Thermal spread is < 2 mm.[2]

When sealing, how much distance should be left between the jaws of the device and critical structures (i.e., main pulmonary branch)?

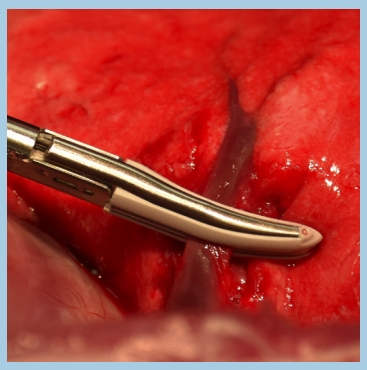
Ensure there is 2 to 4 mm of distance between the jaws and critical structures to account for potential thermal spread.[3]



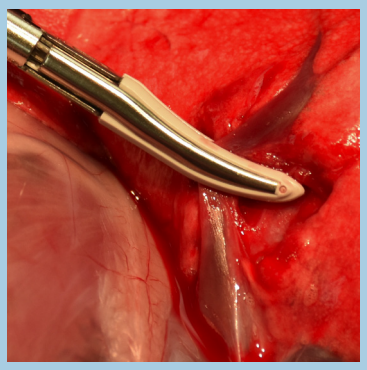
Keep **2 to 4 mm** between the jaws and critical structures

Should I avoid tension when sealing?

Yes. Eliminate tension on the tissue when sealing and cutting to ensure proper function.[1]



Correct (no tension)



Incorrect (with tension)

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Is it OK for me to double seal?

All of our devices are qualified using single seals. If a surgeon elects to seal adjacent tissue (double seal), they should overlap the edge of the existing seal. The second seal should be distal to the first seal to increase seal margin.[1]

What should I do if, after activating the device, I do not hear a two-pulse tone to indicate a completed seal?

A tone with more than two pulses indicates that the seal cycle was not completed. Do not cut tissue. If possible, reposition the instrument and regrasp tissue in a location that overlaps the previous seal. Reactivate the device and wait until the seal complete (two-tone) sound is heard before cutting through tissue.[1]

Should I avoid sealing or cutting over clips and staples?

Do not attempt to seal or cut over clips or staples as incomplete seals will be formed and damage to the cutter may occur.[1]

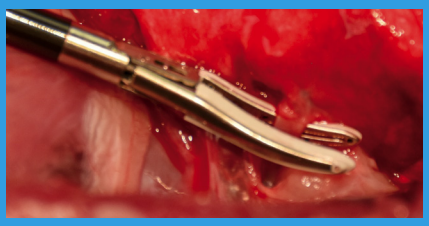
Can I seal parenchyma with this device?

The safety and efficacy of radiofrequency (RF) energy **has not** been established for use on lung parenchyma.[1]

How do I ensure tip visibility prior to sealing (similar to stapler use)?

Follow these steps to ensure complete seal creation:

1. Verify that the vessel and/or tissue is adequately centered and contained completely within the jaws.[1]
2. Ensure that you do not overfill the jaws of the instrument with tissue, as this may reduce device performance.[1]
3. Verify that the distal tips of the top and bottom jaws are fully visible before activating energy to ensure complete seal creation.



Ensure jaw tips are visible before activating energy

What preclinical testing was performed to verify this device?[1]

Product performance of the device was established in a chronic in-vivo porcine model for systemic vasculature and in chronic in-vivo canine model for pulmonary vasculature. The results showed that no animals studied experienced any hemostatic complications related to the device during the 21-day survival period. A variety of tissue types and vessels were evaluated to demonstrate effective sealing in arteries, veins, pulmonary arteries, and pulmonary veins up to and including 7 mm.[1]

Chronic in-vivo porcine testing

VESSEL TYPE	TISSUE/VESSEL NAME	VESSEL SIZE RANGE
A/V bundle	Splenic Mesentery	≤ 2.0 mm
	Gastrosplenic	3.0–4.5 mm arteries within bundles
	Ovarian Pedicle	Bundles up to 5.0 mm
	Broad Ligament	Bundles up to 4.0 mm
	Short Gastric	4.0–6.0 mm bundles
Artery	Renal	3.5–7.0 mm
	Splenic	4.5–7.0 mm
Vein	Renal	3.0–7.0 mm
	Splenic	7.0 mm

Chronic in-vivo canine testing

VESSEL TYPE	VESSEL SIZE RANGE
Pulmonary Artery	3.0–7.0 mm
Pulmonary Vein	2.0–7.0 mm

1. LigaSure™ Maryland Jaw Thoracic Sealer/Divider Nano-coated [instructions for use]. Boulder, CO: Medtronic; 2017.
2. Based on internal report #RE00128442, GLP Acute pulmonary vasculature hemostasis verification study of the LigaSure™ LF1930T device. December 2017.
3. Based on internal report #RE00158953, Recommended distance from critical structures (memo). August 2018.

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