



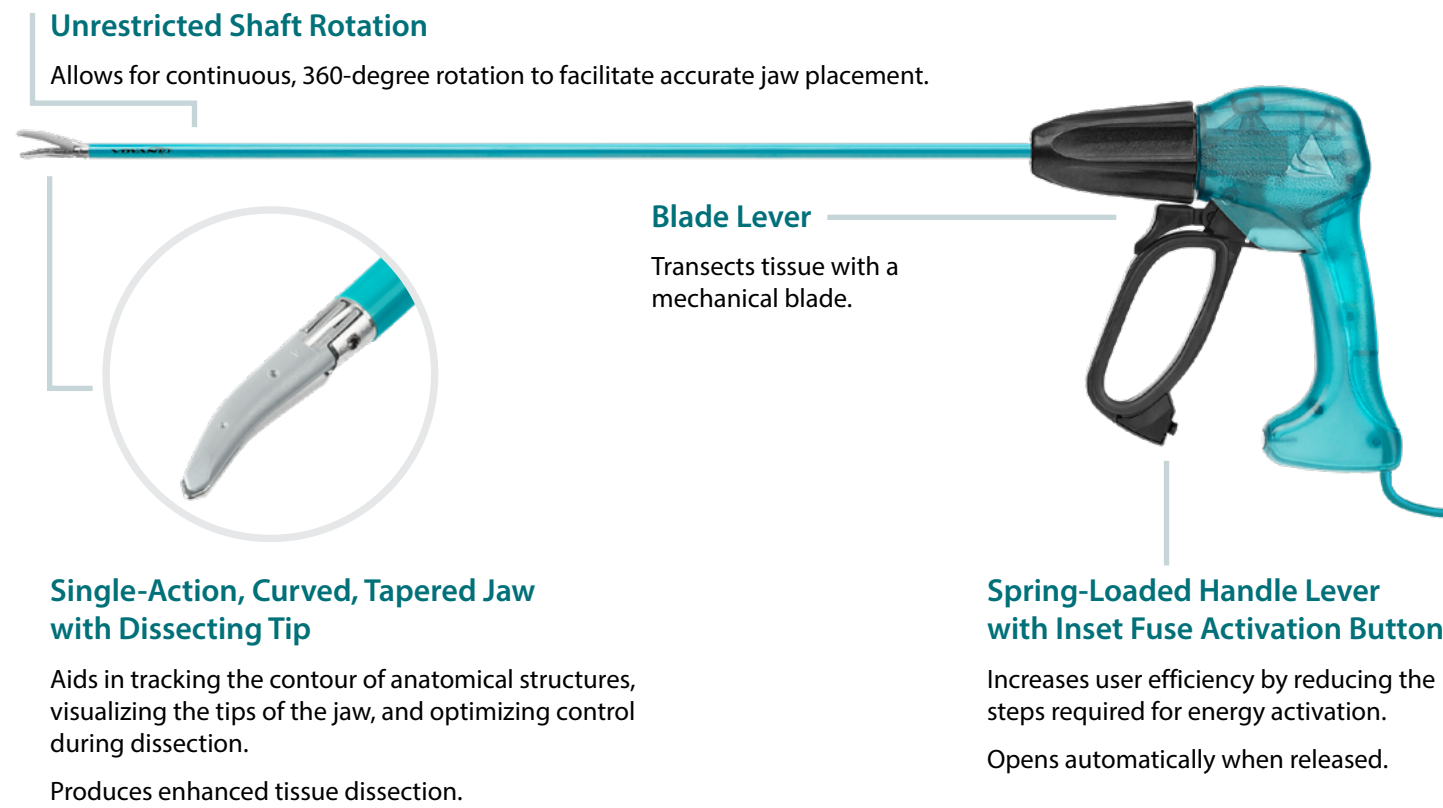
Voyant Maryland Fusion Device with Single-Step Activation

DEVICE GUIDE

Voyant MARYLAND FUSION DEVICE WITH SINGLE-STEP ACTIVATION

OVERVIEW

The Voyant Maryland Fusion device with single-step activation is a bipolar, electrosurgical device used to effectively seal and divide vessels up to and including 7mm in diameter and tissue bundles that can be captured in the jaws of the device. The device features a spring-loaded handle with an inset fuse activation button that reduces the steps required to deliver energy.



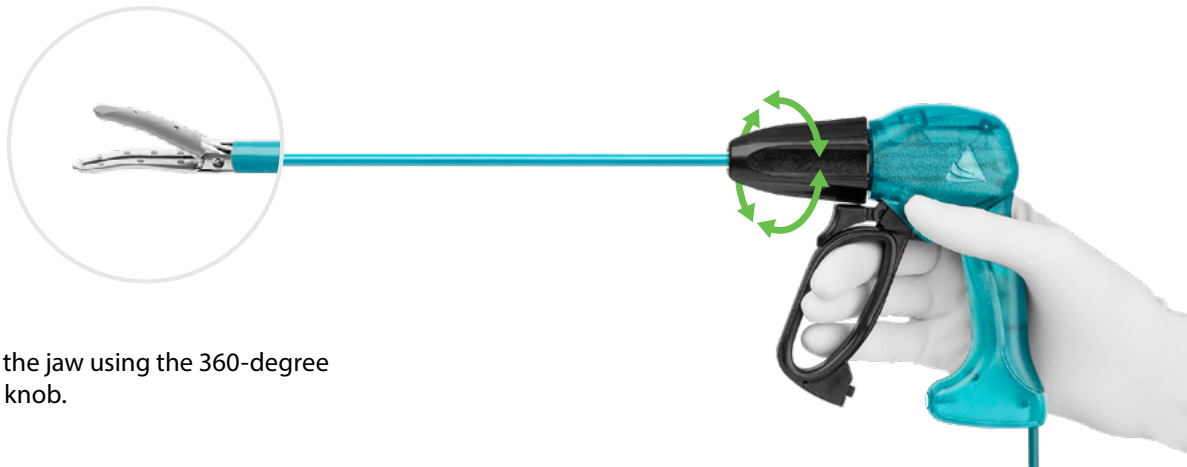
Device Specifications

Model	Shaft Length	Trocar Compatibility	Seal Length	Cut Length
EB212	37cm	5mm or larger	20mm	18mm
EB213	44cm	5mm or larger	20mm	18mm
EB214	23cm	5mm or larger	20mm	18mm

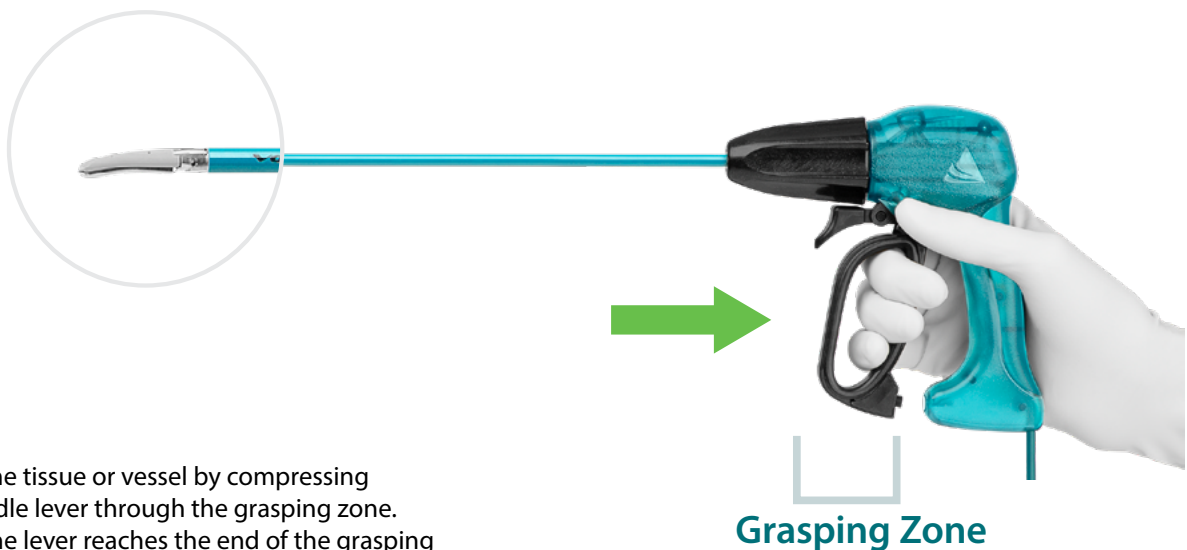
Voyant MARYLAND FUSION DEVICE WITH SINGLE-STEP ACTIVATION

DEMONSTRATION

Note: This guide is not intended to replace the Instructions for Use (IFU). Please refer to the IFU for the indications, contraindications, warnings, precautions, instructions and other information.



1 Position the jaw using the 360-degree rotation knob.



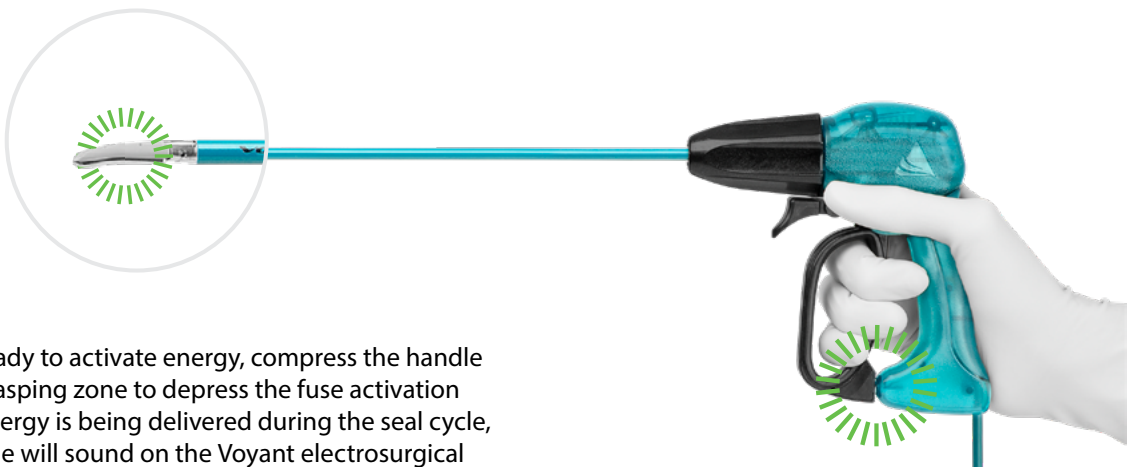
2 Grasp the tissue or vessel by compressing the handle lever through the grasping zone. When the lever reaches the end of the grasping zone, the jaws will have closed.

WARNINGS:

- Do not place the tissue or vessel in the jaw hinge. Place it in the center of the jaw.
- If intending only to grasp or manipulate tissue or vessels, do not advance the handle lever past the grasping zone, as this will deliver energy.

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DEMONSTRATION



3 When you are ready to activate energy, compress the handle lever past the grasping zone to depress the fuse activation button. While energy is being delivered during the seal cycle, an activation tone will sound on the Voyant electrosurgical generator. A separate end-tone will emit from the Voyant generator upon completion of the seal cycle, marking the end of energy delivery.

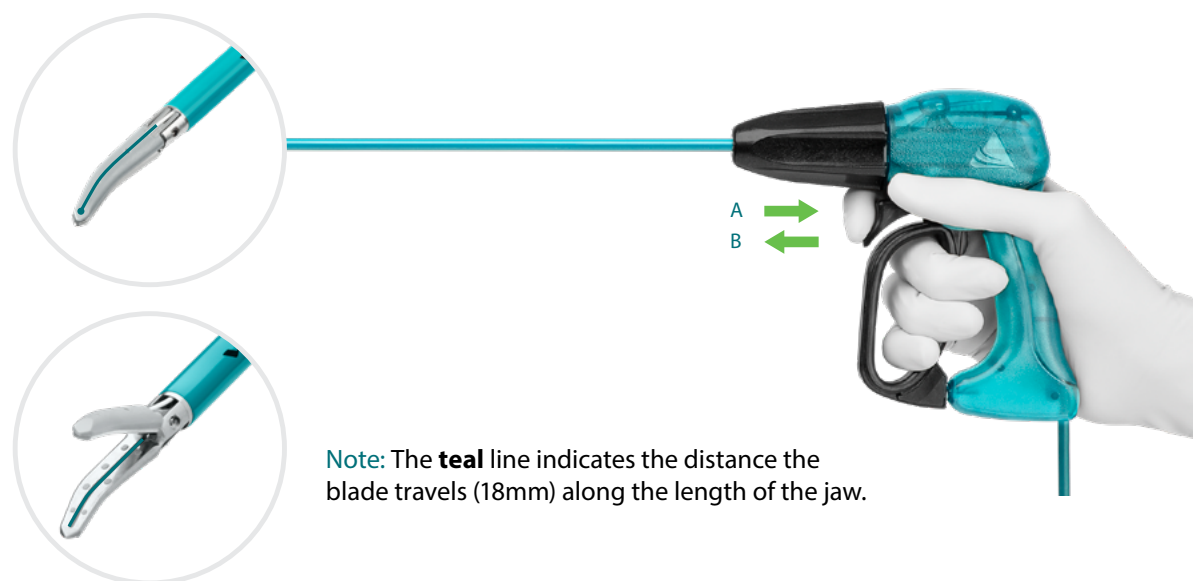
WARNINGS*:

- Do not attempt to seal vessels greater than 7mm in diameter with this device.
- During device activation, seal 1–3mm away from unintended thermally sensitive structures. To prevent unintended thermal injury, care should be taken around structures in close proximity to the jaws and during surgical procedures occurring in confined spaces.
- Keep handle lever fully closed throughout the entire seal cycle to ensure complete sealing. The handle lever does not latch and must be held closed during the duration of the seal cycle.

* Please refer to page 9 for additional warnings.

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DEMONSTRATION

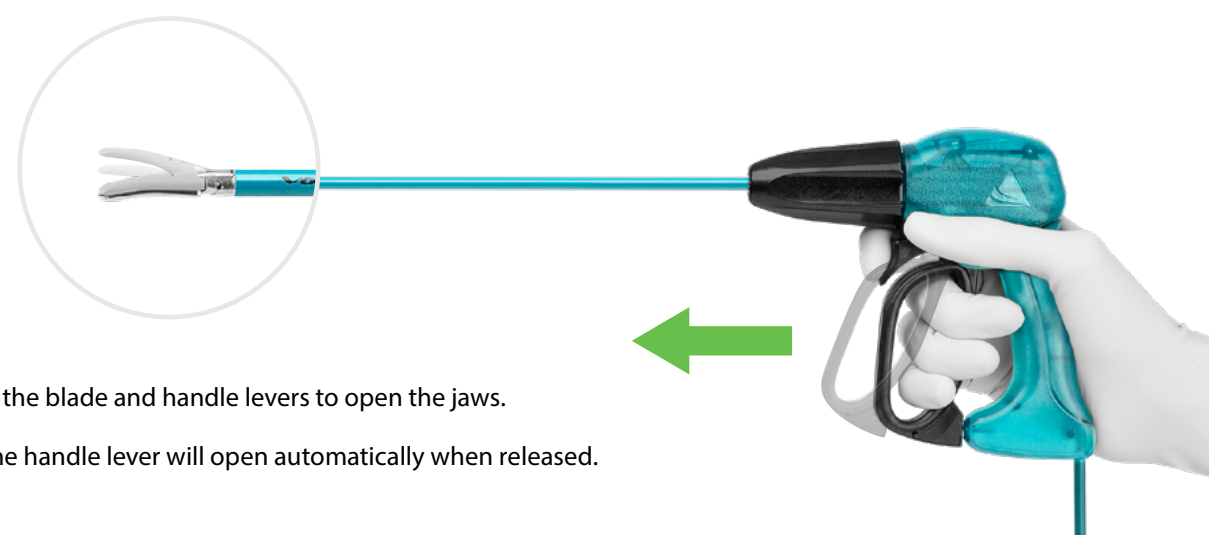


Note: The teal line indicates the distance the blade travels (18mm) along the length of the jaw.

4 (A) Transect tissue by using your index finger to pull the blade lever back fully, then (B) release the blade lever.

WARNINGS:

- Do not deploy the blade until the seal cycle is complete.



5 Release the blade and handle levers to open the jaws.

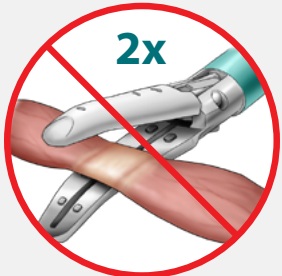
Note: The handle lever will open automatically when released.

Voyant MARYLAND FUSION DEVICE WITH SINGLE-STEP ACTIVATION

ADDITIONAL IN-SERVICE RECOMMENDATIONS

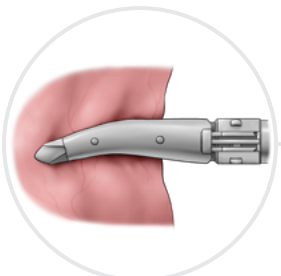
Activating Only Once When Sealing

The Voyant algorithm recognizes the tissue between the jaws. The device needs to be activated only once to create a permanent, fused seal. Multiple activations on the same seal site are not necessary and not recommended per the IFU.

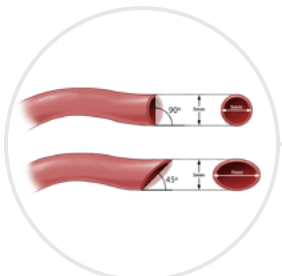


WARNING:

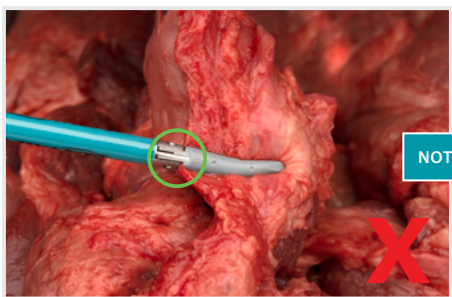
Do not seal directly over an area that is already sealed, or the integrity of the primary seal may be compromised.



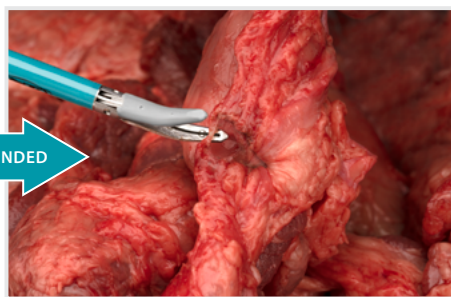
Place the tissue or vessel in the center of the jaw, not in the jaw hinge. Placing the tissue in the hinge can lead to an incomplete seal.



When grasping the tissue or vessel, ensure that the angle of the jaw is **perpendicular** to the vessel or tissue. A seal made at an **acute angle** cannot withstand as much systolic pressure.



Jaws overfilled at the hinge



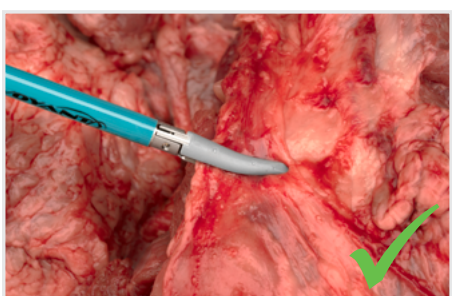
Potential for an incomplete cut

WARNING:

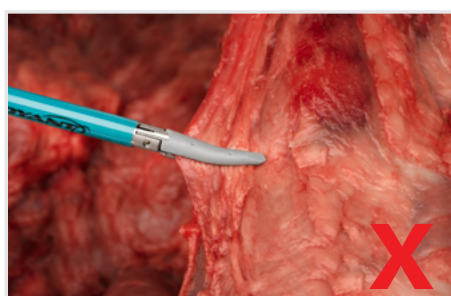
Do not overfill the jaw of the device with tissue. Doing so could compromise the device's sealing and cutting functions, prevent the jaw from opening properly, or result in an incomplete cut.

Sealing Without Applying Tension

To ensure proper function of the device, do not apply tension while sealing and transecting tissue.



No tension (recommended)



High tension (not recommended)

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ADDITIONAL IN-SERVICE RECOMMENDATIONS

Cleaning the Jaws

- For optimal performance, keep the blade channel and jaw surfaces clean. With the jaws closed, pull and release the blade lever to clear the blade channel of eschar buildup.
- Use a gauze pad soaked with sterile water or saline to remove eschar.



1 Release the handle lever to open the jaws.



2 Wet gauze with saline.



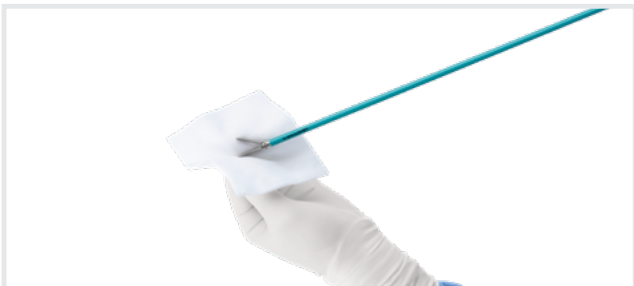
3 Wipe the wet gauze in between and around the jaws thoroughly.



4 Close the jaws without activating energy.



5 Pull and release the blade lever to clear the blade channel of eschar.



6 Wipe the jaws again before continuing the procedure.

WARNINGS*:

- Do not activate the device while cleaning the jaws. Do not attempt to deploy the blade while the jaw is open. In both cases, user injury may result.
- Do not use scratch pads or abrasive pads to clean the jaws, or damage to the electrodes may occur, potentially affecting device performance.

* Please refer to page 9 for additional warnings.

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ADDITIONAL IN-SERVICE RECOMMENDATIONS

Activating Energy

- Do not attempt to seal over clips or staples, as incomplete seals may be formed.
- Do not activate the device when it is in contact with, or in close proximity to, other metal instruments or objects. Burns to the patient and/or surgical team may occur.
- Prior to activating the device, remove any conductive fluid that is in contact with, or in close proximity to, the electrodes of the device. Conductive fluids (e.g., blood, saline, water, etc.) can transfer current, heat, or both, and cause unintended tissue effects.
- Ensure that the jaws of the device are visible prior to and during device activation to avoid unintended tissue effects and/or injury.

Cleaning the Jaws

- Buildup of eschar can negatively affect the device's sealing and cutting performance and/or create embers that present a fire hazard.

NOTES

The Voyant Fusion devices are bipolar, electrosurgical devices used in procedures where the ligation and division of vessels and tissue bundles is desired.

Please contact your Applied Medical representative for more information on availability. This information is intended for dissemination exclusively to healthcare professionals and is not intended to replace labeling and Instructions for Use (IFU). Please refer to the IFU for the indications, contraindications, warnings, precautions, instructions and other information.

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