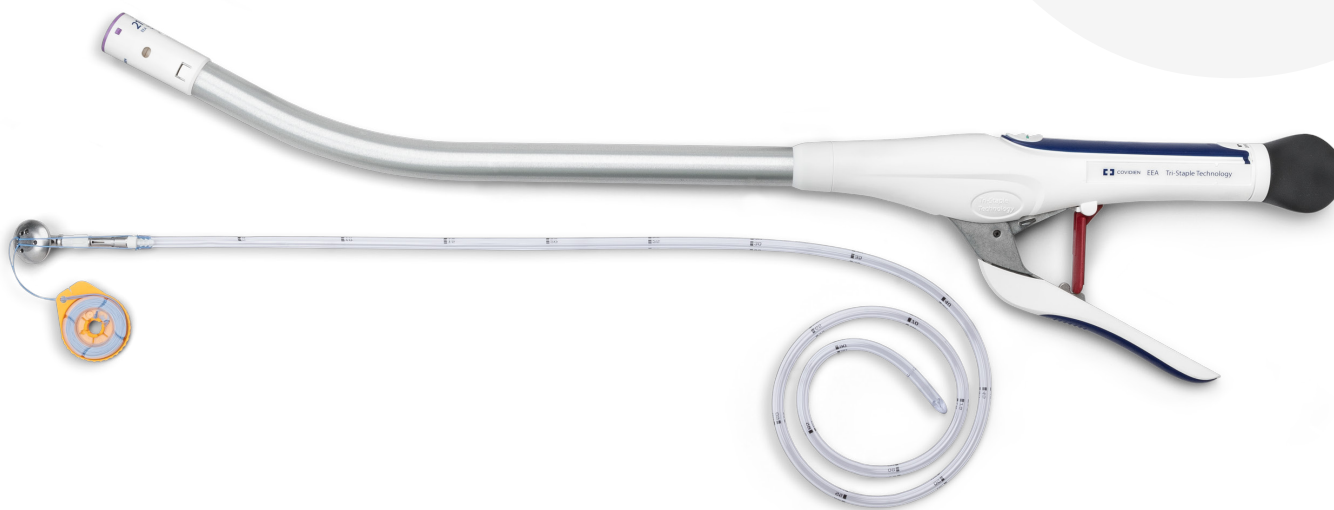


In-service guide

EEA™ circular stapler with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil



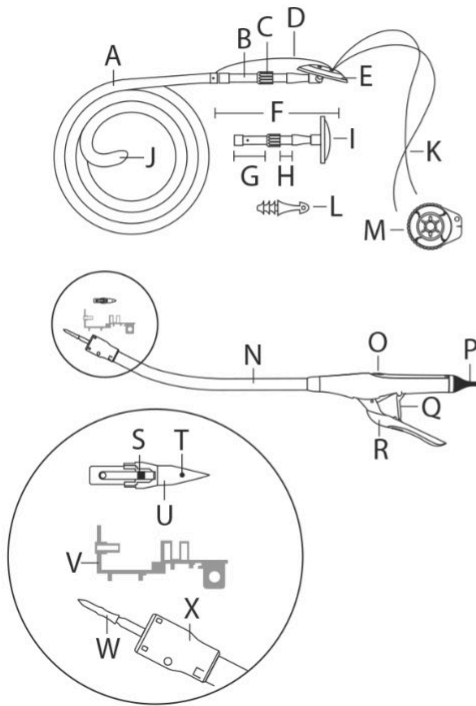
Always refer to the instructions for use (IFU) included with products for complete indications, instructions, warnings, precautions, and contraindications.

Warning: The 21 mm and 25 mm OrVil™ transoral circular stapler anvil devices are compatible with the corresponding diameter EEA™ circular stapler with Tri-Staple™ technology XL stapler length products only; the 21 mm OrVil™ transoral circular stapler anvil is compatible with the 21 mm XL EEA™ circular stapler with Tri-Staple™ technology and the 25 mm OrVil™ transoral circular stapler anvil is compatible with the XL EEA™ circular stapler with Tri-Staple™ technology. They are not compatible with the 22 cm long products or any other EEA™ staplers.

Important: This device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess, or resterilize this device.

Device overview

Familiarize yourself with all listed parts before using the device. Refer to the instructions for use (IFU) for the full product schematic view.



Device overview

EEA™ circular stapler with Tri-Staple™ technology and OrVil™ transoral circular stapler anvil

- | | |
|---|---|
| A. Delivery tube | L. White accessory fitting |
| B. Center rod | M. Reel |
| C. Plastic collar | N. Shaft with integrated trocar |
| D. Anvil retaining suture (nonabsorbable, braided polyester) | O. Indicator window |
| E. Tilt-Top™ Plus anvil head (tilted) | P. Twist knob |
| F. Tilt-Top™ anvil/center rod assembly | Q. Safety release |
| G. Anvil assembly legs | R. Instrument handle |
| H. Grasping notch | S. Black release button |
| I. Tilt-Top™ Plus anvil head (open) | T. Suture hole |
| J. Bulb tip | U. White sharp anvil trocar tip accessory |
| K. Advancing proximal guide suture (nonabsorbable, braided polyester) | V. Shipping wedge |
| | W. Integrated trocar |
| | X. Cartridge |

Steps for use



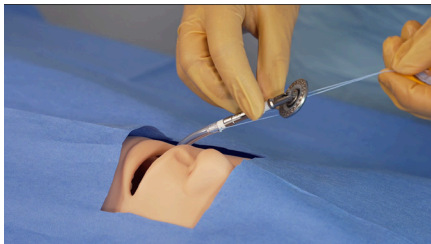
The advancing proximal guide suture is supplied in a reel and can be deployed as needed.



Insert bulb tip of the delivery tube into the appropriate structure (e.g., the esophagus).



Advance the delivery tube to where the anastomosis is desired.

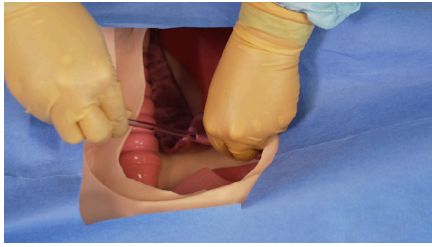


Ensure the reel is retained outside of the patient during the entire process. Deploy the suture from the reel as needed to ensure the reel is controlled outside patient with no contact with unwanted surfaces.

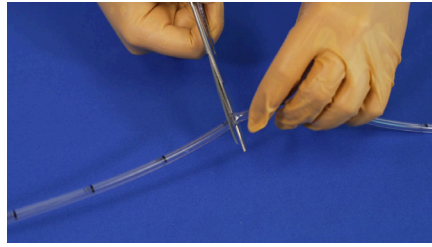


The proximal guide suture can be used to provide proximal control to facilitate the advancement of the delivery tube and attached anvil. In the event that an obstruction impedes the passage of the tube and anvil, the proximal guide suture can be used to facilitate repositioning or removal of the delivery tube and attached anvil.

Warning: Failure to control the advancing proximal guide suture may result in the suture being stapled to the anastomotic site.

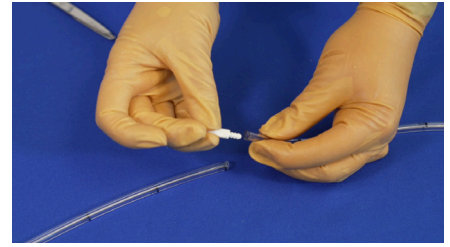


Create an incision in the structure to allow the bulb tip to pass through.

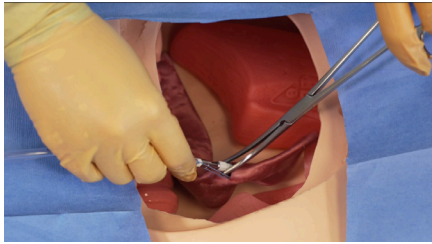


If a shorter length of the delivery tube is desired, the tube may be cut to the appropriate length.

Warning: A shortened delivery tube is not for use in transoral applications.

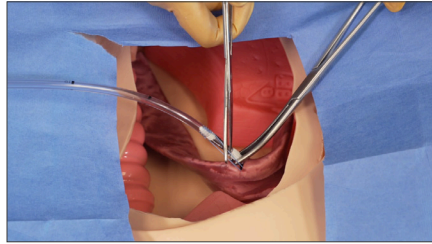


Secure the white accessory fitting at the cut end of the delivery tube by pushing the barbed section of the fitting into the tube until it fully seated. Ensure the fitting is fully seated and secured in the tube prior to use.



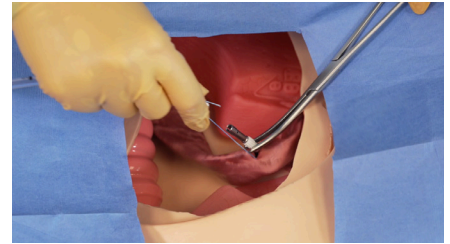
Apply gentle traction when advancing the delivery tube until the plastic collar on the anvil center rod is visible and has passed the incision point. Hold the center rod securely with a grasping device.

Warning: In the event that an obstruction impedes the advancement of the delivery tube, do not apply excessive force as this may result in tissue damage or detachment of the delivery tube from the anvil center rod.

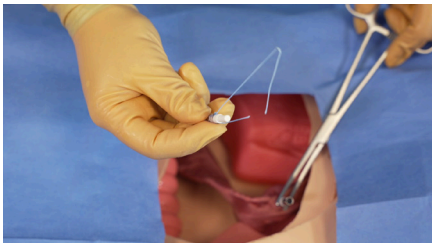


Cut only **one** leg of the anvil retaining suture and separate the delivery tube from the anvil assembly.

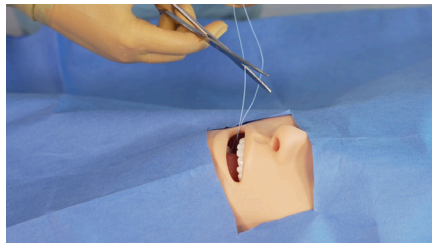
Warning: Improper cutting and removal of anvil retaining suture could leave the suture in place, which may result in the suture being stapled to the anastomotic site.



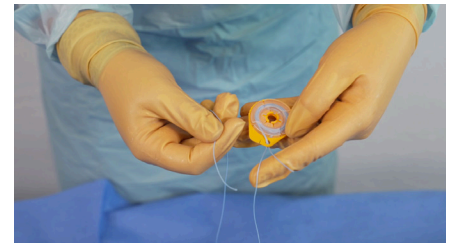
Remove the delivery tube with the retention suture attached. Removal of the tube will pull the suture from the anvil, providing only one leg of the suture has been cut. Once the delivery tube is removed, the anvil head will untit to allow for parallel closure.



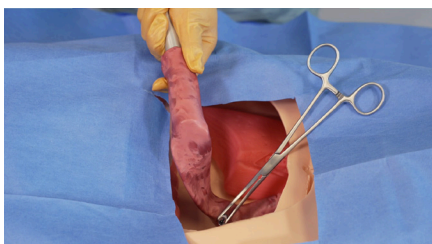
Carefully inspect the delivery tube after removal to ensure the retaining suture has also been removed.



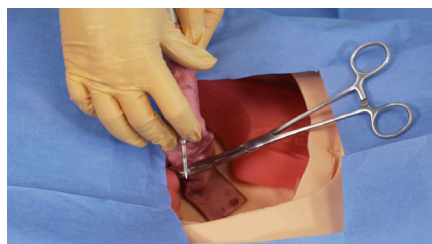
Prior to clamping or after firing, cut one leg of the proximal guide suture out of the oral cavity. Then remove the advancing proximal guide suture from the oral cavity by pulling the suture reel. Pulling the suture reel will pull the advancing proximal guide from the anvil.



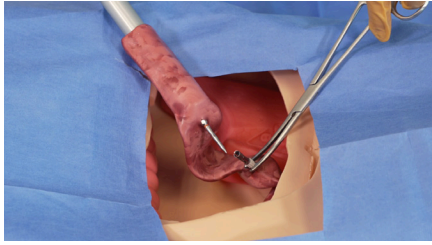
Carefully inspect the anvil head and suture reel to ensure the advancing proximal guide suture has been fully removed.



Depending on each individual patient, apply copious amounts of surgical lubricant to the stapler to ease insertion. Guide the distal end of the stapler to the location of the closed lumen for the anastomosis, following standard surgical procedures.

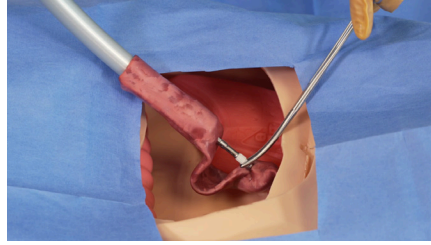


When piercing tissue with the integrated trocar or anvil trocar tip accessory, verify that the orange band on the integrated trocar is visible outside of the structure to be anastomosed.

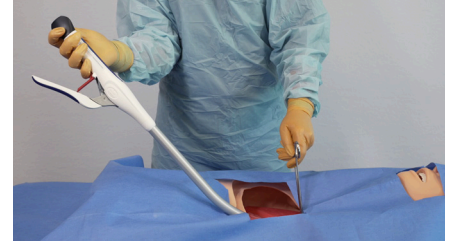


Once the integrated trocar is fully extended, hold the anvil at the grasping notch with a grasping device. Mate the anvil to the integrated trocar by pushing firmly until the instrument shaft clicks into its fully seated position. This click will be tactile.

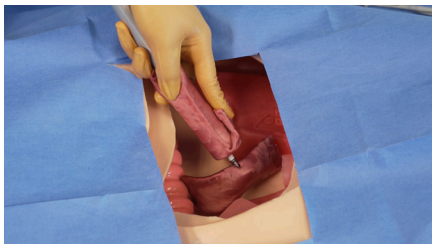
Warning: Do not grasp/clamp on the legs (open end) of the anvil/center rod assembly. Doing so could bend the legs and make it difficult to attach/detach the anvil to the integrated trocar of the stapler.



Manually inspect the attachment to ensure that the anvil and integrated trocar are fully mated. When fully mated, the orange band on the integrated trocar will be fully covered by the anvil.



When attaching the anvil to the instrument, hold the black twist knob firmly to prevent the integrated trocar from moving back slightly into the head of the device.

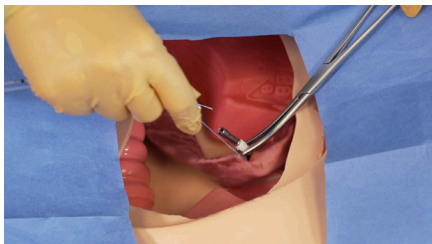


Close the anvil and cartridge snugly to compress the tissue. To approximate the tissue and to close the space between the cartridge and Tilt-Top™ anvil head, turn the twist knob at the rear of the stapler clockwise until it stops.



Proper approximation is verified when a green bar is visible in the indicator window, signifying that the stapler is ready to be fired.

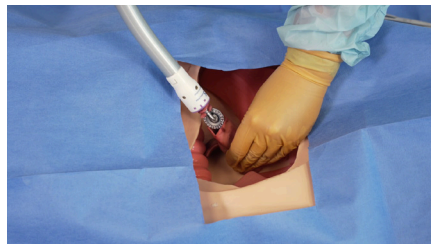
To fire the instrument, release the red safety above the instrument handle and fully squeeze the instrument handle until the metal underside of the handle contacts the stapler body to the fullest extent. An audible and tactile firing indicator will provide additional feedback of firing completion; however, even at the presence of these indicators, it is important to fully squeeze the handle to ensure complete firing. Following release of the handle, return the safety to the locked position.



To remove the instrument, create a space between the cartridge and anvil by turning the twist knob counterclockwise two full turns. The instrument has a tactile indicator that can be felt and heard at two turns.

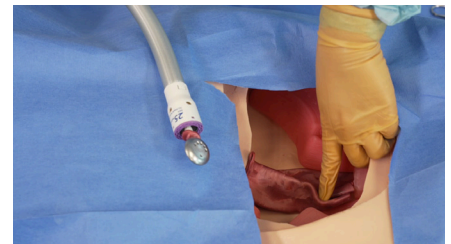
Warning: Do not turn the twist knob more than two full turns, as this may allow the anvil assembly to separate from the instrument.

Warning: Do not try moving the stapler at the same time as opening it. Doing so may result in the anvil catching on the anastomotic lip as it will not have fully tilted, which could cause difficulty in removing the stapler from the patient.



The anvil will now tilt on its side for easy removal. Gently remove the instrument by pulling it straight out of the new anastomosis. Following removal, inspect the staple line for hemostasis and check the anastomosis for integrity.

Important: Relieve any tension by pushing the instrument slightly forward and then pulling straight out.



Inspect the tissue specimens ("donuts") to ensure that all tissue layers have been incorporated in the anastomosis.

Reference:

1. EEA™ Circular Stapler with Tri-Staple™ Technology and OrVil™ Transoral Circular Stapler Anvil [instructions for use]. Mansfield, MA: Covidien; 2021.

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