AEON™ Endoscopic Stapler
Instructions for Use

⚠ REVIEW THE FOLLOWING INFORMATION CAREFULLY BEFORE USING THE DEVICE.

Instructions for Use may also be found at www.lexington-med.com/IFU

NOTE: These Instructions for Use are designed to assist in the use of this product - they are not a reference for surgical techniques.

WARNING: The AEON™ Endoscopic Stapler Handle is provided STERILE and intended for use in a SINGLE PROCEDURE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS.

WARNING: The AEON™ Endoscopic Stapler Reload is provided STERILE and intended for SINGLE USE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS. Reuse, re-processing, or re-sterilization may compromise device integrity and could lead to patient injury, illness, or death.

DEVICE DESCRIPTION

The AEON™ Endoscopic Stapler places two triple-staggered rows of Titanium staples while simultaneously transecting between the two triple-staggered rows of staples. The size of the staples and staple line length are based on the selection of the color-coded Stapler Reload (2.0mm/45mm, 2.5mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, 4.0mm/45mm, 4.0mm/60mm, and 5.0mm/60mm). The AEON™ Endoscopic Stapler Handle will accommodate all AEON™ Endoscopic Stapler Reloads.

The AEON™ Endoscopic Stapler Handle and AEON™ Endoscopic Stapler Reloads 2.0mm/45mm, 2.5mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, 4.0mm/45mm, and 4.0mm/60mm are designed for introduction through a 12mm trocar, or larger with use of a converter.

The AEON™ Endoscopic Stapler Handle, when used with the AEON™ Endoscopic Stapler Reload 5.0mm/60mm, must be inserted through a 15mm trocar.

NOTE: When using the instrument with a 5.0mm/60 mm reload, the instrument MUST be inserted into a 15mm trocar. A smaller size trocar will not accept the 5.0mm/60mm reload.

The AEON™ Endoscopic Stapler Handle may be reloaded and fired up to 25 times in a single procedure.

AEON™ Endoscopic Stapler

These Instructions for Use pertain to the following products:

ENDOSCOPIC STAPLER HANDLES	PRODUCT CODE	SHAFT LENGTH
	AESH060	SHORT (60mm)
	AESH160	MEDIUM (160mm)
	AESH260	LONG (260mm)

ENDOSCOPIC STAPLER RELOADS	PRODUCT CODE	ANVIL TIP	OPEN STAPLE HEIGHT	STAPLE LINE LENGTH	CLOSED STAPLE HEIGHT
	AESR45G	Regular	2.0mm	45mm	0.75mm
	AESR45T	Regular	2.5mm	45mm	1.0mm
	AESR45W	Regular	2.5mm	45mm	1.0mm
	AESR60T	Regular	2.5mm	60mm	1.0mm
	AESR60W	Regular	2.5mm	60mm	1.0mm
	AESR45R	Regular	3.25mm	45mm	1.5mm
	AESR60R	Regular	3.25mm	60mm	1.5mm
	AESR45P	Regular	4.0mm	45mm	1.8mm
	AESR60P	Regular	4.0mm	60mm	1.8mm
	AESR60B	Regular	5.0mm	60mm	2.2mm
	AESC45G	Curved	2.0mm	45mm	0.75mm
	AESC45T	Curved	2.5mm	45mm	1.0mm
	AESC45W	Curved	2.5mm	45mm	1.0mm
	AESC60W	Curved	2.5mm	60mm	1.0mm
	AESC45R	Curved	3.25mm	45mm	1.5mm
	AESC60R	Curved	3.25mm	60mm	1.5mm
	AESC45P	Curved	4.0mm	45mm	1.8mm
	AESC60P	Curved	4.0mm	60mm	1.8mm
	ASR60WS	Short	2.5mm	60mm	1.0mm
	ASR60RS	Short	3.25mm	60mm	1.5mm
	ASR60PS	Short	4.0mm	60mm	1.8mm

INDICATIONS

The AEON™ Endoscopic Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses.

NOTE: The AEON™ Endoscopic Stapler Handle is compatible with AEON™ Endoscopic Stapler Reloads 2.0mm/45mm, 2.5mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, 4.0mm/45mm, 4.0mm/60mm, and 5.0mm/60mm.

NOTE: The AEON™ Endoscopic Stapler Handles are also compatible with the following Medtronic Covidien Stapler Reloads:

030416 Endo GIA™ Universal Straight 30 - 2.0 Loading Unit - Gray
030418 Endo GIA™ Universal Straight 30 - 2.5 Loading Unit - White
030419 Endo GIA™ Universal Straight 30 - 3.5 Loading Unit - Blue
030426 Endo GIA™ Universal Straight 45 - 2.0 Loading Unit - Gray
030425 Endo GIA™ Universal Straight 45 - 2.5 Loading Unit - White
030422 Endo GIA™ Universal Straight 45 - 3.5 Loading Unit - Blue
030423 Endo GIA™ Universal Straight 45 - 4.8 Loading Unit - Green
030412 Endo GIA™ Universal Straight 60 - 2.5 Loading Unit - White
030414 Endo GIA™ Universal Straight 60 - 3.5 Loading Unit - Blue
030415 Endo GIA™ Universal Straight 60 - 4.8 Loading Unit - Green
030450 Endo GIA™ Universal Roticulator™ 30 - 2.0 Loading Unit - Gray
030451 Endo GIA™ Universal Roticulator™ 30 - 2.5 Loading Unit - White
030452 Endo GIA™ Universal Roticulator™ 30 - 3.5 Loading Unit - Blue
030453 Endo GIA™ Universal Roticulator™ 45 - 2.0 Loading Unit - Gray
030454 Endo GIA™ Universal Roticulator™ 45 - 2.5 Loading Unit - White
030455 Endo GIA™ Universal Roticulator™ 45 - 3.5 Loading Unit - Blue
030456 Endo GIA™ Universal Roticulator™ 45 - 4.8 Loading Unit - Green
030457 Endo GIA™ Universal Roticulator™ 60 - 2.5 Loading Unit - White
030458 Endo GIA™ Universal Roticulator™ 60 - 3.5 Loading Unit - Blue
030459 Endo GIA™ Universal Roticulator™ 60 - 4.8 Loading Unit - Green
EGIA30AV* Endo GIA™ 30 mm Articulating Vascular Reload – Gray
EGIA45AV Endo GIA™ 45 mm Articulating Vascular Loading Unit - Gray
EGIA45AXT Endo GIA™ 45 mm Articulating Extra-Thick Reload with Tri-Staple™ Technology Black
EGIA60AXT Endo GIA™ 60 mm Articulating Extra-Thick Reload with Tri-Staple™ Technology Black
EGIA30AVM Endo GIA™ 30 mm Articulating Vascular/Medium Reload with Tri-Staple™ Technology Tan
EGIA30AMT Endo GIA™ 30 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology Purple
EGIA30CTAVM Endo GIA™ 30 mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology Tan
EGIA45CTAV Endo GIA™ 45 mm Curved Tip Articulating Vascular Reload Gray
EGIA30CTAVM Endo GIA™ 30 mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology Tan
EGIA45CTAVM Endo GIA™ 45 mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology Tan

EGIA60CTAVM Endo GIA™ 60 mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology Tan
EGIA45CTAMT Endo GIA™ 45 mm Curved Tip Articulating Medium/Thick Reload with Tri-Staple™ Technology Purple
EGIA60CTAMT Endo GIA™ 60 mm Curved Tip Articulating Medium/Thick Reload with Tri-Staple™ Technology Purple
EGIA45AMT Endo GIA™ 45 mm Articulating Medium/Thick Loading Unit Purple
EGIA60AMT Endo GIA™ 60 mm Articulating Medium/Thick Loading Unit Purple
EGIA45AVM Endo GIA™ 45 mm Articulating Vascular/Medium Loading Unit Tan
EGIA60AVM Endo GIA™ 60 mm Articulating Vascular/Medium Loading Unit Tan

NOTE: The AEON™ Endoscopic Stapler Reloads 2.0mm/45mm, 2.5mm/45mm, 2.5mm/60mm, 3.25mm/45mm, 3.25mm/60mm, 4.0mm/45mm, 4.0mm/60mm, and 5.0mm/60mm are also compatible with the following Medtronic Covidien Stapler Handles:

EGIAUSHORT Endo GIA™ Ultra Universal Short Stapler
EGIAUSTND Endo GIA™ Ultra Universal Standard
EGIAUXL Endo GIA™ Ultra Generation XL
030403 GIA™ Universal Stapler
030449 Endo GIA™ Universal Stapler
EGIAUNIVXL Endo GIA™ Universal XL Stapler
SIGPHANDLE Signia™ Stapling System handle and SIGADAPTXL Signia™ Linear Adapter XL

NOTE: The AEON™ Endoscopic Stapler Reload 4.0mm/60mm is compatible with Gore® SeamGuard® Bioabsorbable Staple Line Reinforcement model 1BSGTRI60P and Gunze NEOVEIL™ Absorbable Polyglycolic Acid Felt model NV-ET-M60A-2. The AEON™ Endoscopic Stapler Reload 5.0mm/60mm is compatible with Gunze NEOVEIL™ Absorbable Polyglycolic Acid Felt model NV-ET-M60E-2.

WARNING: The AEON™ Endoscopic Stapler Handle is provided STERILE and intended for use in a SINGLE PROCEDURE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS.

WARNING: The AEON™ Endoscopic Stapler Reload is provided STERILE and intended for SINGLE USE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS. Reuse, re-processing, or re-sterilization may compromise device integrity and could lead to patient injury, illness, or death.

WARNING: Ensure that only structures to be cut and stapled are within the stapler jaws. Unintentional transection of tissue could lead to patient injury, illness, or death.

CONTRAINDICATIONS

1) The AEON™ Endoscopic Stapler is contraindicated for use on the heart, central circulatory system, or central nervous system.
2) Do not use the AEON™ Endoscopic Stapler 2.0 mm staples on the aorta, any tissue that compresses to less than 0.75 mm in thickness, or any tissue that does not comfortably compress to 0.75 mm.
3) Do not use the AEON™ Endoscopic Stapler 2.5 mm staples on the aorta, any tissue that compresses to less than 1.0 mm in thickness, or any tissue that does not comfortably compress to 1.0 mm.
4) Do not use the AEON™ Endoscopic Stapler 3.25 mm staples on the aorta, any tissue that compresses to less than 1.5 mm in thickness, or any tissue that does not comfortably compress to 1.5 mm.
5) Do not use the AEON™ Endoscopic 4.0 mm staples on the aorta, any tissue that compresses to less than 1.8 mm in thickness, or any tissue that does not comfortably compress to 1.8 mm.
6) Do not use the AEON™ Endoscopic Stapler 5.0 mm staples on the aorta, any tissue that compresses to less than 2.2 mm in thickness, or any tissue that does not comfortably compress to 2.2 mm.
7) The AEON™ Endoscopic Stapler should not be used on tissue where compressibility of the tissue could be destructive, such as the liver or spleen.
   Do not use the AEON™ Endoscopic Stapler where hemostasis cannot be verified visually after application.

WARNINGS

1) The AEON™ Endoscopic Stapler Handle is provided STERILE and intended for use in a SINGLE PROCEDURE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS.
2) The AEON™ Endoscopic Stapler Reload is provided STERILE and intended for SINGLE USE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS. Inspect the tissue thickness before applying the stapler to the tissue. Tissue that is overly thick or thin may result in unacceptable staple formation.
3) The stapler will cut and staple any tissue, vessel, or other structure included in the jaws. Ensure that only structures to be cut and stapled are within the stapler jaws.
4) Ensure tissue has not extended beyond the tissue stop proximally. Tissue forced into the instrument proximal to the tissue stop may be transected without stapling.
5) Ensure that no obstructions, such as clips, are incorporated into the stapler jaws before closing the jaws and firing. Applying staples over an obstruction may result in incomplete transection and/or incorrectly formed staples.
6) Ensure that the Stapler Reload is completely fired. Failure to completely fire the Stapler Reload will result in an incomplete cut and/or incomplete staple formation, which may result in inadequate hemostasis and/or leakage. However, if an unusually high firing force is experienced mid-firing, consider stopping the firing and retracting the Stapler Reload.

An unusually high firing force could indicate that the tissue is overly thick or that an obstruction is within the jaws.

7) After firing the stapler, always inspect the staple line and the surrounding site for hemostasis or leakage. Minor bleeding or leakage may be controlled by electrocautery or manual sutures.
8) Endoscopic procedures using this device should only be performed by physicians having adequate training with endoscopic surgical techniques.
9) Electrosurgical and laser procedures involving the use of this device should only be performed by physicians having adequate training with these techniques. Verify compatibility of all instruments and accessories used in the procedure to ensure that electrical isolation or grounding is not compromised.
10) The AEON™ Endoscopic Stapler Handle is provided STERILE and intended for use in a SINGLE PROCEDURE ONLY. The AEON™ Endoscopic Stapler Reload is provided STERILE and intended for SINGLE USE ONLY. DISCARD AFTER USE. DO NOT REUSE. DO NOT RE-STERILIZE. DO NOT RE-PROCESS. Reuse, even after re-sterilization, may create a risk of contamination and lead to patient infection. Reuse, re-processing, or re-sterilization may compromise device integrity and could lead to patient injury, illness, or death.

PRECAUTIONS

1) Preoperative radiotherapy may result in changes to tissue thickness or composition. Consideration should be given to any pre-surgical treatment in selection of staple size.
2) Any tissue extending beyond the cut line will not be transected. Placement of tissue proximal to the tissue stops on the Stapler Reload may result in stapler malfunction.
3) Ensure that provisions are made for proximal and distal control before using the stapler on major vessels.
4) If reinforcement is used, always include the combined thickness of both the tissue and the reinforcement material when choosing the proper Stapler Reload.
5) Do not exceed 25 firings for a single Stapler Handle during a single procedure. Exceeding the Stapler Handle firing limit may result in device malfunction.
6) Do not use the stapler on ischemic or necrotic tissue.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the implantable staple made of titanium (Ti3Al2.5V) alloy in all AEON Endoscopic Stapler reloads are MR Conditional. A patient with this implant can be safely scanned in an MR system meeting the following conditions:

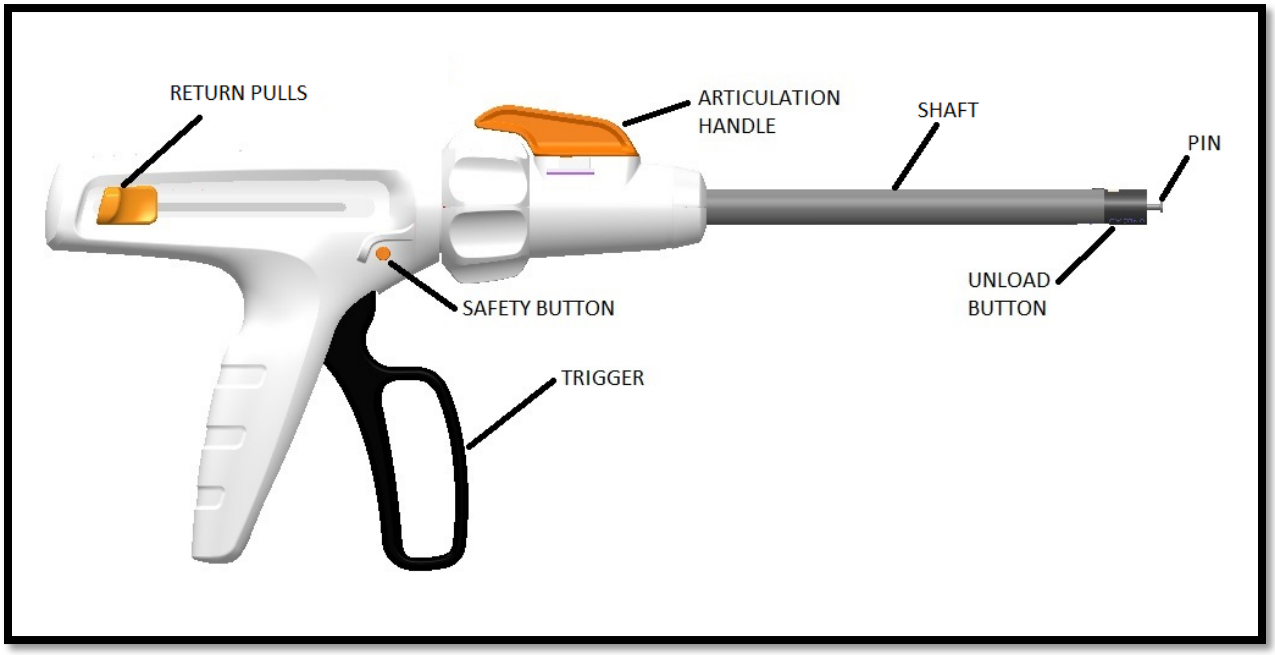
- Static magnetic field of 1.5T and 3.0 T;
- Maximum spatial field gradient of 4,000 G/cm (40 T/m);

- Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg (Normal Mode).

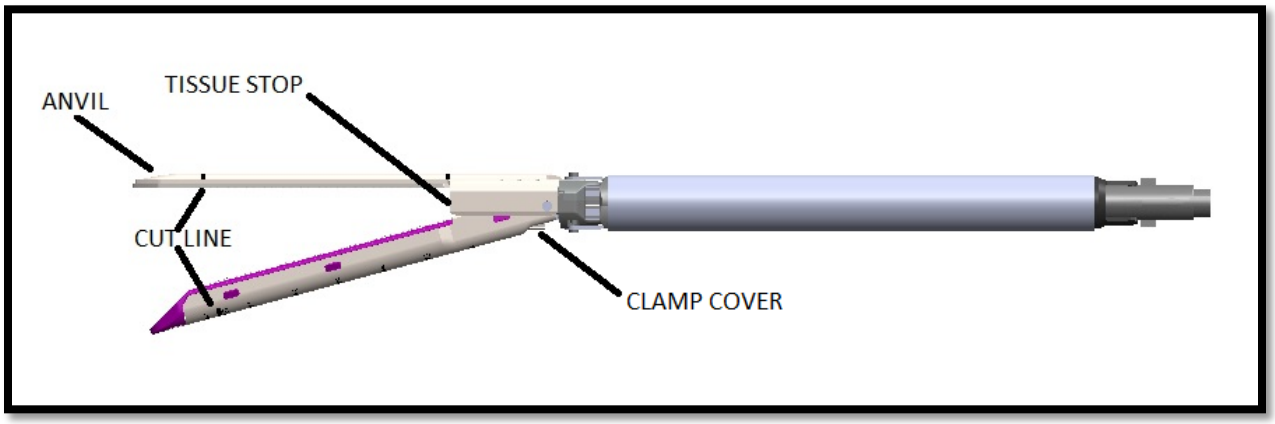
Under the scan conditions defined above, the Lexington Medical implantable staple is expected to produce a maximum temperature rise of less than 2.0 ˚C after 15 minutes of continuous scanning at 1.5 T and less than 2.0 ˚C after 15 minutes of continuous scanning at 3 T.

In non-clinical testing, the image artifact caused by the implantable staple extends approximately 3.7 mm from the staple when imaged with a gradient echo pulse sequence and a 3 T MRI system.

STAPLER HANDLE SCHEMATIC:



STAPLER RELOAD SCHEMATIC:



INSTRUCTIONS FOR LOADING

WARNING: Select a Stapler Reload with the appropriate staple size for the tissue thickness. Overly thick or thin tissue may result in unacceptable staple formation. If reinforcement is used, always include the combined thickness of both the tissue and the reinforcement material when choosing the proper Stapler Reload.

NOTE: Do not attempt to remove the yellow shipping wedge from the Stapler Reload until after the Stapler Reload is loaded onto the Stapler Handle. Removing the shipping wedge from the Stapler Reload before the Stapler Reload is loaded onto the Stapler Handle may cause device malfunction.

NOTE: If present, remove the protective shipping cap from the end of the Stapler Handle before use.

1) The Stapler Reload is packaged in the open position – do not attempt to close the Stapler Reload jaws.
2) If present, remove the protective shipping cap from the distal end of the Stapler Handle.
3) Ensure that the Return Pulls on the device are fully retracted to the proximal position and that the Articulation Handle is centered on the device.
4) To load the Stapler Reload, first align the loading arrow on the distal end of the Stapler Handle with the loading arrow on the proximal end of the Stapler Reload.
5) With the loading arrows aligned, Insert the Stapler Reload over the Pin extending from the distal end of the Stapler Handle.
6) Twist the Stapler Reload clockwise approximately 45° to lock into place.

NOTE: Remove the yellow shipping wedge before closing the Stapler Reload jaws.

7) Remove the yellow shipping wedge from the Stapler Reload before confirming proper loading and inserting the device into the trocar.
8) To confirm proper loading, squeeze the Stapler Handle Trigger through a full stroke once to close the jaws. Retract the Return Pulls and confirm that the stapler jaws open fully.

INSTRUCTIONS FOR UNLOADING

1) In order to unload the Stapler Reload from the Stapler Handle, the Return Pulls on the Stapler Handle must be fully retracted to the proximal position and the Articulation Handle must be centered on the device.
2) To unload the Stapler Reload, activate the Unload Button on the distal end of the Stapler Handle by sliding proximally.
3) While holding the Unload Button in the proximal position, rotate the Stapler Reload approximately 45° and pull distally until it disengages from the Stapler Handle.
4) Release the Unload Button.

INSTRUCTIONS FOR USE

NOTE: Ensure that stapler reload jaws are closed prior to introducing the stapler into the trocar.

1) Squeeze the Stapler Handle Trigger through a full stroke once to close the jaws before inserting into the Trocar.
2) Insert the stapler into an appropriately-sized trocar and open the stapler jaws by retracting the Return Pulls fully to the proximal position.

NOTE: The stapler anvil must be completely visible past the distal end of the trocar prior to opening the reload jaws within the body cavity.

NOTE: Do not squeeze the Stapler Handle Trigger while retracting the Return Pulls.

The AEON™ Endoscopic Stapler Handle shaft can rotate 360° in either direction, and can articulate the Stapler Reload jaws up to approximately 45° in either direction Left-Right using the Articulation Handle.

3) Apply the Stapler Reload jaws to the tissue to be transected. The device will not cut tissue beyond the Cut Line indicated on both sides of the jaws. More than one Stapler Reload application may be required for tissue exceeding the length of the staple line (30mm, 45mm, or 60mm). For Curved Tip Stapler Reloads, only clamp on structures that do not extend beyond the Cut Line.
4) Close the jaws of the device across the tissue to be transected by activating the Stapler Handle Trigger through a full stroke. The jaws may be repositioned if necessary by retracting the Return Pulls proximally to open the jaws, repositioning, and squeezing the Trigger to close the jaws.

WARNING: Ensure that only structures to be cut and stapled are within the stapler jaws. Unintentional transection of tissue could lead to patient injury, illness, or death.

WARNING: Ensure that no obstructions, such as clips, are incorporated into the stapler jaws before application. Applying staples over an obstruction may result in incomplete transection and/or incorrectly formed staples.

WARNING: Ensure tissue has not extended beyond the tissue stop proximally. Tissue forced into the instrument proximal to the tissue stop may be transected without stapling.

CAUTION: Any tissue extending beyond the cut line will not be transected. Placement of tissue proximal to the tissue stops (on the reload) may result in stapler malfunction.

5) After closing the jaws across the tissue to be transected, the Safety Button must be activated by pressing from either side of the Stapler Handle before firing. Allow the tissue to adequately compress before firing (wait approximately 15 seconds after clamping).
6) After activating the Safety Button, the device is fired by pulling on the Trigger to commence transecting the tissue while simultaneously forming staples. Squeeze the Trigger sequentially until the Stapler Reload Clamp Cover reaches the distal end of the jaws and the Stapler Handle locks. Stop squeezing the trigger when the distal end of the

reload is reached and the trigger locks. The number of sequential squeezes is dependent upon the length of the Stapler Reload staple line (30mm, 45mm, or 60mm).

If using Stapler Handle with "Standard/Thick" mode switch:

- The "Standard/Thick" mode switch on the side of the stapler handle allows the user to change the lever point of the handle trigger, which allows the device to be fired with less trigger force.
- The "Standard/Thick" mode switch can be activated after activating the Safety Button or at any position in the reload firing stroke.
- If the device is unclamped and re-positioned, the switch will reset to "Standard" mode and must be activated again.
- The switch will automatically reset to "Standard" mode after return pulls are retracted.
- **NOTE:** If the switch does not automatically reset after retraction, do not continue to use the handle as device malfunction may result.
- **NOTE:** Do not attempt to switch from "Thick" mode to "Standard" mode during device firing, as this can cause device malfunction.

WARNING: Ensure that the Stapler Reload is completely fired. Failure to completely fire the Stapler Reload will result in an incomplete cut and/or incomplete staple formation, which may result in inadequate hemostasis and/or leakage.

NOTE: A safety interlock prevents an empty Stapler Reload from being fired twice. Do not attempt to override the safety interlock, as overriding the safety interlock will cause device malfunction.

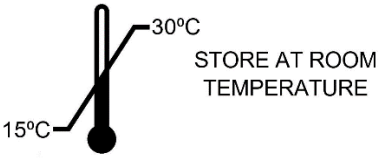
7) Once the device has been fully-fired, open the jaws by retracting the Return Pulls completely back to the proximal position. Gently remove the device from the tissue and inspect the staple line for hemostasis.
8) After removing the device from the tissue, close the stapler jaws by squeezing once on the Trigger through a complete stroke and center the Articulation Handle before removing the device from the body cavity.
9) Remove the device from the body cavity and unload the Stapler Reload.
10) Dispose of used instruments in accordance with the end-user's medical and biological waste disposal requirements.

NOTE: Ensure that the Articulation Handle is centered on the device before removing the stapler from the trocar.

WARNING: After firing the stapler, always inspect the staple line and the surrounding site for hemostasis or leakage. Minor bleeding or leakage may be controlled by electrocautery or manual sutures.

CAUTION: Do not exceed 25 firings for a single Stapler Handle during a single procedure. Exceeding the Stapler Handle firing limit may result in device malfunction.

STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.



This device for sale by or on the order of a physician.

SINGLE PATIENT USE

DO NOT RESTERILIZE

LATEX FREE

DO NOT USE PACKAGE IF DAMAGED

KEEP DRY

CONSULT INSTRUCTIONS FOR USE

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Instructions for Use Label P/N 900368 Rev-G