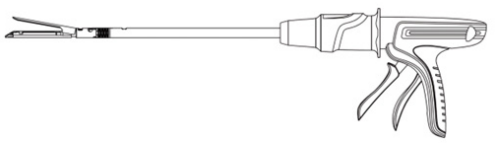
REACH SURGICAL | ENDO REACH

ENDO REACH REC STAPLERS
ENDO REACH REC RELOADS



en Endoscopic Linear Cutting Staplers & Single Use Loading Units for Endoscopic Linear Cutting Staplers (Instructions)

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Illustrations

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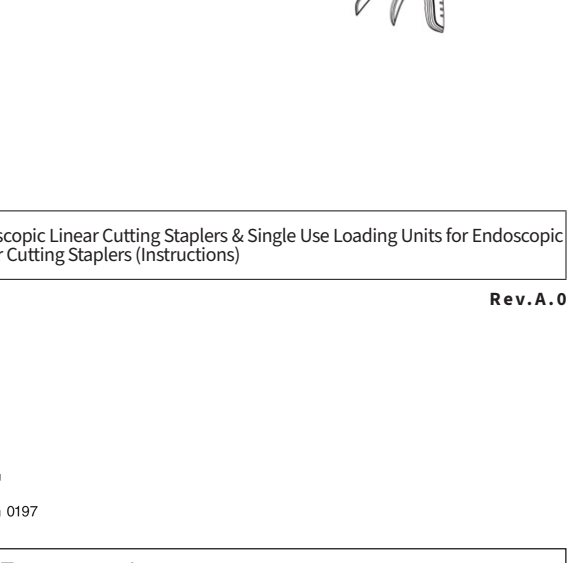

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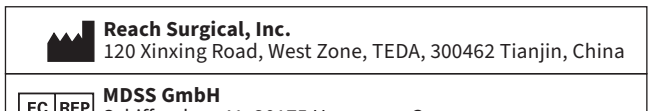

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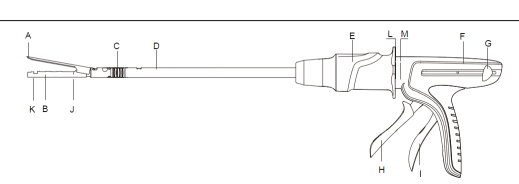

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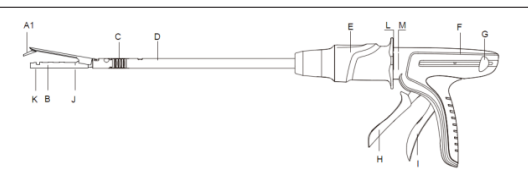

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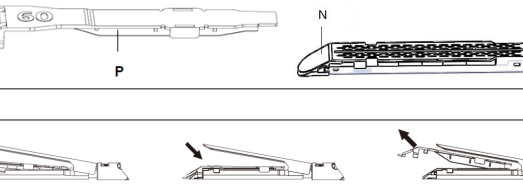

en

Endoscopic Linear Cutting Staplers & Single Use Loading Units for Endoscopic Linear Cutting Staplers (Instructions)

Intended Use
This instrument is intended for transection, resection of tissues and/or creation of anastomoses.

Indications
The instrument is intended for transection, resection, and/or creation of anastomoses. It has applications in open and minimally invasive surgeries including thoracic, and abdominal surgeries. It is used for transection and resection of the lungs and alimentary tract.

Intended User
The instrument is used for healthcare professional and people who use this instrument for surgical purposes.

Intended Use Environment
This instrument is intended to be used in a hospital.

Intended patient population
General population requiring resection and reconstruction of organs and tissues in the thoracic and abdominal cavities.

Clinical Benefit
The instrument can be used safely and effectively in transection, resection of tissues, and/or creation of anastomoses.

Contraindications
• Do not use the instruments on the aorta, heart and central circulatory system.
• Do not use the instruments on ischemic or necrotic tissue.
• Tissue thickness should be carefully evaluated before applying any stapler. Refer to **Reload Staple Size Chart** below for a guide to the staple size selection. If tissue cannot be comfortably compressed to the closed staple height or easily compressed to less than the closed staple height, the tissue is contraindicated as it may be too thick or too thin for the selected staple size.
• The instruments are not intended for use when surgical stapling is contraindicated.

MR Conditional
Non-clinical testing has demonstrated the implantable Staples are MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:
- Static magnetic field of 1.5-Tesla and 3.0-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm(40-T/m)
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2- W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the Staple is expected to produce a maximum temperature rise of 1.8°C after 15-minutes of continuous scanning (i.e., per pulse sequence).
In the non-clinical testing, the image artifact caused by the Staple extends approximately 3-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Device Description
The Stapler and Reload are sterile, single patient use instruments that simultaneously staple and transect tissue. There are six staggered rows of titanium staples, three on either side of the cut line. The Stapler have staple lines that are approximately 45 mm and 60mm long and cut lines that are 41 mm and 56 mm long respectively. The shaft can rotate freely in both directions. The distal portion can be articulated left or right to facilitate lateral access to the operative site. The Max Articulation angle is not less than 45°.
The stapling instrument is provided unloaded to allow the user to select the proper Reload for the tissue to be transected. The instrument must be reloaded for each subsequent firing. A Staple Retaining Cap is provided with each Reload to protect the staples during shipping and handling and must be removed after loading. Each Reload has a lock-out to prevent a spent or improperly installed Reload from being refired or an instrument from being fired without a Reload.

The used time of staples that are made of Titanium/ Titanium alloy is long term in body.

How Supplied: The Stapler and Reload are supplied sterile for single patient use. PROPERLY DISPOSE OF AFTER USE. DO NOT RESTERILIZE.

Caution: Do not load the Reload more than 12 times for a maximum of 12 firings per Stapler.

Instrument Description and Product Codes for the Stapler

Endo REACH Instrument Selection Chart

Product Code	Staple Line Length	Trocar Compatibility	Description	Shaft Length	Total Length
REC60AL	60 mm	12mm	Long Articulating	448mm	715 mm
REC45AL	45 mm	12mm	Long Articulating	432mm	700 mm
REC60A	60 mm	12mm	Articulating	348mm	615 mm
REC45A	45 mm	12mm	Articulating	332mm	600 mm
REC60AS	60 mm	12mm	Short Articulating	298mm	565 mm
REC45AS	45 mm	12mm	Short Articulating	282mm	550 mm
REC60BAL	60 mm	12mm	Long Articulating	459mm	727 mm
REC45BAL	45 mm	12mm	Long Articulating	443mm	712 mm
REC60BA	60 mm	12mm	Articulating	359mm	627 mm
REC45BA	45 mm	12mm	Articulating	343mm	612 mm
REC60BAS	60 mm	12mm	Short Articulating	309mm	577 mm
REC45BAS	45 mm	12mm	Short Articulating	293mm	562 mm

ENDO REACH Reload 12 mm (Sold Separately):
WARNING: The Stapler is only compatible with Reloads listed below.

Reload Selection Chart:

Product Code	Tissue Thickness	Color	Open Staple Height	Closed Staple Height	Staple Line Length	Number of Staples
REC45GRA	Extra Thin tissue	Gray	2.0 mm	0.75 mm	45mm	66
REC45WHT	Thin tissue	White	2.5 mm	1.0 mm	45 mm	66
REC45BLU	regular tissue	Blue	3.5 mm	1.5 mm	45 mm	66
REC45GLD	regular/thick tissue	Gold	3.8 mm	1.75 mm	45 mm	66
REC45GRN	thick tissue	Green	4.1 mm	2.0 mm	45 mm	66
REC45BLK	very thick tissue	Black	4.4 mm	2.2 mm	45mm	66
REC60GRA	Extra Thin tissue	Gray	2.0 mm	0.75 mm	60 mm	90
REC60WHT	Thin tissue	White	2.5 mm	1.0 mm	60 mm	90
REC60BLU	regular tissue	Blue	3.5 mm	1.5 mm	60 mm	90
REC60GLD	regular/thick tissue	Gold	3.8 mm	1.75 mm	60 mm	90
REC60GRN	thick tissue	Green	4.1 mm	2.0 mm	60 mm	90
REC60BLK	very thick tissue	Black	4.4 mm	2.2 mm	60 mm	90

Illustration 1 - Nomenclature
A) Anvil Jaw
A1) Beak
B) Reload Jaw
C) Articulation Joint
D) Shaft
E) Rotation Knob
F) Handle
G) Return Knobs
H) Firing Trigger
I) Closing Trigger
J) Proximal Mark
K) Cut Mark
L) Rotation Position
M) Articulation Position
N) Reload (Cartridge)
O) Knife
P) Staple Retaining Cap
Illustration 2 – Load Reload
Illustration 3 – Unload Reload
Illustration 4 - Rotate and Articulate
Illustration 5 - Close Jaws
Illustration 6 – Open Jaws/Return Knobs
Illustration 7 – Fire the Stapler

Instructions for Use
1. Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).
2. Verify that the Reload size matches the instrument size to be used (e.g. use an 60mm Reload with an 60mm instrument).
3. Using sterile technique, remove the instrument and the selected Reload from their respective packages.
4. Prior to loading the Reload, ensure the instrument jaws are in the open position and the Articulation Joint is in the straight position i.e. not articulated (Illustration 1).
5. Examine the Reload for the presence of a Staple Retaining Cap. If the retainer is not in place, discard the Reload.
   Caution: Tissue thickness should be carefully evaluated prior to using the instrument. Refer to the **Reload Selection Chart** for proper Reload selection.
6. Load the Reload by sliding it against the top of the jaw until the Reload alignment tab snaps in the Reload alignment slot. Remove the Staple Retaining Cap and discard. (Illustration 2) The instrument is now loaded and ready for use.
   Caution: Make sure the knife doesn't touch the bottom of the jaw, prevent the knife from being moved or deformed when loading the Reload; otherwise, the device may be lock out and can't be fired.
   Caution: After removing the Staple Retaining Cap, observe the surface of the loaded Reload. The Reload must be replaced with another Reload if any colored drivers are visible. If colored drivers are visible, the Reload may not contain staples.
7. To articulate, pull the Rotation Knob to the Articulation Position. Rotating the Rotation Knob will articulate the jaws to a maximum angle of 45 degrees. The resistance will increase significantly to signal that the maximum articulation angle is reached.
   Caution: Make sure the jaw is open when rotating the jaw by rotating the Rotation Knob; otherwise, the operation of rotation may fail
   Caution: Make sure that no external force is applied to the jaws when articulating the jaw; otherwise, the device may be damaged.
8. Close the jaws of the instrument by squeezing the Closing Trigger until it locks in place (Illustration 5).
   Caution: Do not pull the Firing Trigger until the jaws are closed and locked. The instrument may be partially or completely fired and will need to be reloaded before using on tissue.
9. Visually inspect the stapler to ensure proper Reload seating. Introduce the instrument into the body cavity through a trocar of the appropriate size or through an incision. When using a trocar, the instrument jaws must be past the trocar sleeve before opening.
   Caution: For insertion and removal, the jaws of the instrument must be closed and straight, in line with the shaft of the instrument. Failure to have the instrument jaws in the straight position will result in difficult insertion or withdrawal of the instrument and may result in damage to the instrument or trocar.
   Caution: When placing the instrument through the trocar or incision, avoid inadvertently pulling the Firing Trigger. If the instrument is partially or completely fired, it will need to be reloaded before using on tissue. If the instrument is partially fired, remove the instrument and replace the Reload.
10. Once in the cavity, open the jaws by pulling the Return Knobs proximally (Illustration 6).
11. If needed, rotate the jaws by pushing the Rotation Knob distally to the Rotation Position. With the index finger, rotate the fins of the Rotation Knob in either direction (Illustration 4). The instrument shaft will rotate freely 360° in either direction.
12. If needed, articulate the jaws by pulling the Rotation Knob proximally to the Articulation Position and rotate the fins of the Rotation Knob in either direction (Illustration 4); the jaws must be open in order to articulate the instrument.
   Caution: The instrument can achieve a maximum articulation angle of 45°. When the maximum angle is reached, the force will increase, indicating the maximum angle has been reached.
13. Position the instrument jaws around the tissue to be transected.
   Caution: Ensure that the tissue lies flat and is positioned properly between the jaws. Any "bunching" of tissue along the Reload, particularly near the Cut Mark and Proximal Mark of the jaws, may result in an incomplete staple line and inadvertent lockout. The Cut Mark on the Reload Jaw designates the end of the staple line.
   Caution: When positioning the jaws on the application site, ensure that no obstructions such as clips, stents, guide wires, etc. are within the instrument jaws. Firing over an obstruction may result in incomplete cutting action, improperly formed staples, and/or inability to open the instrument jaws.
14. After positioning the instrument jaws, close the jaws by squeezing the Closing Trigger until it locks (Illustration 5).
   Caution: Ensure that tissue has not squeezed (extended) proximal to the Proximal Mark/Tissue Stop on the instrument. Tissue forced into the instrument proximal to the Proximal Mark/Tissue Stop may be transected without staples. When firing across thick tissue, holding the jaws in place for 15 seconds after closing and prior to firing may result in better compression and staple formation.
   Caution: If the Closing Trigger is difficult to lock:
   a) Ensure that the proper Reload selection has been made (Refer to the Reload Selection Chart).
   b) Reposition the instrument and reduce the amount of tissue to be clamped.
   c) When clamping across thick tissue, holding the jaws in place for 15 seconds after closing and prior to firing may result in better compression and staple formation.
   Caution: If the clamping mechanism becomes inoperative and the jaws do not clamp on tissue, do not fire the instrument. Remove and do not continue to use the instrument.
15. Fire the instrument by pulling the Firing Trigger repeatedly until I beam under the Reload Jaw travel to Cut Mark (Illustration 7). The times for which the trigger is pulled depend on the length of stapling line (45mm or 60mm).
The times of REC60A/REC60AL/REC60AS are 5; the times of REC45A/REC45AL/REC45AS are 4.
   Caution: The instrument should be replaced if it does not fire smoothly or the firing mechanism becomes inoperative. Attempting to force the device to complete the firing stroke under very high load may cause a snap sound and a sudden decrease in force to fire; if this occurs, discontinue the use of the instrument and thoroughly inspect the staple line integrity.
   Caution: Crossing staple lines may shorten the life of the instrument (may reduce the number of times that the device may be fired).
   Caution: Make sure I beam under the Reload Jaw travel to Cut Mark when the firing is complete; if firing is not complete, it may be difficult to remove the Reload when unloading the Reload.
16. To complete the firing sequence: Release the Firing Trigger and pull the Return Knobs proximally to the original position (Illustration 6); this will also open the instrument jaws.
   Caution: Gently pull the instrument away from the transected tissue and ensure it is released from the jaws before removing.
   Caution: Examine the staple lines for pneumostasis/hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.
17. Before removing an articulated instrument, move the jaws away from any obstruction inside the body cavity while keeping the jaws open and within the field of view, and pull proximally on the fins of the Rotation Knob, twist the knob until the jaws return to the straight position.
   Caution: For insertion and removal, the jaws of the instrument must be straight, in line with the shaft of the instrument. Failure to have the instrument jaws in the straight position will result in difficult insertion or withdrawal of the instrument and may result in damage to the instrument.
18. To remove the instrument from the cavity, squeeze the Closing Trigger until it locks, closing the jaws (Illustration 5).
19. Completely withdraw the instrument in the closed position.
20. Pull the Return Knobs proximally to open the instrument jaws (Illustration 6).
21. Push upward (toward the Anvil Jaw) to unsnap the spent Reload from the Reload Jaw. Discard the used Reload. (Illustration 3)
   Caution: Prior to reloading the instrument, hold the instrument in a vertical position, with Anvil Jaw and Reload Jaw completely submerged in sterile solution. Swish vigorously and then wipe the inside and outside surfaces of the Anvil Jaw and Reload Jaw to clean any unused staples from the instrument. Do not use the instrument until it has been visually inspected to confirm there are no staples on the Anvil Jaw or Reload Jaw.
   Caution: Before unloading the Reload, make sure the jaws and the shaft are in a straight line. Otherwise, the device may be damaged.
22. Reload and use the instrument by repeating steps 3-21. The instrument can be fired up for a total of 12 times.

Warnings and Precautions
1. Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or staple line disruption.
2. Do not load the instrument more than 12 times for a maximum of 12 firings per instrument.
3. Minimally invasive and stapling procedures should be performed only by persons having adequate training and familiarity with the techniques. Consult relative medical literature for techniques, complications, and hazards prior to performing any minimally invasive procedure.
4. When minimally invasive instruments and accessories from different manufacturers are used together in a procedure, verify compatibility prior to initiation of the procedure.
5. When using other technologies (e.g., electrosurgery devices), observe the precautions suggested by the manufacturer to avoid the hazards associated with their use.
6. The Stapler instruments may only be used with ENDO REACH Reload.
7. After removing the Staple Retaining Cap, observe the surface of each new Reload. The Reload must be replaced with another Reload if any colored driver is visible because the Reload may not contain staples.
8. For insertion and removal of instruments, the jaws of the instrument must be straight, in line with the Shaft of the instrument. Failure to have the instrument jaws in the straight position will result in difficult insertion or withdrawal of the instrument and may result in damage to the instrument or trocar.
9. When placing the instrument through the trocar or incision, avoid inadvertently pulling the Firing Trigger. If the instrument is partially or completely fired, it will need to be reloaded before using on tissue. If the instrument is partially fired, remove the instrument and replace the Reload.
10. The instrument can achieve a maximum articulation angle of 45°. When the force increases, it indicates the maximum angle has been reached.
11. Ensure that the tissue lies flat and is positioned properly between the jaws. Any "bunching" of tissue along the Reload, particularly near the Proximal Mark of the jaws, may result in an incomplete staple line. The Cut Mark on the Reload Jaw designates the end of the staple line.
12. When positioning the jaws on the application site, ensure that no obstructions such as clips, stents, guide wires, etc. are within the instrument jaws. Firing over an obstruction may result in incomplete cutting action, improperly formed staples, and/or inability to open the instrument jaws.
13. Ensure that tissue has not squeezed (extended) proximal to the Proximal Mark on the instrument. Tissue forced into the instrument proximal to the Proximal Mark may be transected without staples. When firing across thick tissue, holding the jaws in place for 15 seconds after closing and prior to firing may result in better compression and staple formation.
14. If the clamping mechanism becomes inoperative and the jaws do not clamp on tissue, do not fire the instrument. Remove and do not continue to use the instrument.
15. The instrument should be replaced if it does not fire smoothly or the firing mechanism becomes inoperative. Attempting to force the device to complete the firing stroke under very high load may cause a snap sound and a sudden decrease in force to fire; if this occurs, discontinue the use of the instrument and thoroughly inspect the staple line integrity.
16. Examine the staple lines for pneumostasis/hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.
17. Prior to reloading the instrument, hold the instrument in a vertical position, with Anvil Jaw and Reload Jaw completely submerged in sterile solution. Swish vigorously and then wipe the inside and outside surfaces of the Anvil Jaw and Reload Jaw to clean any unused staples from

the instrument. Do not use the instrument until it has been visually inspected to confirm that there are no staples on the Anvil Jaw or Reload Jaw.
18. Gently pull the instrument away from the transected tissue and ensure it is released from the jaws before removing.
19. When selecting the Reload, careful consideration should be given to existing pathologic conditions as well as any pre-surgical treatment, such as radiotherapy, that the patient may have undergone. Certain conditions or preoperative treatments may cause change in tissue thickness that would exceed the indicated range of tissue thickness for the standard choice of Reload.
20. When dividing major vascular structures, be sure to adhere to the basic surgical principle of proximal and distal control.
21. If it needs to be used together with bipolar electrosurgical instrument, please pay attention to protect the anastomosis.
22. Short instrument can be used for thoracoscopic surgery and open surgery.
23. Do not modify this equipment without authorization from the manufacturer.
24. Instruments or devices in contact with body fluids may require special disposal to prevent biological contamination.
25. This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

EFFECTIVE PERIOD OF STERILIZAION

The Stapler and Reload have undergone EO sterilization and the effective period, 5 years, is marked on each package. Do not use the product outside of the effective period.

STORE AT ROOM TEMPERATURE.

DO NOT EXPOSE TO TEMPERATURE ABOVE 130°F (54°C) OR UNDER 14°F (-10°C), OR HUMIDITY GREATER THAN 80%.

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to **Reach Surgical, Inc.** through **Reachquality@reachsurgical.com** and the competent authority of the Member State in which the user and/or patient is established.

The links of Summary of Safety and Clinical Performance (SSCP) refer to **https://www.int.reachsurgical.com/services.**

EO Batch	**EN** Sterilization batch
	EN Peel Here
02 PE-HD	**EN** HDPE recyclable
	EN Recyclable
www.int.reachsurgical.com/support	**EN** Consult instructions for use or consult electronic instructions for use
EC REP	**EN** Authorized Representative in the European Community
	EN Do not use if package is damaged.
2 STERILIZE	**EN** Do not resterilize
	EN Manufacturer
	EN Date of manufacture
SN	**EN** Serial number
LOT	**EN** Batch code
	EN Use-by date
	EN Fragile, handle with care
	EN Keep dry
	EN Keep away from sunlight
	EN Up
	EN Do not re-use
	EN Caution
REF	**EN** Catalogue number
	EN Storage temperature limit
	EN Storage humidity limitation

	EN Single sterile barrier system
CN	**EN** Country of manufacture
MD	**EN** Medical device
UDI	**EN** Unique device identifier
STERILE EO	**EN** Sterilized by Ethylene Oxide.