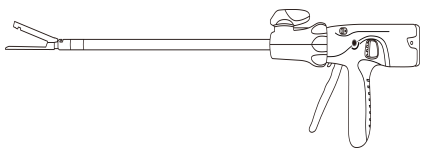
REACH SURGICAL | iREACH Magnum

IREACH MAGNUM PLUS Staplers



EN Endoscopic Motorized Cutting Stapler
Instructions

Rev.A.0

CE 0197

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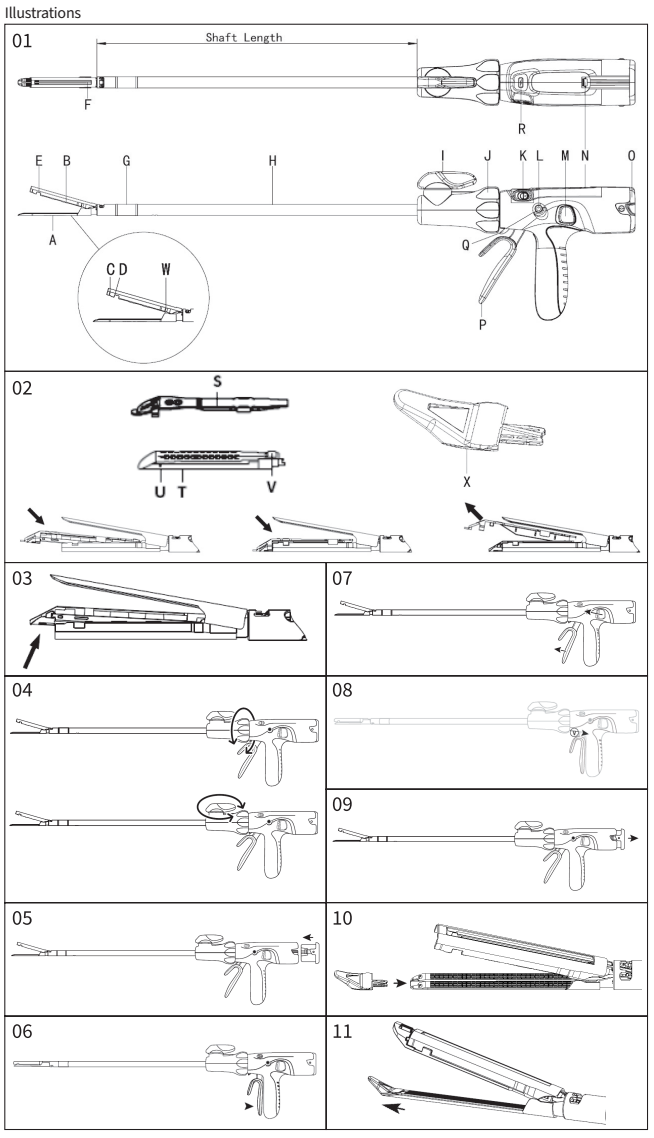
Illustrations



EN

Endoscopic Motorized Cutting Stapler (Instructions)

Before you use this Stapler, please read the following contents carefully.
This document is designed to assist in using this product. It is not a reference for surgical techniques. This Stapler is designed, inspected and manufactured for single procedure only. Reuse or reprocessing may result in product failure or cause patient injury. Do not reuse, reprocess or resterilize this Stapler.

Device Description

The Endoscopic Motorized Cutting Staplers (hereinafter referred to as the Stapler) are sterile, single patient use instruments that simultaneously cut and staple tissue. There are six staggered rows of staples, three on either side of the cut line. The Shaft can be rotated freely in both directions and an articulation mechanism enables the distal portion of the Shaft to pivot to facilitate lateral access to the operative site.
The Staplers are packaged with a primary Battery Pack that must be installed prior to use. There are specific requirements for disposing of the Battery Pack. Refer to the Battery Pack Disposal section.
The Staplers are packaged without Reloads and must be loaded prior to use. A Staple Retaining Cap on the Reload protects the loading unit staples points during shipping and transportation. The Stapler's lock-out feature is designed to prevent a used or improperly installed Reload from being refired or a Stapler from being fired without a Reload.

Caution:
Do not load the Stapler more than 16 times.
The Stapler can be fired for a maximum of 16 times.
Use of staple line reinforcement material may reduce the maximum number of firings.

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

Indications
This instrument is intended to be used with the Reloads for transection, resection, and/or creation of anastomoses. This instrument has applications in open and minimally invasive surgeries including thoracic, abdominal, gynecological and urological surgeries. It is used for transection and resection of lungs, bronchial tissue, intestines, stomach, urethra, kidney, uteru.

Intended User
This instrument is used for healthcare professionals who use this instrument for surgical purposes.

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

Intended patient population:
Patients aged 3 and older requiring resection and reconstruction of organs and tissues in the thoracic and abdominal cavities.

Clinical benefit:
•Shorter operative time;
•Less intraoperative blood loss;
•Reduced postoperative complications such as anastomotic leak.

Contraindications

1. Do not use the Stapler on edematous tissue, tissue with a muscle layer that is too thick, or tissue with bad healing ability.
2. Do not use the Stapler on tissue with suspected cancer cell residual.
3. Do not use the Stapler on the aorta.
4. Do not use the Stapler on ischemic or necrotic tissue.
5. Do not use the Stapler on major vessels without making provision for proximal and distal control.
6. Do not use on tissue that cannot be properly compressed to the closed staple height or easily compressed to less than the closed staple height.
7.The Stapler is not intended for use when surgical stapling is contraindicated.

Compatibility Information

The Stapler is designed to be compatible with Battery Pack, Curved Tip Accessory and Reloads referred in this document. Third party accessories are not compatible.
When the Stapler is used for minimally invasive surgery, a trocar is needed.
Note: The Stapler is designed to be passed through a 12mm diameter trocar.
The Stapler is designed to be used with IREACH MAGNUM PLUS Reloads and ENDO REACH REC Reloads (hereinafter referred to as the Reloads) manufactured by Reach Surgical, Inc. Product Code and tissue thickness reference are listed as follows:

Product Codes and Specifications

Table 1 Product Codes and specifications

Product Code	Staple Line length (mm)	Shaft Length (mm)	Trocar Compatibility (mm)	Battery included in the package
IMS60L	60	365	12	YES
IMS60M	60	265	12	YES
IMS60S	60	215	12	YES
IMS45L	45	365	12	YES
IMS45M	45	265	12	YES
IMS45S	45	215	12	YES
IMS60L-0	60	365	12	NO
IMS60M-0	60	265	12	NO
IMS60S-0	60	215	12	NO
IMS45L-0	45	365	12	NO
IMS45M-0	45	265	12	NO
IMS45S-0	45	215	12	NO

Table 2 Reload Product Codes

Product Code	Tissue Thickness (mm)	Staple Line Length (mm)	Color	Open Staple Height (mm)	Closed Staple Height (mm)
IMST45TAN	Vascular/Thin	45	Tan	2.0/2.5/3.0	0.75 /1.0/1.25
IMST45PUL	Medium/Thick	45	Purple	3.0/3.5/4.0	1.25/1.5/1.75
IMST45BLK	Extra Thick	45	Black	4.0/4.4/4.4	1.75/2.0/2.25
IMST60TAN	Vascular/Thin	60	Tan	2.0/2.5/3.0	0.75 /1.0/1.25
IMST60PUL	Medium/Thick	60	Purple	3.0/3.5/4.0	1.25/1.5/1.75
IMST60BLK	Extra Thick	60	Black	4.0/4.4/4.4	1.75/2.0/2.25
REC45GRA	Extra Thin	45	Gray	2.0	0.75
REC45WHT	Thin tissue	45	White	2.5	1.0
REC45BLU	Regular	45	Blue	3.5	1.5
REC45GLD	Regular/thick	45	Gold	3.8	1.75
REC45GRN	Thick tissue	45	Green	4.1	2.0
REC45BLK	Extra thick	45	Black	4.4	2.2
REC60GRA	Extra Thin	60	Gray	2.0	0.75
REC60WHT	Thin	60	White	2.5	1.0
REC60BLU	Regular	60	Blue	3.5	1.5
REC60GLD	Regular/thick	60	Gold	3.8	1.75
REC60GRN	Thick	60	Green	4.1	2.0
REC60BLK	Extra thick	60	Black	4.4	2.2

Table 3 Accessory

Trade Name	Product Code
IREACH Powered Battery	PB-A
IREACH Curved Tip Accessory	IMB1

Instructions for Use

Nomenclature (Illustration 01)

[A] Anvil Jaw	[B] Reload Jaw
[C] Staple Mark	[D] Cut Mark
[E] Reload Alignment Slot	[F] Knife Blade Indicator
[G] Articulation Joint	[H] Shaft
[I] Articulation Lever	[J] Rotation Knob
[K] Knife Reverse Switch	[L] Safety Release Button
[M]Anvil Release Button	[N] Manual Override
[O] Battery Pack	[P] Closing Trigger
[Q] Firing Trigger	[R] Battery Indicator
[S] Staple Retaining Cap	[T] Reload
[U] Alignment Tab	[V] Blade
[W] Proximal Mark	[X] Curved Tip Accessory

Prior to use

1. Verify the Stapler and Reload codes to be used as well as their compatibility, warnings and precautions.
2. Verify the integrity of the package for all the Stapler and accessories. Do not use if the package is damaged.
3. Verify the integrity of the antimicrobial package for all Stapler and accessories prior to using the Stapler. All Stapler and accessories are sold sterile.

Preparing the Stapler for Use

4. Using sterile technique, remove the Stapler, Battery Pack, and Reload from their respective packages. To avoid damage, do not flip the Stapler, Battery Pack, or Reload into the sterile field.
5. Install the Battery Pack. The Battery Pack must be installed prior to use. It can be inserted in only one orientation. (Illustration 05) Ensure that the Battery Pack is fully inserted into the Stapler. An audible click can be heard when the Battery Pack is fully inserted. The Battery Pack should not have any visible gap when the Battery Pack is fully inserted.
6. Ensure that the jaws are open and the Articulation Joint is straight, not articulated (Illustration 01).
7. Ensure that the Staple Retaining Cap on the Reload is in place; do not use the Reload if the Staple Retaining Cap is missing.
   Caution: Tissue thickness should be carefully evaluated prior to using the Stapler. Refer to the codes and specifications of Single Use Loading Units for Endoscopic Linear Cutting Staplers for proper Reload selection.

Loading

8. 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 02) The Stapler is now loaded and ready for use.
   Caution: Make sure that the knife does not touch the bottom of the jaw as this prevents the knife from being moved or it can become deformed when loading the Reload. Otherwise, the Stapler may be locked out and cannot 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 as it may indicate absence of staples.

Using the Stapler

9. Close the jaws of the Stapler by squeezing the Closing Trigger until it locks in place (Illustration 06). An audible click indicates that the Closing Trigger and the jaws are locked. When the jaws of the stapler are closed, the Firing Trigger will be exposed.
   Caution: Do not press the Safety Release Button at this time. Otherwise the Stapler may be partially or completely fired and will need to be reloaded before using on tissue.
10. Visually inspect the Stapler to ensure proper Reload seating. Introduce the Stapler into the body cavity through a trocar of the appropriate size or through an incision. When using a trocar, the jaws must be visible past the trocar sleeve before opening the jaws.
    Caution: For insertion and removal, the jaws of the Stapler must be closed and straight, in-line with the Shaft of the Stapler. Failure to have the Stapler jaws in the straight position will result in difficult insertion or withdrawal of the Stapler and may result in damage to the Stapler or trocar.
    Caution: When placing the Stapler through the trocar or incision, avoid inadvertently pressing the safety release button and pulling the Firing Trigger. Otherwise the Stapler may be partially or completely fired and will need to be reloaded before using on tissue. If the Stapler is partially fired, remove the Stapler and push the Knife Reverse Switch to return the knife to home position. Remove the Reload and insert a new one. If the Stapler is fired completely, the knife will return to home position automatically. Remove the Stapler and insert a new Reload (see Reloading the Stapler).
    Caution: At any time, if the Knife Reverse Switch does not return the knife to its initial position and the jaws will not open:
    A). First, ensure the Battery Pack is securely installed and the stapler has power; then, try the Knife Reverse Switch again.

B). If the knife still does not return, use the Manual Override. After the Manual Override system is used, the Stapler is disabled and cannot be used for any subsequent firings. To use the Manual Override, remove the access panel labeled "Manual Override" on the top of the Stapler handle. The reset lever and the forced return lever will be exposed. Pull the Reset Lever (marked ①) perpendicular to the stapler handle, move the Return Lever (marked ②) forward and backward until it can no longer be moved. The knife will now be in the initial position. This can be verified by viewing the position of the Knife Blade Indicator on the underside of the Reload Jaw. Discard the Stapler.

11. Once in the cavity, open the jaws by pulling the Anvil Release Button (Illustration 07).
12. If needed, rotate the jaws by pushing on the fins of the Rotation Knob with the index finger using a downward or upward pressure (Illustration 04). The Stapler Shaft will be rotated freely in either direction.
13. To articulate the jaws inside the body cavity, pivot the Articulation Lever clockwise or counter-clockwise to articulate the jaws, ensuring that it stays within the field of view. (the jaws must be open in order to articulate the Stapler). (Illustration 04)
    Caution: The Stapler can only achieve a maximum articulation angle of 65°. When the maximum angle is reached, the force will increase, indicating that the maximum angle has been reached. Avoid applying excessive force to the Articulation Lever as damage to the Stapler may occur.
14. Position the Stapler around the tissue to be stapled.
    Caution: Ensure that the tissue lies flat and is positioned properly between the jaws. Any "bunching" of tissue along the Reload, particularly in the base of the jaws, may result in an incomplete staple line. The Staple Mark on Reload Jaw designate the ends of the staple line. The line on the Reload Jaw that reads "cut" references the cut line on the Stapler.
    Caution: When positioning the Stapler on the application site, ensure that no obstructions such as clips, stents, guide wires, etc. are within the Stapler jaws. Firing over an obstruction may result in an incomplete cutting action, improperly formed staples, and/or inability to open the jaws.
15. After positioning the jaws, close the jaws by squeezing the Closing Trigger until it locks (Illustration 06). An audible click indicates that the jaws are fully closed. When the jaws are fully closed, the Safety Release Button is ready to be activated.
    Caution: Ensure tissue has not been packed (extended) to the Proximal Mark on the Stapler. Tissue forced into the Stapler 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.
    Caution: If the trigger is difficult to lock:
    A) Ensure that the proper Reload selection has been made (Refer to the Reload Selection Chart).
    B) Reposition the Stapler 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 Stapler. Remove and do not continue to use the Stapler.
16. Press the Safety Release Button on either side of the Stapler.
17. Fire the Stapler by pulling the Firing Trigger, so that the motor will be activated audibly (Illustration 08). Continue to depress the trigger until the motor stops (audible feedback), in order to reach the end of the tissue transection.
    Caution: Since the motor may stop if it stalls, it is important to do a visual check to ensure that the Knife Blade Indicator, on the underside of the Reload Jaw, has reached the end of the tissue transection.
    Caution: The firing process may come to stop and the audible tone will be heard if there's excessive tissue between jaws. In such situation, use the Knife Reverse Switch to return the Blade to its original position and reload. It is advised to clamp less tissue and select proper Reload according to the thickness of the tissue.
    Caution: The motor will slow down when device encounters thick tissues.
18. To complete the firing sequence, release the Firing Trigger and the motor will return the knife to home position where the motor will stop. In this position, the Stapler is locked out until the jaws are opened and re-closed.
    Caution: If it is necessary to interrupt the firing sequence or it is interrupted inadvertently by releasing the trigger during the firing sequence, pull the Firing Trigger again to continue. The status of the transection can be determined by observing the Knife Blade Indicator on the underside of the Reload Jaw throughout the firing action. This can be done as often as necessary until the knife reaches its end where releasing the trigger automatically returns the knife to home position.
    Caution: If the Stapler locks out, the motor will stop. Release the Firing Trigger and slide the Knife Reverse Switch forward to return the knife to the home position. While keeping the jaws closed, remove the Stapler from the body cavity, open the jaws and reload in order to continue. To open the jaws, press the Anvil Release Switch on either side of the Stapler while pulling on the Closing Trigger. Slowly release the Closing Trigger while pressure is still applied on the Anvil Release Switch. Follow the instructions for Reloading the Stapler.
    Caution: At any time, if the Knife Reverse Switch does not return the knife to home position and the jaws will not open:
    a. First, ensure the Battery Pack is securely installed and the Stapler has power. Then, try the Knife Reverse Switch again.
    b. If the knife still does not return, use the Manual Override.
    Caution: After the Manual Override system is used, the Stapler is disabled and cannot be used for any subsequent firings. To use the Manual Override, remove the access panel labeled "Manual Override" on the top of the Stapler handle. The Reset Lever and the forced Return Lever will be exposed. Pull the Reset Lever (marked ①) perpendicular to the Stapler handle, Move the Return Lever (marked ②) forward and backward until it can no longer be moved. The knife will now be in the home position. This can be verified by viewing the position of the Knife Blade Indicator on the underside of the Reload Jaw. Discard the Stapler.
    Caution: Incomplete firing may result in malformed staples, incomplete cut line, bleeding, and/or difficult removal of the Stapler.
    Caution: Crossing of staple lines may shorten the life of the Stapler.
    Caution: If the firing mechanism becomes inoperative, do not continue to use the Stapler.
19. To open the jaws, squeeze the Closing Trigger, then simultaneously press the Anvil Release Switch on either side of the Stapler. (Illustration 07).
    Caution: If the jaws do not automatically open after the Anvil Release Switch is pressed, first ensure that the knife is in the home position. The position of the knife can be determined by observing the Knife Blade Indicator under the Reload Jaw. If the Knife Blade Indicator is not in the home position or the position of the knife cannot be determined, slide the Knife Return Switch to activate the motor and return the knife to home position. Try to open the jaws again using the Anvil Release Switch. If the jaws do not open at this point, then gently push the Closing Trigger (1) upward (away from the handle) until both firing and Closing Triggers return to their original positions.
20. Gently pull the Stapler away from the transected tissue and ensure it is released from the jaws.
    Caution: Examine the staple lines for hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.
21. Before removing the articulating Stapler, move the jaws away from any obstruction inside the body cavity while keeping the jaws open and within the field of view, and pivot the Articulation Lever of the Stapler clockwise or counter-clockwise to return the jaws to the straight position manually.
    Caution: For insertion and removal of articulating Stapler, the jaws must be straight, parallel to the Shaft of the Stapler. Failure to have the jaws in the straight position will result in difficult insertion or withdrawal of the articulating Stapler and may result in damage to the Stapler.
22. To remove the Stapler from the cavity, keep the jaws close and completely withdraw the Stapler from the body cavity or the trocar.
23. Push the Anvil Release Button to open the Stapler jaws (Illustration 07).
24. Push upward (toward the Anvil) to unsnap the spent Reload from the Reload Jaw. Discard the used Reload. (Illustration 03)
    Caution: Before loading a new Reload, hold the Stapler in a vertical position, with Anvil and Reload Jaw completely submerged in sterile solution. Swish vigorously and then wipe the inside and outside surfaces of the Anvil and Reload Jaw to clean any unused staples from the Stapler. Do not use the stapler until it has been visually inspected to confirm there are no staples on the Anvil or Reload Jaw.
    Caution: Before unloading the Reload, make sure the jaws and the Shaft are in a straight line. Otherwise, the Stapler may be damaged.
25. When needed, insert the Curved Tip Accessory into the Anvil Jaw (Illustration 10). After use, hold and remove it from the Anvil Jaw. (Illustration 11)
26. Reload and use the Stapler by repeating steps 6-24. The Stapler can be fired up to a total of 16 times.

Instrument and Reload Disposal

Once the instrument has been used, depending on your local regulations, it can be disposed of according to hospital procedure after removing the Battery Pack. If the instrument requires decontamination prior to disposal, follow the hospital protocol and local regulation regarding stapler disposal. The used instrument and Reload also share the same disposal method and are processed as per the Battery Pack's cleaning and disinfection instructions below.

Battery Pack Disposal

The Battery Pack will automatically drain itself if it remained in the instrument.
The Battery Pack should be removed from the instrument prior to disposal. The Battery Pack and the instrument should be disposed separately or handled according to local regulations. If the Battery Pack requires cleaning and disinfection prior to disposal, follow the hospital protocol or the Battery Cleaning and Disinfection instructions below.

Prior to installation into the Instrument

If Battery Pack needs to be disposed of prior to installation into Stapler (e.g. product is beyond expiration date indicated on the package, Battery Pack is dropped), first install the Battery Pack into the instrument, then remove after the Battery Pack is depleted.

After Use

The Battery Pack must be removed from the instrument prior to disposal.
If Battery Pack requires decontamination prior to disposal, follow the hospital protocol or the Battery Pack Cleaning and Disinfection instructions below.
To remove the Battery Pack, squeeze the release tabs and pull the Battery Pack straight back.
Note: It is not necessary to disassemble the Battery Pack.
Caution: The disposable Battery Pack is not allowed to be charged or disassembled after use.

Battery Pack Cleaning and Disinfection

Warning: Do not use hospital autoclaves to sterilize or disinfect Battery Pack.
· Manual Cleaning
Step 1 Remove the Battery Pack from the Stapler before cleaning.
Note: Battery Pack should not be submerged in water or cleaning solutions.
Step 2 Clean the Battery Pack surfaces with a neutral pH detergent or neutral pH enzymatic detergent, prepared according to the manufacturer's instructions.
Step 3 Use soft bristle brush to manually clean the Battery Pack with the cleaning solution.
Step 4 Ensure areas containing crevices are scrubbed thoroughly.
Step 5 Wipe off detergent thoroughly with lukewarm tap water.
Step 6 Perform visual inspection to determine if debris is removed.
Step 7 Repeat cleaning as necessary to obtain a visually clean Battery Pack.
· Chemical Disinfection
Disinfectants should be prepared and used according to the manufacturer's recommendations. It is recommended that the chemical disinfectant be wiped off with tap water.
· 70% Isopropyl alcohol
· 10% Bleach (sodium hypochlorite solution)

Standard Conventions Used

The Use of Caution, Warning, and Note Statements

Information relative to the operation of this Stapler will be supplied in the form of a Caution, Warning, or Note statement. These statements are found throughout the document. These statements should be read before continuing to the next step in a procedure.

Warning: A Warning statement indicates an operating, practice, or condition that, if not strictly observed, could result in personal injury or loss of property.

Caution: A Caution statement indicates an operating, practice, or condition that, if not strictly observed, could result in damage to or destruction of the Stapler.

Note: A Note statement indicates an operating, practice, or condition that is necessary to execute a task efficiently.

Warnings and Precautions

• Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.

• Minimally invasive Staplers may vary in diameter from manufacturer to manufacturer. When minimally invasive Staplers and accessories from different manufacturers are used together in a procedure, verify compatibility prior to initiation of the procedure.

• When using other technologies in the procedure, observe the precautions suggested by the original equipment manufacturer to avoid the hazards associated with their use.

• Prior to using the Stapler, check the endoscope or endoscopic accessories inserted into the human body for rough surfaces, sharp edges or protrusions that may cause safety hazards.

• Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or disruption.

• Do not load the stapler more than 16 times for a maximum of 16 firings per Stapler.

• The Stapler can only be matched with the Battery Pack and Reload manufactured by Reach Surgical.

• Tissue thickness should be carefully evaluated prior to using the Stapler. Refer to the Table 2 in this manual for proper Reload selection.

• After removing the Staple Shipping Wedge, observe the Reload surface of the new 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.)

• For insertion and removal of Stapler, the jaw must be straight, parallel to the Shaft of the Stapler. Failure to have the jaws in the straight position will result in difficult insertion or withdrawal of the Stapler and may result in damage to the Stapler.

• When placing the Stapler through the trocar or incision, avoid inadvertently pressing the Safety Release Button. the Stapler may be partially or completely fired and will need to be reloaded before using on tissue.

• Do not attempt to articulate the jaws when clamping the tissues.

• The Stapler can only achieve a maximum articulation angle of 65°. When the maximum angle is reached, the force will increase indicating the maximum angle has been reached. Avoid applying excessive force to the Articulation Lever, otherwise it may cause damage to the Stapler.

• Ensure that the tissue lies flat and is positioned properly between the jaws. Any “bunching” of tissue along the Reload, particularly in the crotch of the jaws, may result in an incomplete staple line.

• When positioning the Stapler on the application site, ensure that no obstructions such as clips, stents, guide wires, etc. are within the jaws. Firing over an obstruction may result in incomplete cutting action, improperly formed staples, and/or inability to open the jaws.

• Ensure tissue has not extended proximal to the proximal black line on the Reload. Tissue forced into the Reload proximal to the black line may be transected without staples.

• If the trigger is difficult to be squeezed, reposition the Stapler and take a smaller amount of tissue. Ensure that the proper Reload selection has been made.

• If the trigger becomes inoperative and the jaws do not clamp on tissue, do not fire the Stapler. Remove and do not continue to use the Stapler.

• Attempting to force the trigger to complete the firing stroke with too much tissue between the jaws, or with dense/thick tissue between the jaws, may result in motor stall and the knife will stop.

• Since the motor may stop if it stalls, it is important to do a visual check to ensure that the I beam on the underside of the Reload Jaw, has reached the distal end of the tissue transection.

• If the Stapler locks out, the motor will stop. Push the Knife Reverse Switch forward to return the I beam to the home position. In this position, the Stapler should be removed, opened, and reloaded in order to continue.

• If the motor does not run when pushing the Knife Reverse Switch, the Manual Override panel on top of Handle should be opened to access Manual Override which will be used to backward Knife blade to its home position. Then the Stapler can not be used any more.

• Incomplete firing may result in malformed staples, incomplete cut line, bleeding, and/or difficult removal of the Stapler.

• If the firing mechanism becomes inoperative, do not continue to use the Stapler.

• If the jaws do not open after pushing the trigger forward, first ensure that the knife is in the home position. The position of the knife can be determined by observing the Knife Blade Indicator under the Reload Jaw. If the Knife Blade Indicator is not in the home position or the position of the knife cannot be determined, push the Knife Reverse Switch to return the knife to its home position.

• Examine the staple lines for pneumostasis/hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.

• Prior to loading a new Reload, hold the Stapler in a vertical position, with Anvil and Reload Jaw completely submerged in sterile solution. Swish vigorously and then wipe the inside and outside surfaces of the Anvil and Reload Jaw to clean any unused staples from the Stapler. Do not use the Stapler until it has been visually inspected to confirm there are no staples on the Anvil or Reload Jaw.

• Before removing the Stapler, be sure that tissue is cleared from the jaws and then close the jaws.

• 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.

• Do not use hospital autoclaves to sterilize or disinfect Battery Pack and Stapler.

• Use of any other type of battery other than the battery supplied with the Stapler may result in increased EMISSIONS or decreased IMMUNITY of the Stapler.

• Avoid use of the Stapler adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Stapler and the other equipment to assure normal operation.

• Do not modify this device and Battery Pack without authorization from the manufacturer.

• Device or Battery Pack which comes into contact with bodily fluids may require special disposal handling to prevent biological contamination.

• Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this Stapler and result in improper operation.

• This Stapler and Battery Pack are packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Stapler and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use Stapler may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Stapler may lead to injury, illness, or death of the patient.

• The Stapler and the Reload should not be used on tissues such as liver or spleen, as the compression of such tissues may cause damage when the jaws are closed.

• If the hemostasis of the staple line cannot be clearly observed, this Stapler should not be used.

• If Stapler and auxiliary devices from different manufacturers are used in one operation, the compatibility of Stapler with devices from different manufacturers must be checked, and the insulation as well as grounding must be checked.

• User should not try to load the Reload while squeezing the trigger.

• The purchaser or user of the Stapler should use the Stapler under a specified electromagnetic environment. Follow the directions of the following tables when using the device. Otherwise, it may cause that the Stapler cannot work properly.

•The Stapler cannot be operated under oxygen enriched environment.

• 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;

Side effects

Potential complications related to the use of Stapler, Reload and Battery Pack include: hemorrhage, tissue injury, introduction of non-sterile surface or pathogen transfer, inflammatory or accidental tissue reaction, electrical shock, property damage or environmental damage. In addition, incomplete suture, inability to cut or device damage may cause accidental injury, prolongation of operation time or change of operation method.

Technical Parameters

Nominal Voltage: Battery Pack 12V.

The Endoscopic Motorized Cutting Staplers have a power rating of 40 W.

The Stapler is not resistant to fluids ingress and is classified per IEC 60601-1 as IPX0.

The Stapler needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Essential Performance

1. The Stapler and the Reload should be able to be assembled and disassembled smoothly. The movement of moving and rotating parts should be flexible, without any stucking or loosening. The connection between the Stapler and the Reload should be reliable, without any loosening.
2. The safety mechanism of the Stapler should be opened and closed smoothly; it should be safe and reliable. Trigger return spring should have enough elasticity, the trigger should be able to quickly reset when releasing the trigger.
3. The firing and articulating operation should be safe and reliable. The electronic control system and driving motors should be safe and reliable, without any harmful noise, electricity, radiation to the user as well as nearby devices.
4. The Manual Override of the Stapler should be safe and reliable, without any stucking or loosening. Once the Battery Pack could not output enough power to Stapler, the Stapler should be able to finish retraction smoothly by Manual Override back to its original position, without any stuck.

Storage Requirements

Temperature: 5°C~35°C

Relative Humidity: 0%-70%

Air Pressure: 500 hPa~1060 hPa

Transport Requirements

Temperature: -10°C~54°C

Relative Humidity: 0%-70%

Air Pressure: 500 hPa~1060 hPa

Operating Environment Requirements

Temperature: 10°C~40°C

Relative Humidity: 35%-75%

Air Pressure: 800 hPa~1060 hPa

Software information

The Stapler is controlled by an embedded software program with the version of software V01. The software program is intended to detect the current. If the current is too high, the software will cut off the circuit to avoid motor damage.

Expiration Date

The Stapler, Curved Tip Accessory and Battery Pack are sterilized by ethylene oxide and the expiration date is labeled on the package of the Stapler. The Stapler should not be used after its expiration date.

Guidance and manufacturer’s declaration for EMC

WARNING: Use of the Stapler adjacent to or with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the Endoscopic Motorized Cutting Staplers, including cables specified by the MANUFACTURER. Otherwise, the degradation of the performance of this equipment could result.

NOTE: The EMISSIONS characteristics of the Stapler make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), the stapler might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

• The Stapler must be used in a specified electromagnetic environment. Follow the directions of the following tables when using the device.

Guidance and manufacturer’s declaration – electromagnetic emission

The Endoscopic Motorized Cutting Staplers are intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Emission test	Compliance	Electromagnetic environment - guidance
RF emission CISPR 11	Group 1	The Endoscopic Motorized Cutting Staplers use RF energy only for its internal function. Therefore, its RF emissions are low and there is little possibility of producing interference to nearby electronic equipment.
RF emission CISPR 11	Class A	The Endoscopic Motorized Cutting Staplers are suitable for use in professional healthcare facilities.
Harmonic distortion IEC 61000-3-2	N/A	
Voltage fluctuations and flicker IEC 61000-3-3	N/A	

Guidance and manufacturer’s declaration – Electromagnetic immunity

The Endoscopic Motorized Cutting Staplers are intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The floor should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / bursts IEC 61000-4-4	±2 kV 100 kHz repetition frequency	N/A	Battery powered and no signal line >3m
Surges IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground	N/A	Battery powered and no signal line >30m or going out to outdoor
Voltage dips IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°	N/A	Battery powered
Voltage interruptions IEC 61000-4-11	70% U_T; 25 cycles at 0° 0% U_T; 250 cycle		
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz	30 A/m 50Hz	The power frequency magnetic field should have the characteristics for use in a typical place in a typical commercial or hospital environment.

Note: U_T refers to the AC voltage of the power supply before the test voltage is applied.

Guidance and manufacturer’s declaration –Electromagnetic immunity

The Endoscopic Motorized Cutting Staplers are intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3V 0.15 MHz ~ 80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	N/A	
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz ~ 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz ~ 2.7 GHz 80% AM at 1 kHz	

Guidance and manufacturer’s declaration –Electromagnetic immunity

The Endoscopic Motorized Cutting Staplers are intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity to RF wireless communications equipment (IEC 61000-4-3)

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380—390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430—470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704—787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800—960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700—1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400—2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100—5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

EO Batch	**EN** Sterilization batch
	EN Peel Here
02 PE-HD	**EN** HDPE recyclable
	EN Recyclable
	EN Refer to instruction manual
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.
www.int.reachsurgical.com/support	**EN** Consult instructions for use or consult electronic instructions for use