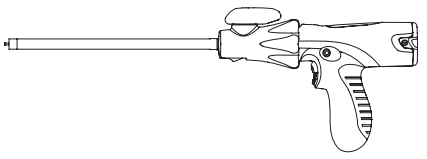
FERDINAND MEDICAL | *iREACH* Omnia
Advanced Equipment, Trusted Care

IREACH OMNIA Staplers



EN Powered Articulating Staplers
Instructions

Rev.A.0

CE 0197

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EC REP

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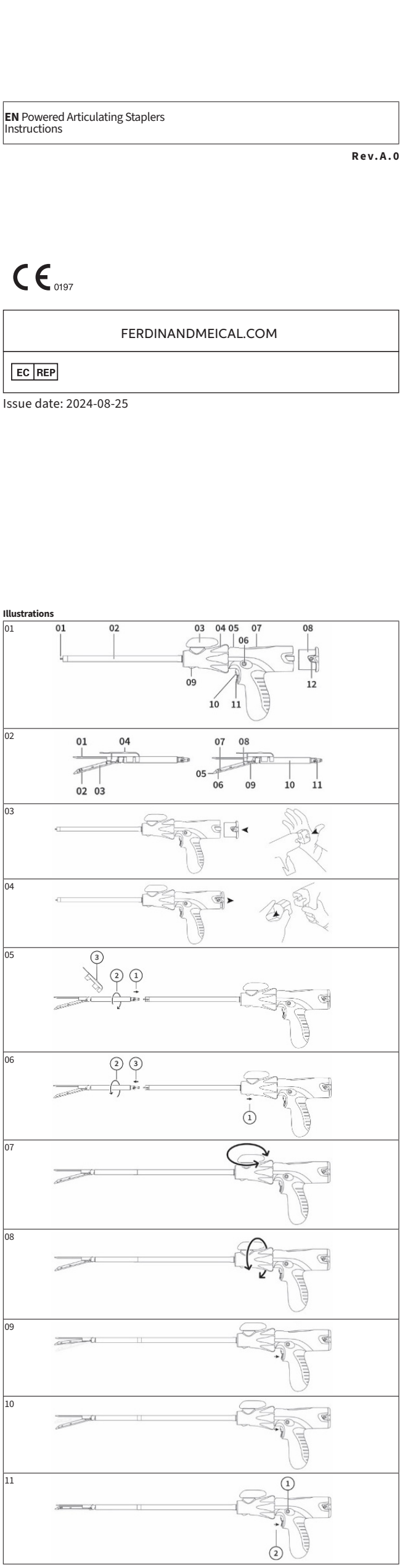
Illustrations



EN/English

Before using this Instrument, please read the following contents carefully.
This document is designed to assist in using this Instrument. It is not a reference for surgical techniques.

Standard Conventions Used: Caution, WARNING, and Note Statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution, WARNING, or Note statement. These statements are found throughout the documentation. These statements should be read before continuing to the next step in a procedure.
Warning: A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.
Caution: A Caution statement alerts the user of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the Instrument and the care necessary to avoid damage to a Instrument that may occur as a result of use or misuse.
Note: A Note statement indicates an operating, practice, or condition that is necessary to execute a task efficiently.

Description

The **iReach Omnia Powered Articulating Staplers** (hereinafter referred to as the Instrument) are EO sterile, single patient use instrument that, when used with Reload Units, can simultaneously cut and staple tissue.
A sterile, hand-held, battery-powered surgical instrument designed to be used during endoscopic surgical procedures for the expeditious transection and resection of tissues and the creation of anastomoses; it may also be used during open surgery. The device is intended to mechanically cut the tissue and simultaneously apply surgical staples to the resulting sides of the cut line, with power from a motor in the handle. This device is typically loaded with staples and may be pistol-like in design. This is a single-use device.

Nomenclature – Instrument (Illustration 01)

[01] Pin	[02] Shaft
[03] Articulation Lever	[04] Rotating Knob
[05] Battery Light	[06] Safety Button
[07] Manual Override Access Panel	[08] Battery
[09] Unload Button	[10] Up Button
[11] Down Button	[12] Release Tab

Nomenclature – Reload Unit (Illustration 02)

[01] Anvil Jaw	[02] Reload Jaw
[03] Reload	[04] Shipping Wedge
[05] Tip	[06] Staple Mark
[07] Cut Mark	[08] Proximal Mark
[09] Knife Blade Indicator	[10] Shaft
[11] Alignment Indicator	

Compatibility Information

The Instrument is only compatible with the Reload Units and battery referenced in this manual. Product Code and tissue thickness reference are listed in **Chart 02 - Reload Units Product Codes**. When the Instrument is used for minimally invasive surgery, a trocar is needed.

Product Specifications

Chart 01 - Instrument Product Codes

Product Code	Description	Instrument Length (mm)	Shaft Length (mm)	Battery included in the package
IDL	Long Articulating	500	255	Yes
IDM	Medium Articulating	400	155	Yes
IDS	Short Articulating	330	85	Yes
IDL-0	Long Articulating	500	255	No
IDM-0	Medium Articulating	400	155	No
IDS-0	Short Articulating	330	85	No

Chart 02 - Reload Units Product Codes

Product Code	Color	Staple Line Length (mm)	Open Staple Height (mm)	Closed Staple Height (mm)	Tissue Thickness Range	Trocar Compatibility (mm)
ID3020	Gray	30	2.0	0.75	Vascular	12
ID4520	Gray	45	2.0	0.75	Vascular	12
ID6020	Gray	60	2.0	0.75	Vascular	12
ID3025	White	30	2.5	1.0	Thin	12
ID4525	White	45	2.5	1.0	Thin	12
ID6025	White	60	2.5	1.0	Thin	12
ID4535	Blue	45	3.5	1.5	Medium	12
ID6035	Blue	60	3.5	1.5	Medium	12
ID4548	Green	45	4.8	2.0	Thick	15
ID6048	Green	60	4.8	2.0	Thick	15
ID30TAN	Tan	30	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID45TAN	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID60TAN	Tan	60	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID30PUL	Purple	30	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
ID45PUL	Purple	45	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
ID60PUL	Purple	60	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
ID45BLK	Black	45	4.0/4.5/5.0	1.75/2.0/2.2	Extra Thick	15
ID60BLK	Black	60	4.0/4.5/5.0	1.75/2.0/2.2	Extra Thick	15
ID3020B	Gray	30	2.0	0.75	Vascular	12
ID4520B	Gray	45	2.0	0.75	Vascular	12
ID6020B	Gray	60	2.0	0.75	Vascular	12
ID3025B	White	30	2.5	1.0	Thin	12
ID4525B	White	45	2.5	1.0	Thin	12
ID6025B	White	60	2.5	1.0	Thin	12
ID4535B	Blue	45	3.5	1.5	Medium	12
ID6035B	Blue	60	3.5	1.5	Medium	12
ID30TANB	Tan	30	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID45TANB	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID60TANB	Tan	60	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID30PULB	Purple	30	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
ID45PULB	Purple	45	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
ID60PULB	Purple	60	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12

Chart 03 – Accessories

Trade Name	Product Code
IREACH Powered Battery	PB-A

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 Reload Units for transection, resection, and/or creation of anastomoses. This instrument has applications in open and minimally invasive surgeries including thoracic, abdominal, gynecological, urological surgeries. It is used for transection and resection of lungs, bronchial tissue, intestines, stomach, urethra, kidney, uterus.

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 and medical condition to be treated

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

Clinical Benefits

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

Contraindications

- Do not use the Instrument on the aorta.
- Do not use the Instrument on ischemic or necrotic tissue.
- Do not use the Instrument on major vessels without making provision for proximal and distal control.
- Tissue thickness should be carefully evaluated before firing. Refer to the **Chart 02 – Reload Units Product Codes** for tissue compression requirement (Closed Staple Height) for each staple size. If tissue cannot comfortably compress to the closed staple height, or easily compresses 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 Instrument is not intended for use when surgical stapling is contraindicated.

Side effects

Potential complications related to the use of the Instrument, Reload Unit and Battery 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 Instrument damage may cause accidental injury, prolongation of operation time or change of operation method.

MR Conditional

Non-clinical testing has demonstrated the implantable staples are MR Conditional. A patient with the staples 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.

Instructions for Use

Prior to use

1. Verify compatibility of the Instrument and accessories prior to use.

Preparation

2. Using sterile technique, remove the Instrument from the package. To avoid damage, do not flip the Instrument into the sterile field. Do not use if the package is damaged.
3. Install the Battery. The Battery must be installed prior to use. It can be inserted in only one orientation. (Illustration 03) Ensure that the Battery is fully inserted into the Instrument. An audible click can be heard when the Battery is fully inserted. The Battery Light will be illuminated. There should be no visible gap between Battery and the Instrument.

Loading

4. Before loading the Instrument with a Reload Unit, ensure the Shipping Wedge is in place, do not use the Reload Unit if the Shipping Wedge is not in place.

WARNING: Tissue thickness should be carefully evaluated prior to loading. Refer to the **Chart 02 - Reload Units Product Codes** for proper selection.
WARNING: Do not remove the Shipping Wedge before the Reload Unit is loaded on the Instrument.
Insert the Pin at the distal end of the Shaft into the Reload Unit. Make sure the arrow sign on the Shaft is aligned with the arrow sign on the Reload Unit. After the Reload Unit is completely inserted into the Shaft, turn 45° clockwise to lock it. Verify that the Unload Button is at its initial position. Remove the staple shipping wedge and discard. (Illustration 05) The Instrument is now loaded and ready for use.
Caution: After the Shipping Wedge is removed, inspect the surface of the Reload Unit. If any staple tray is visible, the Reload Unit cannot be used and must be replaced.
Caution: Do not pull the Down Button before removing the Shipping Wedge.

Unloading

5. To unload the Instrument, first ensure the jaws are open and not articulated. Pull the Unload Button backwards with one hand, twist the Reload Unit counterclockwise 45 degrees with another hand and remove it from the Shaft. Release the Unload Button and verify that it is back to its initial position. Dispose the used Reload Unit. (Illustration 06)

Caution: Before unloading the Instrument, the jaws must be open and not articulated. Unloading while the jaws are articulated and/or closed may damage the Instrument. Use the Articulation Lever to articulate. Press the Up Button to open the jaws.
WARNING: If a Reload Unit is unloaded without being used, the Shipping Wedge must be placed on the Reload Unit at its initial position.

Using the Instrument

6. To completely close the jaws, press and hold the Down Button (Illustration 09).

Note: Alternatively, you can press the Down Button briefly to close the jaws half-way. Press again to completely close the jaws.

7. To open the jaws, press the Up Button (Illustration 10).

Caution: Do not insert or remove the Instrument from the protected incision or trocar while the jaws are open. Failure to do so may result in difficulty inserting or withdrawing and may damage the Instrument or trocar.

8. To articulate, pivot the Articulation Lever to articulate the jaws.

Caution: The Instrument can only articulate to a maximum angle of 45°. There will be significant resistance when the maximum angle is reached. Avoid applying excessive force to the Articulation Lever as it may damage the Instrument.
Caution: To articulate the Instrument inside the body cavity, ensure jaws stay within the field of view (Illustration 07).
Caution: Do not insert or remove the Instrument from the protected incision or trocar while the jaws are articulated. Failure to do so may result in difficulty inserting or withdrawing and may damage the Instrument or trocar.
Caution: Do not articulate the jaws when the jaws are closed.

9. To rotate, spin the Rotating Knob. (Illustration 08). The Shaft can be rotated in either direction.
10. To insert the Instrument through the trocar, first ensure the jaws are straight, not articulated. Then close the jaws by pulling the Down Button. Insert, then pull the Up Button to open the jaws.

Caution: When inserting or removing the Instrument from the protected incision or trocar, pay attention and avoid pressing the Safety Button and the Down Button by accident, as it may result in accidental firing the Instrument.
Caution: If the Instrument is accidentally fired while inserting through the trocar, and the firing process is complete (with audible feedback heard), release the Down Button and wait for the knife to return to its initial position, remove the Instrument from the trocar while keeping the jaws closed; Open the jaws and reload the Instrument.
Caution: If the Instrument is accidentally fired while inserting through the trocar, and the firing process is incomplete, release the Down Button and pull the Up Button till the knife to is returned to its initial position, remove the Instrument from the trocar while keeping the jaws closed; Open the jaws and reload the Instrument.

11. Position the tissue to be transected between the jaws. Pull the Down Button to close the jaws.

Caution: Ensure that the tissue lies flat and is positioned at the mid-section of the jaws. Do not place the tissue at the Proximal Mark or Staple Mark. Avoid any 'bunching' as it may result in an incomplete staple line.
Caution: Before clamping the tissue, ensure there are no obstructions such as clips, stents, guide wires, etc. within the jaws. Firing over an obstruction may result in an incomplete cutting action, improperly formed staples, and/or inability to open the jaws.

12. After positioning the jaws, close the jaws by pulling the Down Button (Illustration 09). The Safety Button will light up after the jaws of are closed.

Caution: Ensure the clamped tissue does not exceed the Proximal Mark. Tissue beyond Proximal Mark may be transected without being stapled.
Caution: If the jaws are not fully closed or unable to close, do not fire the Instrument:
a. Open the jaws and place less tissue between the jaws.
b. Replace the Reload Unit and ensure that the proper Reload Unit is selected for the tissue thickness. (Refer to the **Chart 02 - Reload Units Product Codes**)

13. To fire, first press the Safety Button to disengage the safety mechanism, then pull and hold the Down Button (Illustration 11) to start firing. Continue to pull and hold the Down Button until the motor stops and audible feedback heard.

Note: It is recommended to clamp the tissue for a few seconds before firing to ensure better compression and staple formation. The Instrument will give audible notice once the jaws has been closed for 15 seconds.
Note: The firing can be paused by releasing Down Button. To continue firing, pull and hold the Down Button. To abort firing and retract the knife before reaching Staple Mark, pull and hold the Up Button. Once the knife is returned to its initial position, the Reload Unit is no longer usable and must be replaced.
Caution: The Instrument may decrease its speed when it's cutting through thick tissues.
Caution: If the motor stalls or stops, do a visual check to ensure that the Knife Blade Indicator has reached the Staple Mark. The firing process may come to stop and the audible tone will be heard if there's excessive tissue between jaws. In such situation, pull the Up Button to return the Knife Blade Indicator to its initial position. Open the jaws and reload. It is advised to clamp less tissue or select proper Reload Unit according to tissue thickness.

14. Release the Down Button and the Knife Blade Indicator will return to its initial position. The jaws can be opened by pulling the Up Button. (Illustration 10). Inspect the site of transection before opening the jaws.

Caution: The motor will stop when there is a lock out. Release the Down Button and pull the Up Button to return the knife to its initial position. At this time the jaw is closed, open the jaws by pulling the Up Button in order to pull the Instrument away from the transected tissue. Then close the jaw by pulling the Down Button. Remove the Instrument from the body cavity, open the jaws and reload in order to continue.
Caution: If the knife does not retract:
a. First, ensure the Instrument is powered. This can be verified by checking if the Battery Light is illuminated. Then pull the Up Button again.
b. If the Knife Blade Indicator still does not return, perform Manual Override: first remove the panel marked Manual Override Access Panel on the top of the Instrument. Two levers will be exposed. Pull the lever marked '1' perpendicular to the Instrument, then move the lever marked '2' forward and backward until it can no longer be moved. The Knife Blade Indicator will now be in the initial position. This can be verified by viewing the position of the Knife Blade Indicator on bottom of the Reload Jaw. If the Reload Unit is articulated, pivot the Articulation Lever to return it to its original position. Remove the Instrument from the trocar. The Instrument will no longer be usable after Manual Override.
Caution: Incomplete firing may result in malformed staples, incomplete cut line, bleeding, and/or difficult removal of the Instruments.
Caution: Clamping and firing over staple lines may decrease number of firings.
Caution: Do not continue to use the Instrument if the firing process is not properly functioning.

15. Gently pull the Instrument away from the transected tissue and ensure the tissue 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.

16. Before removing Instrument through trocar, 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 so the jaws are straight, not articulated.

Caution: The jaws must be straight, not articulated when inserting or removing the Instrument from the trocar. Failure to do so may result in difficulty inserting or removing and may result in damage the Instrument.

17. To remove through trocar, first ensure the jaws are straight, not articulated. Then close the jaws by pulling the Down Button. Remove, then pull the Up Button to open the jaws.

Disposal

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

Battery Disposal

The Battery will automatically drain itself if it remained in the instrument.
The Battery should be removed from the instrument prior to disposal. The Battery and the instrument should be disposed separately or handled according to local regulations. If the Battery 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 needs to be disposed of prior to installation into Stapler (e.g. product is beyond expiration date indicated on the package, Battery is dropped), first intall the Battery into the instrument, then remove after the Battery is depleted.

After use

The Battery must be removed from the Instrument prior to disposal.
If Battery requires decontamination prior to disposal, follow the hospital protocol or the Battery Cleaning and Disinfection instructions below.
To remove the Battery, squeeze the Release Tabs on the Battery and pull it out. (Illustration 04)
Warning: Do not disassemble the Battery.
Warning: Do not charge the Battery.

Battery Cleaning and Decontamination

WARNING: Do not use hospital autoclaves to sterilize or disinfect Battery.

Manual Cleaning

- Step 1 Remove the Battery from the Instrument before cleaning.

Note: Battery should not be submerged in water or cleaning solutions.
Step 2 Clean the Battery 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 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.

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)

Warnings and Precautions
- Examine the shipping carton and Instrument for signs of shipping damage. Note any shortages, breakage, or apparent damage, retain the evidence, notify Customer Service or Distributor immediately and replace with a new Instrument. Do not use a damaged product.
- 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.
- Instruments for minimally invasive procedure may vary in diameter from manufacturer to manufacturer. When such Instruments and accessories from different manufacturers are employed together in a procedure, verify their compatibility prior to procedure.
- Do not use the Instrument if the shaft is visibly bent.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- The Instrument must be disposed after procedure once the package is opened.
- The Instrument is designed, inspected, and manufactured for single procedure only. Do not reuse, reprocess or resterilize the Instrument as it may compromise the structural integrity of the Instrument, and/or lead to Instrument failure that in turn may result in patient injury, illness, or death.
- Reusing the Instrument may create risk of contamination, infection, or cross-infection, including, but not limited to, the transmission of infectious diseases, which may lead to injury, illness, or death.
- Do not load the Instrument more than 16 times. The Instrument can fire for a maximum number of 16 times. Use of staple line reinforcement material may reduce the maximum number of firings.
- After removing the Shipping Wedge, observe the surface of the Reload. The Reload Units must be replaced with another Reload Units if any staple tray is visible. (If staple tray is visible, the Reload may not contain staples.)
- Do not articulate when the jaws are closed.
- When selecting the Reload Units, 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 Units.
- Do not use hospital autoclaves to sterilize or disinfect Battery and the Instrument.
- Use of any other type of battery other than the battery supplied with the Instrument may result in increased EMISSIONS or decreased IMMUNITY of the Instrument.
- Avoid using the Instrument adjacent to or stacked with another equipment. If it is necessary to use the Instrument adjacent or stacked with another Instrument, pay attention, and notice any abnormalities.
- Do not modify the Instrument without authorization from the manufacturer.
- 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 Instrument and result in improper function.
- If the hemostasis of the staple line cannot be clearly observed, do not continue using this Instrument.

The Instrument must be used in a specified electromagnetic environment. For more information, refer to **Guidance and manufacturer's declaration for EMC**. Failure to follow these instructions may cause the Instrument to malfunction.
- The Instrument 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.

Technical Parameters
- Battery ratings: DC 12V,1550mAh.
- The Instrument is not resistant to fluids ingress and is classified per IEC 60601-1 as IPX0
- The Instrument 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.

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: 30 % ~ 75 %
Air Pressure: 800 hPa ~ 1060 hPa

Software information
The Instrument 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 Instrument is sterilized by Ethylene Oxide. The expiration date is labeled on the package. Do not use this Instrument beyond its expiration date.

How Supplied
This Instrument is supplied sterile for single patient use. Discard after use.

Guidance and manufacturer's declaration for EMC
WARNING: Use of the Instrument 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 Powered Articulating Staplers and Reload Units, including cables specified by the MANUFACTURER. Otherwise, the degradation of the performance of this equipment could result.
NOTE: The EMISSIONS characteristics of the Instrument 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 Instrument 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.
Electromagnetic interference will not prevent the Instrument from being electrically closed and fired.
The Instrument must be used in a specified electromagnetic environment. Follow the directions of the following tables when using the Instrument.

Guidance and manufacturer's declaration – electromagnetic emission
The Instrument and Reload Units 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 Powered Articulating Staplers and Reload Units 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 Powered Articulating Staplers and Reload Units 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 Powered Articulating Staplers and Reload Units 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 ±2 kV, ±4 kV ±8 kV,±15 kV air	±8 kV contact ±2 kV, ±4 kV ±8 kV,±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 Voltage interruptions IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 70% UT; 25 cycles at 0° 0% UT; 250 cycle	N/A	Battery powered
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 Powered Articulating Staplers and Reload Units 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 Powered Articulating Staplers and Reload Units 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
710 745 780	704—787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800—960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700—1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400—2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100—5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

Guidance and manufacturer's declaration –Proximity magnetic fields immunity
The Powered Articulating Staplers and Reload Units 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 frequency	Modulation	Immunity test level(A/m)
Proximity magnetic fields immunity IEC 61000-4-39:2017	134.2kHz	Pulse modulation, 2.1kHz	65
	13.56MHz	Pulse modulation, 50kHz	7.5

EO Batch	**EN** Sterilization batch
	EN Peel Here
02 PE-HD	**EN** HDPE recyclable
	EN Recyclable
	EN Type BF Applied Part
	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 Storage atmospheric pressure 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