REACH SURGICAL | ENDO REACH

ENDO REACH RLC\SRC\AFT Staplers
ENDO REACH RLC\SRC\AFT Reload Units

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

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Reach Surgical, Inc.
120 Xinxing Road, West Zone, TEDA, 300462 Tianjin, China

EC REP **MDSS GmbH**
Schiffgraben 41, 30175 Hannover, Germany

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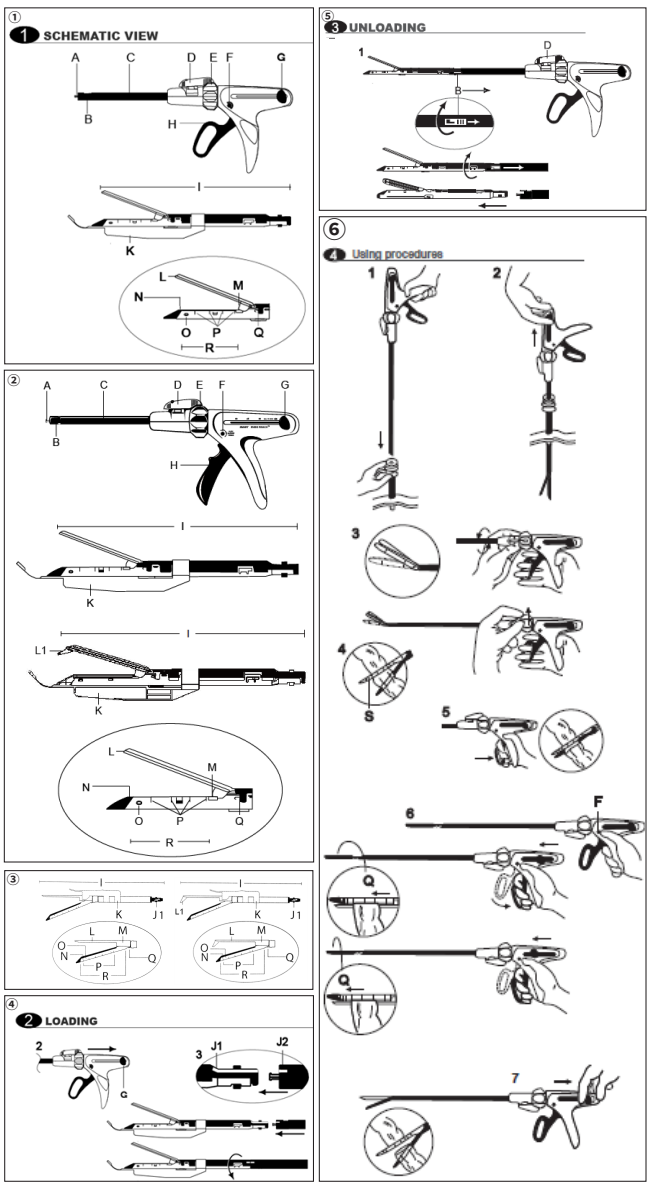
Illustrations



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

⚠ BEFORE USING PRODUCT,PLEASE READ FOLLOWING INFORMATION CAREFULLY.

IMPORTANT!

This booklet is designed to assist in using ENDO REACH Endoscopic Linear Cutting Staplers (Herein after referred as ' Staplers') and Single Use Loading Units for Endoscopic Linear Cutting Staplers (Herein after referred as 'Reloads'). It is not a reference to surgical stapling techniques.

The Staplers and Reloads is designed,tested and manufactured for single patient use only.Please do not reuse,reprocess or resterilize this instrument. Reuse, reprocessing or resterilization of the instrument may result in functional failure, contamination,patient injury or infection.Staplers can be used with various kinds of disposable Reloads of the ENDO REACH series **manufactured by Reach Surgical, Inc.**

INTENDED USE

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

INDICATIONS

This 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 POPULATIN

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.

DESCRIPTION

The Staplers and Reloads place two, triple-staggered rows of titanium staples and simultaneously divide the tissue from central line. The size of the staple is decided by selecting 2.5 mm, 3.5 mm, 4.0 mm, 4.8 mm or 5.0mm Reloads. The Stapler can be adapted for all of the Reloads sizes available.
When using The Stapler with the 2.5, 3.5 ,4.0 Reloads and the tan or purple Reload, a 12 mm trocar sleeve with a converter should be used.
When using The Stapler with the 4.8 Reload ,5.0 Reload and the black Reload, a 15.5 mm trocar sleeve should be used.
ENDO REACH single use articulating Vascular/Medium Reload
-Tan Reload and tan curved tip Reload -three height progressive rows of 2.0mm,2.5mm,3.0mm titanium staples on either side of the cut line.
ENDO REACH single use articulating Medium/Thick Reload
-Purple Reload and purple curved tip Reload -three height progressive rows of 3.0mm,3.5mm,4.0mm titanium staples on either side of the cut line.
ENDO REACH single use articulating Extra Thick Reload
-Black Reload -three height progressive rows of 4.0mm,4.5mm,5.0mm titanium staples on either side of the cut line.
The used time of staples that are made of Titanium/ Titanium alloy is long term in body.

CHOICE OF INSTRUMENTS

Only use the Staplers with the ENDO REACH Reloads manufactured by Reach Surgical, Inc. Staplers **may be reloaded and fired no more than 25 times in a single procedure.**

NOTE: Every instrument can accommodate the following Reload: 45-2.5, 45-3.5, 45-4.8,45-5.0, 60-2.5, 60-3.5, 60-4.0, 60-4.8 ,60-5.0, the 45mm length, tan, tan curved tip, purple, purple curved tip and black Reload; the 60mm length, tan, tan curved tip, purple, purple curved tip and black Reload.

WARNINGS

1. The Stapler with 2.5 mm Reload cannot be used on any tissue that is compressed to less than 1.0 mm in thickness, or that cannot be comfortably compressed to 1.5 mm or on aorta.
2. The Stapler with 3.5 mm Reload cannot be used on any tissue that is compressed to less than 1.5 mm in thickness, or that cannot be comfortably compressed to 2.0 mm or on aorta.
3. The Stapler with 4.0 mm Reload cannot be used on any tissue that is compressed to less than 1.7mm in thickness, or that cannot be comfortably compressed to 2.2mm or on aorta.
4. The Stapler with 4.8mm Reload cannot be used on any tissue that can be compressed to less than 2.0 mm in thickness, or that cannot be comfortably compressed to 2.5mm or on aorta.
5. The Stapler with 5.0mm Reload cannot be used on any tissue that can be compressed to less than 2.2 mm in thickness, or that cannot be comfortably compressed to 2.7mm or on aorta.
6. The Stapler with tan Reload and tan curved tip Reload cannot be used on any tissue that compresses to less than 0.75 mm in thickness, or that cannot comfortably compresses to 1.5 mm or on aorta.
7. The Stapler with purple Reload and purple curved tip Reload cannot be used on any tissue that compresses to less than 1.5 mm in thickness, or that cannot comfortably compresses to 2.25 mm or on aorta.
8. The Stapler with black Reload cannot be used on any tissue that compresses to less than 2.25 mm in thickness, or that cannot comfortably compresses to 3.0 mm or on aorta.
9. The Staplers with Reloads cannot be used on liver, spleen or similar tissue that compression may lead to destructive effects.
10. The Staplers with Reloads cannot be used on the patients who are undergoing anticoagulation therapy.
11. The Staplers with Reloads cannot be used on the tissues whose airproof or integrity of staple line cannot be ensured. Reinforcement material may be used if the Staplers with Reloads should be used.

PRECAUTIONS

1. Preoperative radiotherapy can result in tissue changes, which may cause the tissue thickness exceeds the indicated range for the selected staple size. Careful considerations should be given to any pre-surgical treatment and select the staple size correspondingly.
2. Always inspect the thickness of the tissue and select an appropriate staple size before the application of the Staplers with Reloads. When choosing the Reload of proper staple height, always consider the combined thickness of the tissue and of any staple line reinforcement material.
3. When The Stapler is used with a 4.8 mm and 5.0mm Reload ,a black (4.0mm,4.5mm,5.0mm) Reload, the instrument MUST be introduced through a 15.5 mm trocar. A smaller size trocar will not be suitable for the 4.8 ,5.0 Reload and a black Reload.
4. Always close the jaw of The Staplers with Reloads before introducing and removing the instrument from the trocar sleeve.
5. After firing, the staple line should always be inspected for hemostasis. Minor bleeding can be controlled by electrocautery or manual sutures.
6. Placing tissue proximal to the tissue stops (on the Reload) may cause instrument malfunction. Tissue extending beyond the cut mark will not be transected.
7. When the stapler is used more than once in a SINGLE surgical procedure, make sure to remove the empty Reload and reload a new one. A safety interlock will prevent an empty Reload from being fired a second time. Please do not try to override the safety interlock.
8. Make sure that no obstructions, such as clips, are incorporated into the instrument jaw when positioning the instrument on the application site. Fire the instrument over an obstruction may result in incomplete cutting and/or improper staple formations.
9. Endoscopic procedures should be performed by physicians who have adequate training on endoscopic techniques. Before the performance of any endoscopic procedures, consult the medical literature relating to techniques, complications and hazards.
10. The Reload can be opened within the body cavity only when the anvil is completely visible.
11. When a staple line reinforcement material is used, follow the instructions provided by the manufacturer of the reinforcement material, because the performance of the instrument may be affected by using these materials.
12. The Staplers and Reloads are provided STERILE and intended for use in a SINGLE procedure only. PLEASE DISCARD AFTER USE AND DO NOT RESTERILIZE.
13. Please do not try to load a Reload while the ring handle is squeezed.
14. In laser and electrosurgical procedures, a thorough understanding of the principles is essential to avoid shock and burn hazards to patient and operator(s), and damage to the instrument.
15. The Staplers and Reloads are sterilized with EO. The period of validity is 5 years and has been marked on each layer of product package. PLEASE DO NOT use an expired product clinically.
16. After use, the Endoscopic Linear Cutting Staplers and Reload should be disposed of in appropriate recycling or trash bin.
17. When manipulating the tissue with the curved tip Reload, avoid exerting excessive pressure on fragile structure with the curved tip of the device.

MR CONDITIONAL

Non-clinical testing 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 2.7- 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 1.7°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In 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

Warning: Both the Staplers and Reloads are sold sterile. Before use, check the primary package (namely, aseptic packaging, and tyvek seal), and do not use if seal is broken or damaged.
Schematic View of ENDO RLC Series (Illustrations 1)
Schematic View of ENDO SRC Series (Illustrations 2)
Schematic View of ENDO AFT Series (Illustrations 3)
Note: The following information is based on the schematic view of ENDO RLC Series.

① Schematic View

A) Reload Alignment Pin
B) Unload/Unlock Button
C) Shaft
D) Articulating Lever

E) Rotation Collar
F) Safety Release Button
G) Return Knob
H) Handle
I) Reload (45, 60)
J) Reload Alignment Indicator
K) Shipping Wedge
L) Anvil Jaw
L1) Curved Tip
M) Tissue Stop
N) Staple Mark
O) Cut Mark
P) Increment Markings
Q) Knife Blade Indicator
R) Cartridge

② Loading (Illustrations 4)

1. Remove the Reload out of the package in its open position.

Warning: Choose the suitable Reload according to the thickness of tissue. Tissues that are too thin or too thick may cause malformed staples.

Caution: Do not remove the shipping wedge until the Reload is loaded into The Stapler.

2. Ensure that the black return knobs on the instrument are completed pulled back and the articulating lever is in the neutral position of the instrument.

G) Black Return Knobs

3. To load the Stapler with appropriate Reload, insert the pin located at the distal end of instrument into the Reload. Ensure that the load alignment indicator on the Reload aligns with the load alignment indicator on the instrument shaft. Push the Reload downward and turn 45°clockwise relative to the instrument, so that the Reload will be locked into position. At this point, the load alignment indicators will realign again.

J1) Reload Alignment Indicator (on Reload)
J2) Reload Alignment Indicator (on Shaft)

4. Remove the shipping wedge from the Reload.

Note: Do not close the jaw of the Reload prior to removing shipping wedge.

5. Squeeze the handle once to close the jaw of the Reload. Pull back on the black return knobs and confirm that the jaw of the Reload open completely.

③ Unloading (Illustrations 5)

1. To unload a Reload from The Staplers, make sure the articulating lever in the neutral position, while the jaw of the Reload is open by completely pulling the black return knobs back. Pull the Unload/Unlock button downward relative to the instrument and turn the Reload 45°counterclockwise. Remove the Reload from the instrument shaft.

D) Articulating Lever
B) Unload/Unlock Button

④Using procedures (Illustrations 6)

1. After closing the jaw of the Reload by squeezing the handle once, insert The Staplers with Reloads into an appropriately sized trocar sleeve, or a larger one with the help of a converter.

CAUTION: **The Reload should only be opened within the body cavity when the anvil is completely visible.**

The instrument shaft rotates 360°and articulates 22°and 45°in both directions with use of articulating lever.

NOTE: When The Staplers with Reloads are used with a 4.8 and 5.0 Reload and the black Reload, the instrument MUST be inserted into a 15.5 mm trocar.

2. Once inside the body cavity, completely pull back the black return knobs to open the jaw of the instrument.

CAUTION: Please do not squeeze the instrument handle while pulling back the black knobs.

3. Apply The Staplers and Reload across the tissue that will be transected.

CAUTION: **Make sure that no obstructions, such as clips, are incorporated within the instrument jaw. Firing the instrument over an obstruction may lead to incomplete cutting and/or improper staple formations.**

Note: The instrument will not cut the tissue beyond the cut mark, which is indicated on the Reload. For tissue exceeding the length of the Reload (45 mm, or 60 mm), more than one applications of The Staplers and Reload may be necessary.

S) Cut Mark

CAUTION: Placing the tissue proximal to the tissue stops (on the Reload) may cause instrument malfunction. Tissue which extended beyond the cut mark will not be transected.

4. Squeeze the handle completely to close the jaw of the instrument across the tissue to be transected. The jaw of the instrument can be opened and repositioned on the tissue by completely pulling the black return knobs back. The instrument is designed with a safety interlock. It will not fire the staples and cut tissue until the green button is pushed.

CAUTION: Safety interlock is provided to prevent an empty Reload from firing a second time. Please do not try to override the safety interlock.

5. Push the green button prior to fire the instrument. When firing the instrument, squeeze the handle sequentially until it locks. It may require several squeezes to completely fire the Reload. The total number of squeezes is related to the length of the Reload (45 or 60).

CAUTION: Failure to fire the Reload completely will result in an incomplete cut and/or incomplete staple formation, which may lead to poor hemostasis.

F) Green Button
Q) Lower Clamp Button

6. Once the instrument is fired completely, pulling the black return knobs back completely to open the jaw. Remove the instrument from the tissue gently. The site of the application should be checked for hemostasis after the removal of the instrument. Minor bleeding can be controlled by the application of electrocautery or manual sutures.
7. Close the instrument jaw by squeezing the handle and remove the ENDO REACH Staplers and Reloads from the body cavity. Unload the Reload from the instrument.

Note: Do not attempt to insert or remove the instrument from the trocar sleeve if the instrument is in the articulated position.

The Stapler can be reloaded and fired no more than 25 times in a single procedure.

⑤ Specification

5.1 Stapler and Reload Specification and Compatibility Chart

Stapler Product Codes	Reload Product Codes	Staple Line Length	Color	Open Staple Height	Closed Staple Height
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO RLC4525L	45mm	White	2.5 mm	1.0mm
	ENDO RLC4535L	45mm	Blue	3.5 mm	1.5mm
	ENDO RLC4548L	45mm	Green	4.8 mm	2.0mm
	ENDO RLC6025L	60mm	White	2.5 mm	1.0mm
	ENDO RLC6035L	60mm	Blue	3.5 mm	1.5mm
	ENDO RLC6040L	60mm	Gold	4.0 mm	1.75mm
	ENDO RLC6048L	60mm	Green	4.8 mm	2.0mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO RLC4525R	45mm	White	2.5 mm	1.0mm
	ENDO RLC4535R	45mm	Blue	3.5 mm	1.5 mm
	ENDO RLC4548R	45mm	Green	4.8 mm	2.0 mm
	ENDO RLC6025R	60mm	White	2.5 mm	1.0mm
	ENDO RLC6035R	60mm	Blue	3.5 mm	1.5 mm
	ENDO RLC6040R	60mm	Gold	4.0 mm	1.75mm
	ENDO RLC6048R	60mm	Green	4.8 mm	2.0 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525L	45mm	White	3mm 2.5mm	1.0mm
	ENDO SRC4535L	45mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC4548L	45mm	Green	3mm 4.8mm	2.0 mm
	ENDO SRC6025L	60mm	White	3mm 2.5mm	1.0mm
	ENDO SRC6035L	60mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC6040L	60mm	Gold	3mm 4.0mm	1.75mm
	ENDO SRC6048L	60mm	Green	3mm 4.8mm	2.0mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525R	45mm	White	3mm 2.5mm	1.0mm
	ENDO SRC4535R	45mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC4548R	45mm	Green	3mm 4.8mm	2.0 mm
	ENDO SRC4550R	45mm	Black	3mm 5.0mm	2.2 mm
	ENDO SRC6025R	60mm	White	3mm 2.5mm	1.0mm
	ENDO SRC6035R	60mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC6040R	60mm	Gold	3mm 4.0mm	1.75mm
	ENDO SRC6048R	60mm	Green	3mm 4.8mm	2.0mm
	ENDO SRC6050R	60mm	Black	3mm 5.0mm	2.2 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525BL	45mm	White	3mm 2.5mm	1.0mm
	ENDO SRC4535BL	45mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC4548BL	45mm	Green	3mm 4.8mm	2.0 mm
	ENDO SRC6025BL	60mm	White	3mm 2.5mm	1.0mm
	ENDO SRC6035BL	60mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC6040BL	60mm	Gold	3mm 4.0mm	1.75mm
	ENDO SRC6048BL	60mm	Green	3mm 4.8mm	2.0mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525BR	45mm	White	3mm 2.5mm	1.0mm
	ENDO SRC4535BR	45mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC4548BR	45mm	Green	3mm 4.8mm	2.0 mm
	ENDO SRC4550BR	45mm	Black	3mm 5.0mm	2.2 mm
	ENDO SRC6025BR	60mm	White	3mm 2.5mm	1.0mm
	ENDO SRC6035BR	60mm	Blue	3mm 3.5mm	1.5mm
	ENDO SRC6040BR	60mm	Gold	3mm 4.0mm	1.75mm
	ENDO SRC6048BR	60mm	Green	3mm 4.8mm	2.0mm
	ENDO SRC6050BR	60mm	Black	3mm 5.0mm	2.2 mm

Stapler Product Codes	Reload Product Codes	Staple Line Length	Color	Open Staple Height	Closed Staple Height
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO AFT45TNR	45mm	Tan	3mm 2mm 3mm 2.5mm 3mm 3mm	0.75mm,1.0mm, 1.25mm
	ENDO AFT45PLR	45mm	Purple	3mm 3mm 3mm 3.5mm 3mm 4.0mm	1.25mm,1.5mm, 1.75mm
	ENDO AFT45BKR	45mm	Black	3mm 4.0mm 3mm 4.5mm 3mm 5.0mm	1.75mm,2.0mm, 2.2mm
	ENDO AFT60TNR	60mm	Tan	3mm 2mm 3mm 2.5mm 3mm 3mm	0.75mm,1.0mm, 1.25mm
	ENDO AFT60PLR	60mm	Purple	3mm 3mm 3mm 3.5mm 3mm 4.0mm	1.25mm,1.5mm, 1.75mm
	ENDO AFT60BKR	60mm	Black	3mm 4.0mm 3mm 4.5mm 3mm 5.0mm	1.75mm,2.0mm, 2.2mm
	ENDO AFT45TNBR	45mm	Tan	3mm 2mm 3mm 2.5mm 3mm 3mm	0.75mm,1.0mm, 1.25mm
	ENDO AFT45PLBR	45mm	Purple	3mm 3mm 3mm 3.5mm 3mm 4.0mm	1.25mm,1.5mm, 1.75mm
	ENDO AFT60TNBR	60mm	Tan	3mm 2mm 3mm 2.5mm 3mm 3mm	0.75mm,1.0mm, 1.25mm
	ENDO AFT60PLBR	60mm	Purple	3mm 3mm 3mm 3.5mm 3mm 4.0mm	1.25mm,1.5mm, 1.75mm

EFFECTIVE PERIOD OF STERILIZAION

The Staplers and Reloads 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.

STORAGE CONDITIONS

DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F (54°C)OR BELOW 14°F (-10°C)OR HUMIDITIES 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.
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.