Summary of safety and clinical performance

（SSCP）

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the instructions for use as the main document to ensure the safe use of Single Use Loading Units for Endoscopic Linear Cutting Staplers and Reload Units, nor to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

Contents

1. Device identification and general information

1.1 Device trade names

Product Description	Single Use Loading Units for Endoscopic Linear Cutting Staplers	Reload Units
Trade Name	ENDO REACH RLC Reload Units	IREACH OMNIA Reload Units
	ENDO REACH SRC Reload Units	
	ENDO REACH AFT Reload Units	
	ENDO REACH REC Reloads	
	IREACH MAGNUM PLUS Reloads	

1.2 Manufacturer's name and address

Name: Reach Surgical. Inc

Address: 120 Xinxing Road, West Zone, TEDA, 300462 Tianjin, P.R.China

1.3 Manufacturer's SRN

SRN Code: CN-MF-000011148

1.4 Basic UDI-DI

Tabel-1 Product and models and basic UDI-DI information

Trade Name	Models	Basic UDI-DI	Difference
ENDO REACH RLC Reload Units	ENDO RLC4525L	69538158H3632	L: Refer to straight function when connect with Endo Endoscopic Linear Cutting Staplers, all of the models are mirror different in tip top structure and size, The intended use and classification is same. The implantation material is Ti.
	ENDO RLC4535L		
	ENDO RLC4548L		
	ENDO RLC6025L		
	ENDO RLC6035L		
	ENDO RLC6040L		
	ENDO RLC6048L		
ENDO REACH SRC Reload Units	ENDO SRC4525L		
	ENDO SRC4535L		
	ENDO SRC4548L		
	ENDO SRC6035L		
	ENDO SRC6040L		
	ENDO SRC6025L		
	ENDO SRC6048L		
	ENDO SRC4525BL		
	ENDO SRC4535BL		

Trade Name	Models	Basic UDI-DI	Difference
	ENDO SRC4548BL		
	ENDO SRC6025BL		
	ENDO SRC6035BL		
	ENDO SRC6040BL		
	ENDO SRC6048BL		
ENDO REACH RLC Reload Units	ENDO RLC4525R		R: Bent function when connect with Endoscopic Linear Cutting Staplers all of the models are mirror different in tip top structure and size, The intended use and classification is same The implantation material is Ti.
	ENDO RLC4535R		
	ENDO RLC4548R		
	ENDO RLC6025R		
	ENDO RLC6035R		
	ENDO RLC6040R		
	ENDO RLC6048R		
ENDO REACH SRC Reload Units	ENDO SRC4525R	69538158H3836	
	ENDO SRC4535R		
	ENDO SRC4548R		
	ENDO SRC6025R		
	ENDO SRC6035R		
	ENDO SRC6040R		
	ENDO SRC6048R		
	ENDO SRC4550R		
	ENDO SRC6050R		
	ENDO SRC4525BR		
	ENDO SRC4535BR		
	ENDO SRC4548BR		
	ENDO SRC4550BR		
	ENDO SRC6025BR		
	ENDO SRC6035BR		
	ENDO SRC6040BR		
	ENDO SRC6048BR		
	ENDO SRC6050BR		
ENDO REACH AFT Reload Units	ENDO AFT45TNR	69538158H442QW	There are different high size of Ti staple compare with Endo RLC/SRC xxxL and R. The implantation material is Ti.
	ENDO AFT45PLR		
	ENDO AFT45BKR		
	ENDO AFT60TNR		
	ENDO AFT60PLR		
	ENDO AFT60BKR		
	ENDO AFT45TNBR		
	ENDO AFT45PLBR		
	ENDO AFT60TNBR		

Trade Name	Models	Basic UDI-DI	Difference
	ENDO AFT60PLBR		
ENDO REACH REC Reloads	REC45GRA	69538158P634D	The design structure and size are different with Endo RLC/SRC/AFT The implantation material is Ti.
	REC45WHT		
	REC45BLU		
	REC45GLD		
	REC60GRA		
	REC60WHT		
	REC60BLU		
	REC60GLD		
IREACH MAGNUM PLUS Reloads	IMST60TAN		The design structure and size are different with ENDO REACH REC Reloads and Compare with IREACH MAGNUM PLUS Staplers The implantation material is Ti.
	IMST60PUL		
	IMST45TAN		
	IMST45PUL		
	REC60BLK		
	REC45GRN		
	REC45BLK		

Product Name	Models	Basic UDI-DI	Different
IREACH OMNIA Reloads Units	ID3020	69538158W427UB	Design structure is same with AFT series, just size and parts of connect with Handel are different. The implantation material is Ti.
	ID4520		
	ID6020		
	ID3025		
	ID4525		
	ID4535		
	ID4548		
	ID6025		
	ID6035		
	ID6048		
	ID3020B		
	ID4520B		
	ID6020B		
	ID3025B		
	ID4535B		
	ID6035B		
	ID4525B		
	ID6025B		
	ID30TAN	69538158W427UB	There are different high size of Ti staple compare with Powered Endo
	ID30PUL		

Product Name	Models	Basic UDI-DI	Different
	ID45TAN		ID series. The implantation material is Ti.
	ID45PUL		
	ID45BLK		
	ID60TAN		
	ID60PUL		
	ID60BLK		
	ID30TANB		
	ID45TANB		
	ID30PULB		
	ID45PULB		
	ID60TANB		
	ID60PULB		

Product Name	Models	Basic UDI-DI	Different
IREACH OMNIA Reloads Units	IDSV3025	69538158W427UB	There are different high size of Ti staple compare with Powered Endo ID series/ Endo Series Staplers. The implantation material is Ti.
	IDSV4525		
	IDSV6025		
	IDSV4535		
	IDSV6035		
	IDSV4548		
	IDSV6048		
	IDSV30TAN		
	IDSV45TAN		
	IDSV60TAN		
	IDSV45PUL		
	IDSV60PUL		
	IDSV45BLK		
	IDSV60BLK		
	IDSV3025B		
	IDSV4525B		
	IDSV30TANB		
	IDSV45TANB		
	IDSTV30TAN		
	IDSTV45TAN		
	IDSTV60TAN		
	IDSTV45PUL		
	IDSTV60PUL		
	IDSTV45BLK		

Product Name	Models	Basic UDI-DI	Different
	IDSTV60BLK		
	IDSTV30PUL		
	IDSTV30TANB		
	IDSTV45TANB		
	IDSTV60TANB		
	IDSTV30PULB		
	IDSTV45PULB		
	IDSTV60PULB		

1.5 Medical device nomenclature description

EMDN code: H020301 LINEAR STAPLERS, VIDEO-ASSISTED SURGERY

1.6 Class of device

Class II b

1.7 Year when the first certificate (CE) was issued covering the device

ENDO REACH RLC Reload Units: 2011

ENDO REACH SRC Reload Units: 2017

ENDO REACH REC Reloads: 2018

ENDO REACH AFT Reload Units: 2020

IREACH OMNIA Reload Units (ID series):2023

IREACH OMNIA Reload Units (IDS series): MDR certified started in Nov.2024.

IREACH MAGNMU PLUS Reloads (IMS series): MDR certified started in Nov.2024.

1.8 Authorised representative name and the SRN

AR Name: MDSS GmbH

SRN: DE-AR-000005430

1.9 NB's name and the NB's single identification number

NB Name: TÜV Rheinland LGA Products GmbH

Single Identification Number: 0197

2. Intended use of the device

2.1 Intended purpose

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

2.2 Indication(s) and target population(s)

- **Indications:**

Single Use Loading Units with Endoscopic Linear Cutting Staplers (ENDO REACH RLC/SRC/AFT Reload Units and ENDO REACH REC Reloads and IREACH MAGNUM PLUS Reloads)

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 trans ection and resection of the lungs and alimentary tract.

Reload Units（IREACH OMINIA Reload Units） is intended to be used with the Powered Articulating Staplers for transection, resection and/or creation of anastomoses. It 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.

- **Target population(s)**

Single Use Loading Units with Endoscopic Linear Cutting Staplers (ENDO REACH RLC/SRC/AFT Reload Units and ENDO REACH REC Reloads and IREACH MAGNUM PLUS Reloads)

Adults and children requiring resection and reconstruction of organs and tissues in the thoracic and abdominal cavities.

Reload Units (IREACH OMNIA Reload Units）

Adults and children requiring resection and reconstruction of organs and tissues in the thoracic and abdominal cavities.

2.3 Contraindications or restrictions for use or limitations

Contraindications：

ENDO REACH RLC/SRC/AFT Reloads Units:

- 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 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.

ENDO REACH REC Reloads and IREACH MAGNUM PLUS Reloads:

- 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 staple size selection. If tissue cannot be comfortably compressed 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 instruments are not intended for use when surgical stapling is contraindicated.

IREACH OMNIA Reload Units

- Do not use the instruments on the aorta, heart and central circulatory system.
- Do not use the Instrument on ischemic or necrotic tissue.
- Tissue thickness should be carefully evaluated before firing. Refer to the Chart 01 – 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.

Restrictions:

ENDO REACH RLC/SRC/AFT Reload Units:

- Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or staple line disruption.
- Do not load the instrument more than 12 times for a maximum of 12 firings per instrument.
- Minimally invasive and stapling procedures should be performed only by persons having adequate training and familiarity with the techniques. Consult relative medical literature for techniques, complications, and hazards prior to performing any minimally invasive procedure.
- When minimally invasive instruments and accessories from different manufacturers are used together in a procedure, verify compatibility prior to initiation of the procedure.
- When using other technologies (e.g., electrosurgery devices), observe the precautions suggested by the manufacturer to avoid the hazards associated with their use.
- The Stapler instruments may only be used with ENDO REACH Reload.
- After removing the Staple Retaining Cap, observe the surface of each new Reload. The Reload must be replaced with another Reload if any colored driver is visible because the Reload may not contain staples.
- For insertion and removal of instruments, the jaws of the instrument must be straight, in line with the Shaft of the instrument. Failure to have the instrument jaws in the straight position will result in difficult insertion or withdrawal of the instrument and may result in damage to the instrument or trocar.
- When placing the instrument through the trocar or incision, avoid inadvertently pulling the Firing Trigger. If the instrument is partially or completely fired, it will need to be reloaded before using on tissue. If the instrument is partially fired, remove the instrument and replace the Reload.
- The instrument can achieve a maximum articulation angle of 45°. When the force increases, it indicates the maximum angle has been reached.
- Ensure that the tissue lies flat and is positioned properly between the jaws. Any “bunching” of tissue along the Reload, particularly near the Proximal Mark of the jaws, may result in an

incomplete staple line. The Cut Mark on the Reload Jaw designates the end of the staple line.

- When positioning the jaws on the application site, ensure that no obstructions such as clips, stents, guide wires, etc. are within the instrument jaws. Firing over an obstruction may result in incomplete cutting action, improperly formed staples, and/or inability to open the instrument jaws.
- Ensure that tissue has not squeezed (extended) proximal to the Proximal Mark on the instrument. Tissue forced into the instrument proximal to the Proximal Mark may be transected without staples. When firing across thick tissue, holding the jaws in place for 15 seconds after closing and prior to firing may result in better compression and staple formation.
- If the clamping mechanism becomes inoperative and the jaws do not clamp on tissue, do not fire the instrument. Remove and do not continue to use the instrument.
- The instrument should be replaced if it does not fire smoothly or the firing mechanism becomes inoperative. Attempting to force the device to complete the firing stroke under very high load may cause a snap sound and a sudden decrease in force to fire; if this occurs, discontinue the use of the instrument and thoroughly inspect the staple line integrity.
- 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 reloading the instrument, hold the instrument in a vertical position, with Anvil Jaw and Reload Jaw completely submerged in sterile solution. Swish vigorously and then wipe the inside and outside surfaces of the Anvil Jaw and Reload Jaw to clean any unused staples from the instrument. Do not use the instrument until it has been visually inspected to confirm that there are no staples on the Anvil Jaw or Reload Jaw.
- Gently pull the instrument away from the transected tissue and ensure it is released from the jaws before removing.
- 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.

- When dividing major vascular structures, be sure to adhere to the basic surgical principle of proximal and distal control.
- If it needs to be used together with bipolar electrosurgical instrument, please pay attention to protect the anastomosis.
- Short instrument can be used for thoracoscopic surgery and open surgery.
- Do not modify this equipment without authorization from the manufacturer.
- Instruments or devices in contact with body fluids may require special disposal to prevent biological contamination.
- This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

ENDO REACH REC Reloads IREACH MAGNUM PLUS Reloads:

- 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 Stapler may vary in diameter from manufacturer to manufacturer. When minimally invasive Stapler 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.
- Tissue thickness should be carefully evaluated prior to using the Stapler. Refer to Reload Units Product Codes 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.)
- 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.
- 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.

- Examine the staple lines for pneumatosis/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.
- 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.
- 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.

IREACH OMNIA Reload Units

- 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 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.
- Do not articulate when the jaws are closed.
- 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 and the instrument.
- 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.
- The Protective Sleeve is single-use only. Do not remove it from the Anvil Jaw after installati on. If needed, insert the Protective Sleeve into the Anvil Jaw.

3. Device description

3.1 Description of the device

ENDO REACH RLC/SRC/AFT/IMS Reloads Units and ENDO REACH REC Reloads and IREACH MAGUNM PLUS Reload Units are six staggered rows of titanium staples, three on either side of the cut line. The Staplers have staple lines that are approximately 45 mm and 60mm long and cut lines that are 41 mm and 56 mm long respectively. The shaft can rotate freely in both directions. The distal portion can be articulated left or right to facilitate lateral access to the operative site. The Max Articulation angle is not less than 45°.

Reload Units (Hereinafter referred to as IREACH OMNIA Reload Units) are sterile, single patient use Instrument that, when used with IREACH OMNIA Staplers, can simultaneously cut and staple tissue. There are six staggered rows of staples, three on either side of the cut line. The Instrument is safe and applicable to the general population, including adults and children.

All the models of **ENDO REACH Reloads family and IREACH Reload Units** family are non-active implant material.

Intended mode of action:

For all the devices and models in this file the achieving intended mode of action was same as below:

In the operation, a wedge pushing device in turn pushes staples one by one. Under the guidance o f groove on the anvil, staples are formed to complete the tissue suture. With the advancement of staples molding process, the knife gradually cuts the sutured tissue from the middle of the suture, and staples molding is completed simultaneously with the cutting.

The instrument models and description and material/substances in contact with patient tissues for each model please see article 1.4 Basic UDI table-1 in this file.

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

Previous Device information

Single Use Loading Units for Endoscopic Linear Cutting Staplers (ENDO REACH RLC Reload Units) It was the first generation of ENDO products, Obtained CE certificate in 2010.

ENDO REACH SRC Reload Units Devices belong to the second generation of products.

ENDO REACH AFT Reload Units is a new model of ENDO REACH SRC Staplers.

ENDO REACH REC Reloads is the third generation of ENDO REACH products.

IREACH OMNIA Reload Units is a new reloads model of the third generation of products, are almost identical to ENDO REACH AFT Reload Units in structure, materials of parts and same in function mechanism, same in packaging, Same in main manufacturing process, same in method and storage.

IREACH MAGNUM PLUS Reload Unites is a minor design changing from ENDO REACH REC Reloads structure, materials of parts and same in function mechanism, same in packaging, Same in main manufacturing process, same in method and storage.

3.3 Description of any accessories which are intended to be used in combination with the device

Accessories:

- **ENDO REACH RLC/SRC/AFT/REC and IREACH MAGNUM Plus Reload Units:**

There are no accessories of ENDO REACH Series Staplers and Reloads and IREACH MAGNUM Plus Reload Units.

- **IREACH OMNIA Reload Units:**

There has one accessory of IREACH Protective Sleeve for IREACH OMNIA Reload Units ID/IDS series models which manufact in Reach Surgical, Inc. The user can choose use or not during surgery, Once it is chosen, the IREACH Protective Sleeve needs to be installed on the reload units prior to use. The accessory details refer to **Table 2.**

Table 2 Accessories information

Trade Name	Product Name	Product Code
IREACH Protective Sleeve	Protective Sleeve	IDP1

The accessory IDP1 compatible ID series models as below:

ID3020, ID4520, ID6020, ID3025, ID4525, ID6025, ID4535, ID6035,

ID30TAN, ID45TAN, ID60TAN, ID30PUL, ID45PUL, ID60PUL, IDSV3025, IDSV4525, IDSV6025, IDSV4535, IDSV6035,

The accessory IDP1 compatible IDS series models as below:

IDSV30TAN, IDSV45TAN, IDSV60TAN, IDSV30PUL, IDSV45PUL, IDSV60PUL,

IDSTV30TAN, IDSTV45TAN, IDSTV60TAN, IDSTV30PUL, IDSTV45PUL, IDSTV60PUL,

3.4 Description of any other devices and products which are intended to be used in combination with the device

Single Use Loading Units for Endoscopic Linear Cutting Staplers (ENDO REACH RLC/SRC/REC/AFT) are intended to be used with the device of Endoscopic Linear Cutting Staplers (ENDO REACH RLC/SRC/REC Staplers) and ENDO REC Series reloads also intended to be used with the device of IREACH MAGNUM Staplers which manufact in Reach Surgical, Inc. and different diameter of Trocar, and Endoscopic when used in the operation, the Endoscopic in operation was no special requirements when used together.

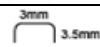
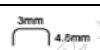
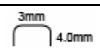
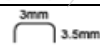
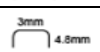
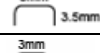
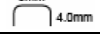
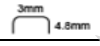
Single Use Loading Units for Endoscopic Linear Cutting Staplers (ENDO REC Series reloads) intended to be used with the device of IREACH MAGNUM Staplers (IM Series staplers) and IREACH MAGNUM PLUS Staplers (IMS Series staplers) which manufact in Reach Surgical, Inc. and different diameter of Trocar, and Endoscopic when used in the operation, the Endoscopic in operation was no special requirements when used together.

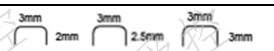
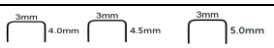
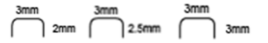
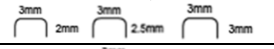
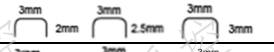
IREACH MAGNUM PLUS RELOADS (IMS Series reloads) also intended to be used with the device of IREACH MAGNUM PLUS Staplers (IMS Series staplers) which manufact in Reach Surgical, Inc. and different diameter of Trocar, and Endoscopic when used in the operation, the Endoscopic in operation was no special requirements when used together.

Reload Units（IREACH OMNIA Reloads ID Series） are intended to be used with the device of Powered Articulating Staplers (IREACH OMNIA Staplers) and **（IREACH OMNIA Reloads IDS Series）**models are intended to be used with ENDO REACH RLCZ/RLC LZ/RLC SZ series staplers which manufact in Reach Surgical, Inc. and different diameter of Trocar, and

Endoscopic when used in the operation, the Endoscopic in operation was no special requirements when used together.

Combination details as the list:

ENDO REACH RLC/SRC/AFT Reloads Units Specification and Compatibility ENDO RLC/SRC Staplers List					
Stapler Product Codes	**Reload Product Codes**	**Staple Line Length（±2mm）**	**Color**	**Open Staple Height（±0.2mm）**	**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		1.0mm
	ENDO SRC4535L	45mm	Blue		1.5mm
	ENDO SRC4548L	45mm	Green		2.0 mm
	ENDO SRC6025L	60mm	White		1.0mm
	ENDO SRC6035L	60mm	Blue		1.5mm
	ENDO SRC6040L	60mm	Gold		1.75mm
	ENDO SRC6048L	60mm	Green		2.0mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525R	45mm	White		1.0mm
	ENDO SRC4535R	45mm	Blue		1.5mm
	ENDO SRC4548R	45mm	Green		2.0 mm
	ENDO SRC4550R	45mm	Black		2.2 mm
	ENDO SRC6025R	60mm	White		1.0mm
	ENDO SRC6035R	60mm	Blue		1.5mm
	ENDO SRC6040R	60mm	Gold		1.75mm
	ENDO SRC6048R	60mm	Green		2.0mm
	ENDO SRC6050R	60mm	Black		2.2 mm

ENDO REACH RLC/SRC/AFT Reloads Units Specification and Compatibility ENDO RLC/SRC Staplers List					
Stapler Product Codes	**Reload Product Codes**	**Staple Line Length（±2mm）**	**Color**	**Open Staple Height（±0.2mm）**	**Closed Staple Height**
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525BL	45mm	White		1.0mm
	ENDO SRC4535BL	45mm	Blue		1.5mm
	ENDO SRC4548BL	45mm	Green		2.0 mm
	ENDO SRC6025BL	60mm	White		1.0mm
	ENDO SRC6035BL	60mm	Blue		1.5mm
	ENDO SRC6040BL	60mm	Gold		1.75mm
	ENDO SRC6048BL	60mm	Green		2.0mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO SRC4525BR	45mm	White		1.0mm
	ENDO SRC4535BR	45mm	Blue		1.5mm
	ENDO SRC4548BR	45mm	Green		2.0 mm
	ENDO SRC4550BR	45mm	Black		2.2 mm
	ENDO SRC6025BR	60mm	White		1.0mm
	ENDO SRC6035BR	60mm	Blue		1.5mm
	ENDO SRC6040BR	60mm	Gold		1.75mm
	ENDO SRC6048BR	60mm	Green		2.0mm
	ENDO SRC6050BR	60mm	Black		2.2 mm
ENDO RLC ENDO RLCS ENDO RLCL ENDO SRC ENDO SRCS ENDO SRCL	ENDO AFT45TNR	45mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT45PLR	45mm	Purple		1.25mm,1.5mm,1.75mm
	ENDO AFT45BKR	45mm	Black		1.75mm,2.0mm,2.2mm
	ENDO AFT60TNR	60mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT60PLR	60mm	Purple		1.25mm,1.5mm,1.75mm
	ENDO AFT60BKR	60mm	Black		1.75mm,2.0mm,2.2mm
	ENDO AFT45TNBR	45mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT45PLBR	45mm	Purple		1.25mm,1.5mm,1.75mm
	ENDO AFT60TNBR	60mm	Tan		0.75mm,1.0mm,1.25mm
	ENDO AFT60PLBR	60mm	Purple		1.25mm,1.5mm,1.75mm

ENDO REACH REC Reloads and Specification					
Device code	Tissue Thickness	Staple Line Length (±2mm)	Cartridge Color	Staple height(±0.2mm)	Formed Staple height (+0.2/-0.5mm)
REC45GRA	Extra Thin	45mm	Gray	2.0 mm	0.75 mm
REC45WHT	Vascular	45mm	White	2.5 mm	1.0 mm

ENDO REACH REC Reloads and Specification					
Device code	Tissue Thickness	Staple Line Length (±2mm)	Cartridge Color	Staple height(± 0.2mm)	Formed Staple height (+0.2/-0.5mm)
REC45BLU	Thin	45mm	Blue	3.5 mm	1.5 mm
REC45GLD	Medium	45mm	Gold	3.8 mm	1.75 mm
REC45GRN	Thick	45mm	Green	4.1 mm	2.0 mm
REC45BLK	Extra Thick	45mm	Black	4.4 mm	2.2 mm
REC60GRA	Extra Thin	60mm	Gray	2.0 mm	0.75 mm
REC60WHT	Vascular	60mm	White	2.5 mm	1.0 mm
REC60BLU	Thin	60mm	Blue	3.5 mm	1.5 mm
REC60GLD	Medium	60mm	Gold	3.8 mm	1.75 mm
REC60GRN	Thick	60mm	Green	4.1 mm	2.0 mm
REC60BLK	Extra Thick	60mm	Black	4.4 mm	2.2 mm

ENDO REACH REC Reloads Compatibility ENDO REACH REC Staplers List						
Models	**Length L1 mm**		**Shaft D1 mm**		**Maximum pendulum Angle**	
	Base Size	**Tolerance**	**Base Size**	**Tolerance**	**Base Size**	**Tolerance**
REC45A	600	±5	12.7	±0.1	45°	+10°/0
REC60A	615	±5	12.7	±0.1	45°	+10°/0
REC45AS	550	±5	12.7	±0.1	45°	+10°/0
REC60AS	565	±5	12.7	±0.1	45°	+10°/0
REC45	600	±5	12.7	±0.1	/	/
REC60	615	±5	12.7	±0.1	/	/
REC45S	550	±5	12.7	±0.1	/	/
REC60S	565	±5	12.7	±0.1	/	/
REC60AL	715	±5	12.7	±0.1	45°	+10°/0
REC45AL	700	±5	12.7	±0.1	45°	+10°/0

IREACH MAGNUM PLUS Reloads Specification						
Product Code	**Color**	**Staple Line Length (± 2mm)**	**Open Staple Height (± 0.2mm)**	**Closed Staple Height (+ 0.2/-0.5mm)**	**Tissue Thickness Range**	**Trocar Compatibility (mm)**

IMST45TAN	Tan	45	2.0/2.5/3.0	0.75 /1.0/1.25	Vascular/Thin	12
IMST45PUL	Purple	45	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IMST60TAN	Tan	60	2.0/2.5/3.0	0.75 /1.0/1.25	Vascular/Thin	12
IMST60PUL	Purple	60	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12

IREACH MAGNUM PLUS Reloads Compatibility IREACH MAGNUM PLUS Staplers List			
Product Model	**Length of staple line (mm)**	**Shaft Length (mm)**	**Trocar Compatibility (mm)**
IMS60L/IMS60L-0	60	365	12
IMS60M/IMS60M-0	60	265	12
IMS60S/IMS60S-0	60	215	12
IMS45L/IMS45L-0	45	365	12
IMS45M/IMS45M-0	45	265	12
IMS45S/IMS45S-0	45	215	12

IREACH OMNIA Reloads Units Specification List						
Product Code	**Color**	**Staple Line Length (± 2mm)**	**Open Staple Height (± 0.2mm)**	**Closed Staple Height (0.4 ≤ H2 ≤ H2 + 0.2 mm)**	**Intended Tissue Thickness**	**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

IREACH OMNIA Reloads Units Specification List						
Product Code	**Color**	**Staple Line Length (± 2mm)**	**Open Staple Height (± 0.2mm)**	**Closed Staple Height (0.4 ≤ H2 ≤ H2 + 0.2 mm)**	**Intended Tissue Thickness**	**Trocar Compatibility (mm)**
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

IREACH OMNIA Reloads Units Specification List						
Product Code	Color	Staple Line Length (± 2mm)	Open Staple Height (± 0.2mm)	Closed Staple Height (0.4 ≤ H2 ≤ H2 + 0.2 (mm)	Intended Tissue Thickness	Trocar Compatibility (mm)
IDSV3025	White	30	2.5	1.0	Thin	12
IDSV4525	White	45	2.5	1.0	Thin	12
IDSV6025	White	60	2.5	1.0	Thin	12
IDSV4535	Blue	45	3.5	1.5	Medium	12
IDSV6035	Blue	60	3.5	1.5	Medium	12
IDSV4548	Green	45	4.8	2.0	Thick	15
IDSV6048	Green	60	4.8	2.0	Thick	15
IDSV30TAN	Tan	30	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSV45TAN	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12

IREACH OMNIA Reloads Units Specification List						
Product Code	Color	Staple Line Length (± 2mm)	Open Staple Height (± 0.2mm)	Closed Staple Height (0.4 ≤ H2 ≤ H2 + 0.2 (mm)	Intended Tissue Thickness	Trocar Compatibility (mm)
IDSV60TAN	Tan	60	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSV45PUL	Purple	45	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IDSV60PUL	Purple	60	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IDSV45BLK	Black	45	4.0/4.5/5.0	1.75/2.0/2.2	Extra Thick	15
IDSV60BLK	Black	60	4.0/4.5/5.0	1.75/2.0/2.2	Extra Thick	15
IDSV3025B	White	30	2.5	1.0	Thin	12
IDSV4525B	White	45	2.5	1.0	Thin	12
IDSV30TANB	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSV45TANB	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSTV30TAN	Tan	30	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSTV45TAN	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSTV60TAN	Tan	60	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSTV30PUL	Purple	30	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IDSTV45PUL	Purple	45	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IDSTV60PUL	Purple	60	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IDSTV45BLK	Black	45	4.0/4.5/5.0	1.75/2.0/2.2	Extra Thick	15
IDSTV60BLK	Black	60	4.0/4.5/5.0	1.75/2.0/2.2	Extra Thick	15
IDSTV30TANB	Tan	30	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSTV45TANB	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSTV60TANB	Tan	60	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
IDSTV30PULB	Purple	30	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IDSTV45PULB	Purple	45	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
IDSTV60PULB	Purple	60	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12

ID Series Reloads Units Compatibility IREACH OMNIA Staplers List			
Product Code	**Description**	**Instrument Length (mm)**	**Shaft Length (mm)**
IDL	Long Articulating	500	255
IDM	Medium Articulating	400	155
IDS	Short Articulating	330	85

IDL-0	Long Articulating	255	494
IDM-0	Medium Articulating	155	394
IDS-0	Short Articulating	85	324

IDS Series Reloads Units Compatibility IREACH OMNIA Staplers List		
Product Code	Length(mm)	Diameter(+ 0.5/ − 1mm)
ENDO RLCSZ	311	12.4
ENDO RLCZ	381	12.4
ENDO RLCLZ	481	12.4

4. Risks and warnings

4.1 Statement, how potential risks have been controlled or managed

In the design and development stage, potential risks have been identified, analyzed and controlled from the aspects of cleaning, disinfection, sterilization, transportation, filling, usability, clinical and end-of-life disposal of equipment after use in accordance with relate risk management regulations and standards. The comprehensive residual risk after the implementation of risk control measures is evaluated, and the comprehensive residual risk is acceptable. The remaining risks are reflected in the product instructions in the form of warnings and precautions.

After the device is launched, post-marketing information will continue to be collected as PMS supervision required, and risk management throughout the full life cycle will be carried out to ensure that the comprehensive residual risk of the device is acceptable.

4.2 Residual risks and undesirable effects

Potential complications related to the use of the Instrument 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.

4.3 Warnings and Precautions

4.3.1 Warning- ENDO REACH RLC/SRC/AFT Reloads Units:

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.

4.3.2 Precautions: ENDO REACH RLC/SRC/AFT Reloads Units

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.

4.3.3 Warnings and Precautions - ENDO REACH REC Reloads and IREACH MAGNUM PLUS Reloads

1. Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or staple line disruption.
2. Do not load the instrument more than 12 times for a maximum of 12 firings per instrument.
3. Minimally invasive and stapling procedures should be performed only by persons having adequate training and familiarity with the techniques. Consult relative medical literature for techniques, complications, and hazards prior to performing any minimally invasive procedure.
4. When minimally invasive instruments and accessories from different manufacturers are used together in a procedure, verify compatibility prior to initiation of the procedure.
5. When using other technologies (e.g., electrosurgery devices), observe the precautions suggested by the manufacturer to avoid the hazards associated with their use.
6. The Stapler instruments may only be used with ENDO REACH REC Staplers.
7. After removing the Staple Retaining Cap, observe the surface of each new reload. The Reload must be replaced with another Reload if any colored driver is visible because the Reload may not contain staples.
8. For insertion and removal of instruments, the jaws of the instrument must be straight, in line with the Shaft of the instrument. Failure to have the instrument jaws in the straight position will result in difficult insertion or withdrawal of the instrument and may result in damage to the instrument or trocar.
9. When placing the instrument through the trocar or incision, avoid inadvertently pulling the Firing Trigger. If the instrument is partially or completely fired, it will need to be reloaded before using on tissue. If the instrument is partially fired, remove the instrument and replace the Reload.
10. The instrument can achieve a maximum articulation angle of 45°. When the force increases, it indicates the maximum angle has been reached.
11. Ensure that the tissue lies flat and is positioned properly between the jaws. Any “bunching” of tissue along the Reload, particularly near the Proximal Mark of the jaws, may result in an incomplete staple line. The Cut Mark on the Reload Jaw designates the end of the staple line.
12. When positioning the jaws on the application site, ensure that no obstructions such as

clips, stents, guide wires, etc. are within the instrument jaws. Firing over an obstruction may result in incomplete cutting action, improperly formed staples, and/or inability to open the instrument jaws.

13. Ensure that tissue has not squeezed (extended) proximal to the Proximal Mark on the instrument. Tissue forced into the instrument proximal to the Proximal Mark may be transected without staples. When firing across thick tissue, holding the jaws in place for 15 seconds after closing and prior to firing may result in better compression and staple formation.
14. If the clamping mechanism becomes inoperative and the jaws do not clamp on tissue, do not fire the instrument. Remove and do not continue to use the instrument.
15. The instrument should be replaced if it does not fire smoothly or the firing mechanism becomes inoperative. Attempting to force the device to complete the firing stroke under very high load may cause a snap sound and a sudden decrease in force to fire; if this occurs, discontinue the use of the instrument and thoroughly inspect the staple line integrity.
16. Examine the staple lines for pneumostasis/hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.
17. Prior to reloading the instrument, hold the instrument in a vertical position, with Anvil Jaw and Reload Jaw completely submerged in sterile solution. Swish vigorously and then wipe the inside and outside surfaces of the Anvil Jaw and Reload Jaw to clean any unused staples from the instrument. Do not use the instrument until it has been visually inspected to confirm that there are no staples on the Anvil Jaw or Reload Jaw.
18. Gently pull the instrument away from the transected tissue and ensure it is released from the jaws before removing.
19. When selecting the Reload, careful consideration should be given to existing pathologic conditions as well as any pre-surgical treatment, such as radiotherapy, that the patient may have undergone. Certain conditions or preoperative treatments may cause change in tissue thickness that would exceed the indicated range of tissue thickness for the standard choice of Reload.
20. When dividing major vascular structures, be sure to adhere to the basic surgical principle of proximal and distal control.
21. If it needs to be used together with bipolar electrosurgical instrument, please pay attention to protect the anastomosis.
22. Short instrument can be used for thoracoscopic surgery and open surgery.
23. Do not modify this equipment without authorization from the manufacturer.
24. Instruments or devices in contact with body fluids may require special disposal to prevent biological contamination.
25. This device is packaged and sterilized for single use only. Do not reuse, reprocess or

resterilize. Reuse, reprocessing, or re sterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or re sterilization of single use devices may create a risk of contamination and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

4.3.4 Warnings and Precautions - IREACH MAGNUM PLUS Reloads

1. 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.
2. Minimally invasive Stapler may vary in diameter from manufacturer to manufacturer. When minimally invasive Stapler and accessories from different manufacturers are used together in a procedure, verify compatibility prior to initiation of the procedure.
3. When using other technologies in the procedure, observe the precautions suggested by the original equipment manufacturer to avoid the hazards associated with their use.
4. 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.
5. Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or disruption.
6. Tissue thickness should be carefully evaluated prior to using the Stapler. Refer to Reload Units Product Codes in this manual for proper Reload selection.
7. 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.)
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.

13. 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.
14. Incomplete firing may result in malformed staples, incomplete cut line, bleeding, and/or difficult removal of the Stapler.
15. If the firing mechanism becomes inoperative, do not continue to use the Stapler.
16. Examine the staple lines for pneumatosis/hemostasis and proper staple closure. Minor bleeding can be controlled with manual sutures or other appropriate techniques.
17. 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.
18. 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.
19. 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.
20. If the hemostasis of the staple line cannot be clearly observed, this Stapler should not be used.
21. 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.
22. User should not try to load the Reload while squeezing the trigger.
23. 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.

4.3.5 Warnings and Precautions -IREACH OMNIA Reload Units

1. 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.
2. 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.

3. 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.
4. Do not use the Instrument if the shaft is visibly bent.
5. Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
6. The Instrument must be disposed after procedure once the package is opened.
7. The Instrument is designed, inspected, and manufactured for single procedure only. Do not reuse, reprocess or re sterilize 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.
8. 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.
9. Prior to installing instrument to the stapler, make sure the stapler is not articulated.
10. Do not remove the Shipping Wedge before the Reload Unit is loaded on the Instrument.
11. 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.
12. 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.)
13. Do not articulate when the jaws are closed.
14. 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.

15. 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.
16. Do not modify the Instrument without authorization from the manufacturer.
17. 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.
18. The Instrument cannot be operated under oxygen enriched environment.
19. 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.
20. The links of Summary of Safety and Clinical Performance (SSCP) refer to https://www.int.reachsurgical.com/support
21. If needed, insert the Protective Sleeve into the Anvil Jaw (Illustration 01).
22. The Protective Sleeve is single-use only. Do not remove it from the Anvil Jaw after installation.

4.3.6 Lifetime

From production date to the end date of follow-up period.

4.4 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

There have been no field safety corrective actions associated with the instrument, and no other relevant aspects of safety to be discussed.

5. Summary of clinical evaluation and post-marketing clinical follow-up related data

The clinical evaluation is based on a comprehensive analysis of available pre-market and post-market clinical data relevant to the intended purpose of the device in question, including clinical performance data and clinical safety data.

There are discrete stages in performing a clinical evaluation:

CER was conducted to assess the safety and performance of The Staplers.

A review of published clinical data, post-market surveillance data, and public vigilance databases, in conjunction with the product risk analyses, we found there is no death or fatal injury event occurred yet. No recall or advisory notice related to The ENDO REACH staplers. It demonstrates that the use of this product by medical professionals does not pose any undue risks to patients and that The ENDO REACH Staplers can be used safely and effectively for their intended use.

Further, this clinical evaluation report provides evidence that the benefits of use outweigh anticipated or reported risks to the patients for The ENDO REACH Staplers. The staplers have a good effect on performance in general, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses. It can successfully resection or anastomoses the target tissue, while provides a high probability of shorter operative time, lower blood loss/transfusion rates, and reduced postoperative complications among patients compared to manual cutting. Any risks identified in this evaluation have been adequately addressed in the risk management documentation.

Based on a review of current and generally accepted options for the intended use of The ENDO REACH Staplers, the System aligns with the state of the art for relevant clinical use. And there is no novelty or brand new technology introduced in the design phase of The ENDO REACH staplers. This product is considered to be based on well-established technology and not novel.

Based on the analysis of intended use, internal and external clinical data, and safety/performance analysis, it is concluded that The ENDO REACH Staplers is compliant with MDR General Safety and Performance Requirements.

The System has been designed and manufactured such that the System will not compromise the

clinical condition or the safety of patients，or the safety and health of users and/or，other applicable persons when The Staplers is used under the conditions and for the purposes intended. The risks associated with the System are identified and mitigated as far as possible to an acceptable level when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety by meeting applicable standards and/or specifications.

The System has achieved the specified performances intended by REACH and was designed manufactured and packed such that they are suitable for the intended functions.

The System has thoroughly evaluated that undesirable side effects constitute an acceptable risk when weighed against the intended performances.

The device implements and maintains a PMS system that routinely monitors the clinical performance and clinical safety of the device as part of its quality management system. PMCF is a continuous process that reviews and updates the clinical evaluation during the post-market phase. According to PMCF confirming the safety and performance, including the clinical benefit of the device throughout its expected lifetime:

C1. Post-market surveillance

The ENDO REACH Series Staplers adverse complaints analysis results from January 01, 2021 to January 01, 2022.there were no death, no serious adverse events during this period. And there were no reports of death across the public vigilance databases searched of the Reach Surgical Staplers.

Post-market surveillance which included internal complaint reporting and public vigilance data showed the adverse events of The ENDO REACH staplers in overseas markets have all come from the Brazilian market, and the probability of occurrence is 0.01% since 2018. And all adverse events were non-serious injury events. Since the increase of usage in the Brazilian market in 2018, the complaint rate has shown an upward trend. After product quality has been improved, the complaint rate has dropped to 0.12%.

In a search of public vigilance databases, there is no death or fatal injury event occurred. And no recall or advisory notice related to The ENDO REACH Series Staplers were found.

For internal complaints and public vigilance reports review against the potential hazards and harms addressed in the Endo XXX PSUR (KF-H68-LC-10-202203) confirmed that no new or unknown hazards were identified for these devices.

C2. Screening of scientific literature and other sources of clinical data

We searched the clinical literature data on the product since its launched, and collected a total of 17 articles related to The ENDO REACH Series Staplers, overall level of evidence per the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence was good, including 5 randomized controlled trials in level II, 8 case-control studies in level III, and 4 case-series studies in level IV. There were 5 articles of ENDO REACH RLC Stapler, 2 articles of ENDO REACH REC Stapler, 10 articles of other size of SULUS for The ENDO REACH staplers.

A total of 1196 patients were included in these 17 articles related to The ENDO REACH Staplers family and SULUS. These included 6 studies of rectal cancer; 7 studies of digestive-related diseases, such as stomach, intestines, and esophagus; 2 studies of pulmonary diseases; 1 study of splenectomy; and 1 study of Crohn's disease. In these studies, there were two intra-operative minor incidents connected to the closure mechanism that had been initiated too quickly (the cartridge had to be changed without further prejudice), but no injury was caused by this. Another two patients presented with enterorrhagy, after expectant management, both cases progressed without additional bleeding episodes. The articles did not reveal significant differences in the use, and complication rate of handling of the REACH stapler compared with the other two brands studied, therefore, the cost-effectiveness of the REACH product should be considered. While no stapler-related mortality was observed in those articles of the staplers. And there is no serious adverse events related to the stapler were reported in those studies. It’s fully proved the safety and effectiveness of The ENDO REACH Staplers family in clinical use.

The clinical studies demonstrated use of The ENDO REACH Staplers family as intended. It confirmed that the benefits associated with the intended use of the system outweighs the risks. It can improve the surgery, application in general, gynecological, pediatric and thoracic surgery for resection, transection, and creation of anastomoses with a good effect of safety and performance.

Search of ENDO GIA reloads was carried out on Aug. 08, 2024 to evaluate the clinical safety and performance of IREACH MAGNUM PLUS Reloads (IMS Reloads) and IREACH OMNIA Reload Units (IDS reloads). There were 19 clinical articles identified for full text review. The articles comprised a good level of evidence (12 Level 3 studies, 6 Level 4 studies and 1 Level 1 study per the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence).

The included studies evaluated a total of 1127 subjects on whom the equivalent devices were used, with reported ages ranging from 16 to 84 years old. Surgical operation involved are pancreatic resection, bronchial closure, liver resection, gastrectomy, bullae resection, lung cancer resection, radical cyctectomy, radical nephrectomy and vaginal hysterectomy. Reported outcomes demonstrated performance of the reloads as expnnected. No adverse events regarding the reloads were reported.

C3. Surveys

A questionnaire has been sent to the surgeons to evaluate properties concerning resection/transection or creation of anastomoses functions, and ergonomic design of the ENDO REACH Staplers. Through the analysis of the results obtained by the doctor's investigation, the doctor's operation as a whole meets the requirements of product use, and the doctor is satisfied with the use of Reach's product as a whole. Note: Due to the different listings of products in Europe, the number of survey samples for each product is different. Details data analysis reference sub-attachment file KF-000-LC-11-2021-06 report.

5.1 Summary of clinical data related to equivalent device

The ENDO RLC series (1st generation) used the own reports published in peer reviewed scientific literature to apply CE mark under MDD; When applicable for MDR in 2022, this device used the clinical investigations data on ENDO RLC 4535L, ENDO RLC 4548L, ENDO RLC 6035L ENDO RLC6048L models with ENDO RLC Stapler.

The ENDO SRC (2nd generation) used the clinical data of their equivalence device (Endo RLC (1st generation)) to apply CE mark.

The REC/IMS and ID/IDS reloads use the clinical data of their equivalent device (ENDO GIA reloads) to apply CE mark.

According to the comparison, the device under evaluation is equivalence with the predicate device in the following aspects:

Same clinical significance: two devices used for the same clinical condition or purpose, at the same site in the body, in a similar population; have the same relevant critical performance according to the expected clinical effect for the specific intended use.

Same technical: two devices were designed under the same principle, same mechanical structure, same testing requirements; and used under the same conditions; have the same theory, specifications, and similar principles of operation.

Same biocompatibility: two devices used similar materials which contact people, and with the same human tissues, also all were validated according to EN ISO 10993 series standard.

In summary, the Single Use Loading Units for Endoscopic Linear Cutting Staplers and Reload Units used a similar design concept, product structure, and manufacturing technology as ED. No brand new technology was introduced in the design phase of the product. And compared with the existing technologies there is not pose any new risks compared with the existing device.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking

The ENDO RLC series applicable for MDR in 2022, it used the clinical investigations data on ENDO RLC 4535L, ENDO RLC 4548L, ENDO RLC 6035L ENDO RLC6048L models with ENDO RLC Stapler. As a result, the Endo RLC Stapler shown no difference from those imported ones in anastomosis reliability and post-operational complications (anastomotic bleeding, anastomotic fistula, anastomosis gas leak, etc.), which indicated that Endo RLC Stapler reached the same level of imported ones and is a safe and effective stapler for the lung and stomach related surgeries.

For the other models of ENDO RLC/SRC/REC/AFT/IMS/ID/IDS, tthere has no clinical investigation was conducted. Clinical safety and performance were evaluated by clinical data of the equivalent device extracted from publicly published literatures and national vigilance data.

5.3 Summary of clinical data from other sources

According to the description and problems of PMS purpose in PMS plan and the principle of focusing on the continuous safety and effectiveness of products in post-marketing testing, summarize the PMS data and analysis summarized there is no new risk be found and the device is safe and effective.

In addition, we searched the clinical literature data on the product since its launch. We collected a total of 17 articles related to The ENDO REACH Series Staplers, with comprised a good level of evidence. While no death events or serious adverse events related to the stapler were reported in those studies, The ENDO REACH Staplers have been used in a clinical application with a good effect on performance for resection, transection, and creation of anastomoses in general, gynecological, pediatric, and thoracic surgery. It's fully proved the safety and effectiveness of ENDO REACH Staplers s in clinical use.

5.4 An overall summary of the clinical performance and safety

For this evaluation, clinical data held by Reach Surgical, Inc. comprised pre-clinical testing and post-market surveillance data.

From all the data reviewed, the sales figures of The ENDO REACH Staplers are 122,691 in 2021, there is no death or fatal injury event occurred yet. It was anticipated that using The ENDO REACH Staplers would not pose any new risks compared with the existing device.

As demonstrated by the clinical evaluation, The Staplers can improve the surgery, application in general, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses with a good effect on safety and performance, According to the literature search, we analyzed the collected literature and proved our claims that The Staplers have been associated with reducing surgical time compared to manual sewing techniques among patients in general procedures and fewer postoperative complication, such as short operative time, less intraoperative blood loss, etc.

Post-market surveillance included internal complaint reporting and public vigilance data. For internal complaint reporting, in total, for the subject devices during the reporting period, no death

or serious injuries were reported. A total of 95% of the failures were caused by doctors' failure to operate in accordance with the instructions, the training of doctors should be strengthened. Since 2018, the adverse events of The ENDO REACH Staplers in overseas markets have all come from the Brazilian market, and the probability of occurrence is 0.01%. And all adverse events were non-serious injury events. In a search of public vigilance databases, there is no death or fatal injury event occurred. And no recall or advisory notice related to The ENDO REACH Staplers were found.

We searched the clinical literature data on the product since it’s launched and collected a total of 17 articles with comprised a good level of evidence related to The ENDO REACH Staplers and SULUS. No stapler-related mortality was observed in those articles of The ENDO REACH Staplers. There were two intra-operative minor incidents connected to the closure mechanism that had been initiated too quickly (the cartridge had to be changed without further prejudice), but no injury was caused by this. Another two patients presented with enterorrhagia, after expectant management, both cases progressed without additional bleeding episodes. The articles did not reveal significant differences in the use, and complication rate of handling of the REACH stapler compared with the other two brands studied, therefore, the cost-effectiveness of the REACH product should be considered.

19 articles of ENDO GIA reloads were identified to evaluate safety and performance of IMS and IDS reloads. The included studies evaluated a total of 1127 subjects on whom the equivalent devices were used, with reported ages ranging from 16 to 84 years old. Surgical operation involved are pancreatic resection, bronchial closure, liver resection, gastrectomy, bullae resection, lung cancer resection, radical cystectomy, radical nephrectomy and vaginal hysterectomy. Reported outcomes demonstrated performance of the reloads as expected. No adverse events regarding the reloads were reported.

Based on this extensive review, we believe that Single Use Loading Units for Endoscopic Linear Cutting Staplers and Reload Units is designed and manufactured in such a way that, when used by trained persons under the conditions and for the purpose intended, the product will not

compromise the clinical condition(s) and safety of patients, the safety and health of users, or safety and health of other persons.

5.5 Ongoing or planned post-market clinical follow-up

Considering that the device directly contacts human tissue, it is necessary to have a clinical following-up evaluation, the device need to make the PMCF plan and report when they apply for MDR certification and updated the PMCF report at least throughout the life cycle of the device concerned with clinical data and PMS data.

5.6 Possible diagnostic or therapeutic alternatives

The devices and surgical techniques available for general, gynecological, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses are developed and evolved rapidly with the improvement of material science and engineering science. Besides the manual sutures, there are several alternative therapies in related fields including electrocautery devices, ultrasonic scalpel/shear, etc.

After firing by using the stapler in surgical procedures, the staple line should always be inspected for hemostasis. Minor bleeding can be controlled by electrocautery or manual sutures.

Eventually, the surgeon should select anastomotic materials according to the nutritional status of the patient, the nature of the operation, the wound site, and the characteristics of the suture tissue.

5.7 Suggested profile and training for users

IFU content that minimally invasive and stapling procedures should be performed only by persons who had formal education in the relevant field and familiarity with the techniques.

Consult relative medical literature for techniques, complications, and hazards prior to performing any open and minimally invasive procedure.

5.8 Reference to any harmonized standards and CS applied

Essential Standard List		
Item No.	**Standard No.**	**Standard Name**

Essential Standard List		
Item No.	**Standard No.**	**Standard Name**
1	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
2	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
3	CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
4	EN ISO 5832-1:2019	Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel
5	EN ISO 5832-2:2018	Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:2018)
10	EN ISO 14630：2012	Non-active surgical implants - General requirements (ISO 14630:2012
11	EN ISO 7153-1：2016	Surgical instruments - Materials - Part 1: Metals (ISO 7153-1:2016)
13	EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
14	EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014/Amd 1:2018)
15	EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)
16	EN 556-1:2001+AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
17	EN ISO 11737-1:2020	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products

Essential Standard List		
Item No.	**Standard No.**	**Standard Name**
18	EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
19	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
20	EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
21	EN ISO 11138-2:2017	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
22	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments. Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
23	EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
24	EN 17141:2020	Cleanrooms and associated controlled environments - Biocontamination control
25	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
26	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
27	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
28	EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)

Essential Standard List		
Item No.	**Standard No.**	**Standard Name**
29	EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/Amd 1:2019)
30	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
31	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
32	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials(ISO 10993-12:2021)
33	EN ISO10993-18:2020/A1	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process - Amendment 1: Determination of the uncertainty factor (ISO 10993-18:2020/Amd 1:2022)
34	EN ISO 10993-23：2021	Biological evaluation of medical devices - Part 23 Tests for irritation (ISO 10993-23：2021)
35	Scheer Guidance	Scientific Committee on Health, Environmental and Emerging Risks-SCHEER-UPDATE of the GUIDELINES on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties
36	EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1: Application of risk management (ISO 11607-1:2019/Amd 1:2023)
37	EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1: Application of risk management (ISO 11607-2:2019/Amd 1:2023)

Essential Standard List		
Item No.	**Standard No.**	**Standard Name**
38	ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
39	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical DevicesStandard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
40	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
41	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)

5.9 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
KF-H68-SZ-23 Issue Rev: 1.0	9-May-2023	Initial Release	☑Yes Validation language: EN language □No
KF-H68-SZ-23 Issue Rev: 1.1	27-Jun-2023	Change indication description.	☑Yes Validation language: EN language □No
KF-H68-SZ-23 Issue Rev: 1.2	16-Oct-2023	Update the following chapter: 5.1 ENDO SRC/REC equivalent device information; 1.4 BUDI code for material Ti-6Al-4VELI models; 4.2 Statement of how potential risks are being controlled or managed; 8. Standard list.	☑Yes Validation language: EN language □No
KF-H68-SZ-23	25-Oct-2023	1) 4.2.1~4.2.4 is adjusted to 4.3.1~4.3.4；	☑Yes Validation language: EN language

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
Issue Rev: 1.3		2）Add a description of ENDO RLC clinical trials to Clause 5.2; 3) Add OPEN surgery to Clause 7.	□No
KF-H68-SZ-23 Issue Rev: 1.4	10-Mar-2025	Add IMS/IDS models information in full files.	☑Yes Validation language: EN language □No