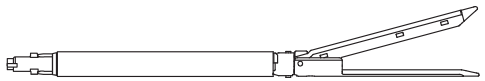
REACH SURGICAL | *iREACH* Omnia

IREACH OMNIA Reload Units



EN Reload Units
Instructions

Rev.A.0

CE 0197

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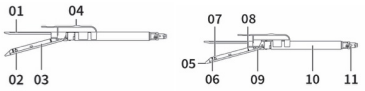
Illustrations

01



EN/English

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

Standard Conventions Used: Caution, WARNING, and Note Statements

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

Description

The **Omnia Reload Units** (hereinafter referred to as the Instrument) are sterile, single patient use Instrument that, when used with iReach Omnia Powered Articulating Staplers, can simultaneously cut and staple tissue. There are six staggered rows of staples, three on either side of the cut line.

Nomenclature – Reload Unit (Illustration 01)

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

Compatibility Information

The Instrument is only compatible with the Powered Articulating Staplers by the manufacturer. When the Instrument is used for minimally invasive surgery, a trocar is needed.

Product Specifications
Chart 01 - Reload Units Product Codes

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

ID6020B	Gray	60	2.0	0.75	Vascular	12
ID3025B	White	30	2.5	1.0	Thin	12
ID4525B	White	45	2.5	1.0	Thin	12
ID6025B	White	60	2.5	1.0	Thin	12
ID4535B	Blue	45	3.5	1.5	Medium	12
ID6035B	Blue	60	3.5	1.5	Medium	12
ID30TANB	Tan	30	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID45TANB	Tan	45	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID60TANB	Tan	60	2.0/2.5/3.0	0.75/1.0/1.25	Vascular/Thin	12
ID30PULB	Purple	30	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
ID45PULB	Purple	45	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12
ID60PULB	Purple	60	3.0/3.5/4.0	1.25/1.5/1.75	Medium/Thick	12

Intended Use

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

Indications

This instrument is intended to be used with the 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.

Intended User

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

Intended Use Environment

This instrument is intended to be used in a hospital.

Intended patient population

General population, including adults and children.

Clinical Benefits

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

Contraindications

- Do not use the Instrument on the aorta.
- Do not use the Instrument on ischemic or necrotic tissue.
- Do not use the Instrument on major vessels without making provision for proximal and distal control.
- Tissue thickness should be carefully evaluated before firing. Refer to the **Chart 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.

Side 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.

MR Conditional

Non-clinical testing has demonstrated the implantable staples are MR Conditional. A patient with the staples can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3.0-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm(40-T/m)
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 2- W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.
- Under the scan conditions defined, the Staple is expected to produce a maximum temperature rise of 1.8°C after 15-minutes of continuous scanning (i.e., per pulse sequence).
- In the non-clinical testing, the image artifact caused by the Staple extends approximately 3-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Instructions for Use

Refer to the Instructions document of the iReach Omnia Powered Articulating Staplers for more information about operating instructions.

Disposal

Once the Instrument is used, dispose properly according to local regulations. If the Instrument requires decontamination prior to disposal, follow the hospital protocol and local regulation.

Warnings and Precautions

- Examine the shipping carton and Instrument for signs of shipping damage. Note any shortages, breakage, or apparent damage, retain the evidence, notify Customer Service or Distributor immediately and replace with a new Instrument. Do not use a damaged product.
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Instruments for minimally invasive procedure may vary in diameter from manufacturer to manufacturer. When such Instruments and accessories from different manufacturers are employed together in a procedure, verify their compatibility prior to procedure.
- Do not use the Instrument if the shaft is visibly bent.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- The Instrument must be disposed after procedure once the package is opened.
- The Instrument is designed, inspected, and manufactured for single procedure only. Do not reuse, reprocess or resterilize the Instrument as it may compromise the structural integrity of the Instrument, and/or lead to Instrument failure that in turn may result in patient injury, illness, or death.
- Reusing the Instrument may create risk of contamination, infection, or cross-infection, including, but not limited to, the transmission of infectious diseases, which may lead to injury, illness, or death.
- After removing the Shipping Wedge, observe the surface of the Reload. The Reload Units must be replaced with another Reload Units if any staple tray is visible. (If staple tray is visible, the Reload may not contain staples.)
- Do not articulate when the jaws are closed.
- When selecting the Reload Units, careful consideration should be given to existing pathologic conditions as well as any pre-surgical treatment, such as radiotherapy, that the patient may have undergone. Certain conditions or preoperative treatments may cause change in tissue thickness that would exceed the indicated range of tissue thickness for the standard choice of Reload Units.
- Avoid using the Instrument adjacent to or stacked with another equipment. If it is necessary to use the Instrument adjacent or stacked with another Instrument, pay attention, and notice any abnormalities.
- Do not modify the Instrument without authorization from the manufacturer.
- Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this Instrument and result in improper function.
- The Instrument cannot be operated under oxygen enriched environment.
- A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to Reach Surgical, Inc. through Reachquality@reachsurgical.com and the competent authority of the Member State in which the user and/or patient is established.

Storage Requirements
Temperature: -10°C ~ 54°C
Relative Humidity: 0 % ~ 70 %

Transport Requirements
Temperature: -10°C ~ 54°C
Relative Humidity: 0 % ~ 70 %

Operating Environment Requirements
Temperature: 10°C ~ 40°C
Relative Humidity: 30 % ~ 75 %

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

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

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.