Disposable endoscopic linear cutter stapler&reloads

Microcure Medical Technology Co.,Ltd.

中华人民共和国医疗器械注册证

注册证编号：苏械注准 20172222515

注册人名称	微至（苏州）医疗科技有限公司
注册人住所	苏州高新区嘉陵江路 188 号
生产地址	苏州高新区嘉陵江路 188 号
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用腔镜下切割吻合器及组件
型号、规格	吻合器：WZULS-A-L、WZULS-A-S、WZULS-A-XL；组件：WZULS-P1-30-2.0、WZULS-P1-30-2.5、WZULS-P1-30-3.5、WZULS-P1-30-4.8、WZULS-P1-45-2.0、WZULS-P1-45-2.5、WZULS-P1-45-3.5、WZULS-P1-45-4.8、WZULS-P1-60-2.5、WZULS-P1-60-3.5、WZULS-P1-60-4.8、WZULS-P2-30-2.0、WZULS-P2-30-2.5、WZULS-P2-30-3.5、WZULS-P2-30-4.8、WZULS-P2-45-2.0、WZULS-P2-45-2.5、WZULS-P2-45-3.5、WZULS-P2-45-4.8、WZULS-P2-60-2.5、WZULS-P2-60-3.5、WZULS-P2-60-4.8
结构及组成	一次性使用腔镜下切割吻合器及组件主要由锁仓套、外套、上下调节外壳、锁销、推块、固定手柄、击发手柄、钉仓、支架、抵钉座、抵钉座盖、压板罩、保险板、缝合钉等零件组成。每把吻合器不自带组件。锁仓套、击发手柄、钉仓、压板罩由 PA 材料制成；外套、支架、抵钉座、抵钉座盖由不锈钢（06Cr19Ni10）制成；调节旋钮、上调节外壳、下调节外壳、锁销、固定手柄、保险板由 ABS 制成；推块由 POM 制成；切割刀由 20Cr13 材料制成；缝合钉由 TA18 制成。吻合器器身根据长度不同分为 WZULS-A-S、WZULS-A-L、WZULS-A-XL 三种规格。吻合器组件根据是否可以旋转分为标准型（P1）和旋转型（P2）两种型号；缝钉高度分为：2.0mm、2.5mm、3.5mm、4.8mm 四种规格；闭合长度分为：30、45、60 三种规格。因此，吻合器组件根据是否可旋转、缝钉高度和闭合长度可分为不同型号规格。吻合后的吻合口应承受不小于 3.6×10^3 Pa 压强，在 15 s 内漏水不超过 10 滴。产品经辐照灭菌后应无菌。
适用范围	适用于胃肠等消化道腔镜手术中组织的切除、横断和吻合。
附　件	产品技术要求
其他内容	
备　注	

审批部门：江苏省食品药品监督管理局　　批准日期：2017 年 12 月 26 日

有效期至：2022 年 12 月 25 日

中华人民共和国
医疗器械注册证

注册证编号：苏械注准 20212021734

注册人名称	微至（苏州）医疗科技有限公司
注册人住所	苏州高新区嘉陵江路 188 号
生产地址	苏州高新区嘉陵江路 188 号
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用腔镜用直线型切割吻合器及组件
型号、规格	器身：VES-A-L、VES-A-S、VES-A-XL、VES-B-L、VES-B-S、VES-B-XL。 组件：VES-P1-3025、VES-P1-3025E、VES-P1-3035、VES-P1-3035E、VES-P1-4525、VES-P1-4525E、VES-P1-4535、VES-P1-4535E、VES-P1-4540、VES-P1-4548、VES-P1-6025、VES-P1-6035、VES-P1-6040、VES-P1-6048、VES-P1-3025F、VES-P1-3025EF、VES-P1-3035F、VES-P1-3035EF、VES-P1-4525F、VES-P1-4525EF、VES-P1-4535F、VES-P1-4535EF、VES-P1-4540F、VES-P1-4548F、VES-P1-6025F、VES-P1-6035F、VES-P1-6040F、VES-P1-6048F； VES-P2-30B、VES-P2-30BE、VES-P2-30P、VES-P2-45B、VES-P2-45BE、VES-P2-45P、VES-P2-45H、VES-P2-60B、VES-P2-60P、VES-P2-60H、VES-P2-30BF、VES-P2-30BEF、VES-P2-

CONTENTS

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Project Background

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Stapler History

Who invented the stapler??

1909 : Dr. Humer ÜltIt invented the first stapler

Do the two generations of staplers look alike?

Stapler invented by the Russians

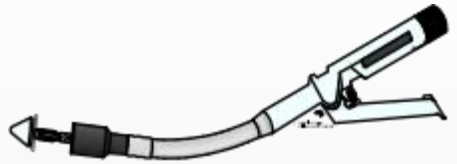
- Dr. Hultl is a surgeon in Budapest. He and his friend instrument designer Fischer successfully developed a repeatable linear stapler for gastroduodenal surgery in 1908.
- On May 9 of the same year, Dr. Hultl successfully used the stapler for gastric cancer resection. In the following 30 years, staplers were developed in Hungary and Germany. Mr. Fischer has applied for patents in European countries.
- During the Second World War, the Russians applied the Hungarian stapler technology to the operation of the wounded. After World War II, a research institute was established in Moscow to develop staplers. However, due to social mechanism reasons, in the later period, stapler technology did not make much progress。

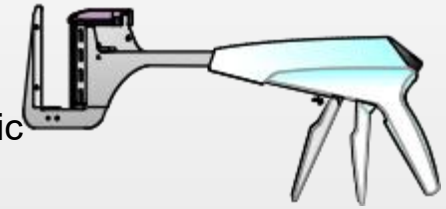
Stapler History

American-developed stapler

Johnson & Johnson ETHICON a Johnson & Johnson company VS Medtronic 美敦力

1958 American physician Mark Ravitch, MD visits Russia
1960 Established American Surgical Company to imitate and produce staplers (Medtronic—Medtronic)
1978 The first single-use skin stapler is introduced (ETHICON-Johnson & Johnson)
1979 Reusable circular stapler (ETHICON)
1980 Disposable circular stapler (Medtronic)
1985 The single-use stapler with replaceable staple cartridges was introduced (ETHICON);
1988 Multifire TA (Medtronic) updated circular stapler
1989 Introducing the linear cutter stapler (ETHICON)
1992 (Johnson & Johnson) ETHICON Endoscopic Surgical Company was established in Cincinnati, USA





1993 Launched a new generation of disposable circular staplers, vascular linear cutting staplers (ETHICON Endoscopic Surgery), Premium Multifire TA (Medtronic)
2015 Covidien (Medtronic) Medtronic introduces the iDrive™ intelligent motion platform - the first electric smart cutting stapler in history. It can not only automatically adjust the firing speed and fire at a constant speed, but also give feedback when the thickness of the grasped tissue is too thick, reminding the doctor to change the position or replace the nail with another height, which effectively improves the safety of the tissue during the anastomosis process. Not to mention that the infinite rotation of the angle of the nail cartridge can be realized by simply manipulating the button at the handle, which greatly facilitates the operation of the doctor.

Type distinction

Surgical stapler products developed in the market today

1. Stapler products for open surgery

Linear Stapler---LS (Linear Stapler)
Linear Cutting Stapler---CTS (Linear Cutter)
Circular Stapler---CS (Circular Stapler Cutter)
Purse --- APS (Auto Purse String)
Thick Curved Cut Contour Stapler---CLC(Overseas Market)
Hemorrhoid Stapler---PPH
Titanium clip

2. Stapler series for endoscopic surgery

Laparoscopic Cutting Stapler——ULS\VES

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Principle classification

Principle of Stapler

The working principle of various staplers and staplers is similar to that of a stapler, that is, two or more rows of staples arranged in parallel and misplaced are fired and implanted into the tissue. After passing through the two layers of tissue, the staples are blocked by the anvil groove in front, and bend inward to form a "B" shape that is misaligned with each other, and the two layers of tissue are permanently stapled together. Since small blood vessels can pass through the gap of the "B"-shaped staple, it does not affect the blood supply of the sutured site and its distal end. This kind of staple can achieve a stable and reasonable relaxation effect, which is conducive to the healing of the anastomotic tissue .

Principle classification

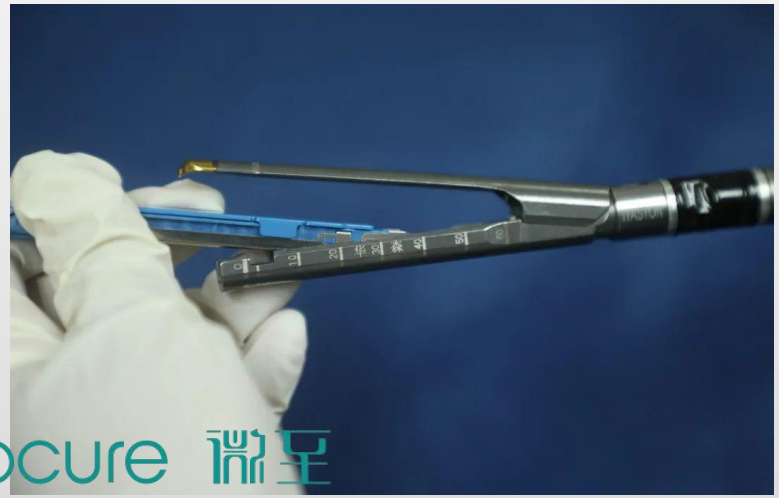
Stapler type	Function	Applicable scope
Linear Stapler	tissue linear suture	Closure of bronchi, esophagus, stomach, intestines, blood vessels, etc.
Circular Stapler	The anastomosis of the cavity, the circular knife cuts off the excess tissue, and forms a circular anastomosis	Anastomosis of esophagus, stomach and other digestive tracts
Linear Cutting Stapler	Tissues are sutured linearly, and tissues are cut and separated at the same time	Stomach and jejunum side-to-side anastomosis, intestinal-intestinal side-to-side anastomosis, esophagus fabrication, incomplete pulmonary fissure separation, partial lung resection, etc.
Purse	purse-string suture	Esophageal and Gastrointestinal Surgery
Skin Fascial Stapler	Fast stapling of skin incisions	longer skin incisions
Laparoscopic Stapler	Stapler developed for thoracic and laparoscopic surgery	laparoscopic surgery

Laparoscopic style

ETHICON
a Johnson & Johnson company

VS

Medtronic
美 敦 力



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02

Product introduction

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Product introduction

Disposable endoscopic linear cutter stapler&reloads

Cutting Components - "Nails"

- Offers two sets of three rows (6 rows) of staples (titanium staples)
- Cut tissue down the middle while suturing
- 3 rows of staples on the specimen side, 3 rows on the patient side

Sterilization method: irradiation

Validity period: 3 years

Stapler body —— “gun”

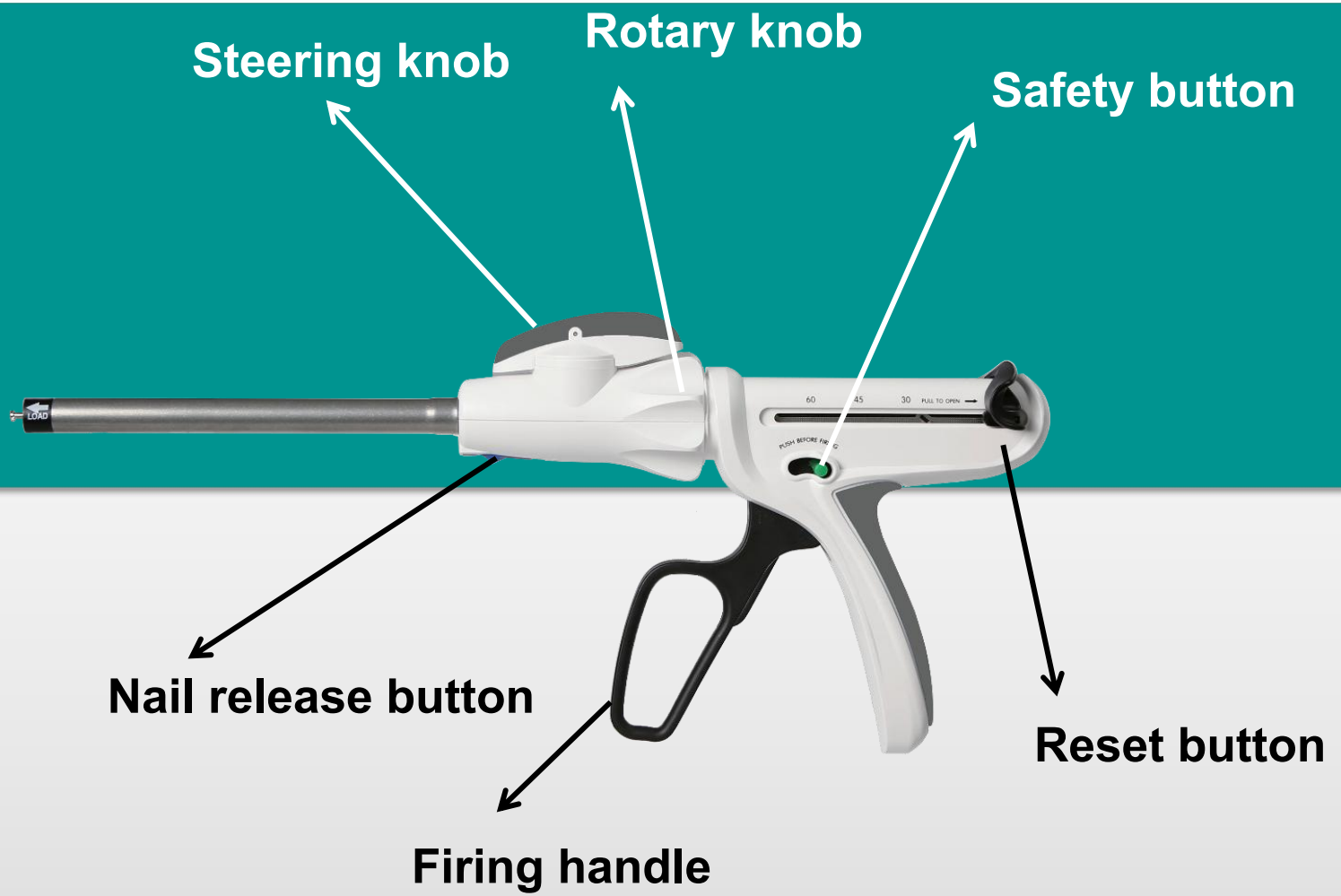
- For single patient use in one procedure
- Various body lengths meet different clinical needs
- Rubberized surface, more comfortable to hold

Product introduction

Stapler body —— “gun”

efficient

concise



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Product Features

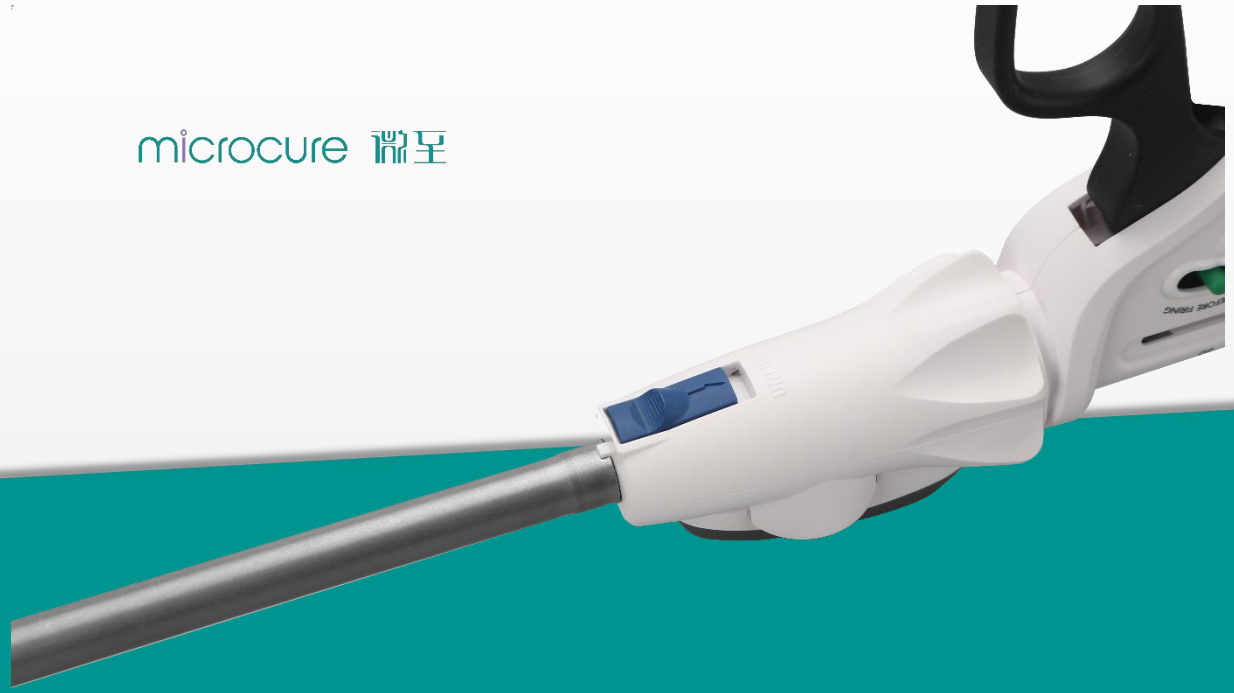
Steering knob

- The unique pinball steering system makes the turning operation more stable
- Five adjustment positions, up to 45 degrees from left to right

Smooth, light and labor-saving

Product Features

Nail release button

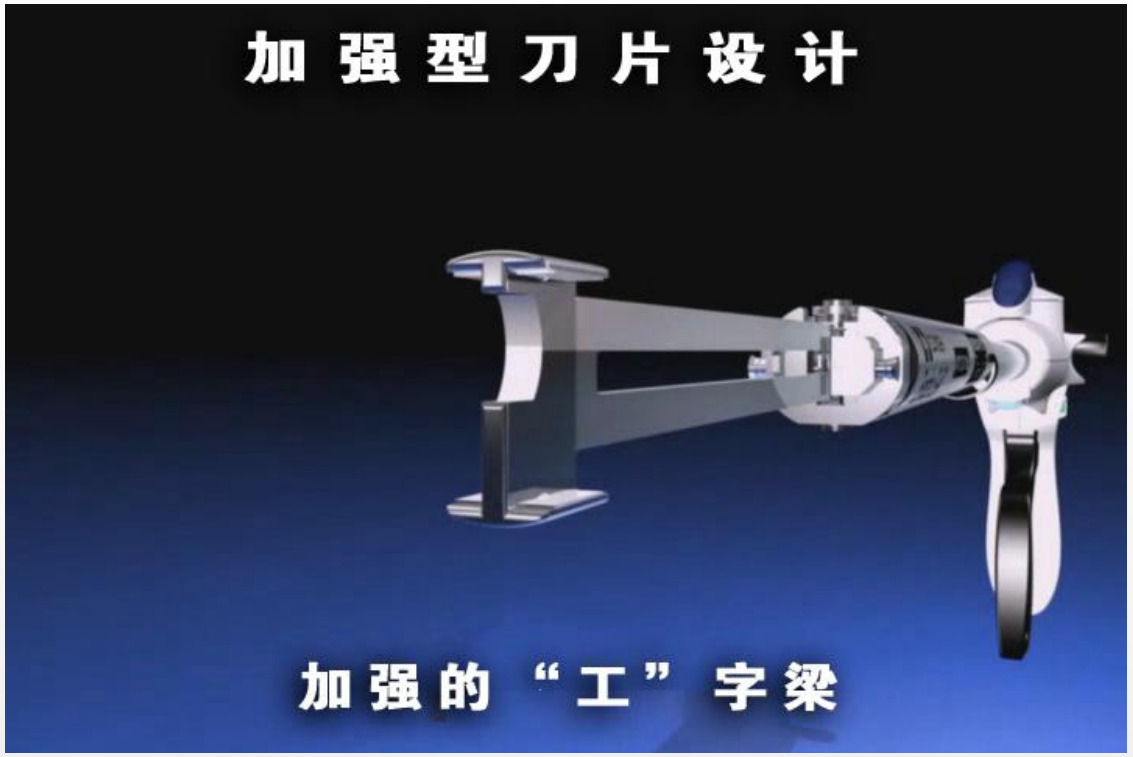


- Located at the front of the rotary knob (at the bottom of the connecting rod), it is more convenient to remove nails
- The bottom of nail release button is equipped with a red indicator mark, which can indicate whether the nail is installed or not.

Product Features

Inner structure of stapler body

- **Strengthened "工" beam nail anvil, nail bin and blade linkage device：** ensures that the staples are accurately formed at the distal end and the proximal end, and that the staple lines are consistent.
- **Meanwhile, the rack is equipped with a "fusing" mechanism：** When the maximum firing force exceeds the maximum bearing force of the drive rack, the rack breaks and the operator is prompted to replace the device
- **large pressing force when cutting thick tissues and ensuring the forming height of nails.**



Product Features

Stapler body features summary

✓ Universal gun body: fully compatible with a variety of components (6 types of staple cartridges, 3 suture lengths)	✓ Steering knob:The unique pinball steering system makes the turning operation stable,light and labor-saving	✓ Firing handle: with a larger leverage ratio design, the firing is more labor-saving	✓ Reset button： Unique oblique plane design, easy to pull back after firing, saving effort
✓ Nail release button： Located at the front of the rotary knob (at the bottom of the connecting rod).The bottom is equipped with a red indicator mark, which can indicate whether the nail is installed or not.	✓ the rack equipped with a "fusing" mechanism： When the maximum firing force exceeds the maximum bearing force of the drive rack, the rack breaks and the operator is prompted to replace the device	✓ Rubberized handle design:more comfortable to hold and increase friction during surgery	✓ From raw materials to finished products, the gun body has undergone strict sterilization operations, and finally irradiated to ensure that the product is sterile

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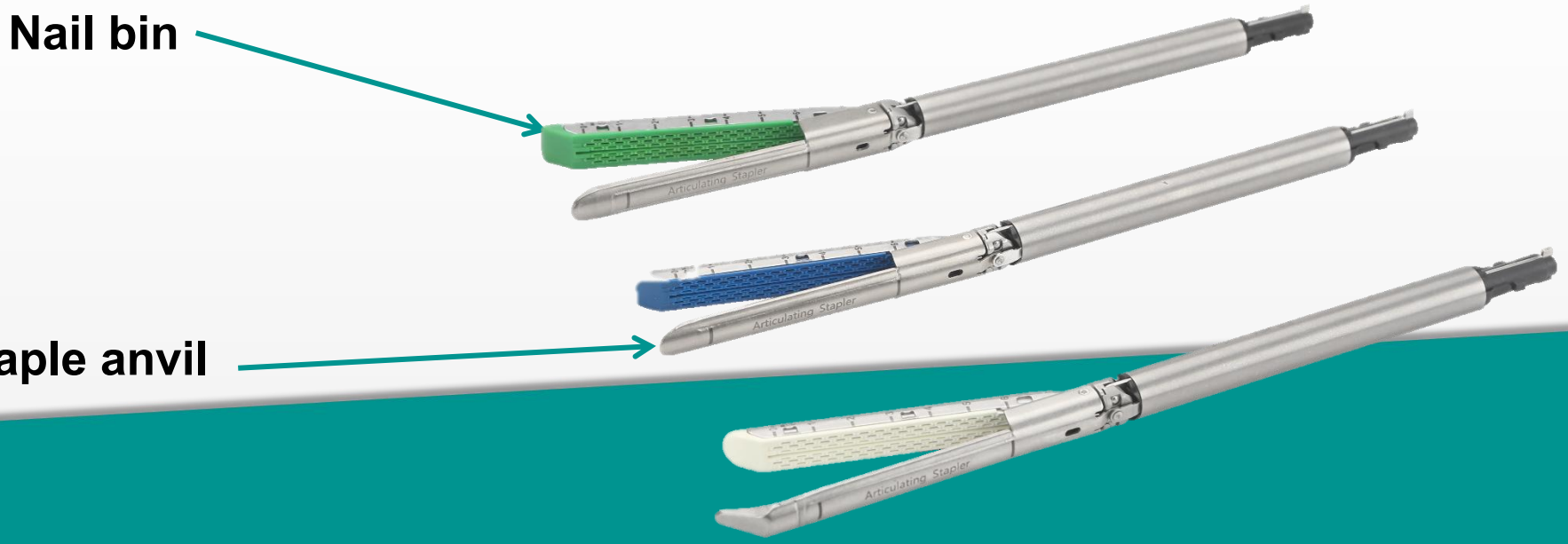
Product Introduction

Cutting Components - "Nails"



- The middle is a cutting line with three rows of staples on each side.
- The cutting knife is accommodated in the assembly

Product Features

The special" droplets" shaping groove design

- can ensure B-shape staple stapler formation and pocide better hemostatic effect and air tightness effect for clinical operation

Product Features

Unibody nail anvil

- It adopts complex machining and heat treatment to provide more stable clamping force for clinical use and ensure no deformation when clamping thicker tissues.
- When firing, the anvil remains fixed and the staple cartridge moves.

Product Features

“Olecranon ” separating hook:

- Can be used for blunt separation and free tissue during operation.
- The frequency of instrument replacement during operation can be reduced.
- Can easily pass through blood vessels embedded in tissues.

Product Features

Cutting components features summary

droplets" shaping groove design: ensure B-shape staple stapler formation Reduced risk of bleeding, poor sutures	**Unibody nail anvil:** complex machining and heat treatment ensure no deformation when clamping thicker tissues.	**Strengthened "工" beam nail anvil blade** (blade strength over 3000N), ensures that the staples are accurately formed at the distal end and the proximal end, and that the staple lines are consistent.
"Olecranon " separating hook: easily pass through blood vessels embedded in tissues; used for blunt separation and free tissue during operation	Gecko Claw Design: Increase the staple guide during suturing to ensure the stability of the staple, while reducing the overflow of the clamped tissue during firing and improving the suture effect	Alligator mouth spill-proof design:A unique crocodile mouth design is added to the front of the staple cartridge to increase the front-end barrier during the cutting process to ensure that the tissue cannot come out

03

Model Specifications

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Model Specifications

Stapler body Specifications

WZULS-A-L

Stapler body-third identifier

XL: Extension rod(for laparoscopic bariatric surgery)

L: Standard rod(for general laparoscopic surgery)

S: Short rod(for thoracoscopic or open surgery)

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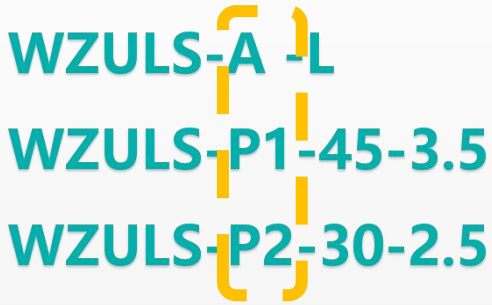
Model Specifications

Cutting components Specifications



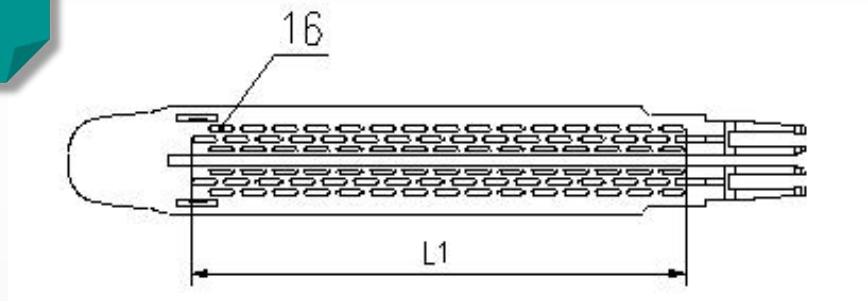
The second digit identifies model number：

A：stapler body

P1： Standard reloads

P2： Articulating reloads

Model Specifications



WZULS-P1-45-3.5

WZULS-P2-30-2.5

Cutting Components - the third identifier refers to the length of the suture:

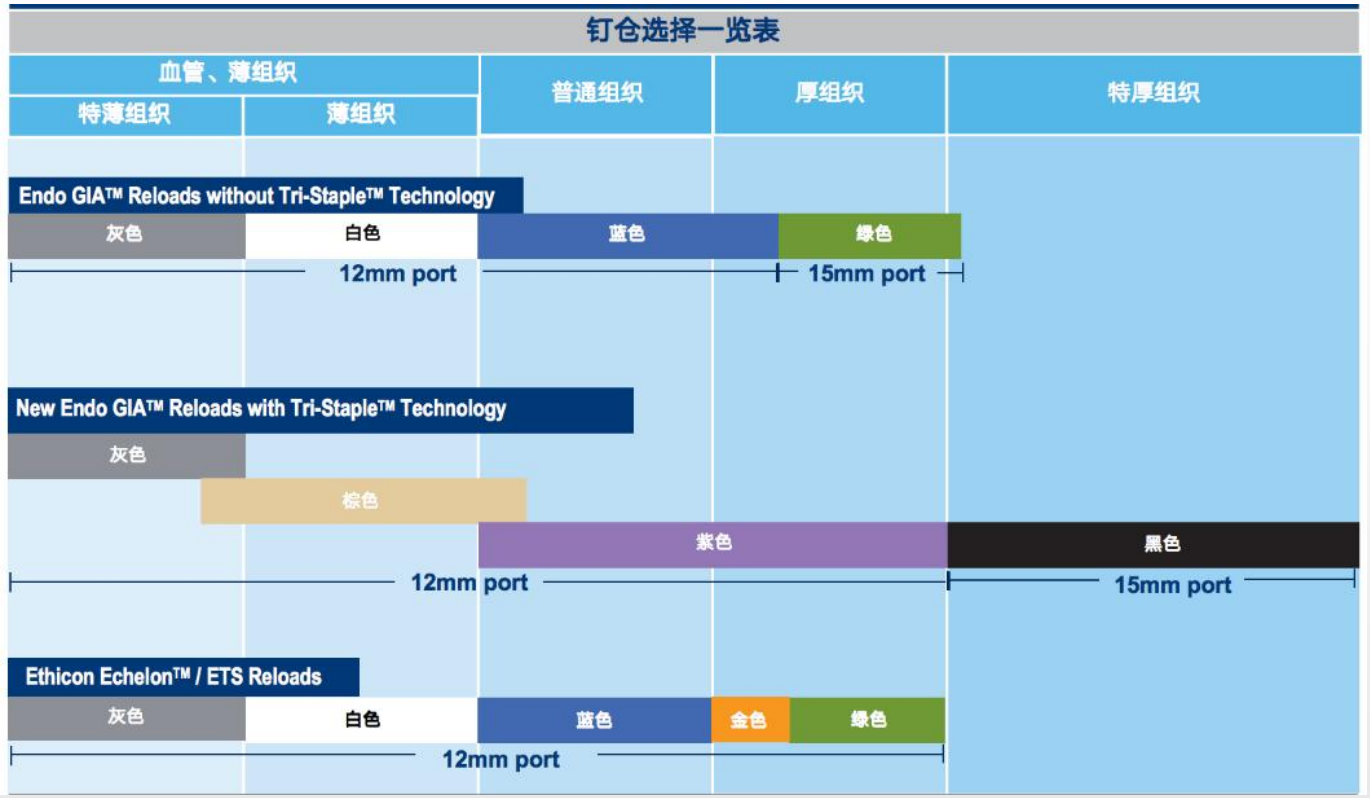
30/45/60 three length --Size of suturing tissue

Cutting Components - the fourth identifier refers to the height of the staple:

2.5/3.5/4.8 three height –Thickness of suturing tissue

COLOR OF RELOADS	Staple height mm	Applicable surgery
	4.8	Main bronchus, pulmonary lobe
	3.5	Tissue of normal thickness, gastrointestinal tract
	2.5	Small bowel laparoscopic surgery

Model Specifications



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Model Specifications

STAPLER/RE-LOADS	MODELS	SPECIFICATIONS mm	COLOR OF RELOADS
STAPLER BODY	WZULS-A	L	N/A
	WZULS-A	S	N/A
	WZULS-A	XL	
Standard reloads	WZULS-P1	30-2.5	
	WZULS-P1	45-2.5	
	WZULS-P1	45-3.5	
	WZULS-P1	45-4.8	
	WZULS-P1	60-2.5	
	WZULS-P1	60-3.5	
	WZULS-P1	60-4.8	
Articulating reloads	WZULS-P2	30-2.5	
	WZULS-P2	45-2.5	
	WZULS-P2	45-3.5	
	WZULS-P2	45-4.8	
	WZULS-P2	60-2.5	
	WZULS-P2	60-3.5	
	WZULS-P2	60-4.8	

04

Using method

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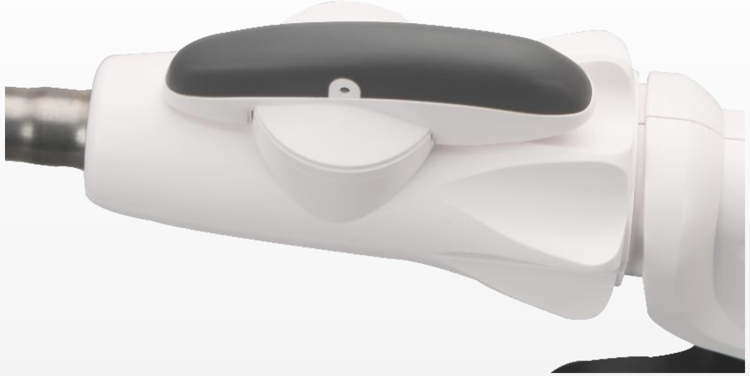
Using method

A.Install nails
B.Firing
C.Unload nails

1.Clear the gun：

- Confirm that the rotating knob is at the angle of o degree.

And pull the reset button back to the original position.

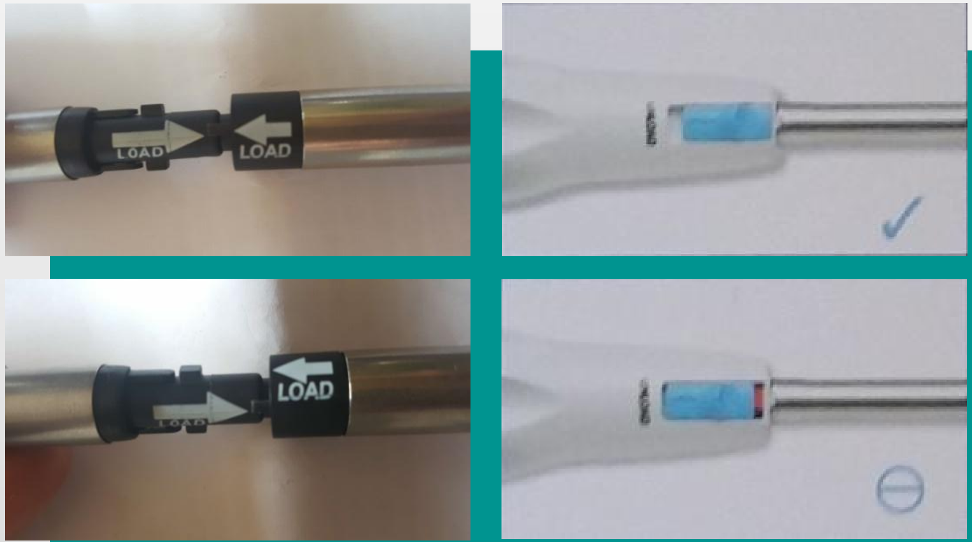


2.Assembly：

- The arrows are aligned, butting first, pressing to the bottom and then rotating.
- whether the blue nail removal button returns to its original position. Red indicates that it is not installed in place

3.Remove the protective cover：

- After confirming that the staple cartridge is loaded in place, remove the yellow protective cover
- gently hold the black handle to close the jaws, pull open the black release key to open the jaws, proving that the installation is in good condition. *(Please do not press the trigger before the yellow protective cover is removed, otherwise it may cause damage to the device)*



Using method

A. Install nails | B.Firing | C.Unload nails

1.Place instruments

- Close the jaws by gripping the black handle, and insert the instrument into the trocar or incision protective sleeve.
- Push the black handle forward again to open the staple cartridge.

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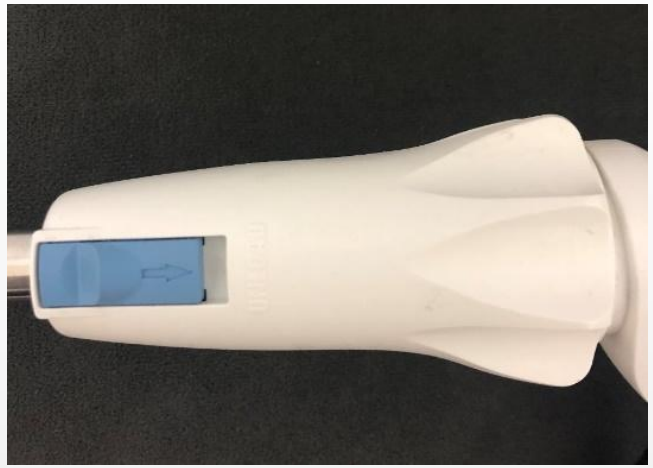
Using method

A. Install nails → B.Firing → C.Unload nails

2.Clamping tissue

- Withdraw the reset button and open the component port
- Two adjustment modes: 360 degree wave rotation and unidirectional 45 degree knob
- Select the appropriate angle, bring the tissue into the incision area, press the firing handle, and clamp the tissue



Using method

A. Install nails → B.Firing → C.Unload nails

3.Press the safety button：

- The green safety button can be pressed from either side of the stapler body, and the black handle will open forward to the firing position

Using method

A. Install nails → B.Firing → C.Unload nails

4.Firing stapler:

- Hold the black handle firmly at a constant speed each time, use the ***15-second uniform firing method, fully pull and fully release,*** advance 15mm every time you fully pull, until you can't hold it anymore

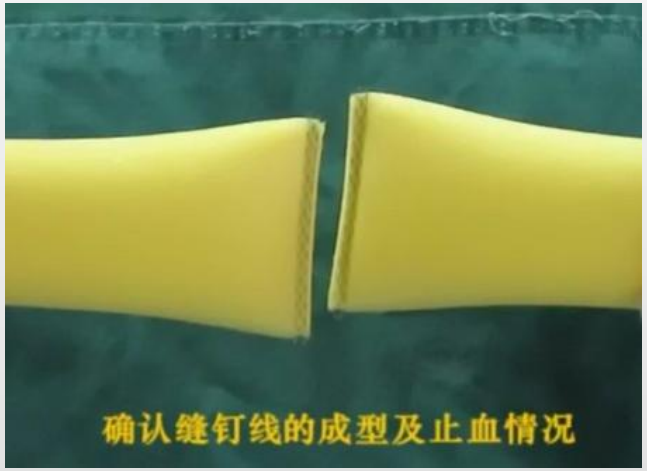
15-second uniform firing method

a. After the jaws are closed, keep them closed for 15 seconds before firing

b. Hold the handle tightly and wait for 15 seconds each time after firing to let the interstitial fluid fully drain before performing the next pull

Using method

A. Install nails → B.Firing → C.Unload nails



5. Release jaw:

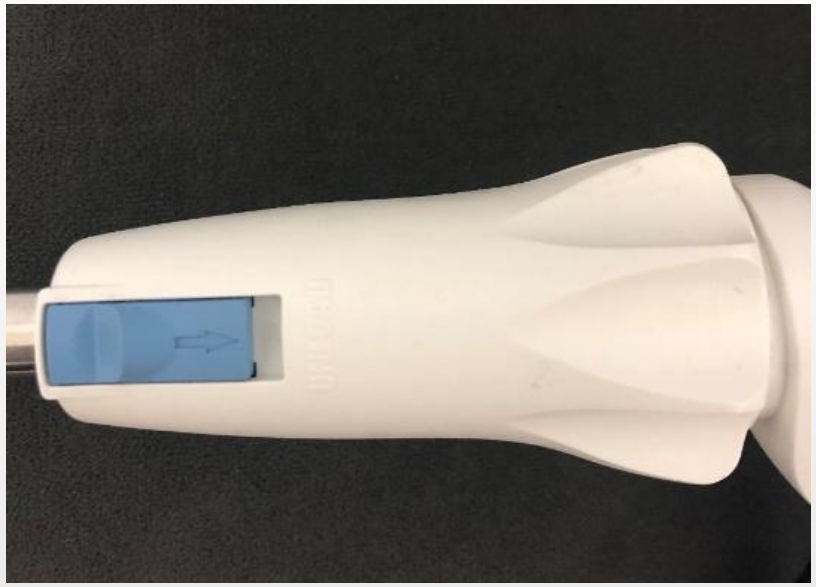
- After confirming full firing, pull back the reset button to release the tissue
- Hold the black handle tightly again, close the opening of the staple cartridge, and take it out from the trocar sleeve

Using method

A.Install nails → B.Firing → C.Unload nails

1. Remove the cutting assembly:

- Pull down the nail release button, turn the cutting assembly counterclockwise, and remove the staple cartridge
- If anastomosis still needs to be performed, take a new cutting assembly and install it in the above-mentioned manner.



In Perfection We believe

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Add：1-101 No.188,Jialingjiang Road,Suzhou
Tel：0512-62916112
Email：export@microcure.com.cn