

mechanism and make unloading difficult or even impossible without damaging the stapler.

- The anvil must be completely past the trocar sleeve prior to opening the reload within the body cavity.
- Placement of tissue proximal to the tissue stops (on the reload) may result in stapler malfunction. Any tissue extending beyond the black “cut” line on the reload will not be transected, all tissue placed within the “cut” line will be transected.
- 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 that the tissue lies flat and is evenly distributed inside the stapling range prior to closing the jaws. “Bunching” tissue may result in staple malformation, poor haemostasis and/or leakage.
- Always completely fire the reload. Partial firing leads to incomplete cut and/or staple malformation, which may result in poor haemostasis and/or leakage.
- The device is equipped with a safety interlock to prevent an empty or partially-fired reload from being fired a second time. Do not attempt to override the safety interlock, as it will cause device malfunction.
- If the clamping or firing mechanism fails to work (excessive resisting force), do not continue with the action. Remove and carefully check the stapler-reload structural integrity following the IFU. The use of excessive force may result in device damage, injury, or tissue damage.
- After firing and removal of the device, always inspect the staple line and the surrounding site for air sealing / haemostasis of the anastomosis line and to see whether the staples are closed properly. Minor bleeding or leakage may be treated by electrocautery, manual suture or other appropriate methods.
- In a single procedure, any JQ series stapler may be reloaded and fired up to 25 times with any JQ or JJII reload. In a single procedure, a BL series stapler may be reloaded and fired up to 12 times with BLR reloads.
- Dispose of all opened devices whether used or unused. Devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination; relevant local regulations shall be respected.
- The implantable staples are MR conditional.

4. PRINCIPLES OF OPERATION

Device is composed of a stapler and a reload. Under normal conditions of use, one procedure needs one stapler and one or multiple reloads. The Device mechanically and simultaneously transforms the “squeezing” force applied on the active handle into:

- Clamping force between the anvil and the cartridge to compress and hold the tissue in the jaws;
- Jacking force to push the “U” shape staples to pierce through the tissue, to form “B” shaped staples against the anvil to close/anastomose the tissue;
- Cutting force to push the knife to transect and separate the tissue in the middle of the two triple rows of staples, formed by the “B” shape staples.

Figure 4-1 Repetitive squeezing to cut and staple the tissue

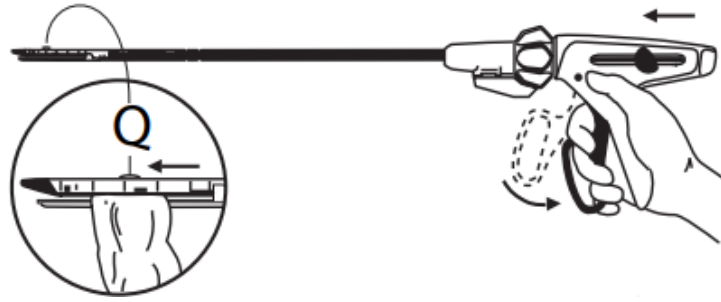
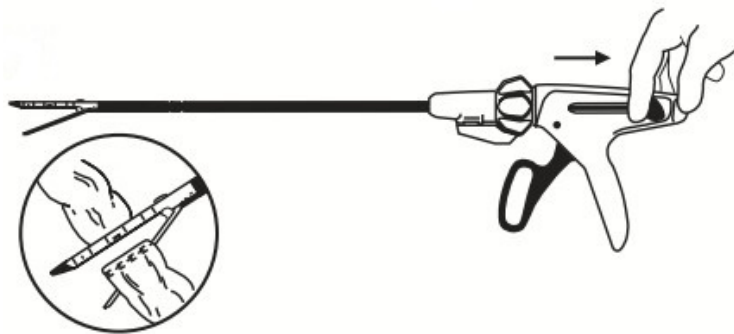


Figure 4-2 Tissue anastomosis / haemostasis / cutting completed



By repeatedly squeezing the active handle till complete firing (number of squeezing actions depends on the length of the staple line), the surgeon may accomplish the actions of anastomosis, resection, and/or transection on the target tissue one squeeze at a time.

5. QUALIFICATION OF THE PRODUCTS AS A DEVICE

As described in **Section 4 - Principles of Operation**, the product is a mass-produced instrument, intended to treat or alleviate human diseases, by cutting and stapling/anastomosing human tissue, using pure mechanical force without any pharmacological, immunological or metabolic means, on one individual during a single procedure. The product is intended to be partially introduced into the human body by clinical intervention, part of the product (staples) may remain in place after the procedure for at least 30 days.

Based on these properties and the definitions of Chapter I, Article 2 of the Medical Device Regulation (EU) 2017/745 (hereinafter referred to as MDR), the product may be qualified as a single-use implantable medical device.

6. RISK CLASS OF THE DEVICE

The risk class of the Device is established according to Annex VIII of the MDR.

The Device is a non-active device composed of a stapler and reload. The staples, which are in the reload, are the only implantable elements. The stapler and the reload (minus the staples)

are only used to apply the staples and cut tissue, and are therefore in short-term contact with human tissue.

Duration of use of the Device is categorized according to Annex VIII, Chapter I, Section 1 of the MDR. Since the stapler and reload (minus the staples) are in contact with human tissue only for simultaneous cutting and staples application in surgery, they belong in the “Transient” category (normally intended for continuous use for less than 60 minutes). The staples, however, are implantable, and therefore belong in the “Long term” category (normally intended for continuous use for more than 30 days).

According to Annex VIII, Chapter I, Section 2.2 of the MDR, the entire Device is an invasive device because it “penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation”.

Rule 6 of Annex VIII of the MDR, which states that “all surgically invasive devices intended for transient use are classified as class IIa,” places the stapler and reload (minus the staples) in class IIa. The exceptions listed in Rule 6 are not applicable to the Device.

Rule 8, which states that “all implantable devices and long-term surgically invasive devices are classified as class IIb”, places the staples in class IIb. The exceptions listed in Rule 8 are not applicable to the Device.

Section 3.5 states that the stricter rule shall apply, therefore the Device is in class IIb.

7. NOVEL FEATURES / DEVICE HISTORY

This is a legacy device and was first CE-marked and introduced in the market in accordance with the Medical Device Directive (Council Directive 93/42/EEC amended by Directive 2007/47/EC, hereinafter referred to as MDD) in 2014. The notified body was TÜV Rheinland. The current certificate has an expiration date of 2023-06-04. No significant changes have been introduced and no unacceptable risks have occurred in terms of design, materials, clinical procedures, anatomical locations, target populations, or the state of the art in stapling industry in general. There are no previous generations of the device.

The manufacturing method and process of some components/parts have evolved over the past decade, with the introduction of new precise machining and high-speed precise injection machines. These machines improve the productivity and contribute largely to the stability, reproducibility, and quality of the product.

8. ACCESSORIES AND DEVICE COMBINATIONS

The Device can be used alone, without accessories. It may be used with general surgical devices such as trocars or graspers, but they are not required. The Device is designed to be used alone, fulfilling its intended operations of resection, transection, and/or anastomosis without other indispensable accessories or combinations. It does not have any accessories.

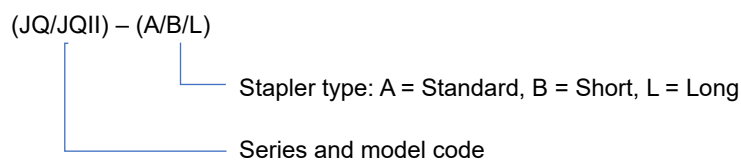
9. LIST OF CONFIGURATIONS AND VARIANTS OF THE DEVICE

The Device is composed of a stapler and a reload. Available configurations and variants of the staplers and reloads are described in this chapter.

Two series of staplers exist: JQ & BL. Each series provides two models: JQ & JQII, BLE & BLC, offering four models in total. Each model has numerous variants (codes) with different specifications in terms of shaft length and anvil length.

Three series of reloads exist: JQ, JJII, and BLR. Each series provides two models: JQZ & JQD, JJIIZ & JJIID, BLRS & BLRP, offering six models in total. JQ and JJII reloads are for use with JQ series staplers, and BLR reloads are used with BL staplers. Each model has numerous variants (codes) with different specifications in terms of staple height and staple line length.

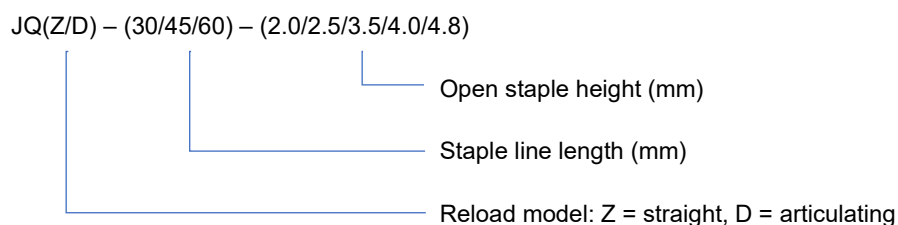
JQ series stapler models & variants are coded according to the following rules:



*Examples: JQ-A represents a JQ model stapler with a standard-length shaft;
JQIIL represents a JQII model stapler with a long shaft.*

The JQII model stapler is an modified version of the JQ model. In addition to “look and feel” changes such as the rubber-coating of the fixed handle, the embellishment of the articulating lever, etc., JQII offers a different handling option. The closed stapler jaws are opened by pushing the active handle forward and releasing it, enabling the surgeon to single-handedly change and reposition the Device to a different site. In comparison, the JQ model stapler requires the surgeon to pull the return knob with another hand.

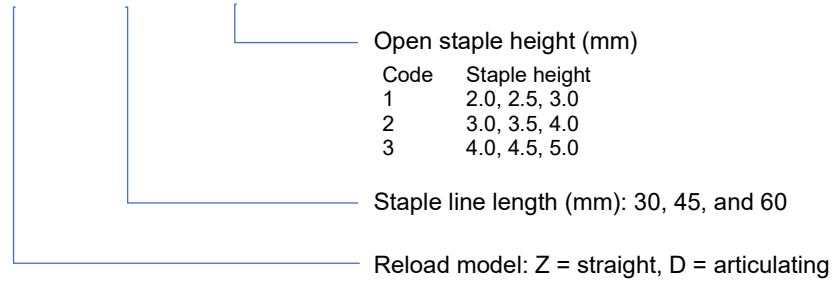
JQ series reload models and variants are coded according to the following rules:



*Examples: JQZ-30-2.0 represents a JQZ model straight reload with 30mm staple line length and 2.0mm height staples;
JQD-60-4.8 represents a JQD model articulating reload with 60mm staple line length and 4.8mm height staple*

JJII series reload models and variants are coded according to the following rules:

JJII(Z/D) – (30/45/60) – (1/2/3)



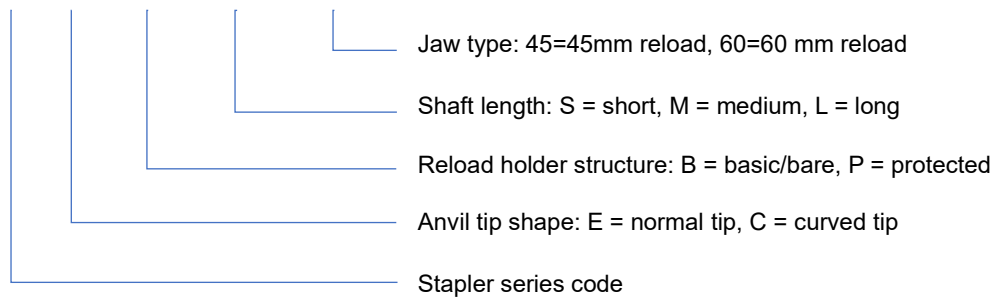
*Examples: JJIIZ301 represents a JJIIZ model straight reload with 30mm staple line length and 1st/2nd/3rd row of staple heights = 2.0/2.5/3.0mm;
 JJIID603 represents a JJIID model articulating reload with 60mm staple line length and 1st/2nd/3rd row of staple heights = 4.0/4.5/5.0mm.*

All JQ & JJII reload series, both straight and articulating, may be used with JQ or JQII stapler models indiscriminately. For illustrations of straight and articulating reloads, see sections 10.5-10.8 of this document.

Stapler Model	Variants	Reload Models
JQ	JQ-(A/B/L)	JQ(Z/D)-(30/45/60)-(2.0/2.5/3.5/4.0/4.8)
JQII	JQII(A/B/L)	JJIIZ(30/45/60)(1/2/3) JJIID(30/45/60)(1/2/3)

BL series stapler models and variants are coded according to the following rules:

BL – (E/C) – (B/P) – (S/M/L) – (45/60)



*Examples: BLEBM45 represents a BLE model stapler with normal anvil tip, a medium shaft, and a basic reload holder that may host a 45mm reload;
 BLCPL60 represents a BLC model stapler with curved anvil tip, a long shaft, and a protected reload holder that may host a 60mm reload.*

The BLC model offers a curved end anvil tip, providing ease of manipulation and better access underneath tissue/vessels. The reload holder structure may be covered/protected (P) or basic/bare (B) to facilitate the stapler’s movement in the body cavity.

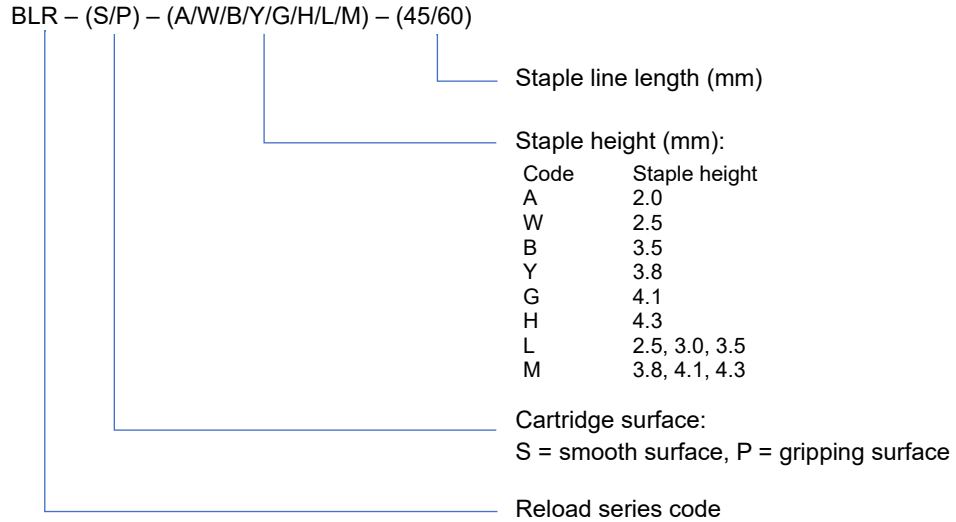


Back view of a basic/bare reload holder structure



Back view of a protected reload holder structure

BLR series reload models and variants are coded according to the following rules:



Example: BLRSA45 represents a BLR model reload with smooth surface cartridge, 2.0mm height staples, and 45mm staple line length;
BLRPH60 represents a BLR model reload with gripping surface cartridge, 4.3mm height staples, and 60mm staple line length;
BLRSM60 represents a BLR model reload with smooth surface cartridge, holding 3 different heights of staples (3.8, 4.1, 4.3 mm), and 60mm staple line length;

BLR series reloads may be used with BL series staplers. For illustrations of normal and curved anvil tips, see sections 10.3 and 10.4 of this document.

Stapler Model	Types	Reload Models
BL	BL(E/C)(B/P)(S/M/L)(45/60)	BLR(S/P)(A/W/B/Y/G/H/L/M)(45/60)

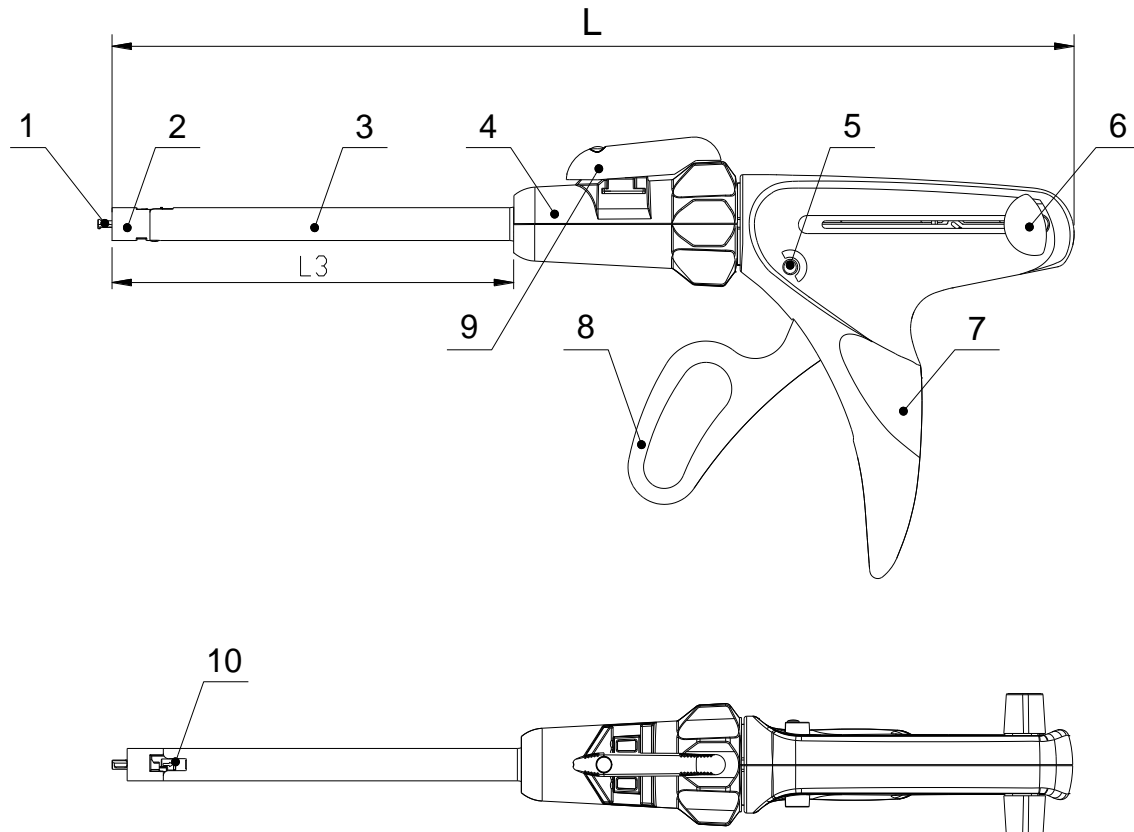
The available models & variants of reloads and the corresponding specifications are listed in Table 12-2 of this document.

10. KEY FUNCTIONAL ELEMENTS

10.1. Key Functional Elements of JQ Model Stapler

The key functional elements of the JQ model stapler are schematically illustrated in the following figures.

Figure 10-1 Key functional elements of JQ model stapler

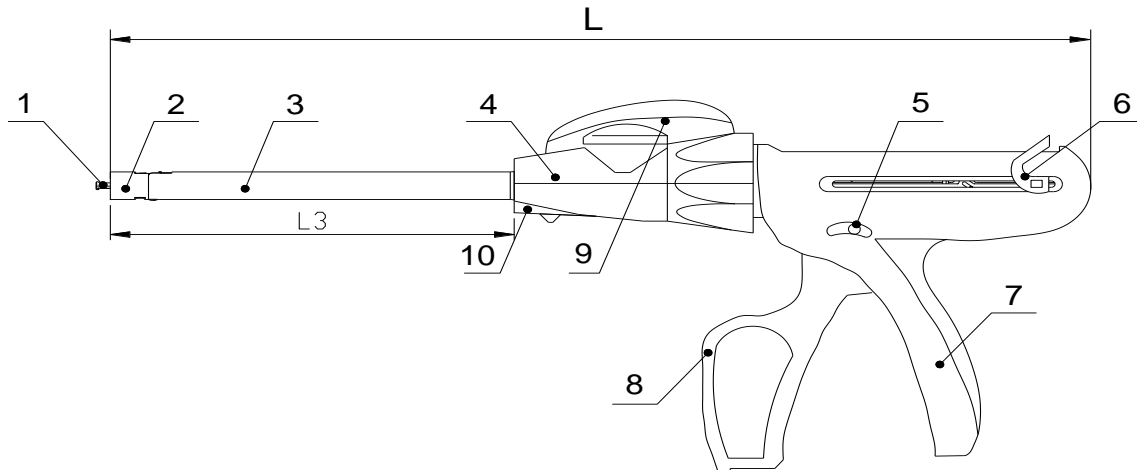


1. **Pin:** connection/disconnection between the stapler and the reload;
2. **Internal rod:** supports internal mechanical parts;
3. **Shaft:** penetration through trocar sleeve or incision;
4. **Rotation collar:** to rotate the shaft freely 360° in both directions;
5. **Safety button:** safety lock to prevent unintentional or inadvertent firing, to be pressed just before firing;
6. **Black return knob:** to open the reload jaws and return the knife to home position;
7. **Fixed handle:** to hold the stapler with one hand;
8. **Movable handle:** to close the jaws or to fire the reload;
9. **Articulating lever:** to pivot the distal portion of articulating reloads left or right, up to 45° on each side;
10. **Unload button:** to unload the reload.

10.2. Key Functional Elements of JQII Model Stapler

The key functional elements of JQII model stapler are schematically illustrated in the following figures.

Figure 10-2 Key functional elements of JQII model stapler

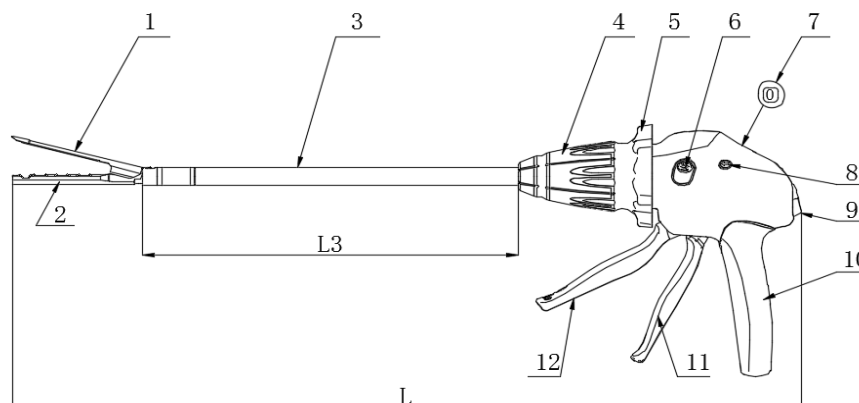


1. **Pin:** connection/disconnection between the stapler and the reload;
2. **Internal rod:** supports internal mechanical parts;
3. **Shaft:** penetration through trocar sleeve or incision;
4. **Rotation collar:** to rotate the shaft freely 360° in both directions;
5. **Safety button:** safety lock to prevent unintentional or inadvertent firing, to be pressed just before firing;
6. **Black return knob:** to open the reload jaws and return the knife to home position;
7. **Fixed handle:** to hold the stapler with one hand;
8. **Movable handle:** to open/close the jaws or to fire the reload;
9. **Articulating lever:** to pivot the distal portion of articulating reloads left or right, up to 45° on each side;
10. **Unload button:** to unload the reload.

10.3. Key Functional Elements of BLE Model Stapler

The key functional elements of BLE model stapler are schematically illustrated in the following figures.

Figure 10-3 Key functional elements of BLE model stapler

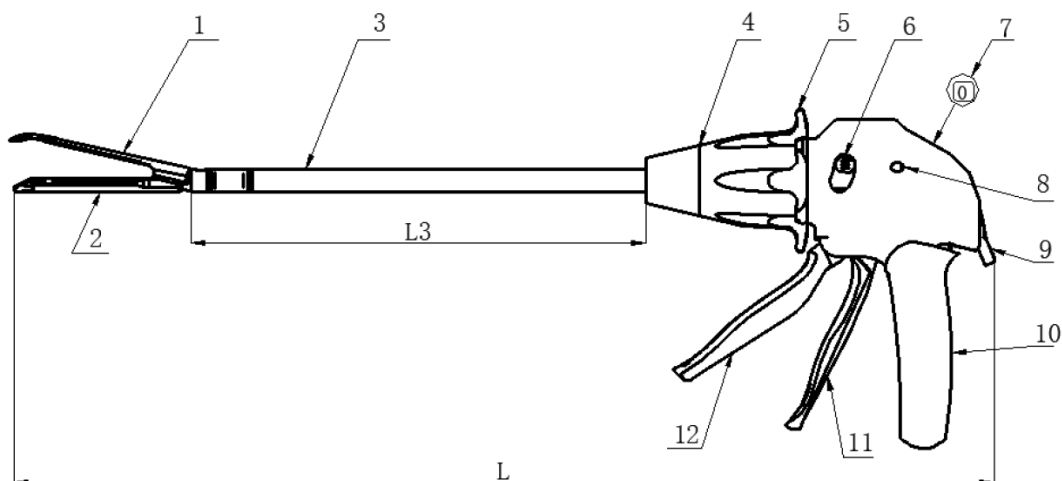


1. **Anvil:** to form the staples into “B” shape, with a normal tip;
2. **Reload holder:** to house the reload;
3. **Shaft:** penetration through trocar sleeve or incision;
4. **Rotation collar:** to rotate the shaft freely 360° in both directions;
5. **Articulating fins:** apply lateral force to articulate the jaws to a desired angle, release to maintain them in the desired angle, and pull to reset to neutral position;
6. **Manual knife reverse switch:** to reverse the knife direction, allowing to pull back the knife by squeezing the firing handle;
7. **Knife position window:** to show the knife position in a character wheel;
8. **Knife direction indication:** to indicate the knife direction (forward/backward);
9. **Release button:** To release the anvil and open the jaws;
10. **Fixed handle:** to hold the stapler;
11. **Closing handle:** to clamp the jaws on the tissue;
12. **Firing handle:** to fire the reload, or (when the knife reverse switch is activated) to pull back the knife.

10.4. Key Functional Elements of BLC Model Stapler

The key functional elements of BLC model stapler are schematically illustrated in the following figures.

Figure 10-4 Key functional elements of BLC model stapler

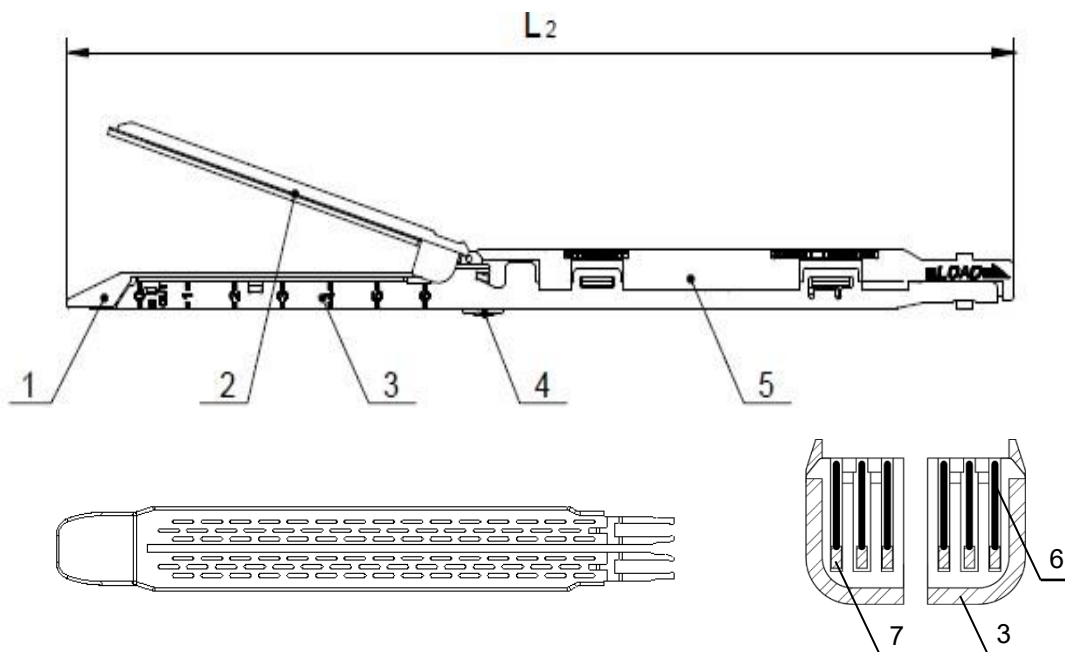


1. **Anvil:** to form the staples into “B” shape, with a curved tip;
2. **Reload holder:** to house the reload;
3. **Shaft:** penetration through trocar sleeve or incision;
4. **Rotation collar:** to rotate the shaft freely 360° in both directions;
5. **Articulating fins:** apply lateral force to articulate the jaws to a desired angle, release to maintain them in the desired angle, and pull to reset to neutral position;
6. **Manual knife reverse switch:** to reverse the knife direction, allowing to pull back the knife by squeezing the firing handle;
7. **Knife position window:** to show the knife position in a character wheel;
8. **Knife direction indication:** to indicate the knife direction (forward/backward);
9. **Release button:** To release the anvil and open the jaws;
10. **Fixed handle:** to hold the stapler;
11. **Closing handle:** to clamp the jaws on the tissue;
12. **Firing handle:** to fire the reload, or (when the knife reverse switch is activated) to pull back the knife.

10.5. Key Functional Elements of JQZ Model Straight Reload

The key functional elements of JQZ model straight reload are schematically illustrated in the following figures.

Figure 10-5 Key functional elements of JQZ model straight reload

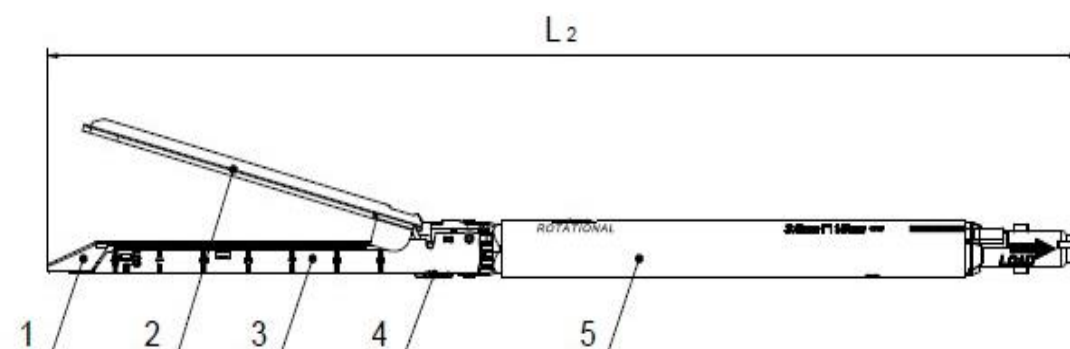


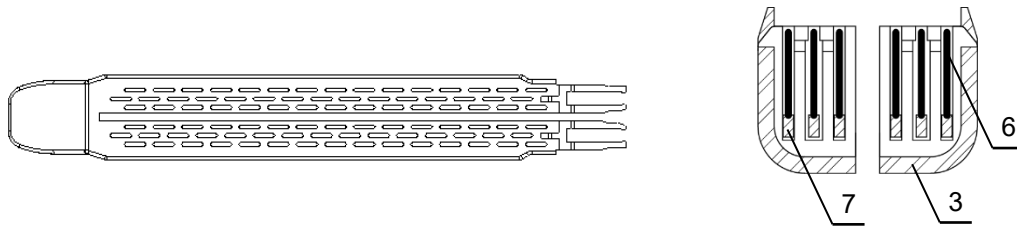
1. **Cartridge:** filled with two triple-staggered rows of staples of the same height;
2. **Anvil:** to form the staples into "B" shape;
3. **Cartridge holder:** to hold the cartridge;
4. **Knife position indicator:** to indicate the knife position;
5. **Shaft protector:** to support and protect reload mechanical parts.
6. **Staple**
7. **Staple pusher**

10.6. Key Functional Elements of JQD Model Articulating Reload

The key functional elements of JQD model articulating reload are schematically illustrated in the following figures.

Figure 10-6 Key functional elements of JQD model articulating reload



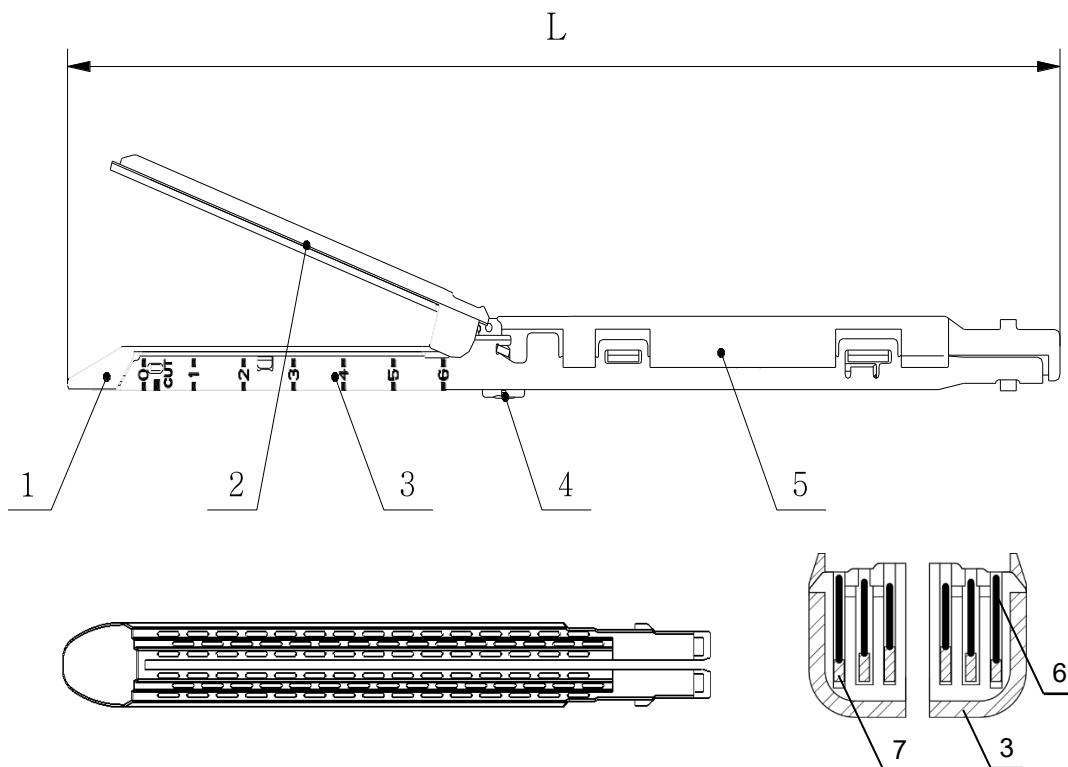


1. **Cartridge:** filled with two triple-staggered rows of staples of the same height;
2. **Anvil:** to form the staples into “B” shape;
3. **Cartridge holder:** to hold the cartridge;
4. **Knife position indicator:** to indicate the knife position;
5. **Shaft protector:** to support and protect reload mechanical parts.
6. **Staple**
7. **Staple pusher**

10.7. Key Functional Elements of JJIIZ Model Straight Reload

The key functional elements of JJIIZ model straight reload are schematically illustrated in the following figures.

Figure 10-7 Key functional elements of JJIIZ model straight reload

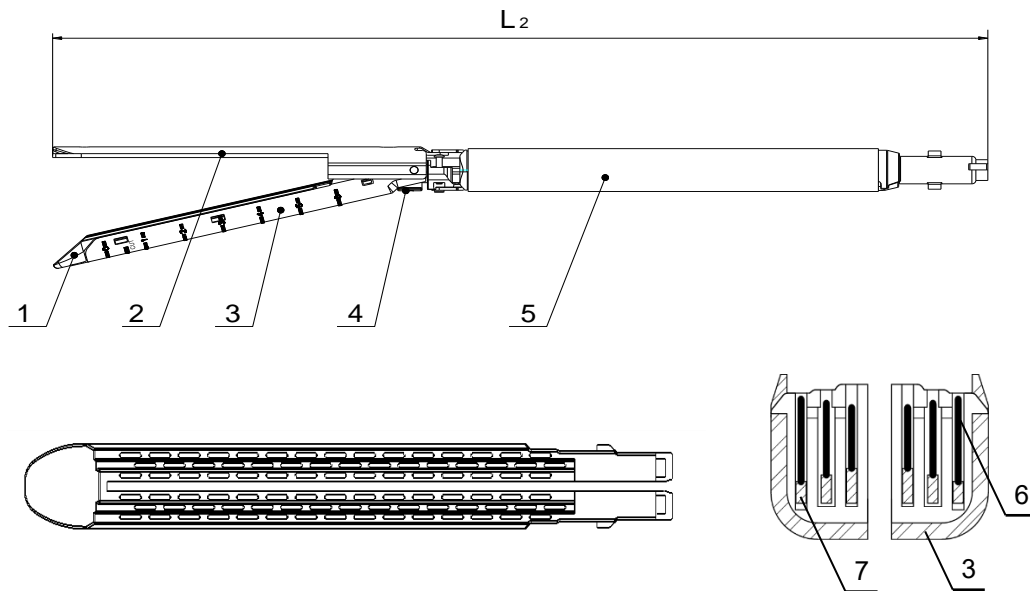


1. **Cartridge:** filled with two triple-staggered height-progressive rows of staples;
2. **Anvil:** to form the staples into “B” shape;
3. **Cartridge holder:** to hold the cartridge;
4. **Knife position indicator:** to indicate the knife position;
5. **Shaft protector:** to support and protect reload mechanical parts.
6. **Staple**
7. **Staple pusher**

10.8. Key Functional Elements of JJIID Model Articulating Reload.

The key functional elements of JJIID model articulating reload are schematically illustrated in the following figures.

Figure 10-8 Key functional elements of JJIID model articulating reload

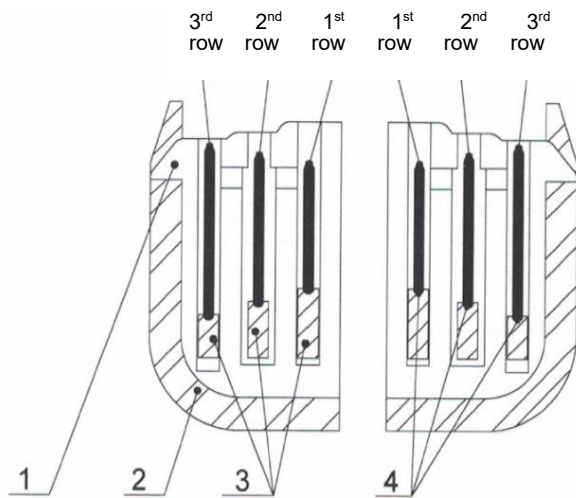


1. **Cartridge:** filled with two triple-staggered height-progressive rows of staples;
2. **Anvil:** to form the staples into "B" form;
3. **Cartridge holder:** to hold the cartridge;
4. **Knife position indicator:** to indicate the knife position;
5. **Shaft protector:** to support and protect reload mechanical parts.
6. **Staple**
7. **Staple pusher**

10.9. Key Functional Elements of BLRS Model Reload

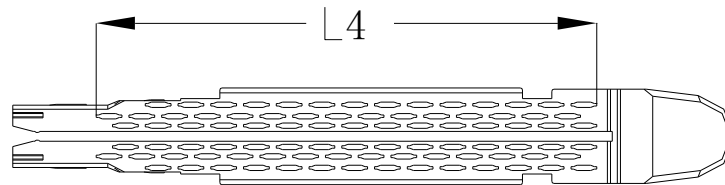
The key functional elements of BLRS model smooth surface cartridge reload are schematically illustrated in the following figures.

Figure 10-9 Key functional elements of BLRS model smooth surface reload



Sectional view of a BLR series reload with two triple-staggered height progressive rows of staples

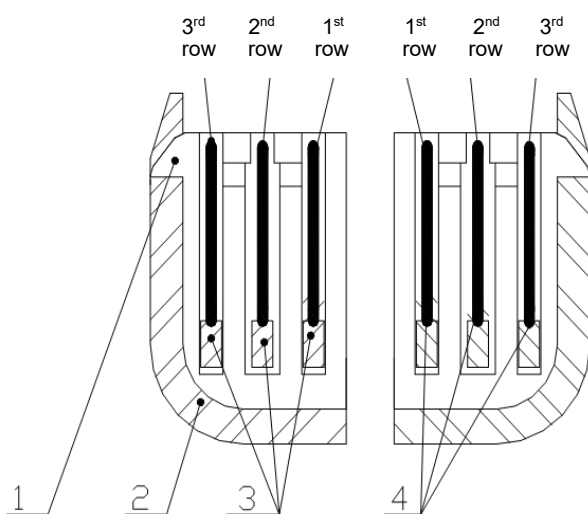
1. Cartridge
2. Cartridge holder
3. Staple pusher
4. Staples of progressive heights



10.10. Key Functional Elements of BLRP Model Reload

The key functional elements of BLRP model gripping surface cartridge reload are schematically illustrated in the following figures.

Figure 10-10 Key functional elements of BLRP model gripping surface cartridge reload



Sectional view of a BLR series reload with two triple-staggered flat rows of staples

1. Cartridge
2. Cartridge holder
3. Staple pusher
4. Staples of same height

Return spring	SUS304	/	No contact	/	/
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12. TECHNICAL SPECIFICATIONS

12.1 Technical Specifications of Staplers

The staplers' available models and variants, as well as the corresponding specifications, are listed in the following table.

Table 12-1 List of models & variants of staplers, and the specifications

JQ series staplers			
Stapler model & variant (code)	Shaft length L3 (mm, ±10mm)	Total stapler length L (mm, ±10mm)	Specifications
JQ-A	155	370	JQ stapler with standard-length shaft
JQ-B	105	320	JQ stapler with short shaft
JQ-L	255	470	JQ stapler with long shaft
JQIIA	155	378	JQII stapler with standard-length shaft
JQIIB	105	328	JQII stapler with short shaft
JQIIL	255	478	JQII stapler with long shaft
BL series staplers			
Stapler model & variant (code)	Shaft length L3 (mm, ±15mm)	Total stapler length L (mm, ±20mm)	Specifications
BLEBS45	190	455	Normal anvil tip form, basic reload holder structure 45mm, short shaft
BLEBS60	190	468	Normal anvil tip form, basic reload holder structure 60mm, short shaft
BLEBM45	250	515	Normal anvil tip form, basic reload holder structure 45mm, medium shaft
BLEBM60	250	528	Normal anvil tip form, basic reload holder structure 60mm, medium shaft
BLEBL45	350	615	Normal anvil tip form, basic reload holder structure 45mm, long shaft
BLEBL60	350	628	Normal anvil tip form, basic reload holder structure 60mm, long shaft
BLEPS45	190	455	Normal anvil tip form, protected reload holder structure 45mm, short shaft
BLEPS60	190	468	Normal anvil tip form, protected reload holder structure 60mm, short shaft
BLEPM45	250	515	Normal anvil tip form, protected reload holder structure 45mm, medium shaft
BLEPM60	250	528	Normal anvil tip form, protected reload holder structure 60mm, medium shaft
BLEPL45	350	615	Normal anvil tip form, protected reload holder structure 45mm, long shaft
BLEPL60	350	628	Normal anvil tip form, protected reload holder structure 60mm, long shaft
BLCBS45	190	455	Curved anvil tip form, basic reload holder structure 45mm, short shaft
BLCBS60	190	468	Curved anvil tip form, basic reload holder structure 60mm, short shaft
BLCBM45	250	515	Curved anvil tip form, basic reload holder structure 45mm, medium shaft
BLCBM60	250	528	Curved anvil tip form, basic reload holder structure 60mm, medium shaft
BLCBL45	350	615	Curved anvil tip form, basic reload holder structure 45mm, long shaft
BLCBL60	350	628	Curved anvil tip form, basic reload holder structure 60mm, long shaft
BLCPS45	190	455	Curved anvil tip form, protected reload holder structure 45mm, short shaft
BLCPS60	190	468	Curved anvil tip form, protected reload holder structure 60mm, short shaft

BLCPM45	250	515	Curved anvil tip form, protected reload holder structure 45mm, medium shaft
BLCPM60	250	528	Curved anvil tip form, protected reload holder structure 60mm, medium shaft
BLCPL45	350	615	Curved anvil tip form, protected reload holder structure 45mm, long shaft
BLCPL60	350	628	Curved anvil tip form, protected reload holder structure 60mm, long shaft

The worst case representatives are the staplers with the longest shaft. For BL, it is the stapler with both the longest shaft and the longest corresponding cut line.

12.2 Technical Specifications of Reloads

The reloads' available models and variants, as well as the corresponding specifications, are listed in the following table.

Table 12-2 List of models & variants of reloads, and the specifications

Reload model: JQZ , straight cartridge, for use with JQ & JQII model staplers						
Reload variant (code)	Open staple height (mm, ±0.2mm)	Reload/ Cartridge colour	Tissue thickness range (mm)	Staple line length (mm, ±2.0mm)	Reload length L2 (mm, ±5.0mm)	Number of staples
JQZ-30-2.0	2.0	Gray	0.75 – 1.00	30.0	170	48
JQZ-30-2.5	2.5	White	1.00 – 1.50			
JQZ-30-3.5	3.5	Blue	1.50 – 2.00			
JQZ-30-4.0	4.0	Gold	1.70 – 2.20			
JQZ-30-4.8	4.8	Green	2.00 – 2.50		178	
JQZ-45-2.0	2.0	Gray	0.75 – 1.00	43.0	184	66
JQZ-45-2.5	2.5	White	1.00 – 1.50			
JQZ-45-3.5	3.5	Blue	1.50 – 2.00			
JQZ-45-4.0	4.0	Gold	1.70 – 2.20			
JQZ-45-4.8	4.8	Green	2.00 – 2.50		193	
JQZ-60-2.0	2.0	Gray	0.75 – 1.00	60.0	199	90
JQZ-60-2.5	2.5	White	1.00 – 1.50			
JQZ-60-3.5	3.5	Blue	1.50 – 2.00			
JQZ-60-4.0	4.0	Gold	1.70 – 2.20			
JQZ-60-4.8	4.8	Green	2.00 – 2.50		209	
Reload Model: JQD , articulating cartridge, for use with JQ & JQII model staplers						
Reload variant (code)	Open staple height (mm, ±0.2mm)	Reload/ Cartridge colour	Tissue thickness range (mm, ±0.2mm)	Staple line length (mm, ±2.0mm)	Reload length L2 (mm, ±5.0mm)	Number of staples
JQD-30-2.0	2.0	Gray	0.75 – 1.00	30.0	205	48
JQD-30-2.5	2.5	White	1.00 – 1.50			
JQD-30-3.5	3.5	Blue	1.50 – 2.00			
JQD-30-4.0	4.0	Gold	1.70 – 2.20			
JQD-30-4.8	4.8	Green	2.00 – 2.50		213	
JQD-45-2.0	2.0	Gray	0.75 – 1.00	43.0	217	66
JQD-45-2.5	2.5	White	1.00 – 1.50			
JQD-45-3.5	3.5	Blue	1.50 – 2.00			
JQD-45-4.0	4.0	Gold	1.70 – 2.20			
JQD-45-4.8	4.8	Green	2.00 – 2.50		225	
JQD-60-2.0	2.0	Gray	0.75 – 1.00	60.0	233	90
JQD-60-2.5	2.5	White	1.00 – 1.50			
JQD-60-3.5	3.5	Blue	1.50 – 2.00			
JQD-60-4.0	4.0	Gold	1.70 – 2.20			
JQD-60-4.8	4.8	Green	2.00 – 2.50		241	
Reload model: JJIIZ , straight cartridge, for use with JQ & JQII model staplers						
Reload variant (code)	Open staple heights (mm, ±0.2mm, 1 st row: nearest to outline, 3 rd row: farthest to outline)	Reload/ Cartridge colour	Tissue thickness range (mm, ±0.2mm)	Staple line length (mm,	Reload length L2 (mm, ±5.0mm)	Number of staples

	1 st row	2 nd row	3 rd row			±2.0mm)		
JJIIZ301	2.0	2.5	3.0	Tan	0.88 – 1.50	30.0	202	48
JJIIZ302	3.0	3.5	4.0	Purple	1.50 – 2.25			
JJIIZ303	4.0	4.5	5.0	Black	2.25 – 3.00			
JJIIZ451	2.0	2.5	3.0	Tan	0.88 – 1.50	43.0	217	66
JJIIZ452	3.0	3.5	4.0	Purple	1.50 – 2.25			
JJIIZ453	4.0	4.5	5.0	Black	2.25 – 3.00			
JJIIZ601	2.0	2.5	3.0	Tan	0.88 – 1.50	60.0	232	90
JJIIZ602	3.0	3.5	4.0	Purple	1.50 – 2.25			
JJIIZ603	4.0	4.5	5.0	Black	2.25 – 3.00			
Reload model: JJII D, articulating cartridge, for use with JQ & JQII model staplers								
Reload variant (code)	Open staple heights (mm, ±0.2mm, 1 st row: nearest to cutline, 3 rd row: farthest to cutline)			Reload/ Cartridge colour	Tissue thickness range (mm, ±0.2mm)	Staple line length (mm, ±2.0mm)	Reload length L2 (mm, ±5.0mm)	Number of staples
	1 st row	2 nd row	3 rd row					
JJIID301	2.0	2.5	3.0	Tan	0.88 – 1.50	30.0	202	48
JJIID302	3.0	3.5	4.0	Purple	1.50 – 2.25			
JJIID303	4.0	4.5	5.0	Black	2.25 – 3.00			
JJIID451	2.0	2.5	3.0	Tan	0.88 – 1.50	43.0	217	66
JJIID452	3.0	3.5	4.0	Purple	1.50 – 2.25			
JJIID453	4.0	4.5	5.0	Black	2.25 – 3.00			
JJIID601	2.0	2.5	3.0	Tan	0.88 – 1.50	60.0	232	90
JJIID602	3.0	3.5	4.0	Purple	1.50 – 2.25			
JJIID603	4.0	4.5	5.0	Black	2.25 – 3.00			
Reload model: BLRS , standard smooth surface cartridge, for use with BLE & BLC model staplers								
Reload variant (code)	Open staple heights (mm, ±0.2mm, 1 st row: nearest to cutline, 3 rd row: farthest to cutline)			Reload/ Cartridge colour	Tissue thickness range (mm, ±0.2mm)	Staple line length L4 (mm, ±2.0mm)	Reload length (mm, ±5.0mm)	Number of staples
	1 st row	2 nd row	3 rd row					
BLRSA45	2.0			Gray	0.75 – 1.0	49.3	76	70
BLRSW45	2.5			White	1.0 – 2.0			
BLRSB45	3.5			Blue	1.5 – 2.4			
BLRSY45	3.8			Gold	1.8 – 3.0			
BLRSG45	4.1			Green	2.0 – 3.3			
BLRSH45	4.3			Black	2.3 – 4.0			
BLRSA60	2.0			Gray	0.75 – 1.0	61.3	88	88
BLRSW60	2.5			White	1.0 – 2.0			
BLRSB60	3.5			Blue	1.5 – 2.4			
BLRSY60	3.8			Gold	1.8 – 3.0			
BLRSG60	4.1			Green	2.0 – 3.3			
BLRSH60	4.3			Black	2.3 – 4.0			
BLRSL45	2.5	3.0	3.5	Tan	1.0 – 2.4	49.3	76	70
BLRSM45	3.8	4.1	4.3	Purple	1.8 – 4.0			
BLRSL60	2.5	3.0	3.5	Tan	1.0 – 2.4	61.3	88	88
BLRSM60	3.8	4.1	4.3	Purple	1.8 – 4.0			

Reload model: BLRP , gripping surface cartridge, for use with BLE & BLC model staplers								
Reload variant (code)	Open staple heights (mm, ± 0.2 mm, 1 st row: nearest to cutline, 3 rd row: farthest to cutline)			Reload/ Cartridge colour	Tissue thickness range (mm, ± 0.2 mm)	Staple line length L4 (mm, ± 2.0 mm)	Reload length (mm, ± 5.0 mm)	Number of staples
	1 st row	2 nd row	3 rd row					
BLRPA45	2.0			Gray	0.75 – 1.0	49.3	76	70
BLRPW45	2.5			White	1.0 – 2.0			
BLRPB45	3.5			Blue	1.5 – 2.4			
BLRPY45	3.8			Gold	1.8 – 3.0			
BLRPG45	4.1			Green	2.0 – 3.3			
BLRPH45	4.3			Black	2.3 – 4.0			
BLRPA60	2.0			Gray	0.75 – 1.0	61.3	88	88
BLRPW60	2.5			White	1.0 – 2.0			
BLRPB60	3.5			Blue	1.5 – 2.4			
BLRPY60	3.8			Gold	1.8 – 3.0			
BLRPG60	4.1			Green	2.0 – 3.3			
BLRPH60	4.3			Black	2.3 – 4.0			
BLRPL45	2.5	3.0	3.5	Tan	1.0 – 2.4	49.3	76	70
BLRPM45	3.8	4.1	4.3	Purple	1.8 – 4.0			
BLRPL60	2.5	3.0	3.5	Tan	1.0 – 2.4	61.3	88	88
BLRPM60	3.8	4.1	4.3	Purple	1.8 – 4.0			

The worst case representatives are the articulating reloads with the longest cut lines and the tallest staple heights.

13. DEVICE PERFORMANCE

The Device's performance attributes are described in this section:

Table 13-1 JQ performance attributes

Items	Requirements
Staple	<ul style="list-style-type: none"> The tensile strength of the staple material should be not less than 240MPa
Appearance	<ul style="list-style-type: none"> Device has smooth shape, clear contours with no burrs, scratches or other defects; Device has clear lettering and markings on the outer surface, without defects such as misalignment or skewing. Staple surface should be free from defects such as burrs and dents, and the tips shall be sharp.
Dimensions	<ul style="list-style-type: none"> The dimensions of the Device should comply with the dimensions described in Table 12-1 and Table 12-2.
Usability	<ul style="list-style-type: none"> The Device should open and close flexibly, without jamming
	<ul style="list-style-type: none"> Reload should be easy to replace and position; After shaking the reload, staples should not be exposed out of the reload surface.
	<ul style="list-style-type: none"> The safety should be flexible to engage and disengage, and safe to use. The green safety button should be audible when pressed and the spring should be sufficiently flexible to be quickly reset when the handle is released. The rotation collar of the stapler body should be able to rotate 360°. After the stapler body is connected to an articulated reload, the articulating lever should be adjusted so that the distal end of the reload can articulate left and right, and the angle should be not