2.0. Product Information

2.1. Product name

Name: Disposable Linear Cutter Staplers and Reloads.

2.2. Product description

Disposable Linear Cutter Staplers and Reloads are made of medical grade biocompatible materials (refer to BOM).

The devices are consisting of disposable linear cutter stapler and cartridge.

It is intended to be used during open surgery (including gastrointestinal, thoracic surgery) for the expeditious transection/resection of tissues and creation of anastomoses.

The device operates by a manual mechanism (e.g., lever, sliding knob) whereby it cuts the tissues and simultaneously applies multiple linear rows of surgical staples to the resulting ends, eliminating the need for temporary clamping.

Staplers make it possible to create a GIS anastomosis quickly and easily with the advantages of enhancing the blood flow across the anastomosis line, causing less tissue trauma, reducing edema and reducing surgery time.

The staple (Ti Gr1/Ti Gr2) is an implantable, single-use device.

The devices are single use and staple is implantable.

2.3. Indication and intended use

It is intended to be used during open surgery (including gastrointestinal, thoracic surgery) for the expeditious transection/resection of tissues and creation of anastomoses.

2.4. Model, specification and/or type

There are 2 types (GH/QAB) according to scalpel on the cartridge or devices. GH is the scalpel on the devices, QAB is the scalpel on the cartridge.

◆GH

There are 3 types (GH55, GH75 and GH100) according to the suture length that 55mm, 75mm and 100mm.

There are 3 sizes (GK**2, GK**3 and GK**4) about staple leg height that 2.5mm, 3.85mm and 4.5mm.

◆QAB

There are 3 types (QAB60, QAB80 and QAB100) according to the suture length that 60mm, 80mm and 100mm.

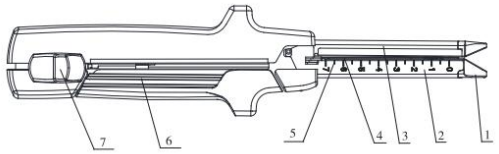
There are 3 sizes (QB**2, QB**3 and QB**4) about staple leg height that 2.5mm, 3.85mm and 4.5mm.

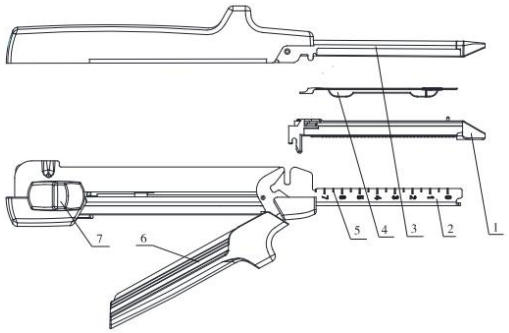
Detailed model and specification was described as following：

Linear cutter stapler (mm)				Reload (mm)		
Code	Type	Total length	Suture line length	Code	Staple legth height	Number of staples
GH	55	250±5	55±2	GK552	2.5±0.2	56
				GK553	3.85±0.2	
				GK554	4.5±0.2	
	75	270±5	75±2	GK752	2.5±0.2	76
				GK753	3.85±0.2	
				GK754	4.5±0.2	
	100	320±5	100±2	GK1002	2.5±0.2	100
				GK1003	3.85±0.2	
				GK1004	4.5±0.2	
QAB	60	250±5	60±5	QB602	2.5±0.2	64
				QB603	3.8±0.2	
				QB604	4.5±0.2	
	80	270±5	80±5	QB802	2.5±0.2	84
				QB803	3.8±0.2	
				QB804	4.5±0.2	
	100	320±5	100±5	QB1002	2.5±0.2	104
				QB1003	3.8±0.2	
				QB1004	4.5±0.2	

2.5. Product schematic diagram

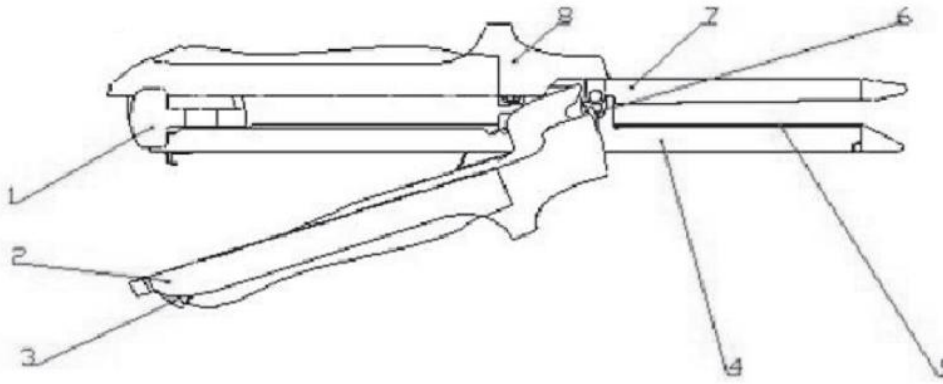
◆GH





1.Cartridge 2.Cartridge Housing 3.Anvil
4.Protector 5.Scale 6.Handle 7.Button

◆QAB



1. Releasing Button 2. Retractable Handle 3. Trigger 4. Cartridge Rack
5. Cartridge 6. Scalpel 7. Anvil 8. Anvil handle

2.6. Bill of material

• **The organization shall purchase incoming materials only from approved suppliers that have satisfied the selection and evaluation criteria as described in the Document Procedure. These suppliers shall be listed in the Approved Supplier List.**

Component	Material	Applied Standard	Supplier
Staple	Ti Gr1/Ti Gr2	ISO 5832-2	Fort Wayne Metals
Anvil, cartridge housing	06Cr19Ni10	EN ISO 7153-1	Shangzhi
Handle, housing, refire	ABS	GB/T 12672-2009 HG/T 2503-1993	Shangzhi
Blade	30Cr13	EN ISO 7153-1:2016	Shangzhi
Primary package	Tyvek 1073B+PETG film	ISO11607-2	Shangzhi

The material purchasing activities have been identified and documented in the DP. A detailed specification for the material used to manufacture is described in the Raw Material List. This information shall be used during material purchasing.

The incoming product quality of each batch of purchased material shall be inspected according to specification.

Inspection methods and purchased product verification activities shall be as described in the DP. The status of acceptance shall be as described in the DP- Identification and Traceability. Trained and competent personnel at site shall perform incoming material verification activities.

2.7. Classification

According to Annex IX, Part III, **Rule 8(2.4.1)** of the Council Directive MDD 93/42/EEC of June 1993, the staples are implanted into the body, then they are in **Class IIb.**

Because this stapler is a transient invasive instrument, and the continuous operation time is less than or equal to 60 minutes, according to classification rule 6, all surgically invasive devices intended for transient use are in Class IIa, so this product belongs to Class IIa;
The staples were implanted into the body， and it is use for more than 30 days. According to classification rule 8, all implantable devices belong to Class IIb, so this product belongs to Class IIb;
Because stapler and staple are used together, the intended use is to implant the staple into the body for a long time to achieve the purpose of operation.
According to classification rule 8, all implantable devices and long-term surgically invasive devices are in Class IIb, so this product belongs to Class IIb.

2.8. Device subcategory

CODE (NBOG's Best Practice Guide)	Devices for wound care
MD 0302	Suture material and clamps

2.9. Generic device group

Name	Definition	Code
Open-surgery manual linear cutting stapler, single-use	A sterile, hand-held, manual surgical instrument intended to be used during open surgery (including abdominal, gynaecological, paediatric, or thoracicsurgery) for the expeditious transection/resection of tissues and creation of anastomoses. The device operates by a manual mechanism (e.g., lever, sliding knob) whereby it cuts the tissues (e.g., colon) and simultaneously applies single or multiple linear rows of surgical staples to the resulting ends, eliminating the need for temporary clamping. The staples and cutting blade may be housed in a single-use loading unit (SULU) which may be included. This is a single-use device.	59870

2.10. Product performances and compatibilities

Product performances have been specified into technical requirements no.YZB/XXX-2013, issued on FY 2013, detailed as following:

- **Material**

  Staple material should be Ti Gr1/Ti Gr2 and chemical component met with ISO 5832-2 requirements.

- **Operation performance**

  Cutting stapler and shaft should be assembled and detached smoothly, freedom of locking and loosen. Staple should be stable and freedom of falling.

  Staple tip should be sharp, cutting stapler should with good cut and suturing performance, shape of formed staple should be “B”, stapling line with 4 lines and blade is free of crack.

Stapler safety should open/close flexible and safely.

- **Hardness**
  Cutting blade hardness is >377$HV_{0.2}$, anvil hardness is >130$HV_{0.2}$.
- **Roughness**
  Metal surface roughness should be ≤0.8μm.
- **Primary package peeling strength**
  Package peeling strength should be 0.1N/mm～0.5 N/mm, and two webs should be smooth and continuous without any delamination or tear.
- **Appearance**
  Appearance should be smooth, no burr and crack.
- **Sterility**
  Products should be sterilized with a validated sterilization process. EO residual should be met with ISO 10993-7 requirements.
- **Biocompatibility**
  Cytoxicity is < grade 1.
  There is no sensitization activity.
  There is no intra-skin irritation activity.

2.11. Shelf-life or lifetime

The shelf-life is 5 **years** after EO sterilization through by aging trial.

2.12. Manufacturing and Testing specifications for routine production

•◆GH

-Standard Operation Procedure no. BLSS-3.2.4/005 for assembling process;

-Standard Operation Procedure no. BLSS-3.2.1/2.023;BLSS-3.2.1/2.024;BLSS-3.2.1/2.025 for in-coming inspection;

-Standard Operation Procedure no. BLSS-3.2.1/3.028 for in-process inspection;

-Standard Operation Procedure no. BLSS-3.2.1/1.005 for final inspection;

◆QAB

-Standard Operation Procedure no. BLSS-3.2.12-021 for assembling process;

-Standard Operation Procedure no. BLSS-3.2.12-065 for in-coming inspection;

-Standard Operation Procedure no. BLSS-3.2.1-3.018 for in-process inspection;

-Standard Operation Procedure no. BLSS-3.2.1/1.020 for final inspection;

3. Labelling

Labelling includes all applicable information required by MDD, Annex I, 13.3 and EN 1041:2008+A1:2013 “Information supplied by the manufacturer of medical devices”.

This information takes the form of symbols. The symbols used are conform to the harmonized standard EN ISO 15223-1:2016 and EN ISO 14630:2012.

Package labeling shall include product type, lot number, quantity, product description, use by date, manufacturing date, do not re-use, do not use if package is damaged, caution, sterilization using EO, manufacturer and EU representative information, etc.

Information for labelling was drafted as per ***Appendix 3.1:*** **Product labelling** in this Technical File.

The Organization shall ensure that only approved packaging labels shall be used and distributed together with the products.

Each product unit is properly packaging to ensure its packing integrity without any damages or deterioration in nature. The production lot number and manufacturing date are identified.

The packaging and storage activities are described in the DP Preservation of Products.

All packaging material shall be properly labeled according the DP Identification and Traceability.

Information on the product, such as manufacturing date, manufacturing number, and origin of manufacturer are identified on the product itself.