Medical Device Product Technical Requirements Number:

Echelon Flex Powered Plus Articulating Endoscopic Linear Cutters and Echelon Flex Powered Plus Articulating Endoscopic Linear Reloads

1. Product Specification:

1.1 Product component:

Stapler component: see figure 1 and Table 1.

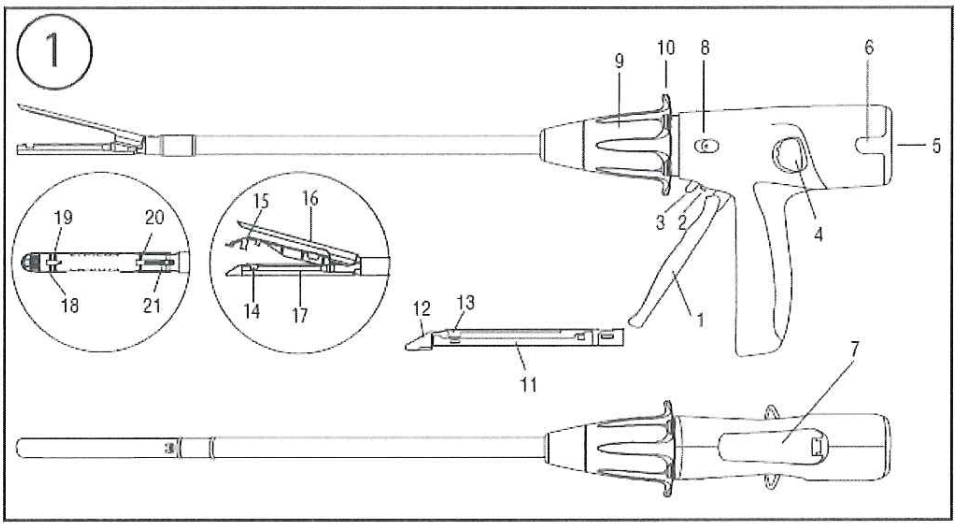


Figure 1:

Table 1			
1	Closing Trigger	12	Reload Gripping Surface
2	Red Firing Trigger Lock	13	Reload Alignment Tab
3	Firing Trigger	14	Reload Alignment Slot
4	Anvil Release Button	15	Staple Retaining Cap
5	Battery Pack	16	Anvil Jaw
6	Battery Pack Release Tab	17	Reload Jaw
7	Manual Override Access Panel	18	Staple Line
8	Knife Reverse Switch	19	Cut Line
9	Rotating Knob	20	Proximal Black Line
10	Articulation Fins	21	Knife Blade Indicator
11	Reload(Cartridge)		

Reload component: see figure 2 and table 2

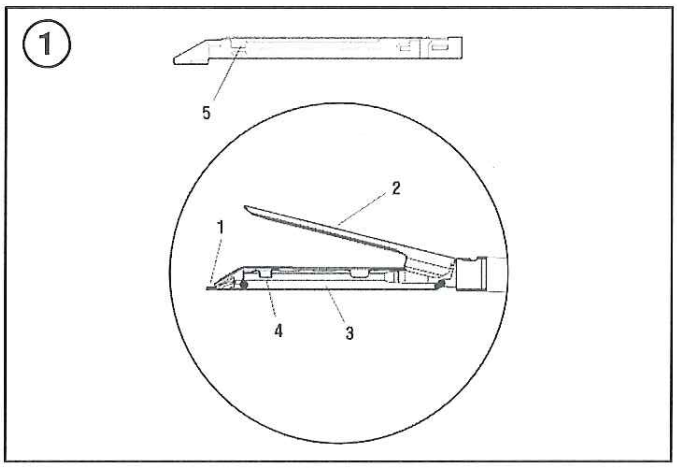


Figure 2:

Table 2			
1	Staple Retaining Cap	4	Reload Alignment Slot
2	Anvil Jaw	5	Reload Alignment Tab
3	Reload Jaw		

1.2 Material:

Table 3: Materials of PSEE45A/PLEE45A/PCEE45A			
Component No. in Figure 1	**Component**	**Material**	**Contact with patient**
1	Closing Trigger	Polyamide 6/6 (Nylon 6/6 60% fiber glass reinforced)	No direct contact
2	Red Firing Trigger Lock	Polyetherimide	No direct contact
3	Firing Trigger	Polyamide 6/6 (Nylon 6/6 60% fiber glass reinforced)	No direct contact
4	Anvil Release Button	Aromatic Polyamide 50% fiber glass reinforced	No direct contact
5	Battery Pack	Lithium battery, Housed by Polycarbonate (20% Glass Filled)	No direct contact
6	Battery Pack	Polycarbonate (20%	No direct contact

Table 3: Materials of PSEE45A/PLEE45A/PCEE45A			
Component No. in Figure 1	**Component**	**Material**	**Contact with patient**
	Release Tab	Glass Filled)	
7	Manual Override Access Panel	Polycarbonate (20% Glass Filled)	No direct contact
8	Knife Reverse Switch	Polycarbonate	No direct contact
9	Rotating Knob	Polycarbonate - 20% filled glass fiber	No direct contact
10	Articulation Fins	Styrene Block Copolymer	No direct contact
11	Reload(Cartridge)	See table 4	See table 4
12	Reload Gripping Surface	Liquid Crystal Polymer	externally communicating with tissue, bone, or dentin contact of less than 24 hours
13	Reload Alignment Tab	Liquid Crystal Polymer	externally communicating with tissue, bone, or dentin contact of less than 24 hours
14	Reload Alignment Slot	17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
15	Staple Retaining Cap	Polycarbonate	No direct contact
16	Anvil Jaw	AISI 416 Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
17	Reload Jaw	17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
18	Staple Line	Laser mark in the cartridge jaw. The	externally communicating with

Table 3: Materials of PSEE45A/PLEE45A/PCEE45A			
Component No. in Figure 1	**Component**	**Material**	**Contact with patient**
		material of cartridge jaw is 17-4 PH Stainless Steel	tissue, bone, or dentin contact of less than 24 hours
19	Cut Line	Laser mark in the cartridge jaw. The material of cartridge jaw is 17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
20	Proximal Black Line	Laser mark in the cartridge jaw. The material of cartridge jaw is 17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
21	Knife Blade Indicator	Laser mark in the cartridge jaw. The material of cartridge jaw is 17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
No numbering part	Shroud (Overmold)	Styrene Block Copolymer-Grey	No direct contact
No numbering part	Shaft	AISI 304Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
No numbering part	Knife	UNS S42000 Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
No numbering part	Ring-closure	17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
No numbering part	Lubricant(stapler)	Polydimethylsiloxane Liquid Lubricant	externally communicating with tissue, bone, or

Table 3: Materials of PSEE45A/PLEE45A/PCEE45A			
Component No. in Figure 1	**Component**	**Material**	**Contact with patient**
			dentin contact of less than 24 hours

Table 4: Material of GST45W/GST45B/GST45D/GST45G/GST45T			
Component No. in Figure 2	**Component**	**Material**	**Contact with patient**
1	Staple Retaining Cap	Polycarbonate	No direct contact
2	Anvil Jaw	AISI 416 Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
3	Reload Jaw	17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
4	Reload Alignment Slot	17-4 PH Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours
5	Reload Alignment Tab	Liquid Crystal Polymer	externally communicating with tissue, bone, or dentin contact of less than 24 hours
No numbering part	Cartridge body	Liquid Crystal Polymer	externally communicating with tissue, bone, or dentin contact of less

Table 4: Material of GST45W/GST45B/GST45D/GST45G/GST45T			
Component No. in Figure 2	**Component**	**Material**	**Contact with patient**
			than 24 hours
No numbering part	lubricant	Sodium stearate	tissue or bone implant devices with greater than 30 days
No numbering part	staple	Titanium Alloy Ti3Al2.5V	tissue or bone implant devices with greater than 30 days
No numbering part	Driver	Polyetherimide 10% glass filled	externally communicating with tissue, bone, or dentin contact of less than 24 hours
No numbering part	Sled	Polyetherimide 20% glass filled	externally communicating with tissue, bone, or dentin contact of less than 24 hours
No numbering part	Pan	AISI 301 Stainless Steel	externally communicating with tissue, bone, or dentin contact of less than 24 hours

1.3 Product specification and dimension: See Table 5 to Table 7

Table 5

Product Code	Description	Staple Line Length (mm, Tolerance± 1)	Cut Line Length (mm, Tolerance± 2)	Shaft Length
PSEE45A	ECHELON FLEX 45mm Powered Plus Articulating Endoscopic Linear Cutter, standard length	47	42	340mm, Tolerance±5.4%)
PLEE45A	ECHELON FLEX 45mm Powered Plus Articulating Endoscopic Linear Cutter, long length	47	42	440mm, Tolerance±4.2%)
PCEE45A	ECHELON FLEX 45 Powered Plus Articulating Endoscopic Linear Cutter, compact length	47	42	280mm, Tolerance±6.5%)

Table 6

Product Code	Open Staple Height (Tolerance ±0.2mm)	Reload Color
GST45W	2.6mm	While
GST45B	3.6mm	Blue
GST45D	3.8mm	Gold
GST45G	4.1mm	Green
GST45T	4.2mm	Black

Table 7	
Product Code	Closed Staple Height
GST45W	1.0mm
GST45B	1.5mm
GST45D	1.8mm
GST45G	2.0mm
GST45T	2.3mm

1.4 Code Naming

Stapler:

PXEE45A

X is variable (S/ L/ C). S represents standard shaft length (340mm); L represents long shaft length (440mm); C represents compact shaft length (280mm); Other parts of the code are invariable.

Reload:

GST45X

X is variable (W/B/D/G/T). The letter represents different color and closed staple height of different reloads. The detail meaning can be found in table 2. Other parts of the code are invariable.

2. Performance Index:

Operation Environment Conditions:

a) Temperature: 10℃~40℃

b) Relative Humidity: 30%~75%

c) Pressure: 800hPa~1060hPa

d) Power Supply: DC voltage: 12V, Power Rating: 40W

e) Environment with no inflammable gas, e.g. anesthetic gases.

Product sterilization method and shelf life:

a) Product sterilization method: Irradiation

b) Product shelf life: 3 years for stapler and reload.

2.1 Material composition of staple:

2.1.1 The staple material is the staple material is Ti-3Al-2.5V Titanium, R2017-04. Chemical composition of staple shall meet the requirement of table 2 as below and shall be in the specification of GB/T 13810-2007.

Table 2

Component	%
C	≤0.08
N	≤0.03
O	≤0.15
V	2.0-3.0
Al	2.5-3.5
Fe	≤0.25
Other Element (Single)	≤0.1
Other Element (Total)	≤0.4
Ti	Remain

2.1.2 Tensile strength for staple material shall be no less than 240MPa.

2.2 Flexibility

2.2.1 The opening and closing of stapler shall be smooth and flexible with no jamming.

2.2.2 The shaft shall be able to turn 360° in both directions.

2.3 Assembly performance

2.3.1 Replacement of cartridge of stapler shall be convenient and reliable.

2.3.2 Staples shall be reliable and stable after assembled into the cartridge with no detachment after been shaken.

2.4 Sharpness

Edges of cutting blades shall be sharp with the cutting force no more than 0.8N.

2.5 Anastomosis and cutting performance

2.5.1 The stapler shall have excellent anastomosis and cutting performances. Replace the cartridge, cutting and anastomosis shall be made for no less than 5 times, and the staple after anastomosis each time shall be similar "B" shaped.

2.5.2 Cutting edges after anastomosis shall be neat with no burrs.

2.5.3 The anastomosis length shall be at least 1.5 staples longer than the cutting line

length.

2.6 Pressure resistant performance

After anastomosis, the anastomotic stoma shall be capable to withstand a pressure of at least 3.6KPa with water leakage less than 10 drips within 15s.

2.7 Safety devices

Stapler shall be equipped with safety devices for empty cartridge housing and guarantee its reliability.

2.8 Surface roughness

The surface roughness for exposed metal surfaces of stapler Ra shall be no more than 0.8 μm.

2.9 Package encapsulation

2.9.1 The package for the stapler and cartridge shall be intact with no channels or perforations in the adhesive sealing zones.

2.9.2 The peel strength of package encapsulation of the stapler and cartridge shall be no less than 0.10N/mm. Both contact surfaces after peeling shall be smooth, continuous and uniform with no detachment or avulsion.

2.10 Appearance

2.10.1 The stapler shall have smooth appearances and sharp profiles. No burrs or cracks shall be permitted.

2.10.2 Words and marks on outer surfaces of the stapler shall be clear and legible with no dislocation or skew.

2.10.3 No defects, e.g. burrs or indentations shall be observed on the surface of staples.

2.11 Dimensions

The dimensions of stapler and cartridge shall comply with the requirements of table 5 and table 6.

2.12 Sterilization

Stapler and cartridge shall be sterilized with Radiation sterilization process. All products shall be sterile.

2.13 Electrical safety: The electrical safety of equipment shall meet the relevant requirements of GB 9706.1-2007.

2.14 Electromagnetic compatibility: The electromagnetic compatibility of equipment shall meet the relevant requirements of YY 0505-2012.

3. Test Method:

3.1 Staple material test:

3.1.1 The chemical analysis shall be carried out per the methods specified in GB/T 13810-2007, shall meet the specifications of 2.1.1.

3.1.2 Tensile strength analysis shall be carried out per the methods specified in GB/T 228.1-2010, shall meet the specifications of 2.1.2.

3.2 Flexibility test

3.2.1 The closing and opening of the stapler shall comply with the requirement of 2.2.1.

3.2.2 Conduct the simulation of operation activities, the test results shall comply with the requirement of 2.2.2.

3.3 Assembly test

3.3.1 The replacement of cartridge shall comply with the requirements of 2.3.1.

3.3.2 Touch the surface of the cartridge housing after shaking the cartridge for at least 5 times. The test results shall comply with the requirements of 2.3.2.

3.3.3 Shake the cartridge 3~5 times, visual inspection, the results shall comply with the requirements of 2.3.3.

3.4 Sharpness test

The sharpness test shall be conducted with methods specified in Appendix A of YY0876-2013 and the test results shall comply with the requirements of 2.4.

3.5 Anastomosis performance test

Anastomose two layers of EVA low foaming boards with the thickness 1/2 – 2/3 times of the height. (see Appendix B of YY 0876-2013) Remove excessive EVA low foaming boards along the edges of staples to expose the patterned staples. The visual inspection results shall comply with the requirements of 2.5.

3.6 Pressure resistant test

It shall be conducted in accordance with methods specified in Appendix C of YY 0876-2013. The test results shall meet the requirement of 2.6.

3.7 Safety device test

Assemble the empty cartridge into the stapler and fire, which shall comply with the requirements of 2.7.

3.8 Surface toughness test

It shall be conducted with the surface roughness comparison specimen. The test results shall comply with the requirement of 2.8.

3.9 Sealing test for packages

3.9.1 Sealing performance test

It shall be conducted with methods specified in Appendix D of YY 0876-2013. The test results shall comply with the requirements of 2.9.1.

3.9.2 Peel strength test

It shall be conducted with methods specified in Appendix E of YY 0876-2013. The test results shall comply with the requirements of 2.9.2.

3.10 Appearance test

Conduct the visual inspection and touch the stapler. The results shall comply with the requirements of 2.10.

3.11 Dimensional inspection

Conduct the dimensional inspection with general measuring tools. The results shall comply with the requirements of 2.11.

3.12 Sterility test

It shall be conducted with methods specified in Chinese pharmacopoeia (edition 2015, Volume IV). The test results shall comply with the requirements of 2.12.

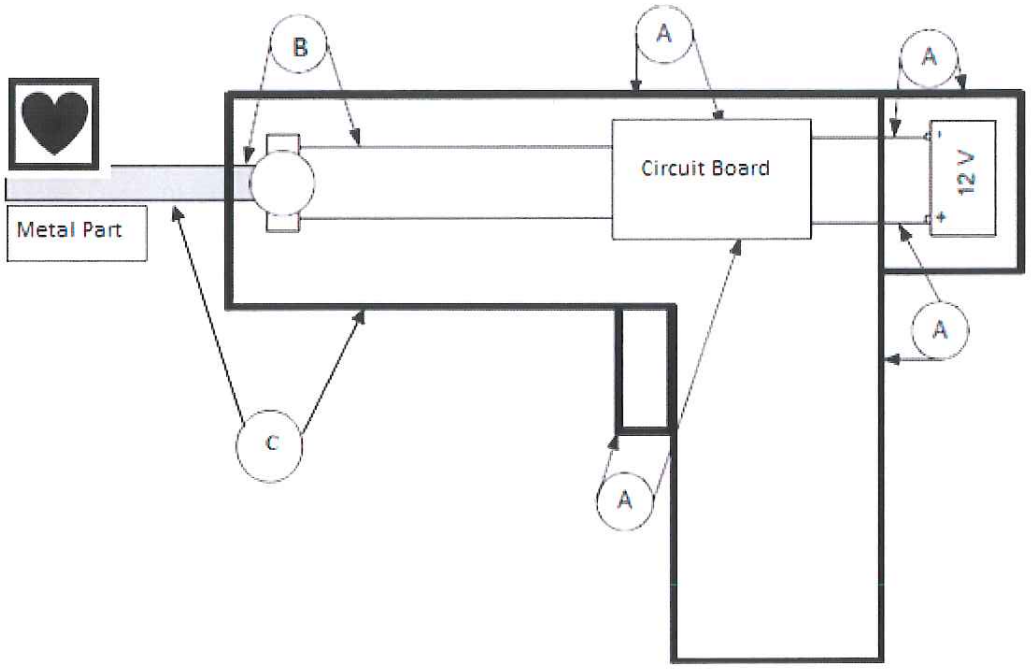
3.13 Electrical safety: It shall be tested in accordance with the relevant requirements of GB 9706.1-2007, and the test results shall meet the requirement of 2.11.

3.14 Electromagnetic compatibility: It shall be tested in accordance with the methods specified in YY 0505-2012, and the test results shall meet the requirement of 2.12.

Appendix A

(Normative)

Safety requirements



Item #	Insulation Path	Insulation Type	Reference Voltage(V)	Test Voltage(V)
A	A-a2	Reinforced Insulation	12 DC	500 DC
B	B-a	Reinforced Insulation	12 DC	1500 DC
C	B-d	Basic Insulation	250 AC	1500 AC

Product Features:

1. Equipment classification: Equipment with internal power supply;
2. Equipment type: CF-type;

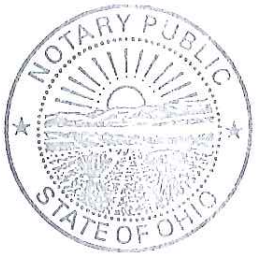
3. Power supply classification of Equipment: Internal power supply; DC voltage: 12V
4. Essential application part of Equipment: Closing lever;
5. The Equipment has no signal input and output unit;
6. Liquid inlet protection level: IPXO;
7. The Equipment is not an AP or APG equipment;
8. Operation mode of Equipment: Continuous service;
9. The Equipment is portable device.

Signed for and on behalf of
Ethicon Endo-Surgery, LLC

12/14/2017

Kim Shoemaker
Senior Director, Regulatory Affairs

Date



14 Dec 2017
MARY GALEANO
Notary Public, State of Ohio
My Commission Expires
October 19, 2018