

УТВЕРЖДАЮ

ООО «Здоровье»

Ю.В. Науман

на основании доверенности № Ю-3

от 01.12.2023 г.



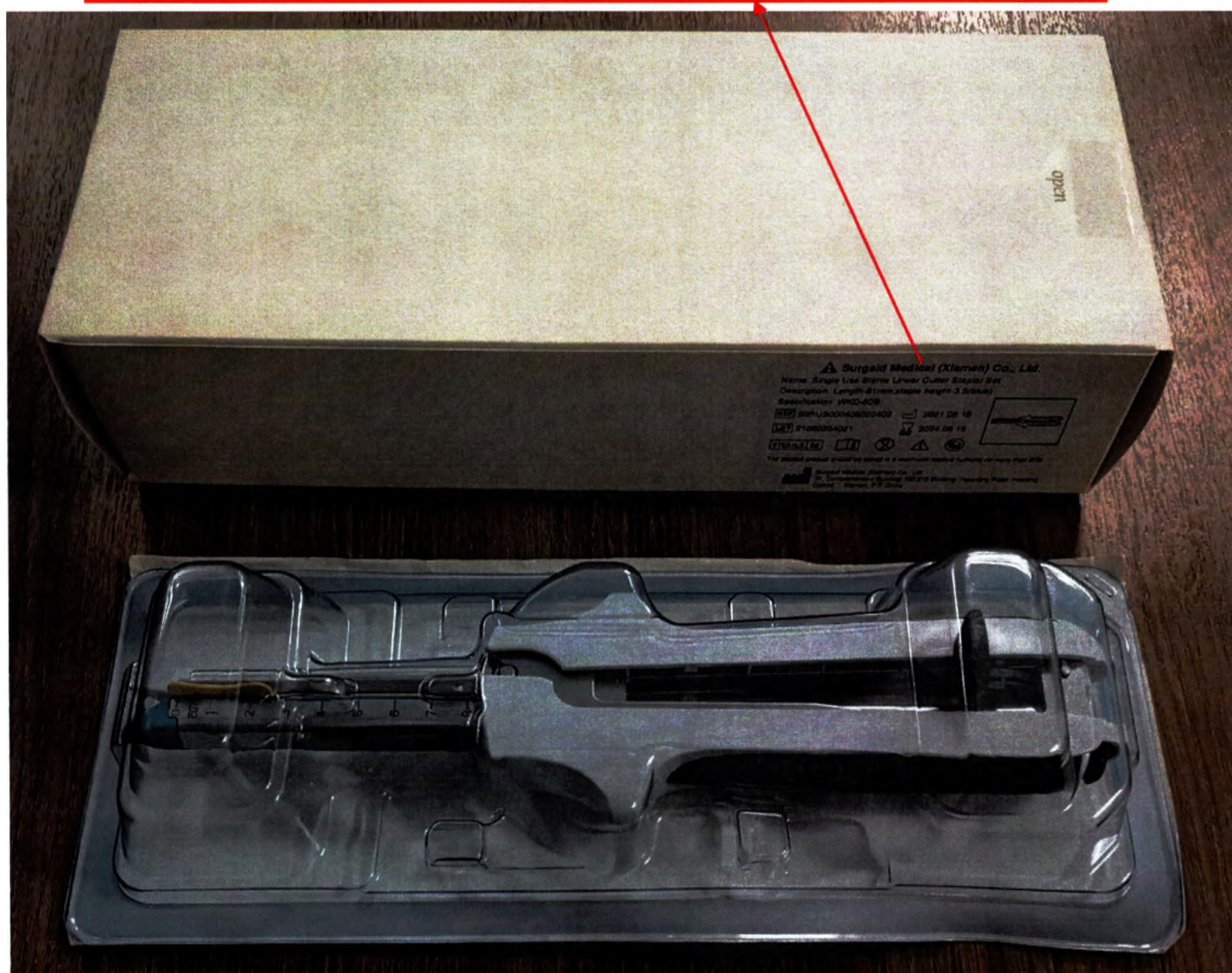
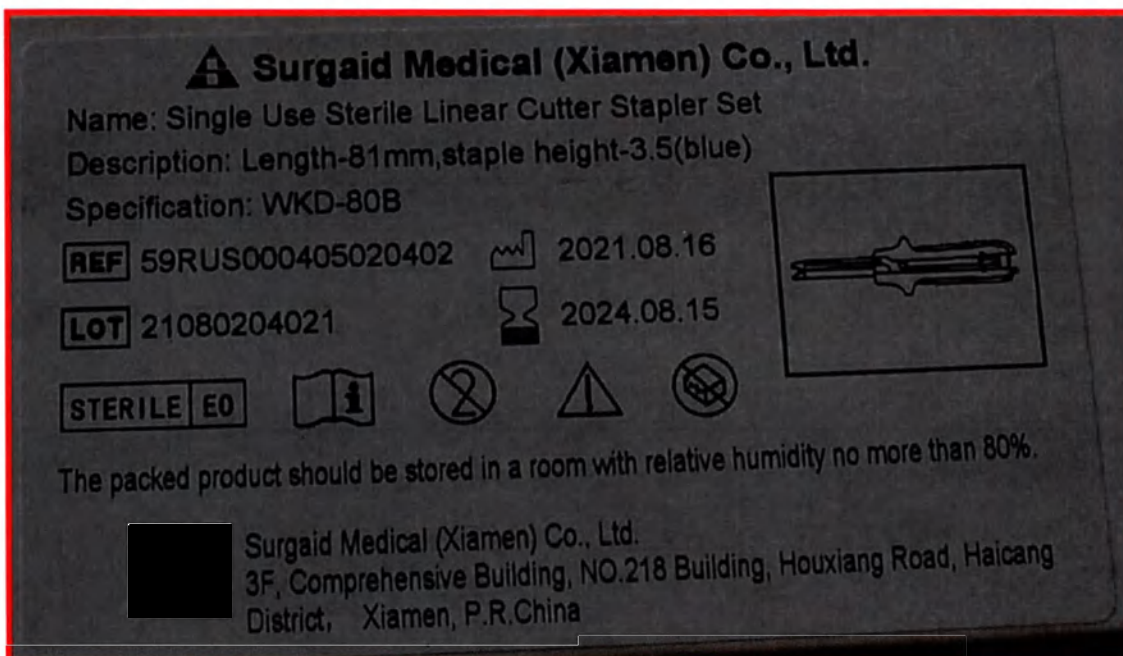
«27» июня 2024 г.

Фотографические изображения общего вида медицинского изделия

Степлер хирургический одноразовый

Степлер хирургический одноразовый с резаком линейный, резак в картридже: WKD-80B, в составе:

1) Степлер хирургический одноразовый с резаком линейный, резак в картридже: WKD-80B – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Linear Cutter Stapler Set

Description: Length-81mm, staple height-3.5(blue)

Specification: WKD-80B

REF 59RUS000405020402 2021.08.16

LOT 21080204021 2024.08.15

STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%.



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China

Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Linear Cutter Stapler Set

Description: Length-81mm, staple height-3.5(blue)

Specification: WKD-80B

REF 59RUS000405020402 2021.08.16

LOT 21080204021 2024.08.15

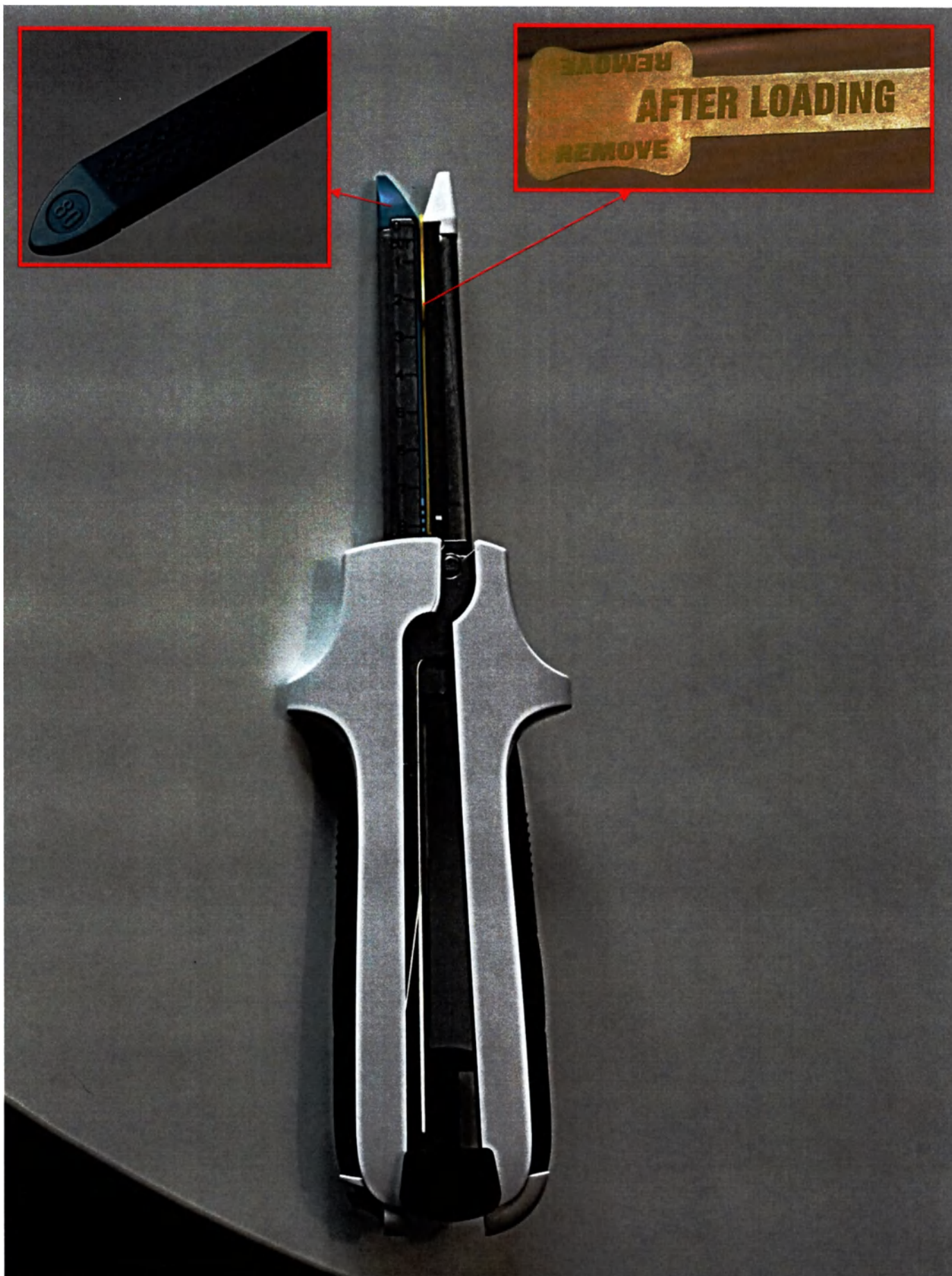
STERILE EO



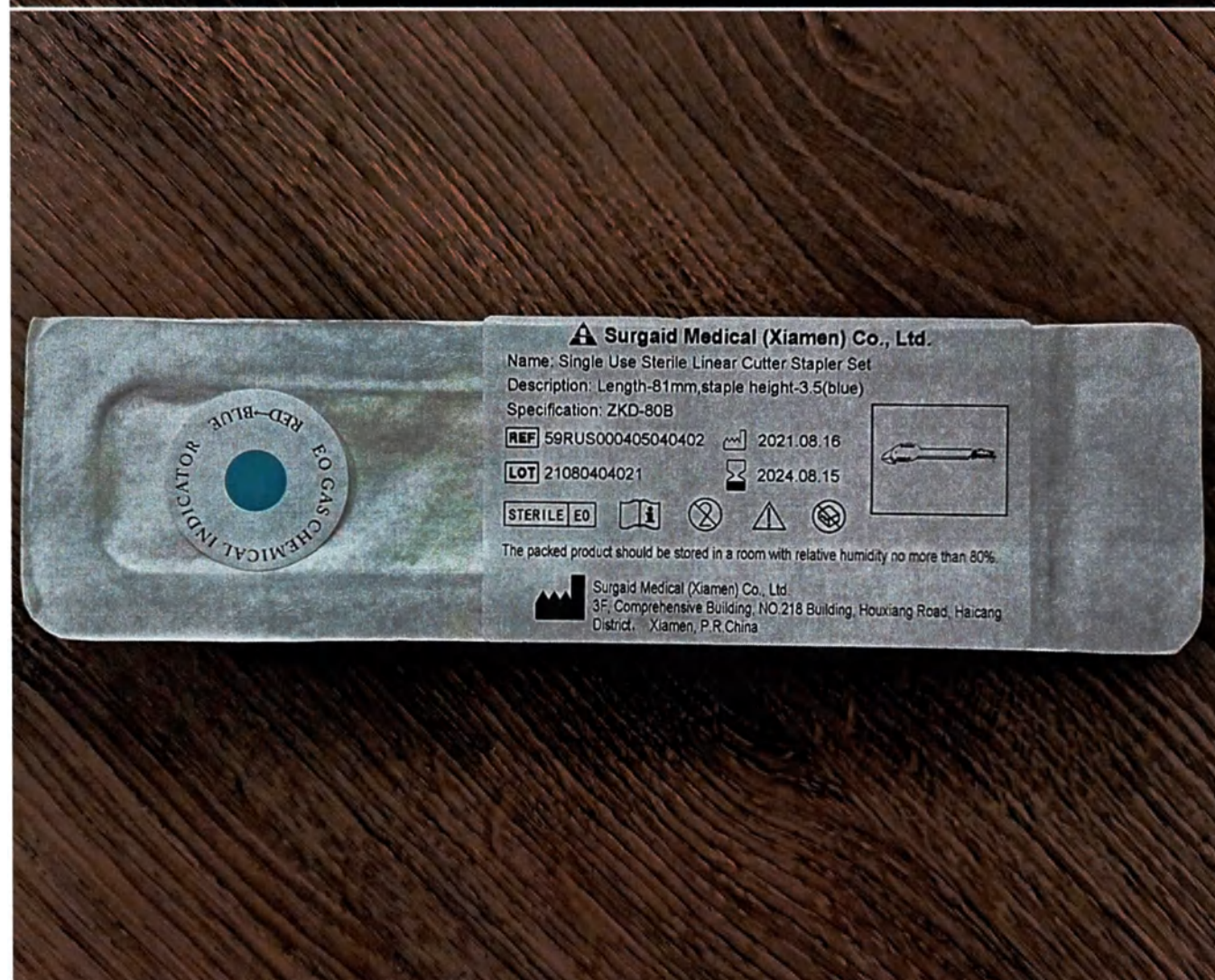
The packed product should be stored in a room with relative humidity no more than 80%.

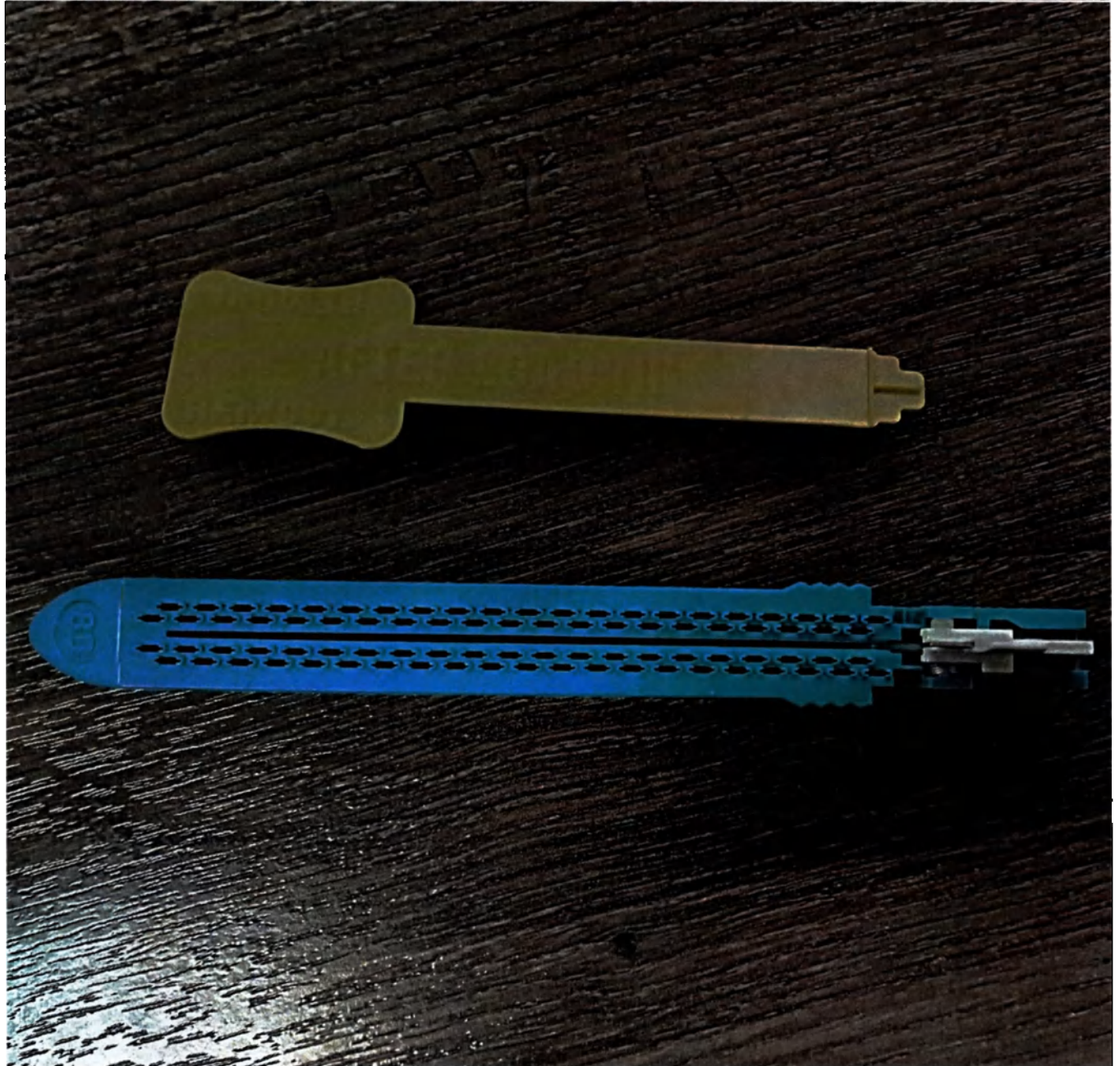


Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China



2) Картридж ZKD-80B – не более 6 шт.;





3) Инструкция по применению на Степлер хирургический одноразовый с резаком линейный, резак в картридже – 1 шт.

Instruction for Use

I. Device Name:

Single Use Sterile Linear Cutter Stapler Set

II. Product performance and major components

1. Performance:

a. Appearance: The Linear Cutter Stapler has smooth surface and well-defined contour without defects such as burrs or scratches. Scales or indications on the device body shall be legible and aligned without malposition. The surface of staple shall not contain any burr or depression.

b. Flexibility: Opening and closure of the linear stapler shall be flexible without jam.

c. Assembly: The cartridge and device body shall be assembled and unloaded successfully. Movable parts can be moved easily with jamming or loosening. The loaded cartridge shall be fixed soundly and the staple shall not project out over the surface of reload when the cartridge is swung.

d. Performance of anastomosis and resection: The linear cutter stapler shall perform well in anastomosis and resection for ≥ 5 times with replaced cartridge. A B-shaped staple shall be formed after each anastomosis. The resection margins shall be neat without trimmings after each anastomosis. The anastomotic line shall be at least 1.5 times of the length of staple.

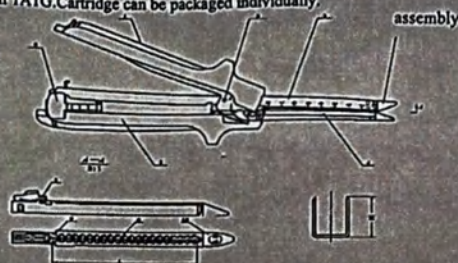
e. Surface roughness: The outer surface roughness (Ra) of mental part of linear stapler shall not exceed $0.8 \mu\text{m}$.

f. Corrosion resistance: The anvil jaw shall have good corrosion resistance.

g. The product shall be sterile. The residual ethylene oxide shall not exceed $10 \mu\text{g/g}$.

2. Major components:

Refer to Figure 1 for product structure. The anvil jaw is made from 06Cr19Ni10, the cutter is made from 30Cr13 while the staple is made from TA1G. Cartridge can be packaged individually.



Linear cutter stapler: 1.Movable handle cover; 2.Movable handle; 3. Cartridge jaw; 4.Anvil jaw; 5. Staple retaining cap; 6. Firing knob Cartridge: 7.Cutter; 8.Pushing plate; 9.Staple; 10.Reload

Figure 1 The structural diagram of Linear Cutter Stapler (Model with D)

III. Indications

The product is applicable for creation of anastomosis and closure of stump or incision in gastrointestinal reconstruction and resection of other organs.

IV. Contraindications

1. Patients with inhomogeneous tissues caused by radiotherapy;
2. Tissues with mucosal oedema, ischemia or necrosis
3. As closure of the product may cause destructive effect on liver or spleen tissues due to the compression property of these organs, do not use the product for liver or spleen tissues;
4. Patients with systematic disease (such as haemorrhagic diathesis, hypoproteinaemia and severe cardiovascular disorder.)

V. Precautions and Warnings

1. Strictly follow the sterile instruction while using the product. Do not use unsealed, damaged or expired products.
2. Please read the ICF carefully and pay attention to manufacturing date and expired date prior to use of the product. Expired products shall not be used.
3. The product shall be used by physicians who have been trained for stapler or used under the guidance of physicians with relevant experience.
4. Ensure that the thickness of tissue is within the specified range and tissues distributed evenly in the stapler. If tissue in one side is more than another side, anastomotic effect may be affected and anastomotic leak could occur.
5. Do not use the product on any tissue whose compressed thickness is less than 1.0 mm since the stapler is unable to clamp soundly and ensure effect of hemostasis.
6. A complete firing shall be done within one operation. Do not partly fire the stapler. Incomplete firing may cause abnormal staple formation, incomplete resection line, bleeding, leakage from suture line and/or difficulties in stapler removal.
7. The stapler shall be fired completely to ensure correct staple formation and tissue resection.
8. After firing, check the hemostatic status near anastomotic line and observe the completeness of anastomosis and status of leakage.
9. The product is for single use. Dispose the product as medical wastes after use to avoid harm to human and environmental pollution.
10. The ICF cannot be used as technical instructions for stapler in clinical use. Please reference relevant literature for the technical instructions or consult our company.
11. MRI warnings: The product has not been tested under magnetic resonance imaging (MRI) condition for temperature elevation, displacement or artifacts.
12. This procedure may cause anastomotic leakage, bleeding.
13. Disposal devices are medical waste and should be handled and disposed of according to local regulations

VI. Instructions for installation and use

Instructions of Model WKD

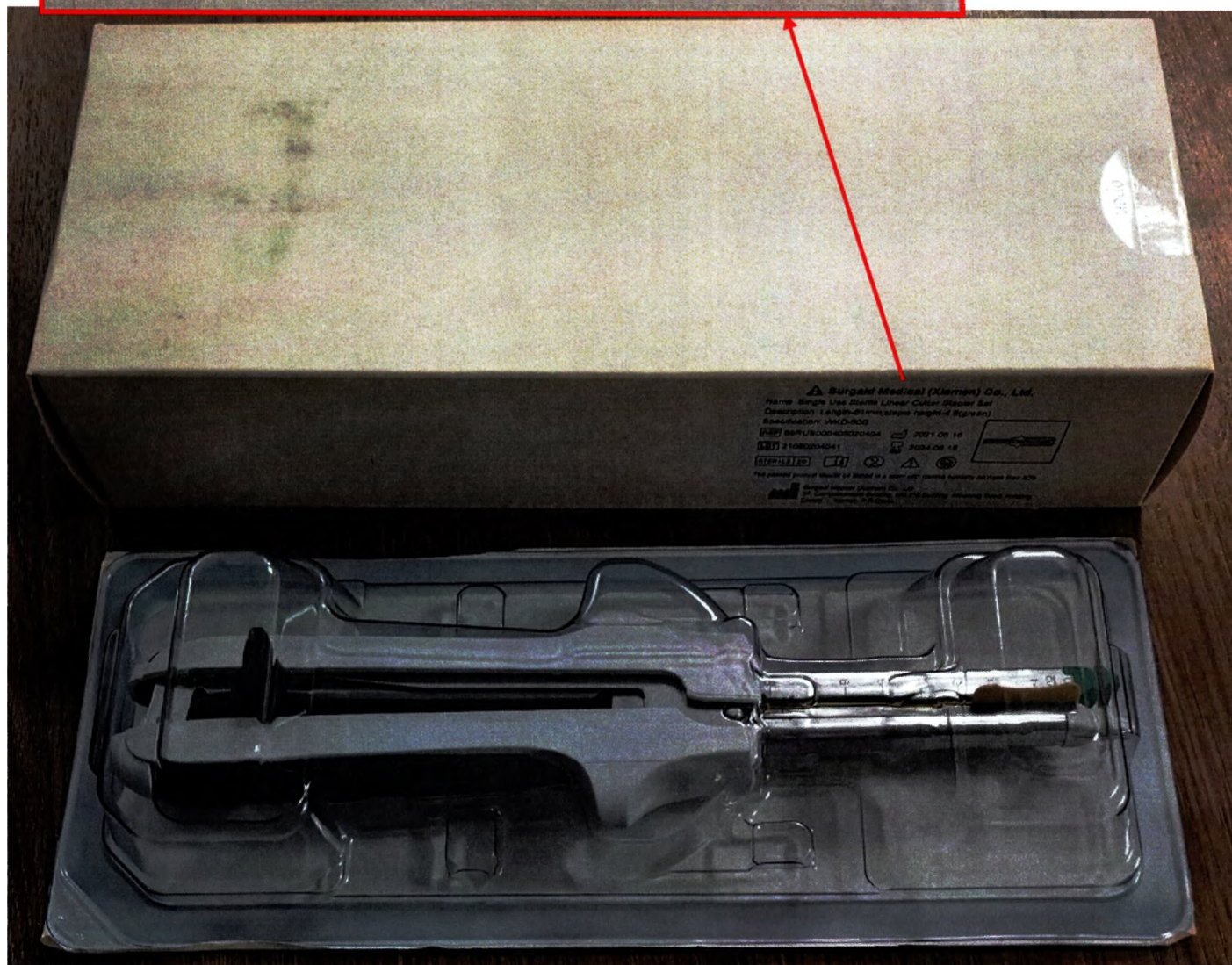
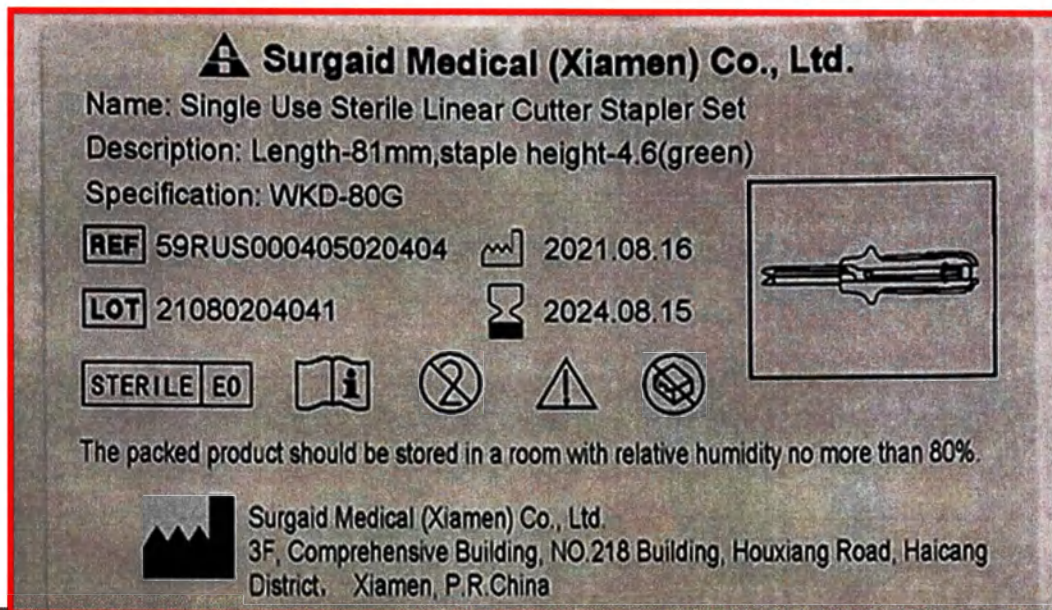
1. Unpack the sterile package, take out the linear cutter stapler from the blister box, press the button at the end of the handle, and remove the retaining cap (Figure 2).



Figure 2

Степлер хирургический одноразовый с резаком линейный, резак в картридже: WKD-80G, в составе:

1) Степлер хирургический одноразовый с резаком линейный, резак в картридже: WKD-80G – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Linear Cutter Stapler Set

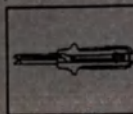
Description: Length-81mm, staple height-4.6(green)

Specification: WKD-80G

REF 59RUS000405020404 2021.08.16

LOT 21080204041 2024.08.15

STERILE EO



The packed product should be stored in a room with relative humidity no more than 60%.



Surgaid Medical (Xiamen) Co., Ltd.
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District, Xiamen, P.R.China

Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Linear Cutter Stapler Set

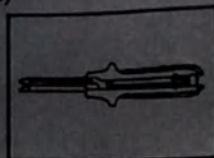
Description: Length-81mm, staple height-4.6(green)

Specification: WKD-80G

REF 59RUS000405020404 2021.08.16

LOT 21080204041 2024.08.15

STERILE EO



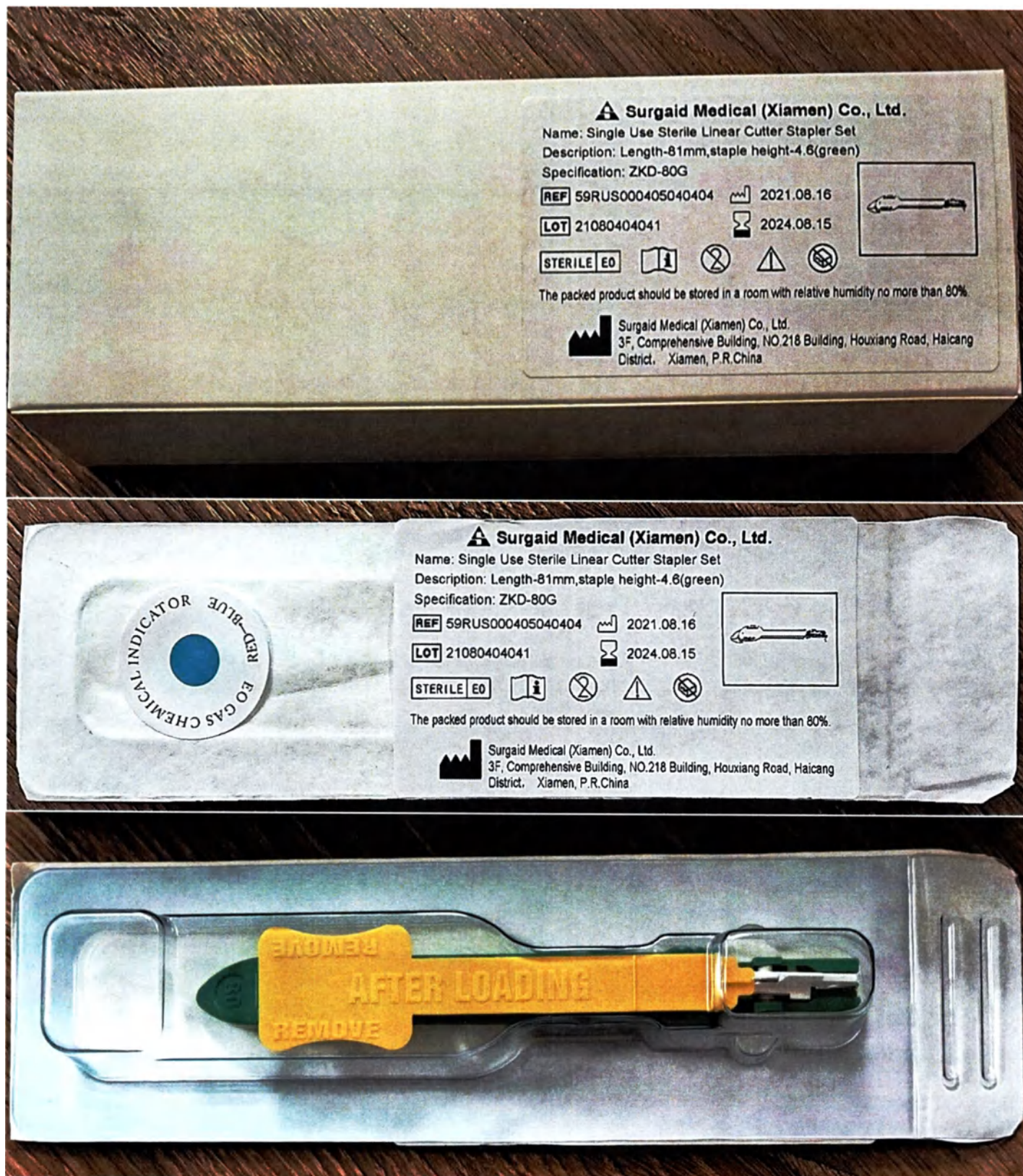
The packed product should be stored in a room with relative humidity no more than 80%.



Surgaid Medical (Xiamen) Co., Ltd.
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District, Xiamen, P.R.China



2) Картридж ZKD-80G – не более 6 шт.;





3) Инструкция по применению на Степлер хирургический одноразовый с резаком линейный, резак в картридже – 1 шт.

Instruction for Use

I. Device Name:

Single Use Sterile Linear Cutter Stapler Set

II. Product performance and major components

1. Performance:

a. Appearance: The Linear Cutter Stapler has smooth surface and well-defined contour without defects such as burrs or scratches. Scales or indications on the device body shall be legible and aligned without malposition. The surface of staple shall not contain any burr or depression.

b. Flexibility: Opening and closure of the linear stapler shall be flexible without jam.

c. Assembly: The cartridge and device body shall be assembled and unloaded successfully. Movable parts can be moved easily with jamming or loosening. The loaded cartridge shall be fixed soundly and the staple shall not project out over the surface of reload when the cartridge is swung.

d. Performance of anastomosis and resection: The linear cutter stapler shall perform well in anastomosis and resection for ≥ 5 times with replaced cartridge. A B-shaped staple shall be formed after each anastomosis. The resection margins shall be neat without trimmings after each anastomosis. The anastomotic line shall be at least 1.5 times of the length of staple.

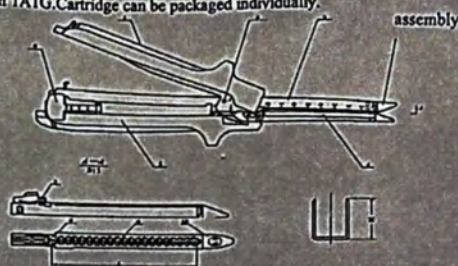
e. Surface roughness: The outer surface roughness (R_a) of metal part of linear stapler shall not exceed $0.8 \mu m$.

f. Corrosion resistance: The anvil jaw shall have good corrosion resistance.

g. The product shall be sterile. The residual ethylene oxide shall not exceed $10 \mu g/g$.

2. Major components:

Refer to Figure 1 for product structure. The anvil jaw is made from 06Cr19Ni10, the cutter is made from 30Cr13 while the staple is made from TAIG. Cartridge can be packaged individually.



Linear cutter stapler: 1.Movable handle cover; 2.Movable handle; 3. Cartridge jaw; 4.Anvil jaw; 5. Staple retaining cap; 6. Firing knob Cartridge: 7.Cutter; 8.Pushing plate; 9.Staple; 10.Reload

Figure 1 The structural diagram of Linear Cutter Stapler (Model with D)

III. Indications

The product is applicable for creation of anastomosis and closure of stump or incision in gastrointestinal reconstruction and resection of other organs.

IV. Contraindications

1. Patients with inhomogeneous tissues caused by radiotherapy;
2. Tissues with mucosal oedema, ischemia or necrosis
3. As closure of the product may cause destructive effect on liver or spleen tissues due to the compression property of these organs, do not use the product for liver or spleen tissues;
4. Patients with systematic disease (such as haemorrhagic diathesis, hypoproteinaemia and severe cardiovascular disorder.)

V. Precautions and Warnings

1. Strictly follow the sterile instruction while using the product. Do not use unscaled, damaged or expired products.
2. Please read the ICF carefully and pay attention to manufacturing date and expired date prior to use of the product. Expired products shall not be used.
3. The product shall be used by physicians who have been trained for stapler or used under the guidance of physicians with relevant experience.
4. Ensure that the thickness of tissue is within the specified range and tissues distributed evenly in the stapler. If tissue in one side is more than another side, anastomotic effect may be affected and anastomotic leak could occur.
5. Do not use the product on any tissue whose compressed thickness is less than 1.0 mm since the stapler is unable to clamp soundly and ensure effect of hemostasis.
6. A complete firing shall be done within one operation. Do not partly fire the stapler. Incomplete firing may cause abnormal staple formation, incomplete resection line, bleeding, leakage from suture line and/or difficulties in stapler removal.
7. The stapler shall be fired completely to ensure correct staple formation and tissue resection.
8. After firing, check the hemostatic status near anastomotic line and observe the completeness of anastomosis and status of leakage.
9. The product is for single use. Dispose the product as medical wastes after use to avoid harm to human and environmental pollution.
10. The ICF cannot be used as technical instructions for stapler in clinical use. Please reference relevant literature for the technical instructions or consult our company.
11. MRI warnings: The product has not been tested under magnetic resonance imaging (MRI) condition for temperature elevation, displacement or artifacts.
12. This procedure may cause anastomotic leakage, bleeding.
13. Disposal devices are medical waste and should be handled and disposed of according to local regulations

VI. Instructions for installation and use

Instructions of Model WKD

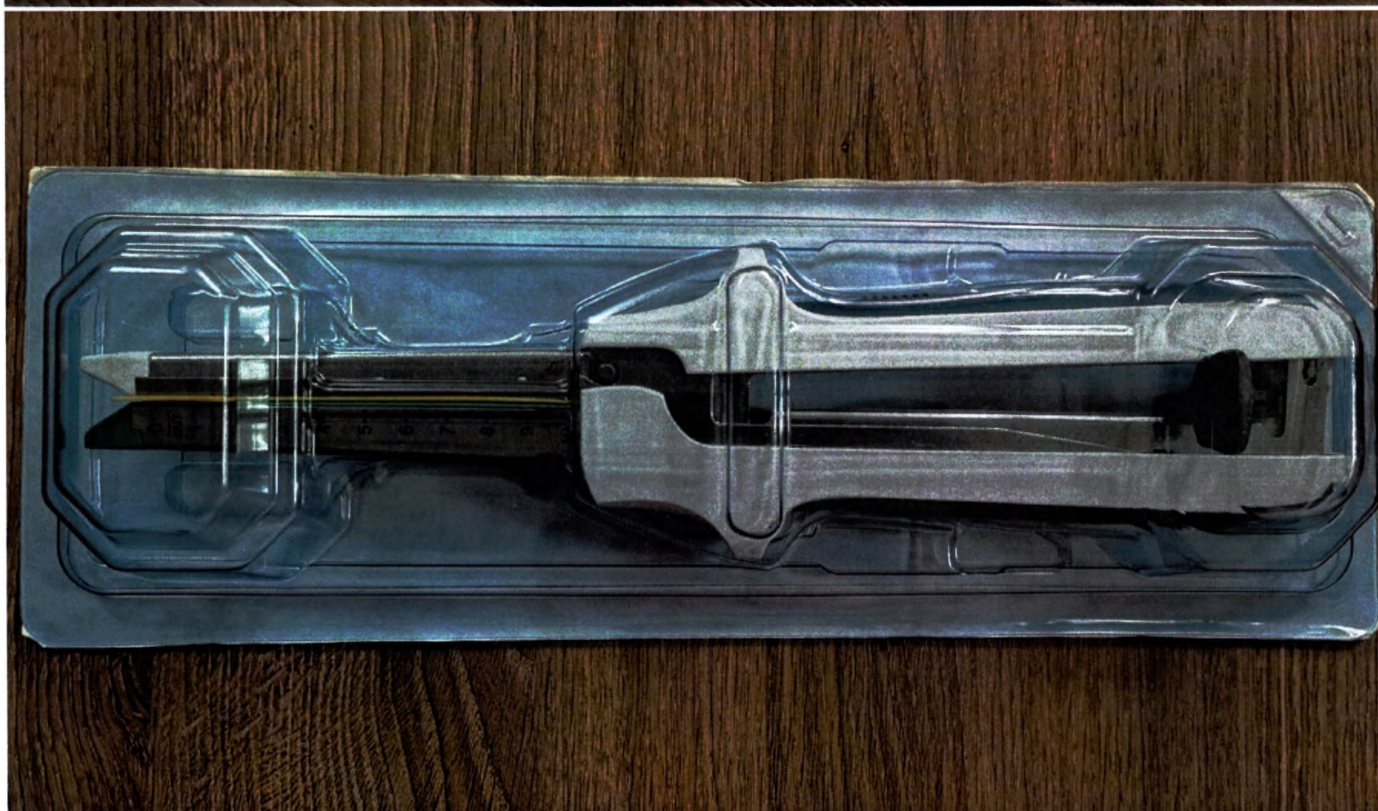
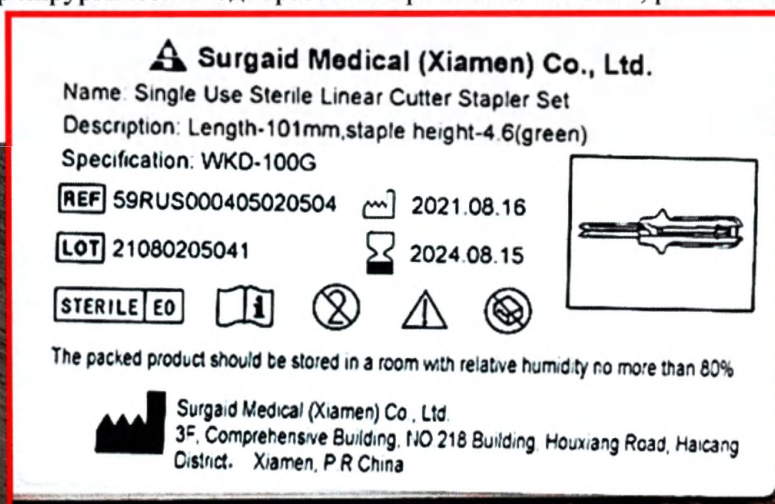
1. Unpack the sterile package, take out the linear cutter stapler from the blister box, press the button at the end of the handle, and remove the retaining cap (Figure 2).



Figure 2

Степлер хирургический одноразовый с резакком линейный, резак в картридже: WKD-100G, в составе:

1) Степлер хирургический одноразовый с резакком линейный, резак в картридже: WKD-100G – 1 шт.;



Surgeid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Linear Cutter Stapler Set

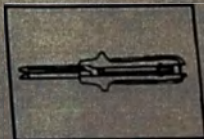
Description: Length-101mm, staple height-4.6(green)

Specification: WKD-100G

REF 59RUS000405020504 2021.08.16

LOT 21080205041 2024.08.15

STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%



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3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China

Surgeid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Linear Cutter Stapler Set

Description: Length-101mm, staple height-4.6(green)

Specification: WKD-100G

REF 59RUS000405020504 2021.08.16

LOT 21080205041 2024.08.15

STERILE EO



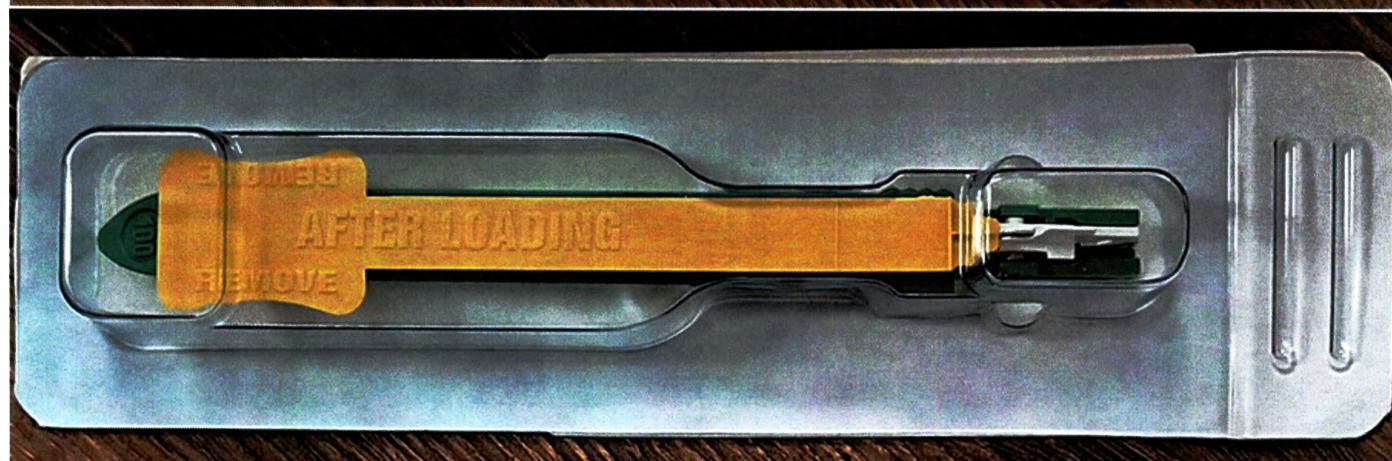
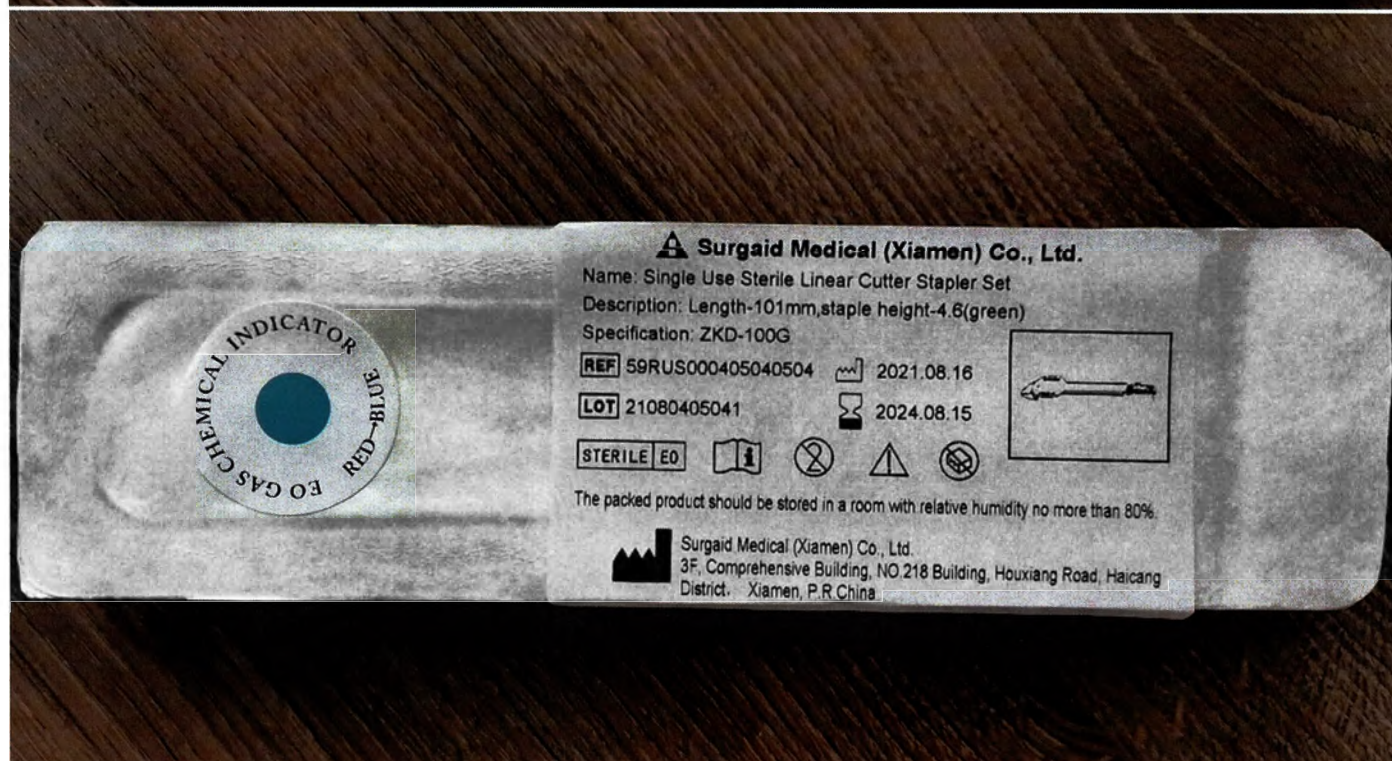
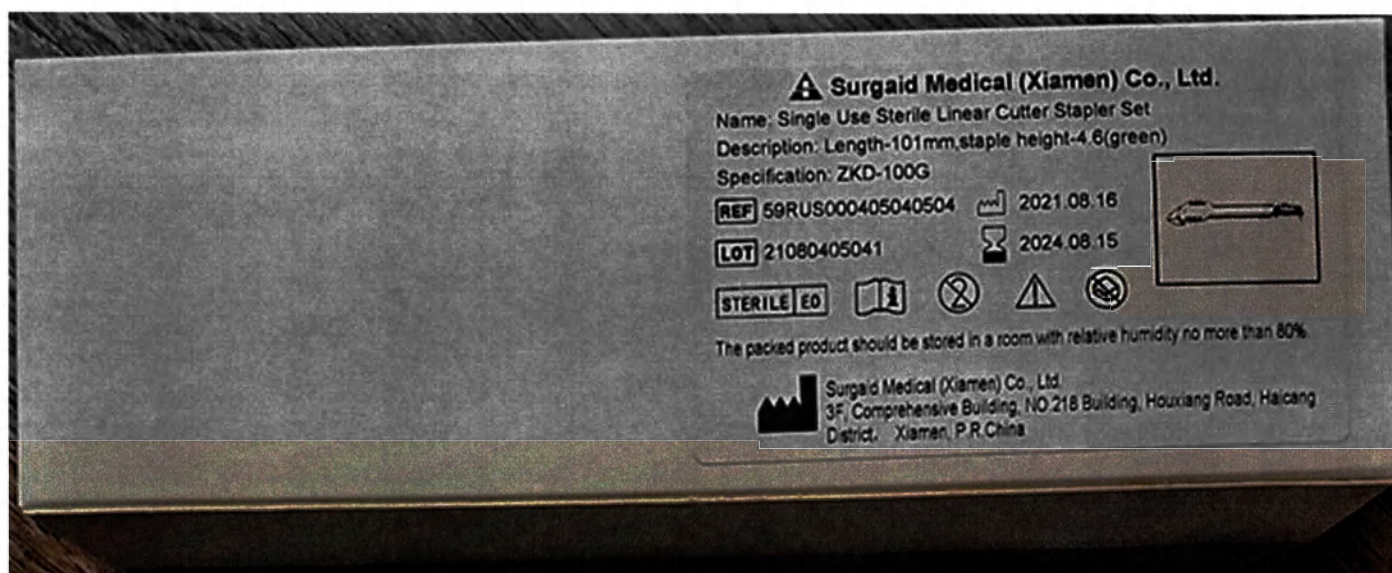
The packed product should be stored in a room with relative humidity no more than 80%

Surgeid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China





2) Картридж ZKD-100G – не более 6 шт.;





3) Инструкция по применению на Степлер хирургический одноразовый с резакком линейный, резак в картридже – 1 шт.

Instruction for Use

I. Device Name:

Single Use Sterile Linear Cutter Stapler Set

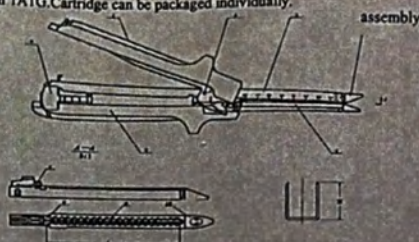
II. Product performance and major components

1. Performance:

- Appearance:** The Linear Cutter Stapler has smooth surface and well-defined contour without defects such as burrs or scratches. Scales or indications on the device body shall be legible and aligned without malposition. The surface of staple shall not contain any burr or depression.
- Flexibility:** Opening and closure of the linear stapler shall be flexible without jam.
- Assemblability:** The cartridge and device body shall be assembled and unloaded successfully. Movable parts can be moved easily with jamming or loosening. The loaded cartridge shall be fixed soundly and the staple shall not project out over the surface of reload, when the cartridge is swung.
- Performance of anastomosis and resection:** The linear cutter stapler shall perform well in anastomosis and resection for ≥ 5 times with replaced cartridge. A B-shaped staple shall be formed after each anastomosis. The resection margins shall be neat without trimmings after each anastomosis. The anastomotic line shall be at least 1.5 times of the length of staple.
- Surface roughness:** The outer surface roughness (R_a) of metal part of linear stapler shall not exceed $0.8 \mu m$.
- Corrosion resistance:** The anvil jaw shall have good corrosion resistance.
- The product shall be sterile.** The residual ethylene oxide shall not exceed $10 \mu g/g$.

2. Major components:

Refer to Figure 1 for product structure. The anvil jaw is made from 06Cr19Ni10, the cutter is made from 30Cr13 while the staple is made from TA1G. Cartridge can be packaged individually.



Linear cutter stapler: 1.Movable handle cover; 2.Movable handle; 3. Cartridge jaw; 4.Anvil jaw; 5. Staple retaining cap; 6. Firing knob Cartridge; 7.Cutter; 8.Pushing plate; 9.Staple; 10.Reload

Figure 1 The structural diagram of Linear Cutter Stapler (Model with D)

III. Indications

The product is applicable for creation of anastomosis and closure of stump or incision in gastrointestinal reconstruction and resection of other organs.

IV. Contraindications

- Patients with inhomogeneous tissues caused by radiotherapy;
- Tissues with mucosal oedema, ischemia or necrosis
- As closure of the product may cause destructive effect on liver or spleen tissues due to the compression property of these organs, do not use the product for liver or spleen tissues;
- Patients with systematic disease (such as haemorrhagic diathesis, hypoproteinaemia and severe cardiovascular disorder.)

V. Precautions and Warnings

- Strictly follow the sterile instruction while using the product. Do not use unsealed, damaged or expired products.
- Please read the ICF carefully and pay attention to manufacturing date and expired date prior to use of the product. Expired products shall not be used.
- The product shall be used by physicians who have been trained for stapler or used under the guidance of physicians with relevant experience.
- Ensure that the thickness of tissue is within the specified range and tissues distributed evenly in the stapler. If tissue in one side is more than another side, anastomotic effect may be affected and anastomotic leak could occur.
- Do not use the product on any tissue whose compressed thickness is less than 1.0 mm since the stapler is unable to clamp soundly and ensure effect of hemostasis.
- A complete firing shall be done within one operation. Do not partly fire the stapler. Incomplete firing may cause abnormal staple formation, incomplete resection line, bleeding, leakage from suture line and/or difficulties in stapler removal.
- The stapler shall be fired completely to ensure correct staple formation and tissue resection.
- After firing, check the hemostatic status near anastomotic line and observe the completeness of anastomosis and status of leakage.
- The product is for single use. Dispose the product as medical wastes after use to avoid harm to human and environmental pollution.
- The ICF cannot be used as technical instructions for stapler in clinical use. Please reference relevant literature for the technical instructions or consult our company.
- MRI warnings:** The product has not been tested under magnetic resonance imaging (MRI) condition for temperature elevation, displacement or artifacts.
- This procedure may cause anastomotic leakage, bleeding.
- Disposal devices are medical waste and should be handled and disposed of according to local regulations

VI. Instructions for installation and use

Instructions of Model WKD

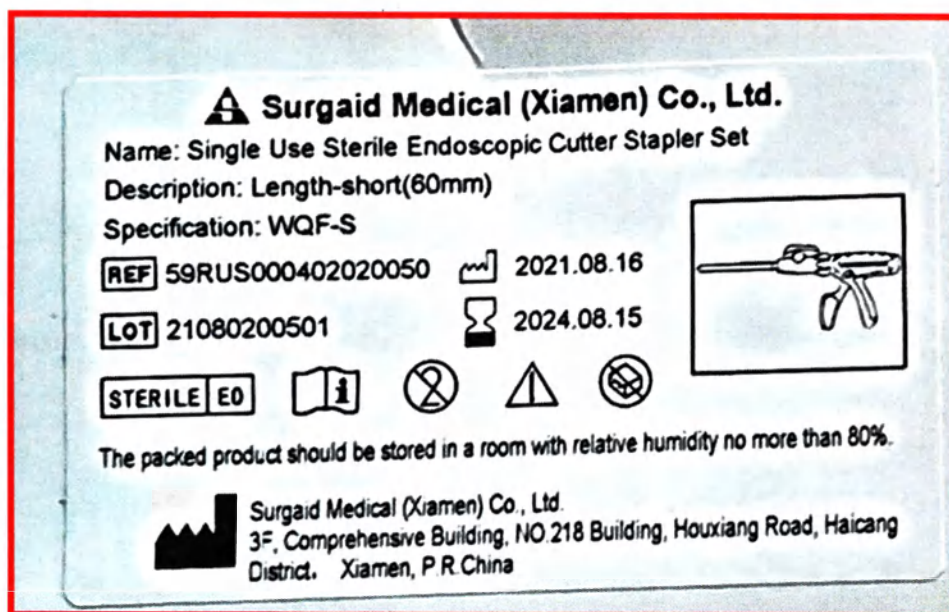
- Unpack the sterile package, take out the linear cutter stapler from the blister box, press the button at the end of the handle, and remove the retaining cap (Figure 2).



Figure 2

Степлер хирургический одноразовый эндоскопический с одинарной рукояткой: WQF-S, в составе:

1) Степлер хирургический одноразовый эндоскопический с одинарной рукояткой: WQF-S – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Endoscopic Cutter Stapler Set
Description: Length-short(60mm)
Specification: WQF-S
REF: 59RUS000402020050 2021.08.16
LOT: 21080200501 2024.08.15
STERILE E0
The packed product should be stored in a room with relative humidity no more than 80%.
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Endoscopic Cutter Stapler Set

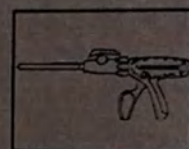
Description: Length-short(60mm)

Specification: WQF-S

REF: 59RUS000402020050 2021.08.16

LOT: 21080200501 2024.08.15

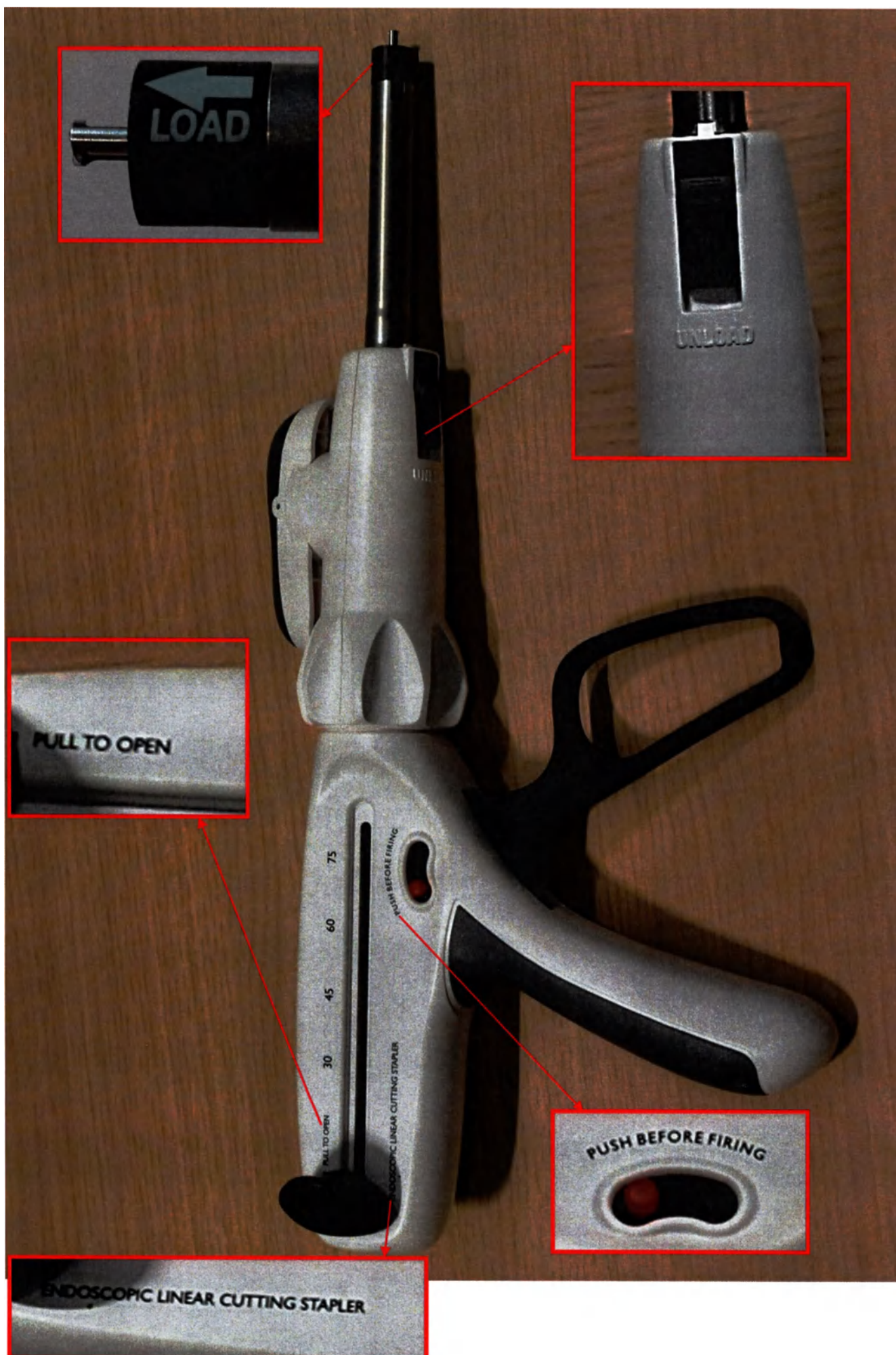
STERILE E0



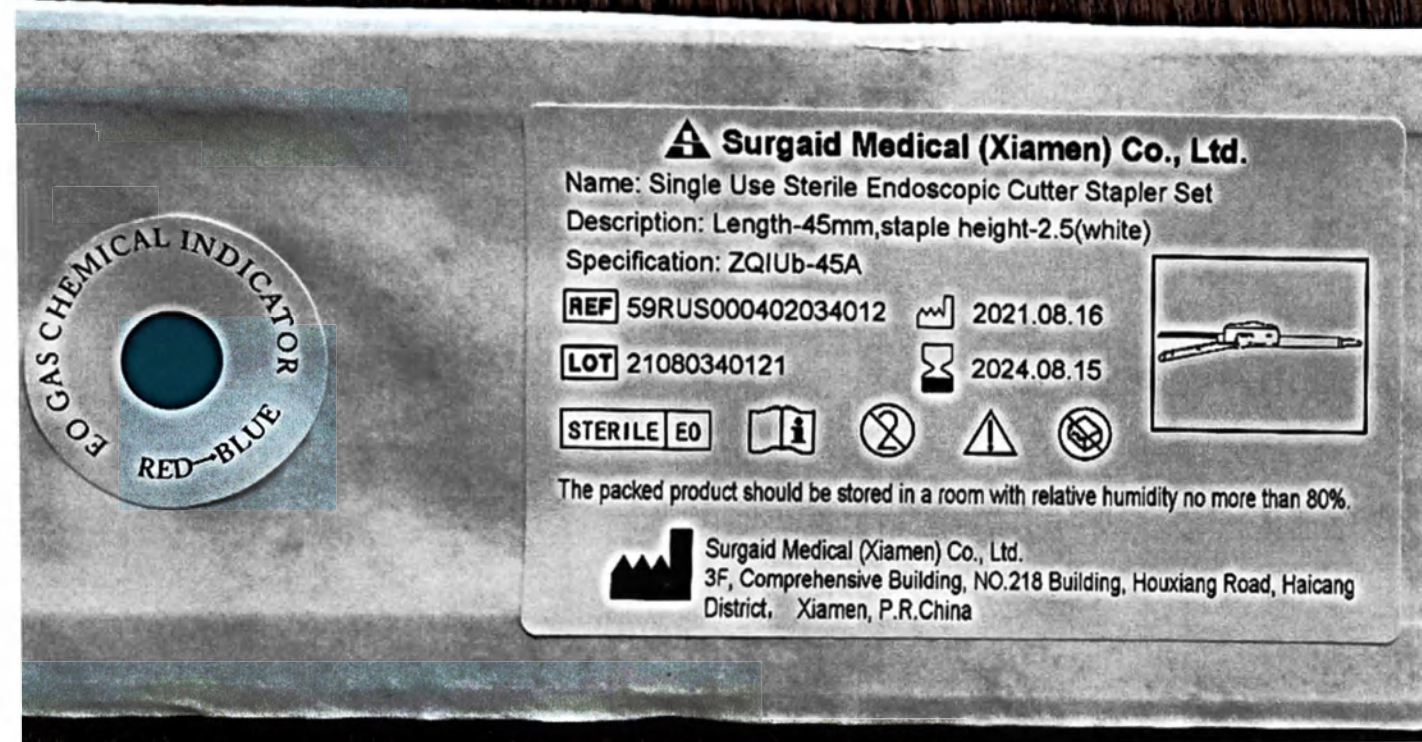
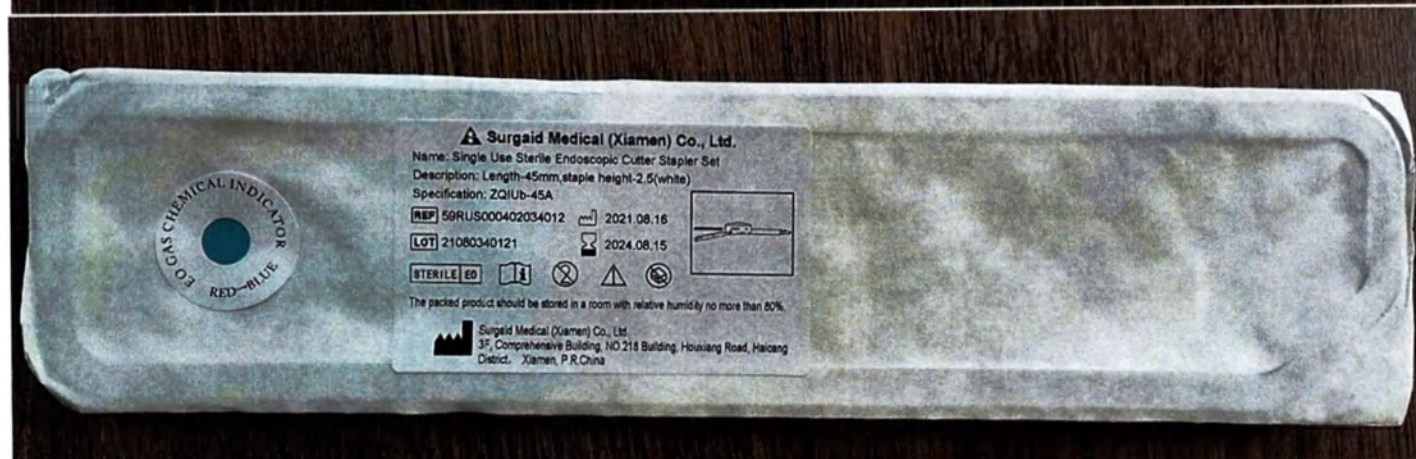
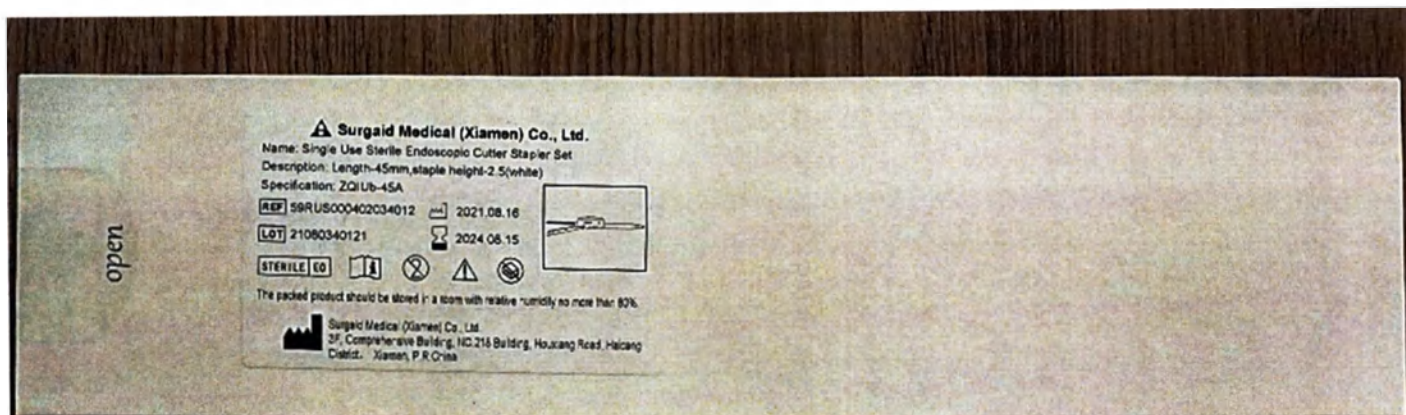
The packed product should be stored in a room with relative humidity no more than 80%.



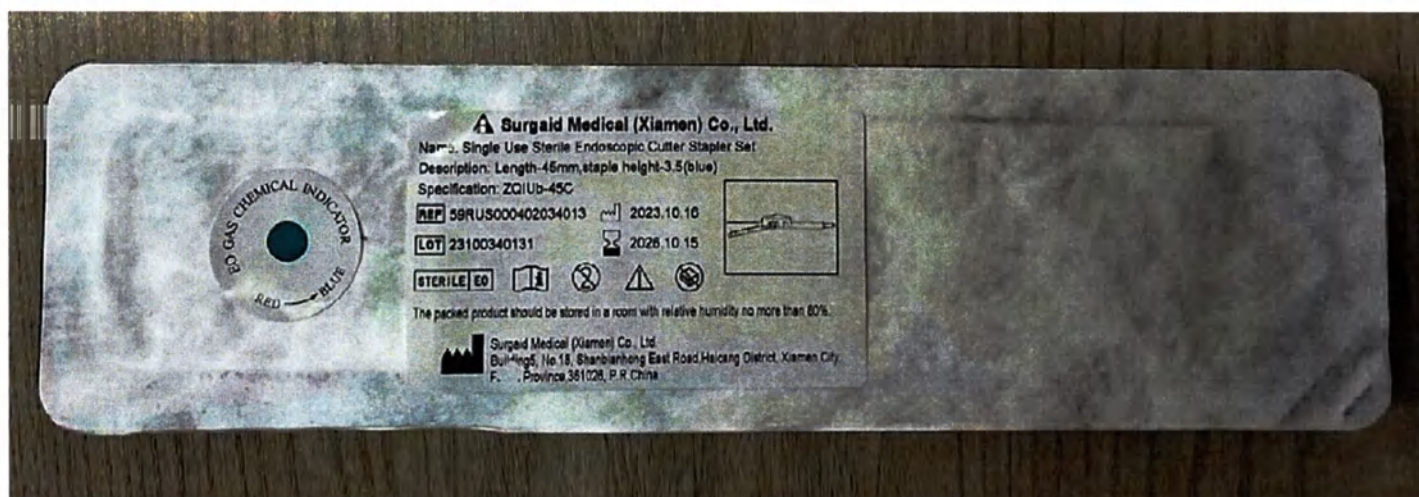
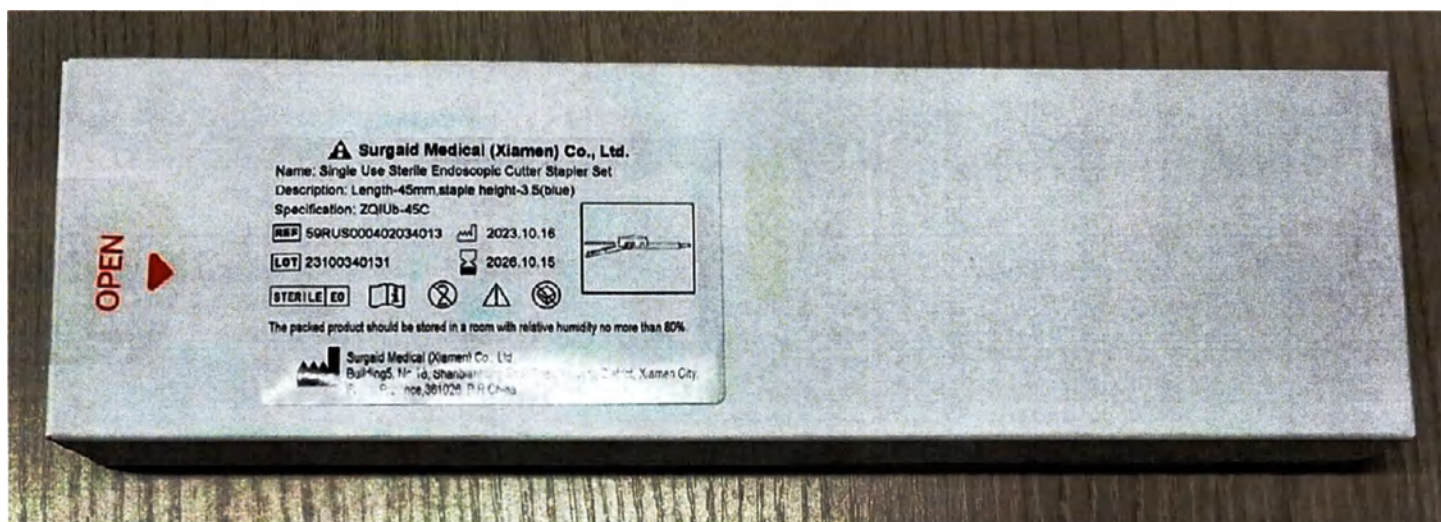
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

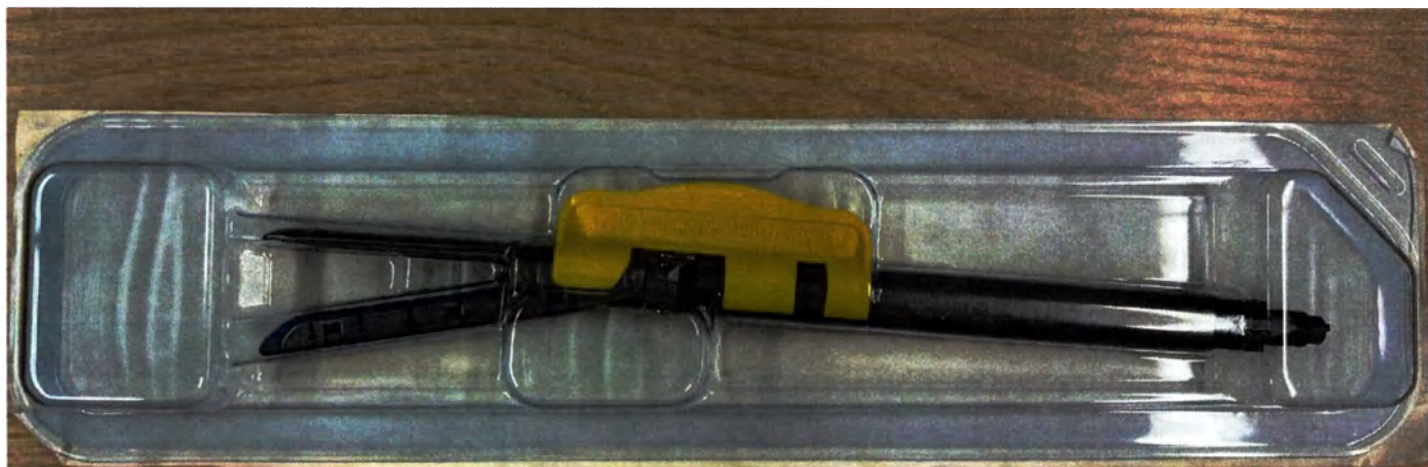


- 2) Картридж для степлера ротационный, в одном из вариантов исполнения:
- Картридж для степлера ротационный, прямой: ZQIUb-45A – не более 6 шт. (при необходимости);

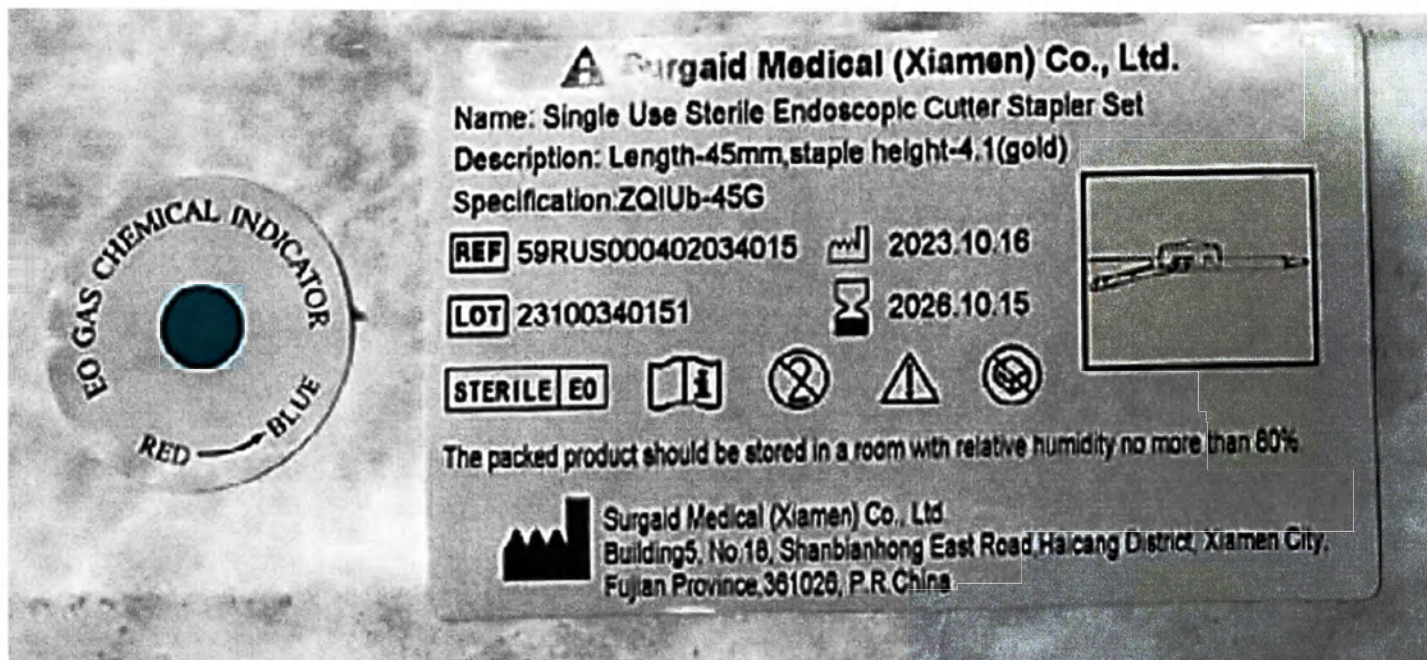
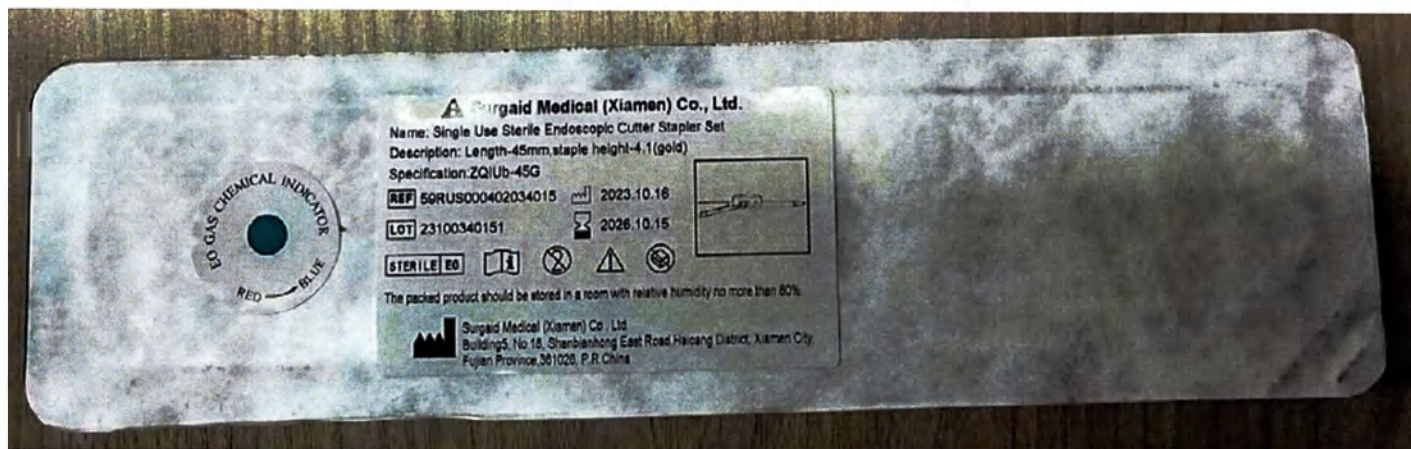
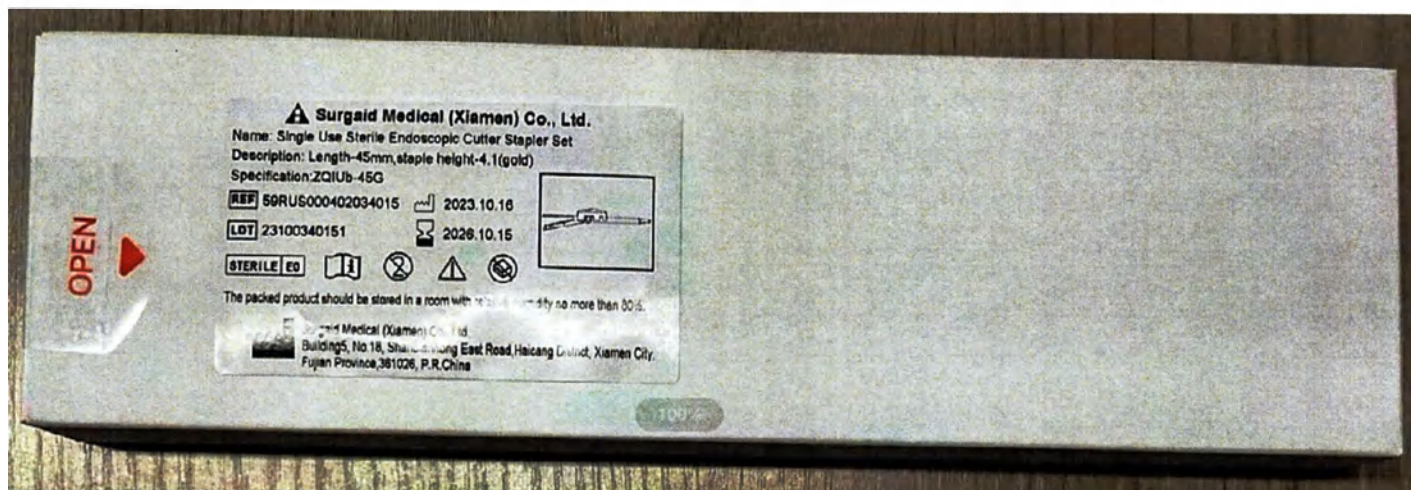


- Картридж для степлера ротационный, прямой: ZQIUb-45C – не более 6 шт. (при необходимости);



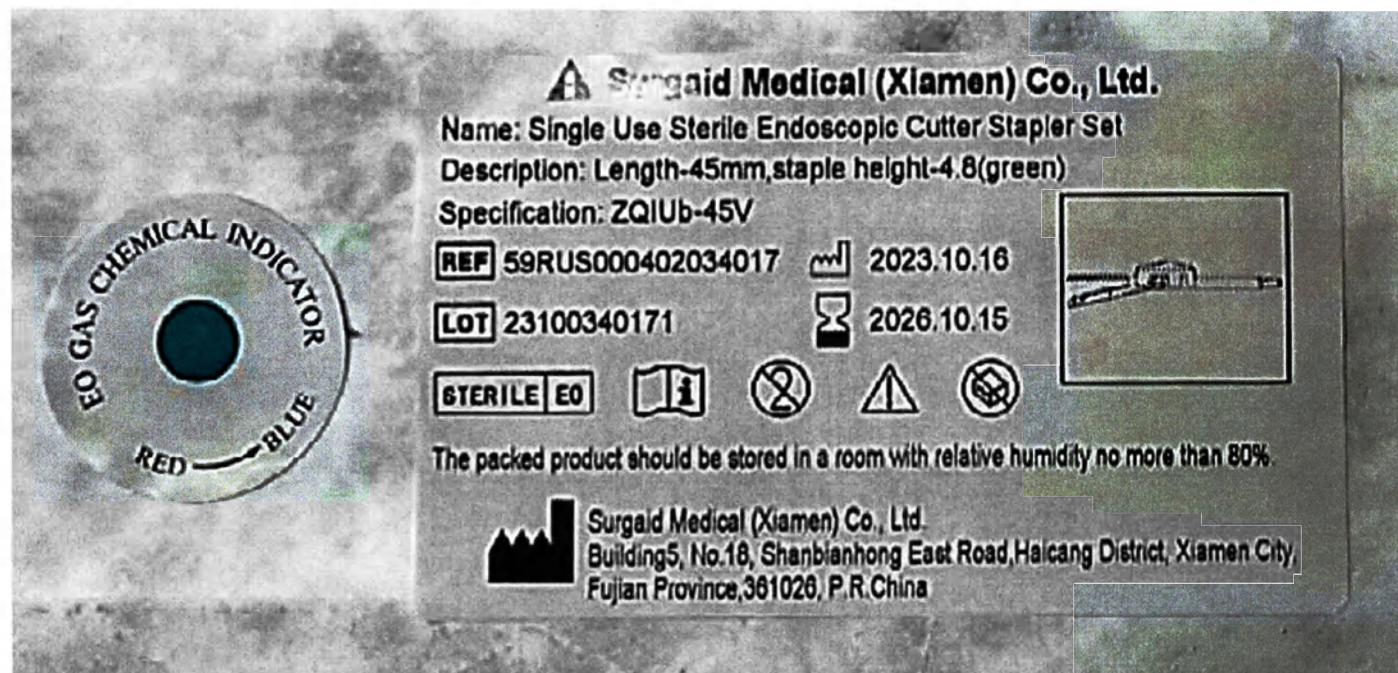
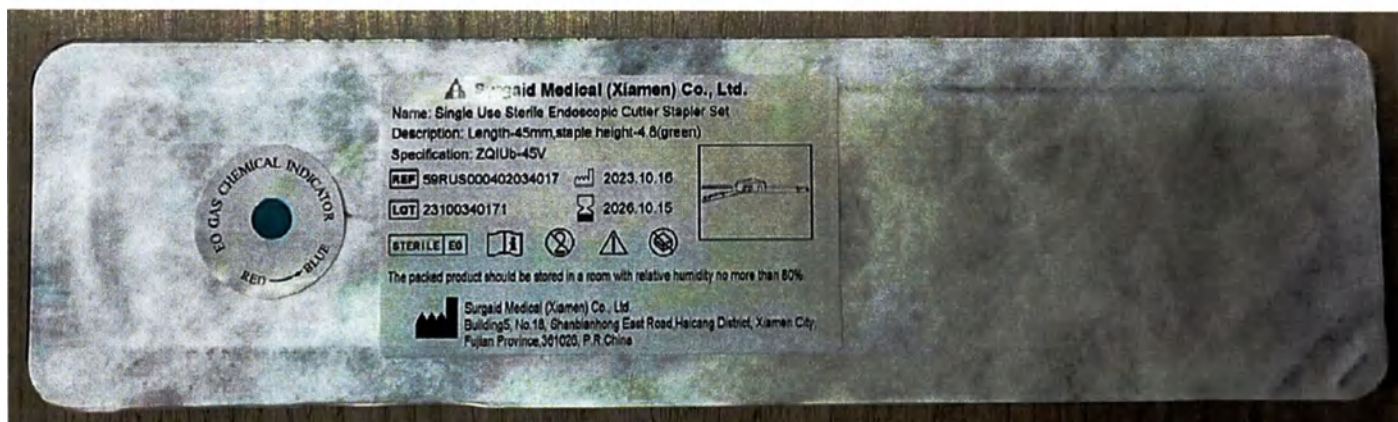
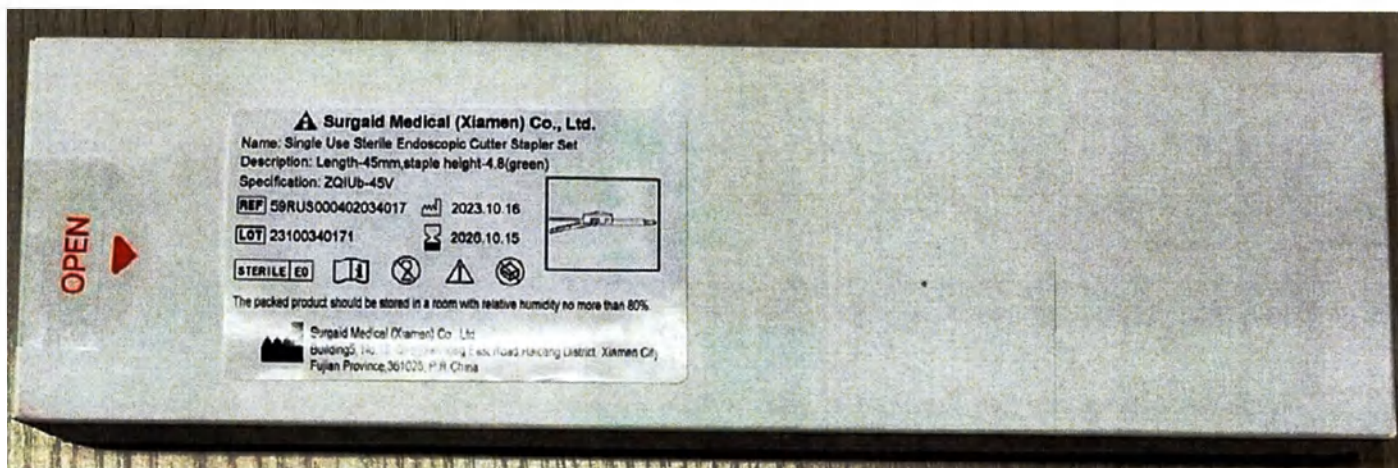


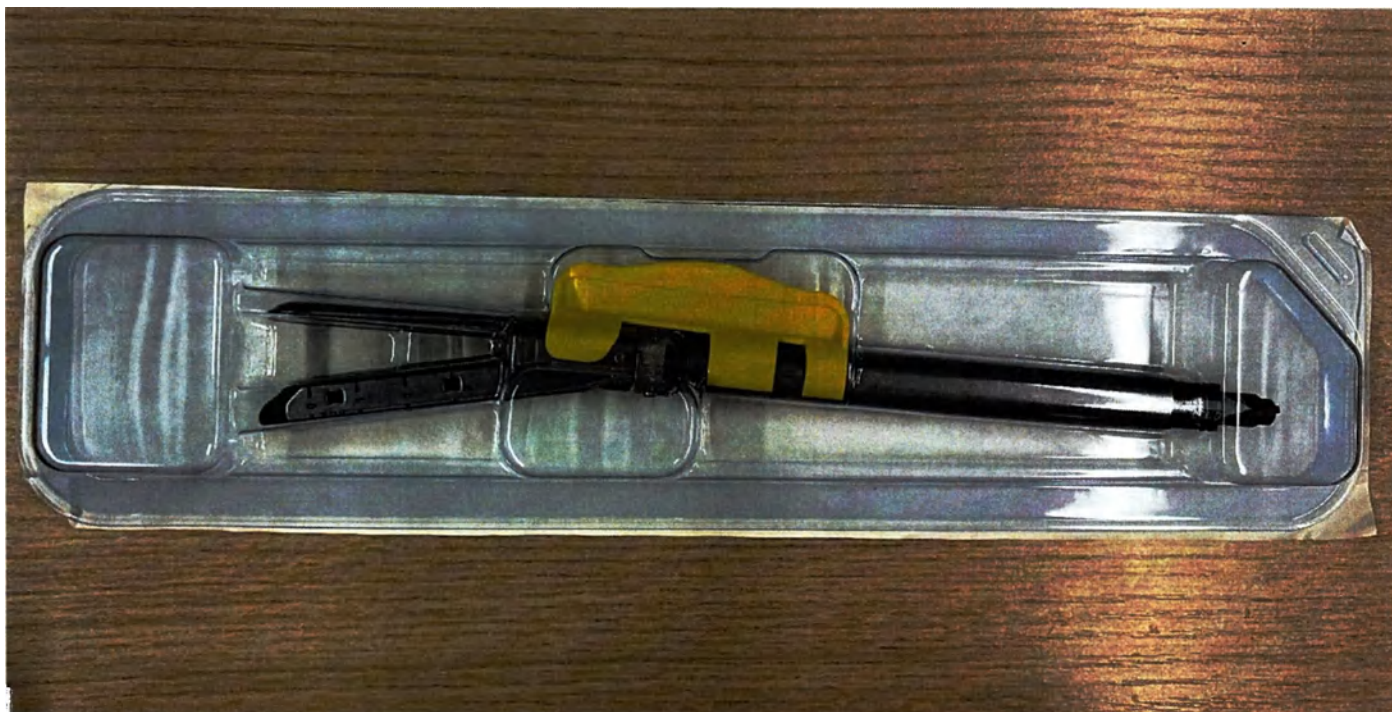
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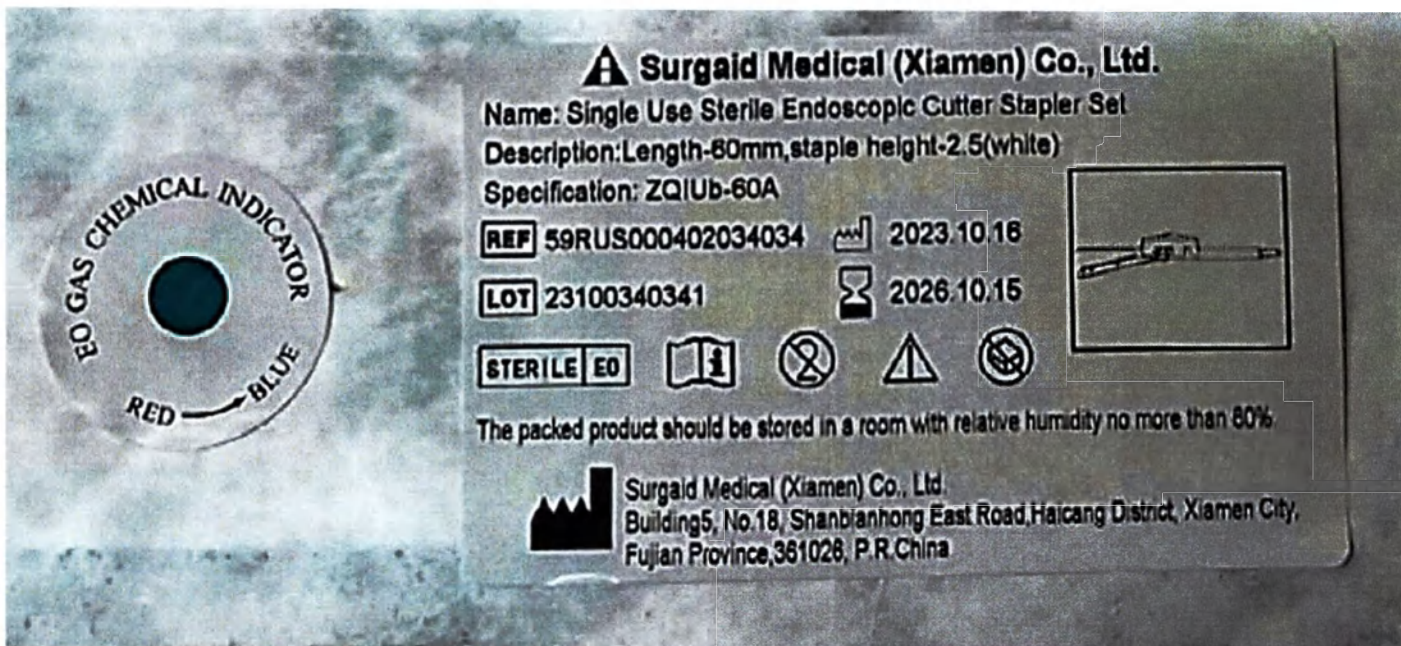
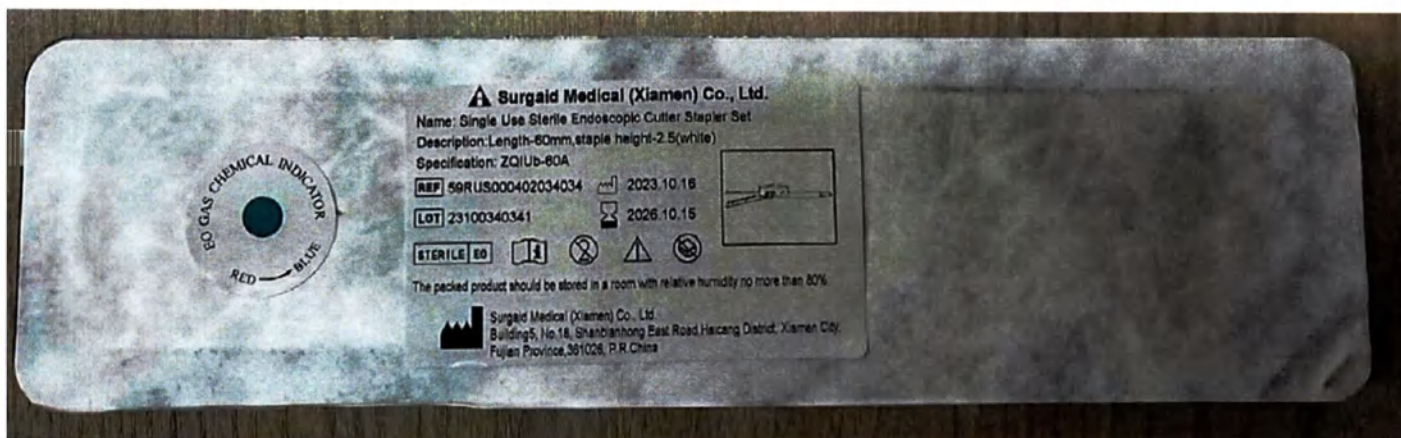
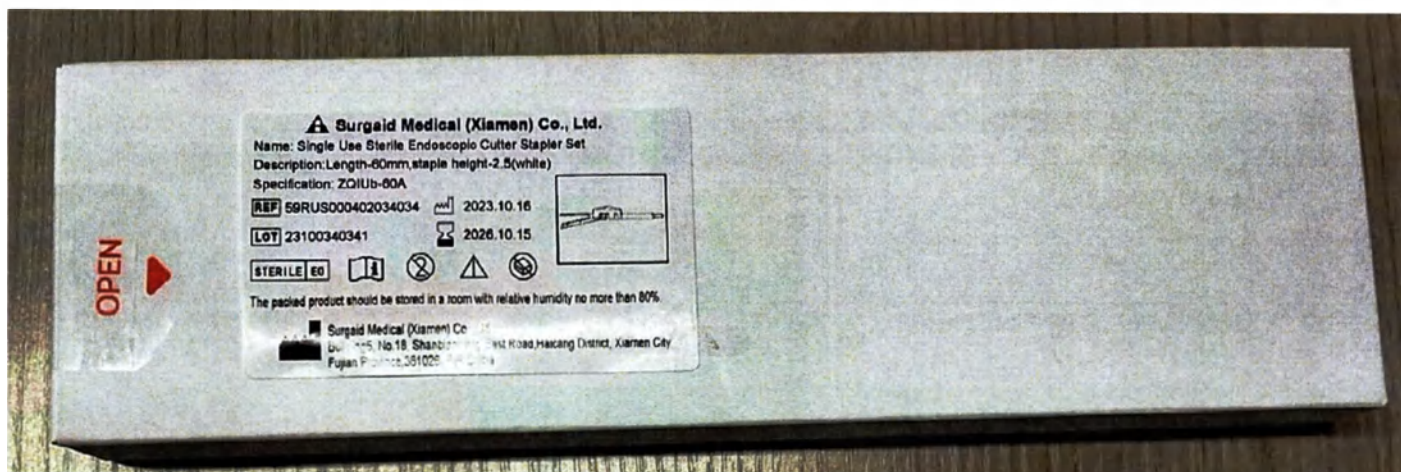


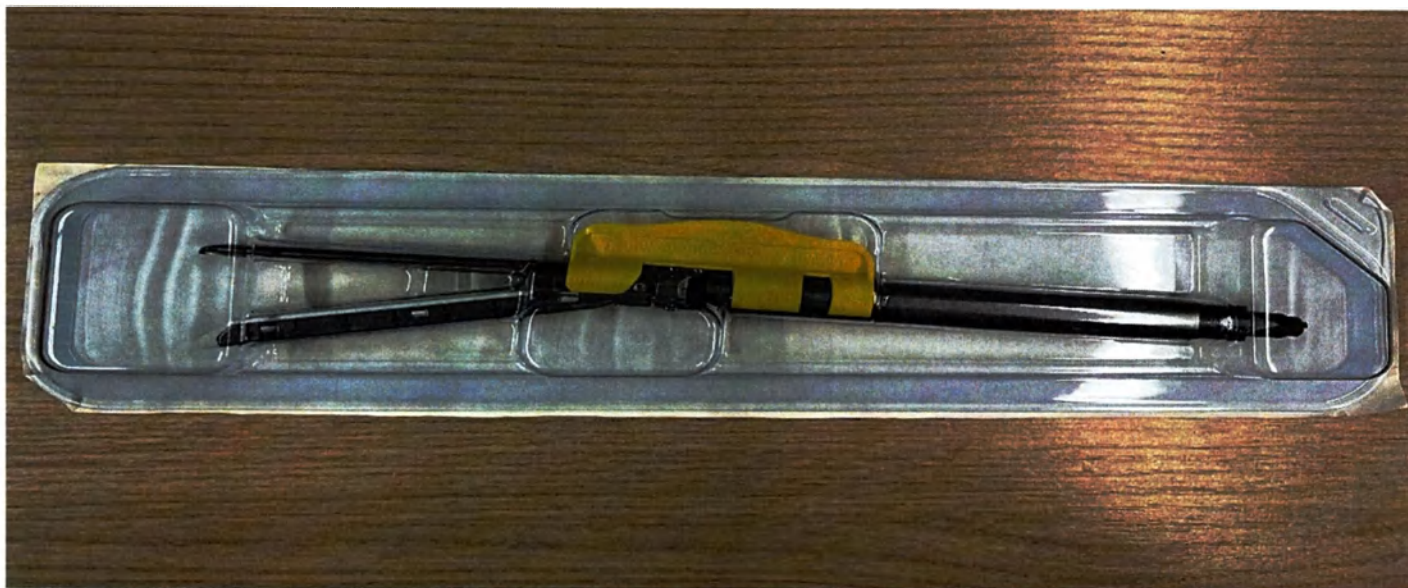
- Картридж для степлера ротационный, прямой: ZQIUb-45V – не более 6 шт. (при необходимости);



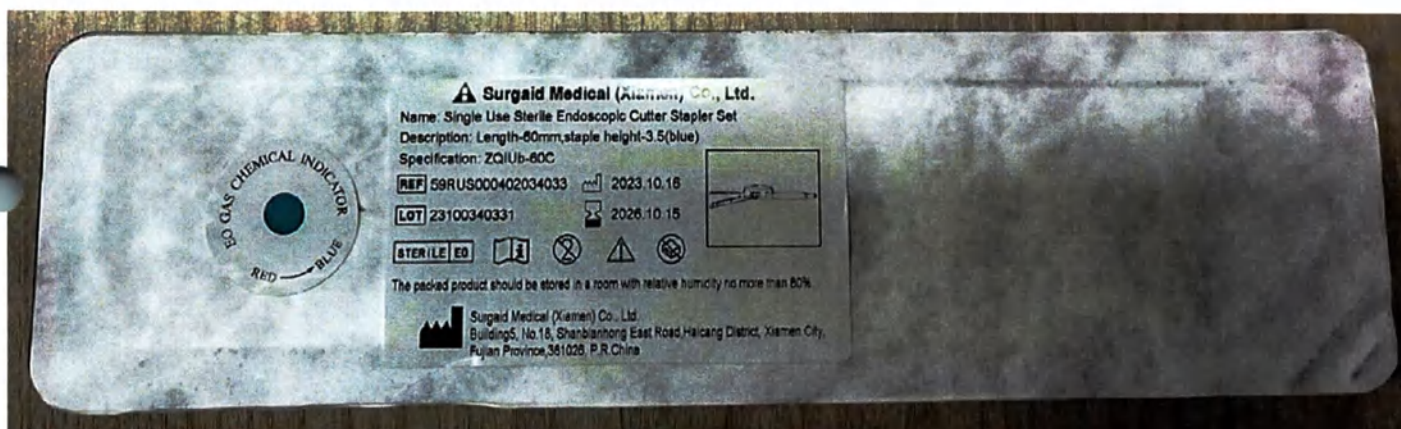
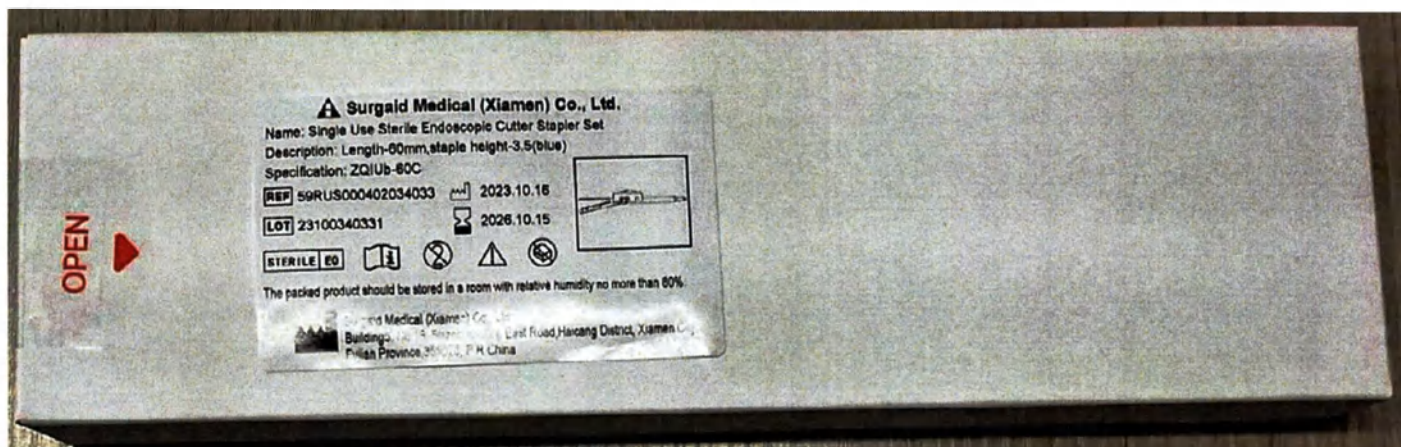


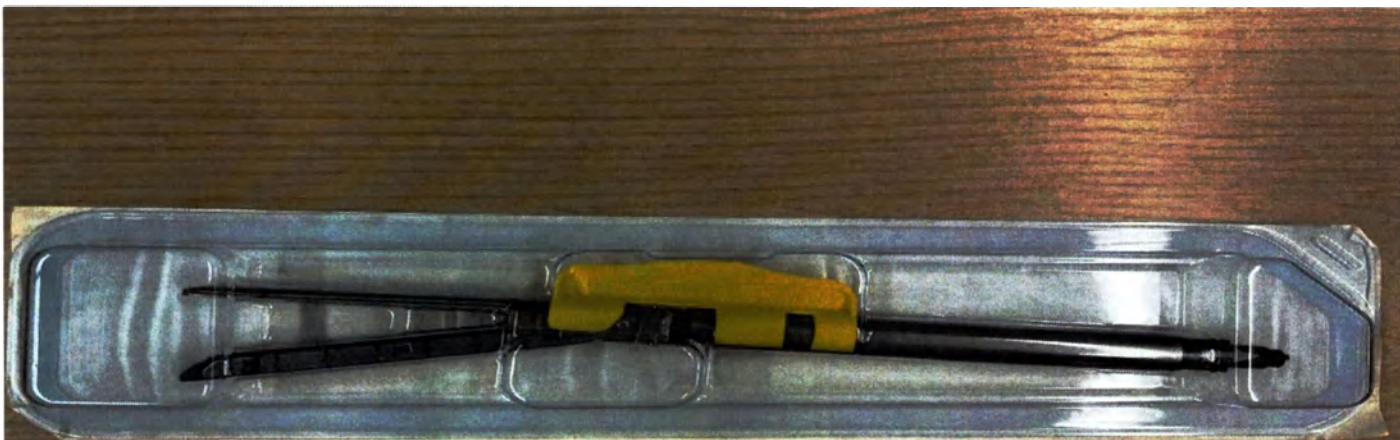
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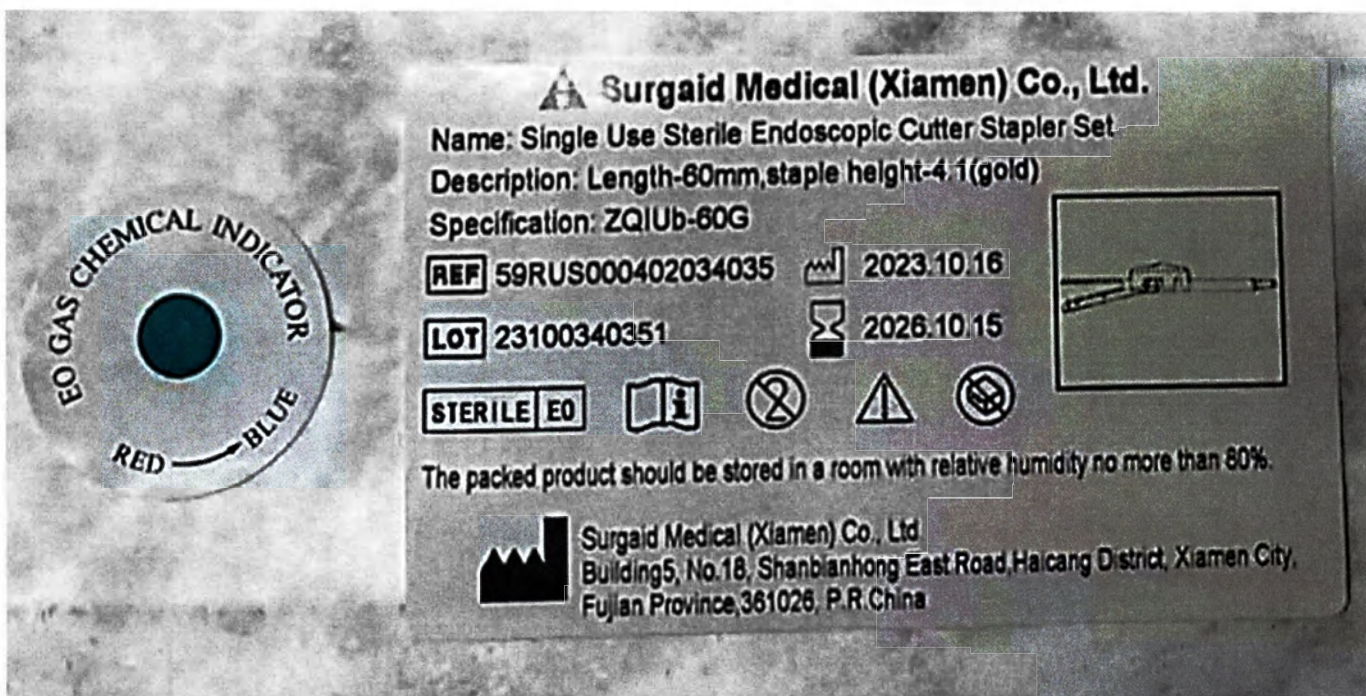
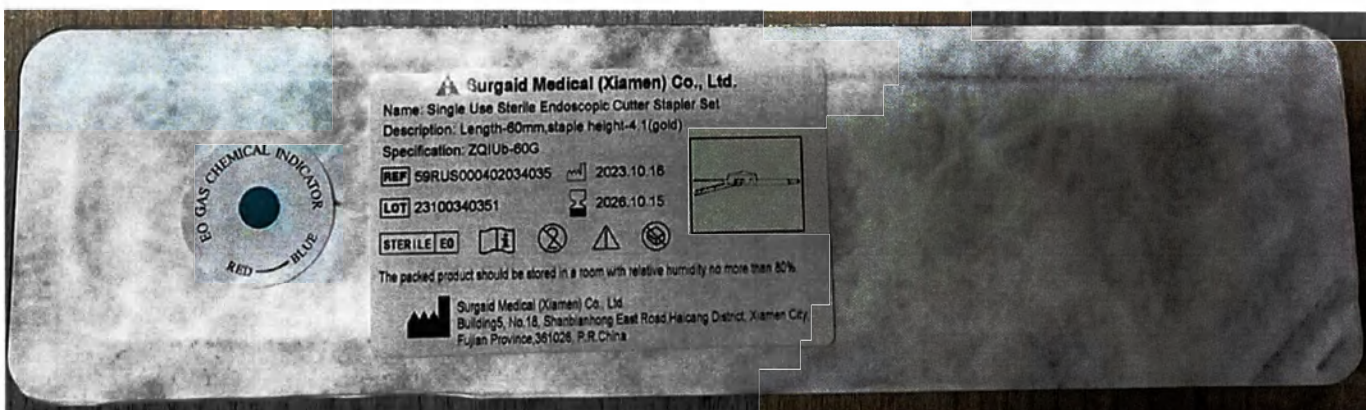
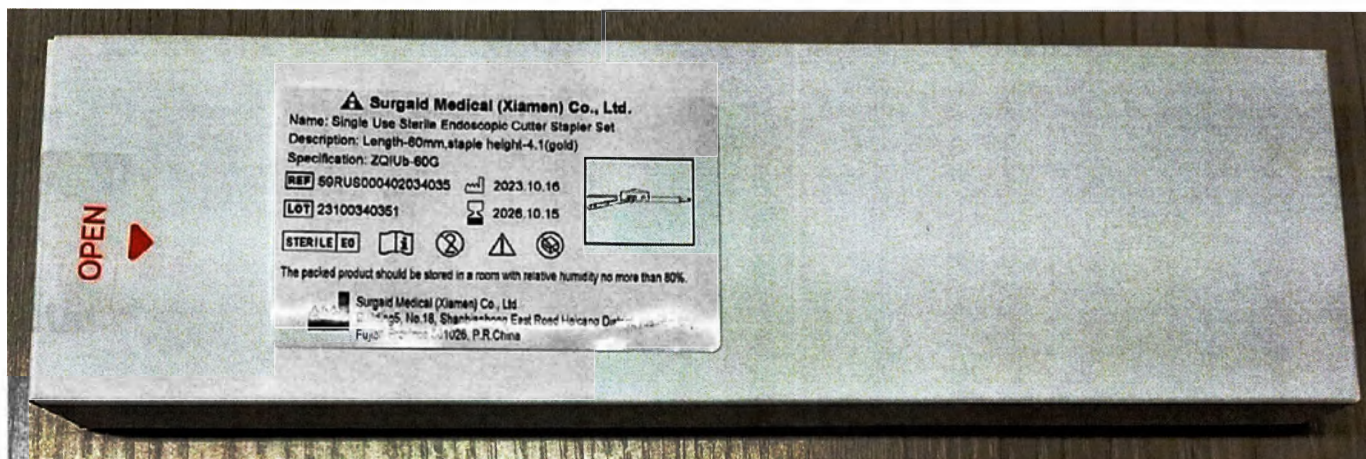


- Картридж для степлера ротационный, прямой: ZQIUб-60С – не более 6 шт. (при необходимости);



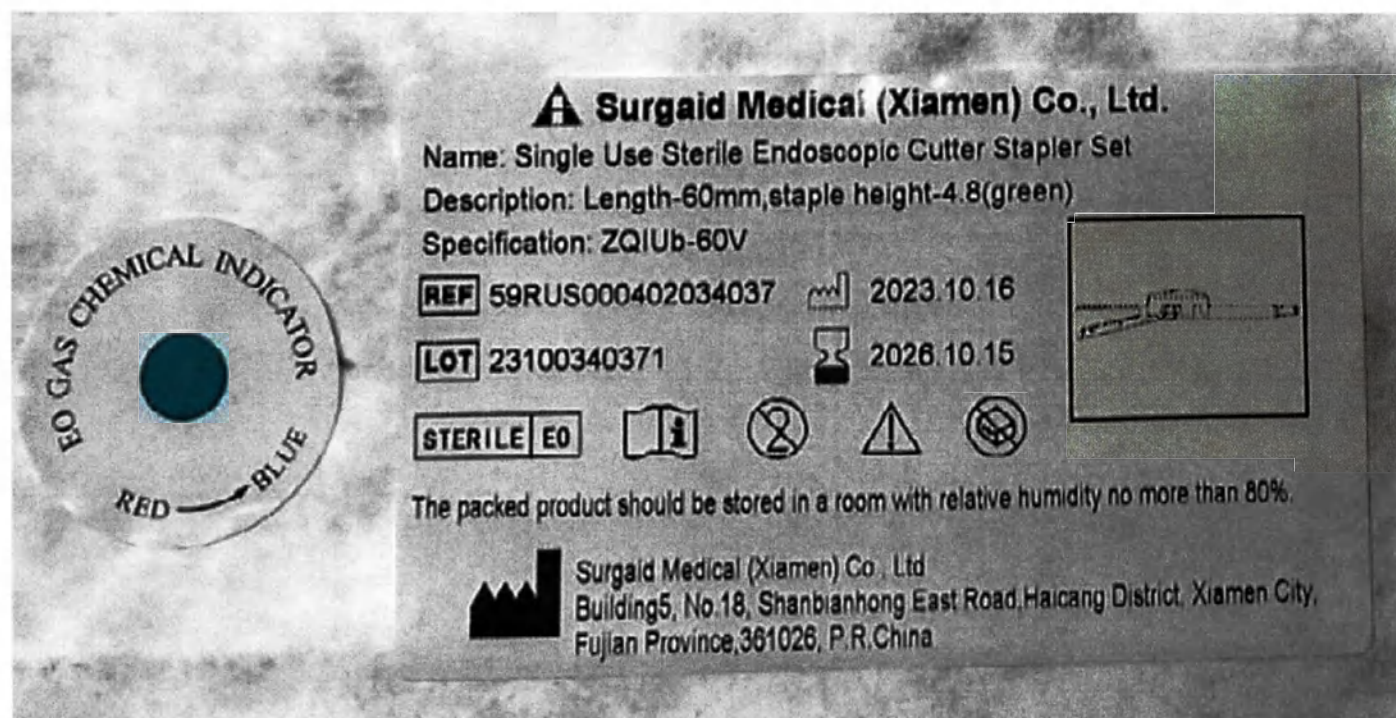
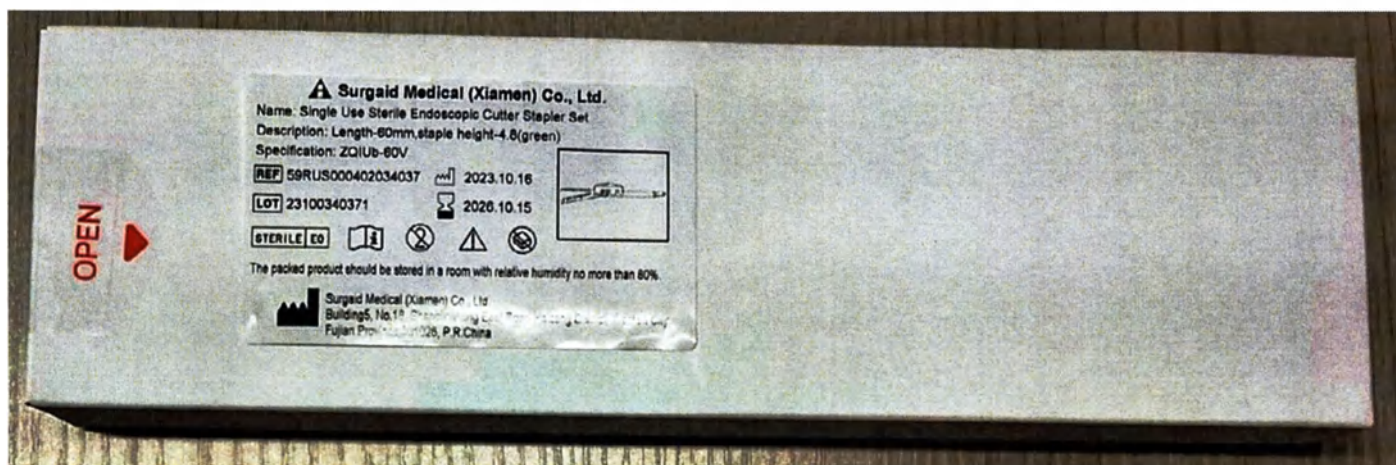


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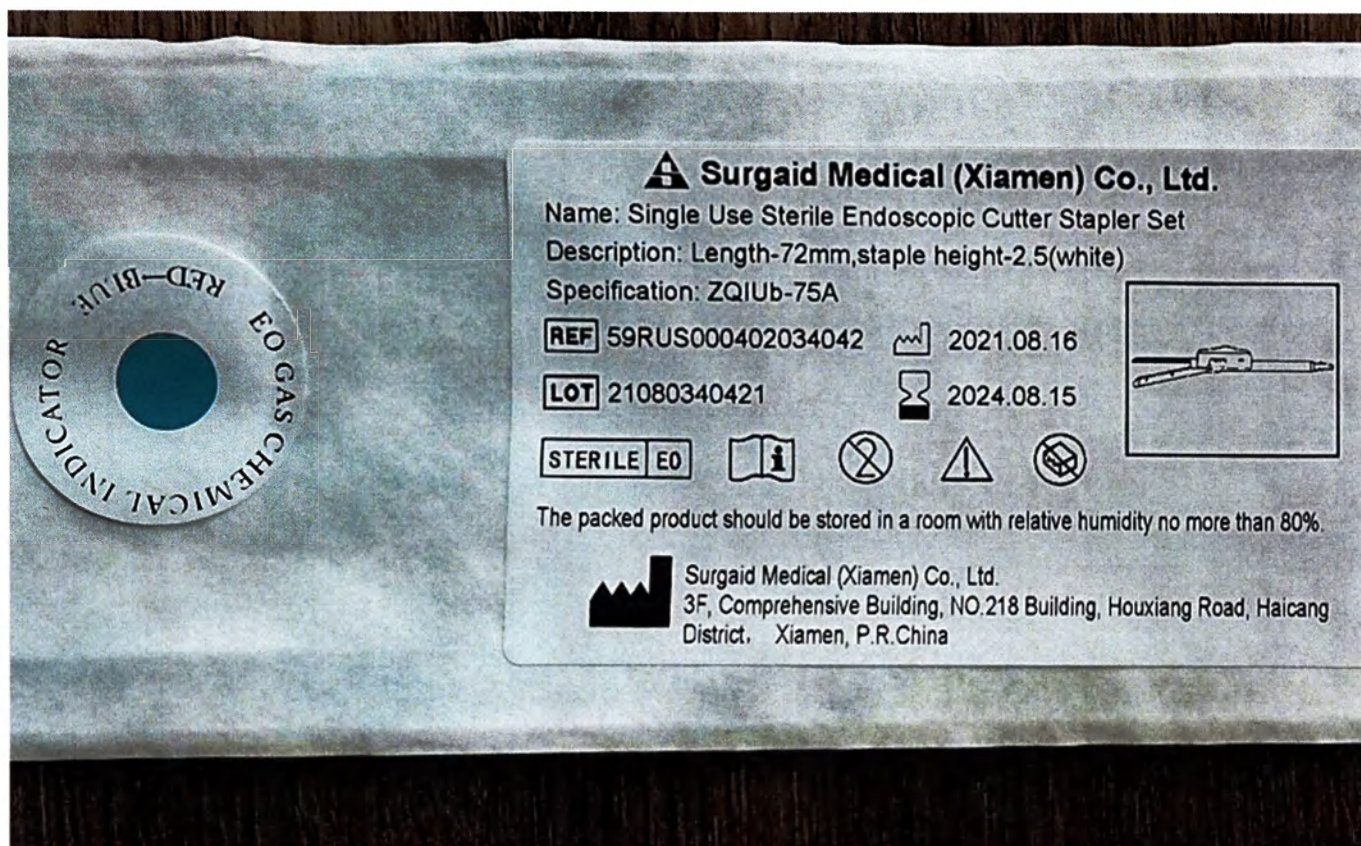
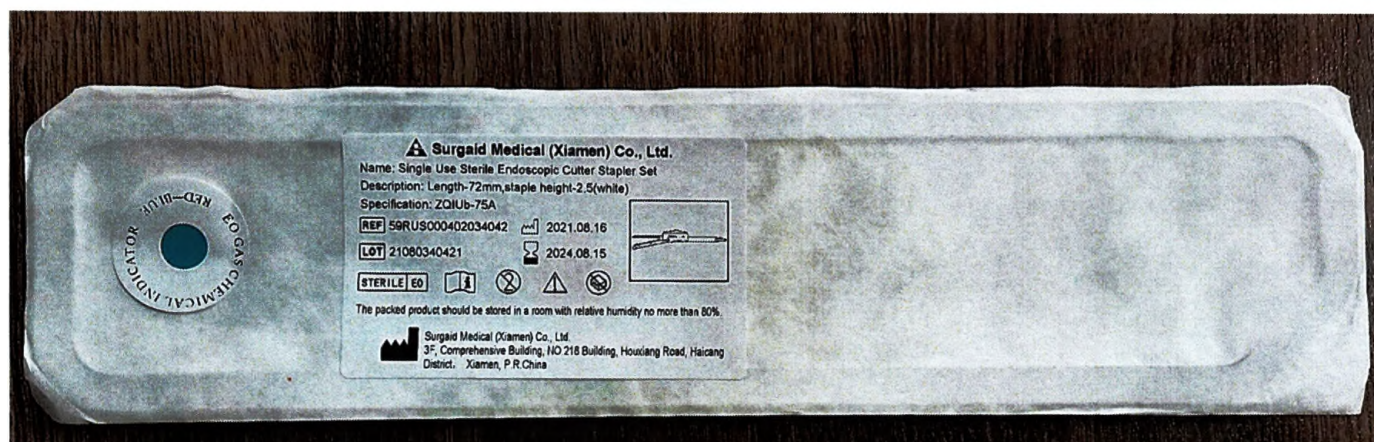
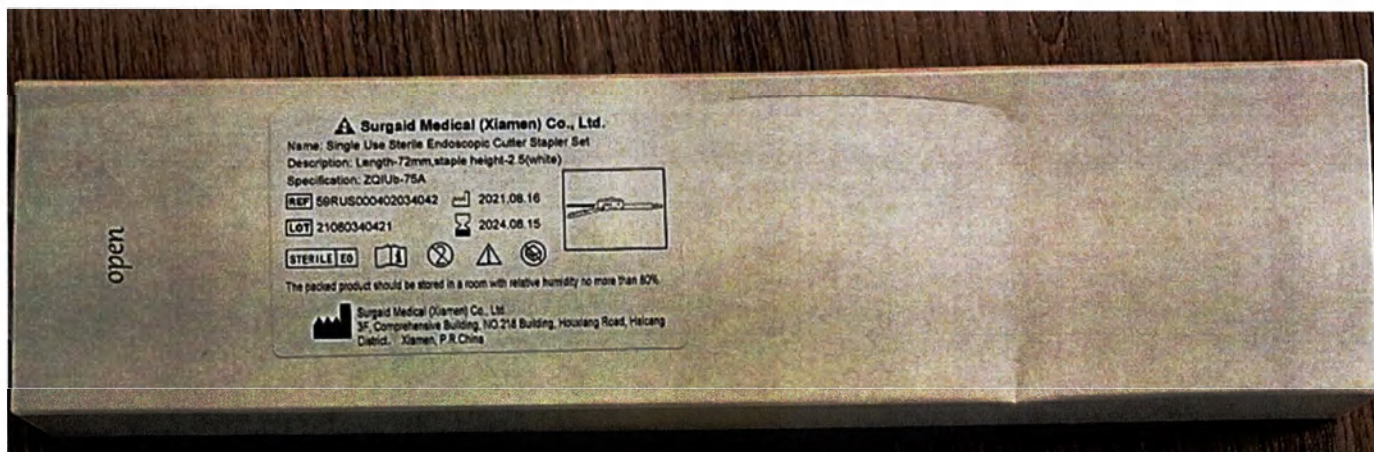


- Картридж для степлера ротационный, прямой: ZQIUb-60V – не более 6 шт. (при необходимости);



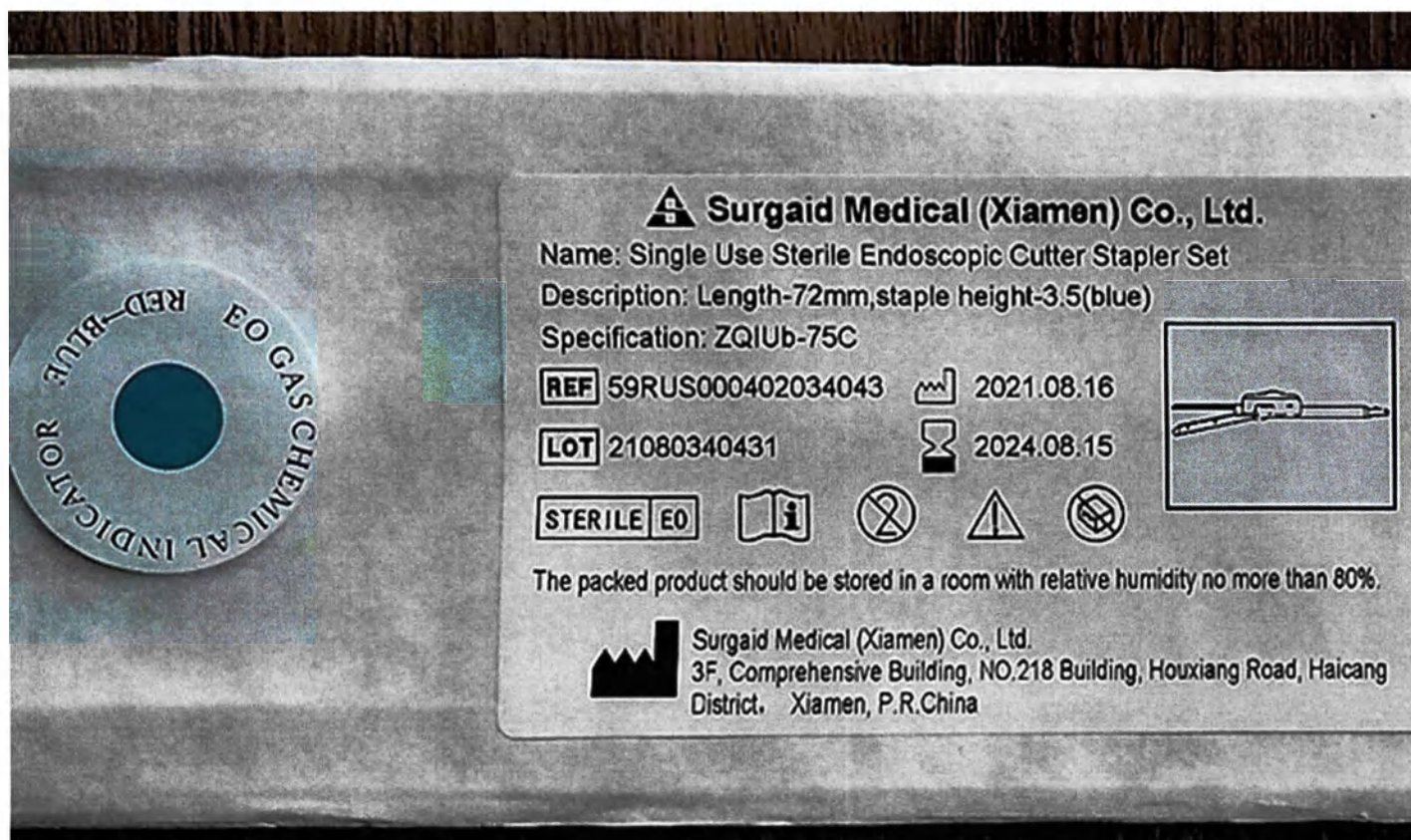
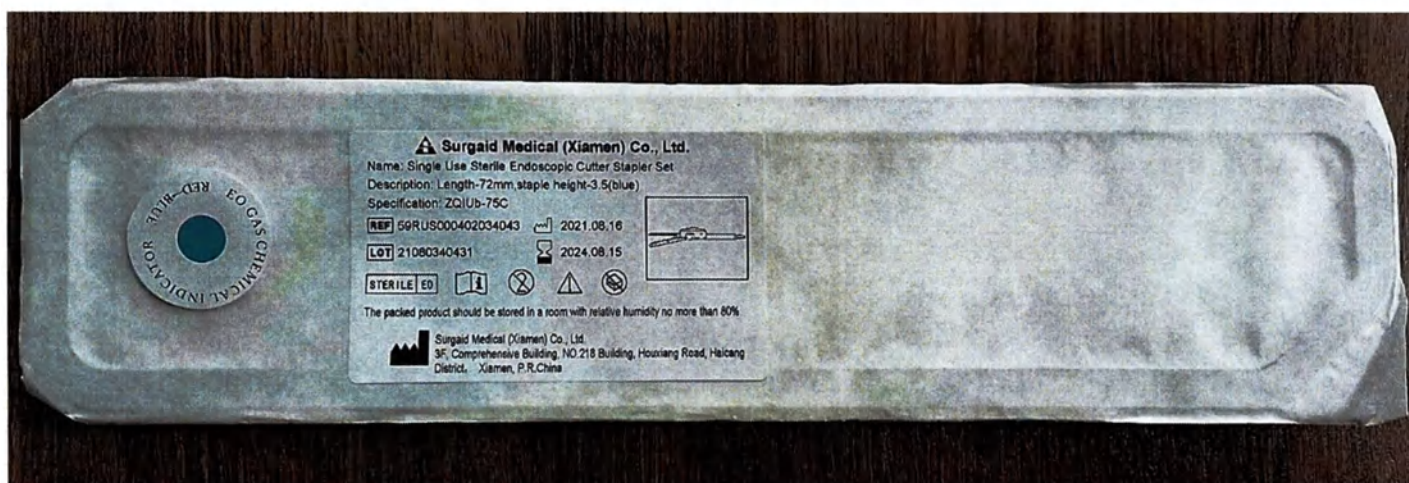
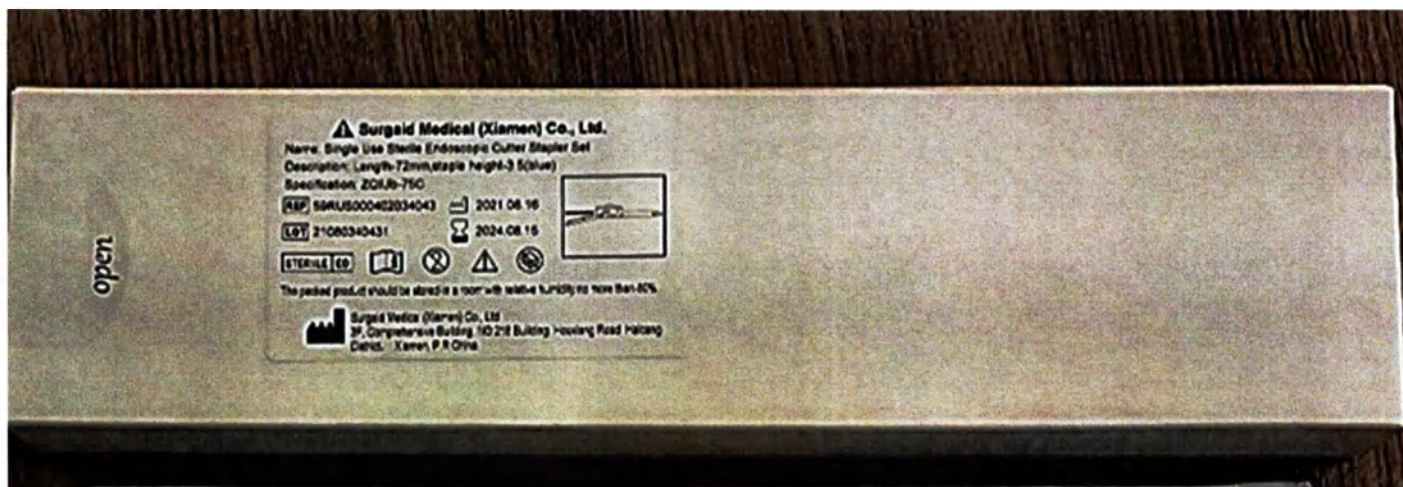


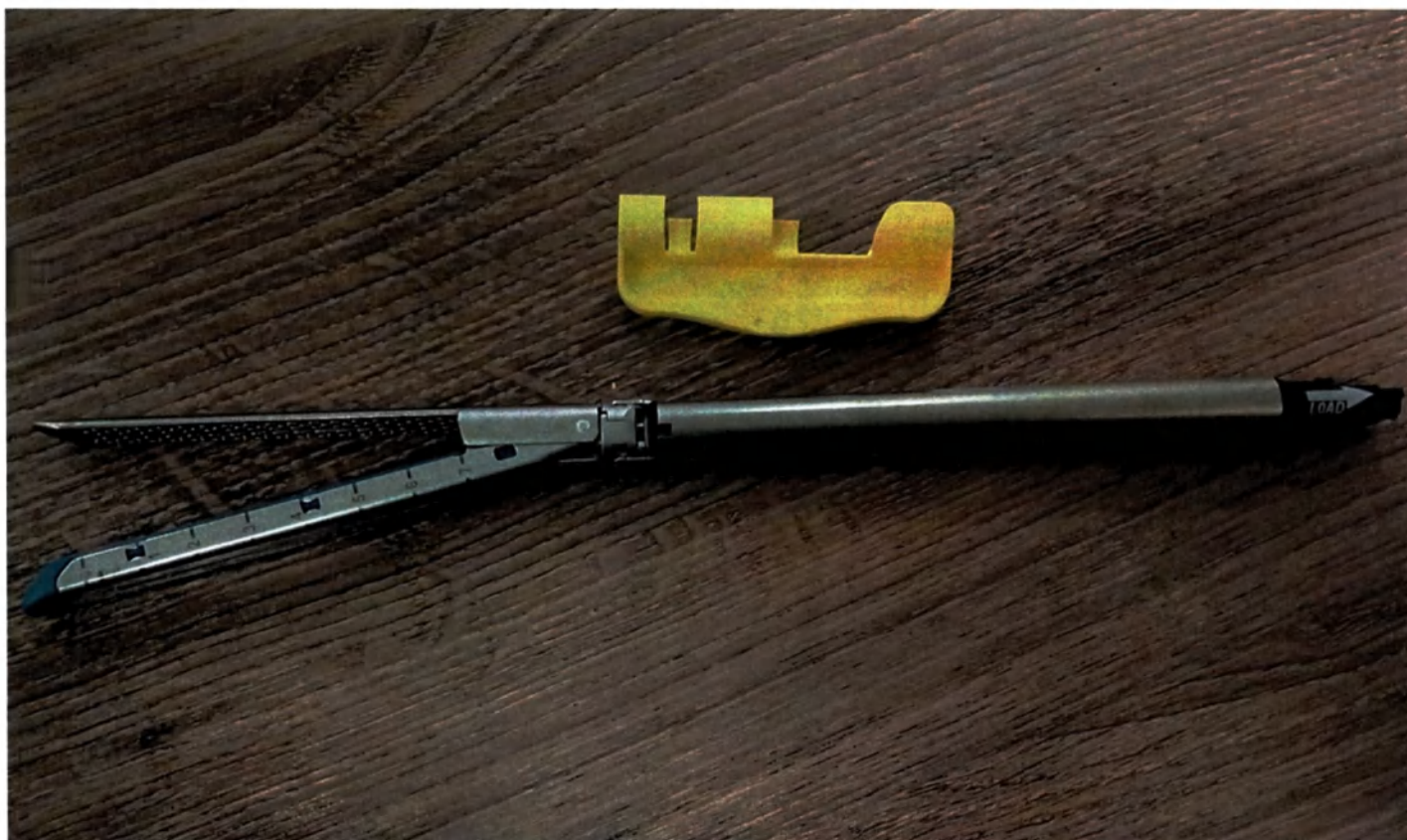
– Картридж для степлера ротационный, прямой: ZQIUb-75A – не более 6 шт. (при необходимости);



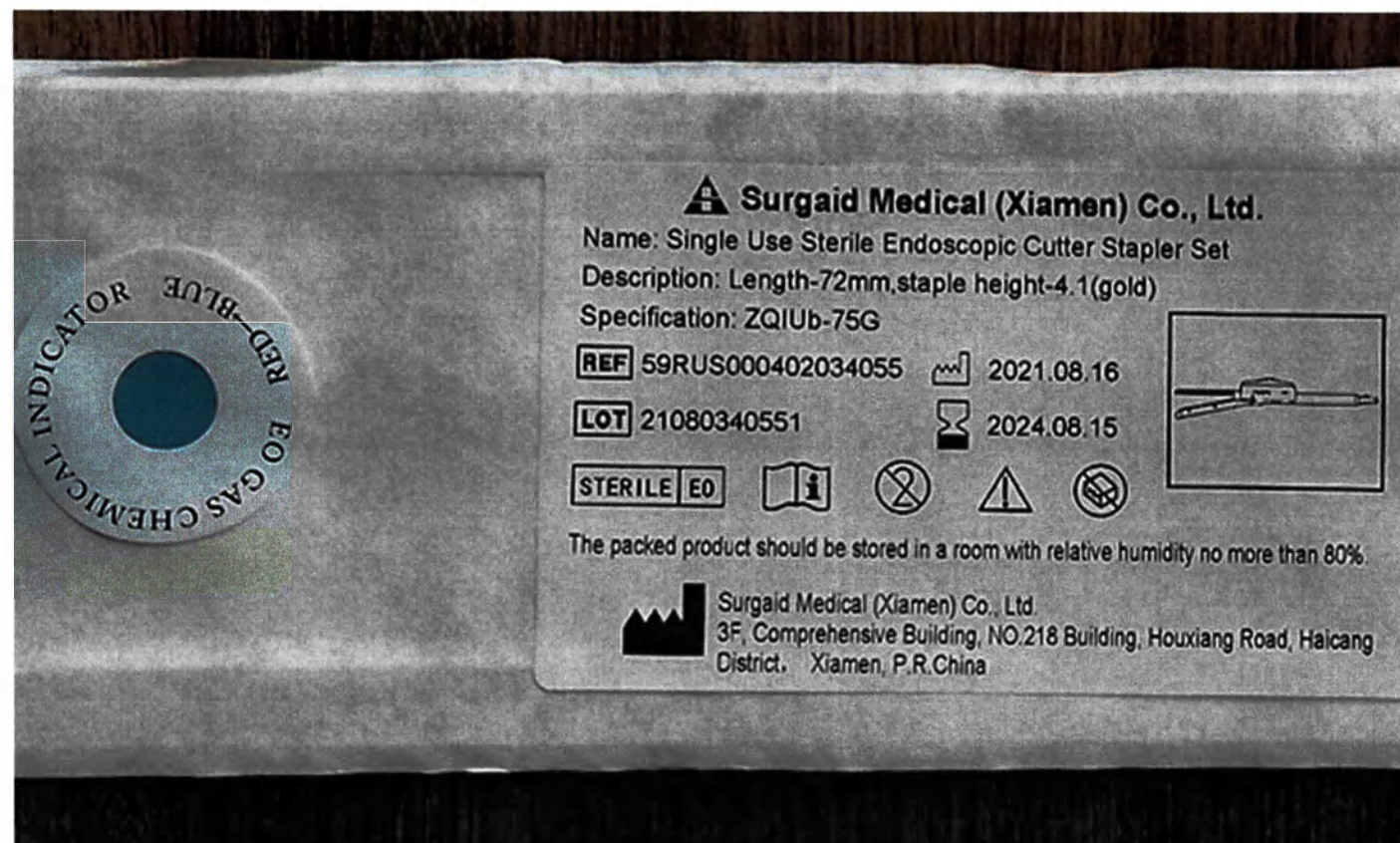
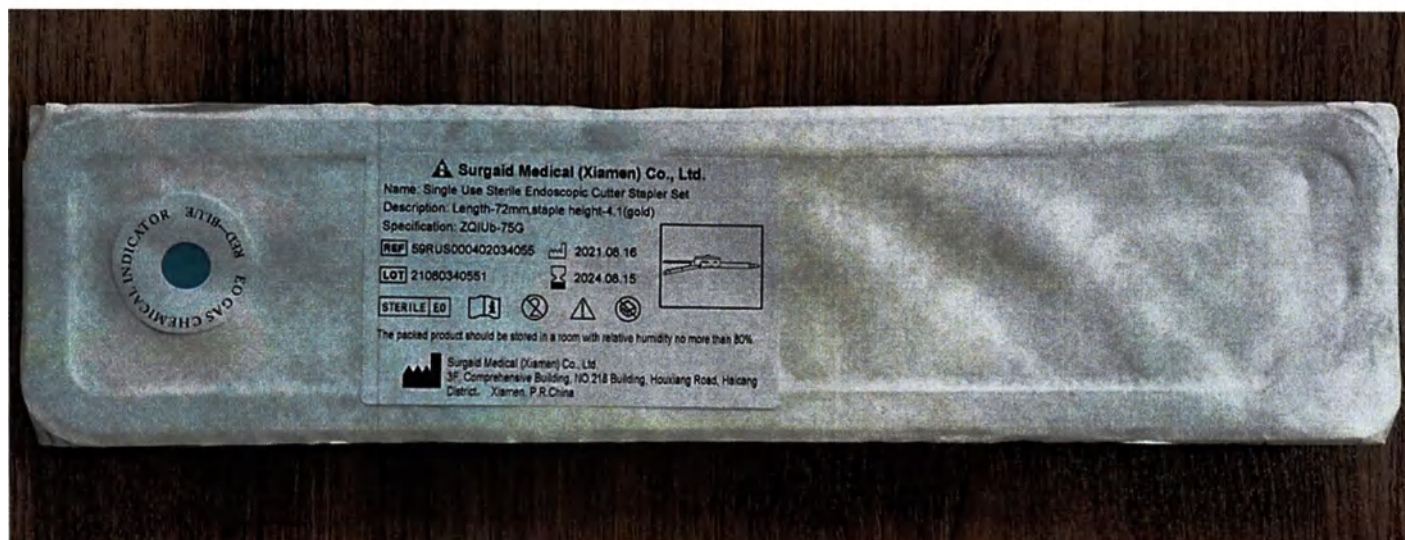
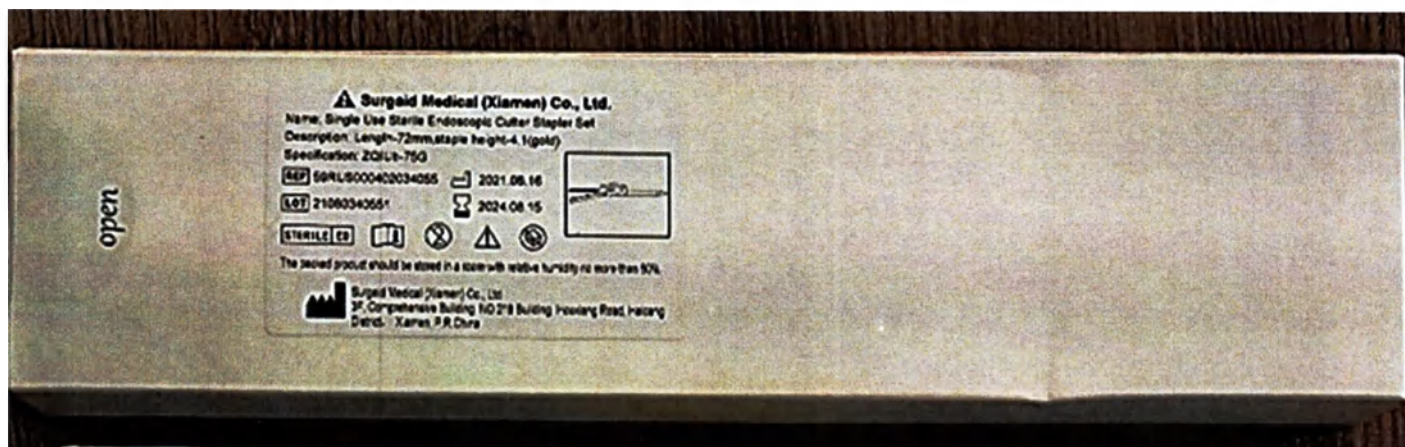


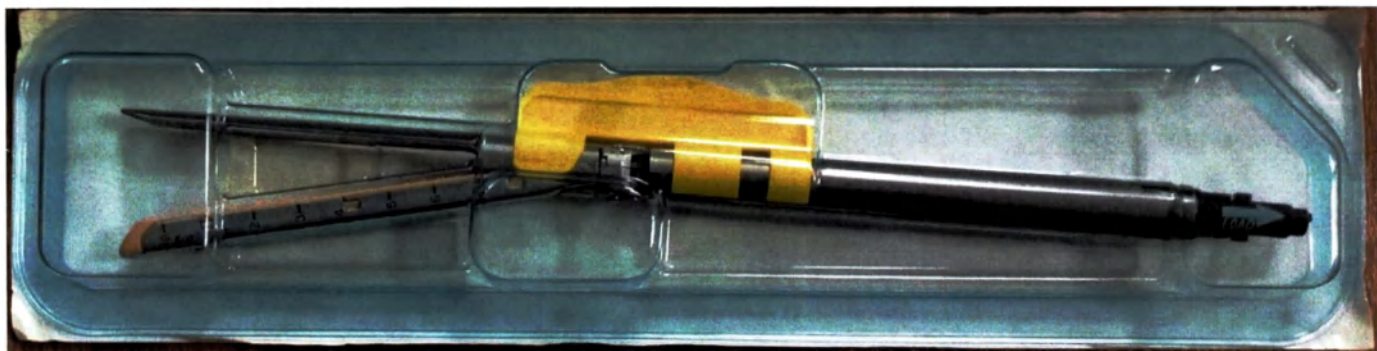
- Картридж для степлера ротационный, прямой: ZQIUb-75C – не более 6 шт. (при необходимости);



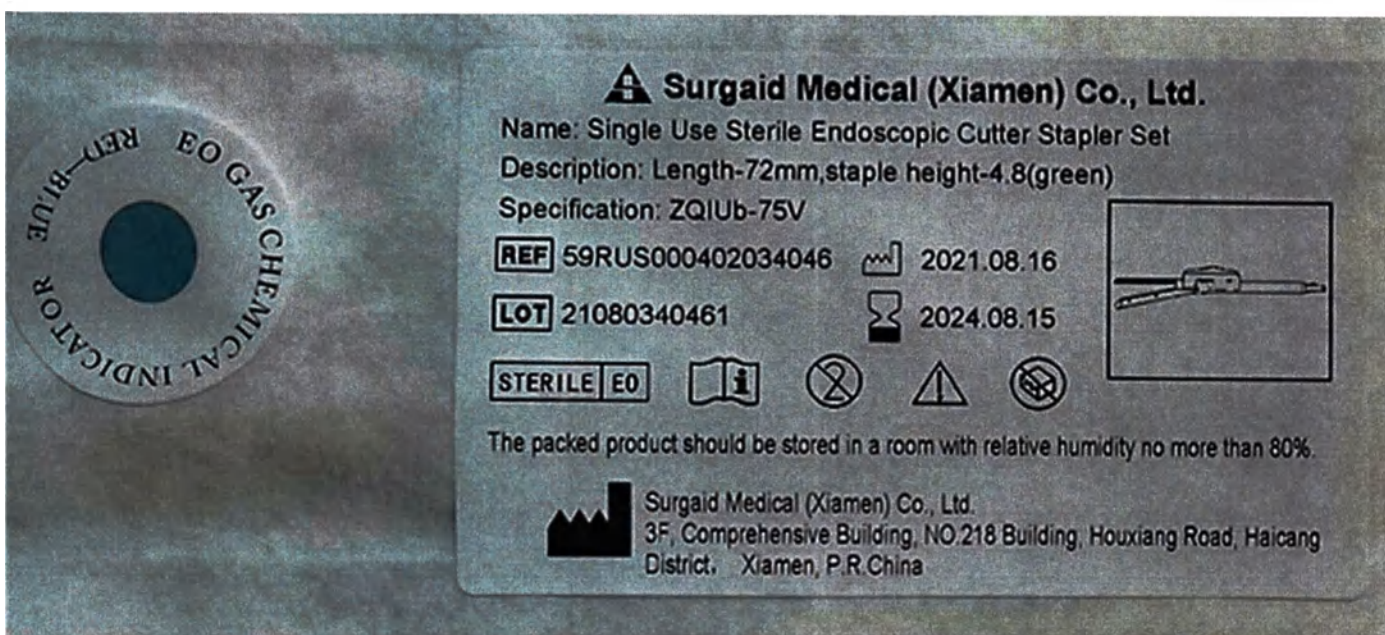
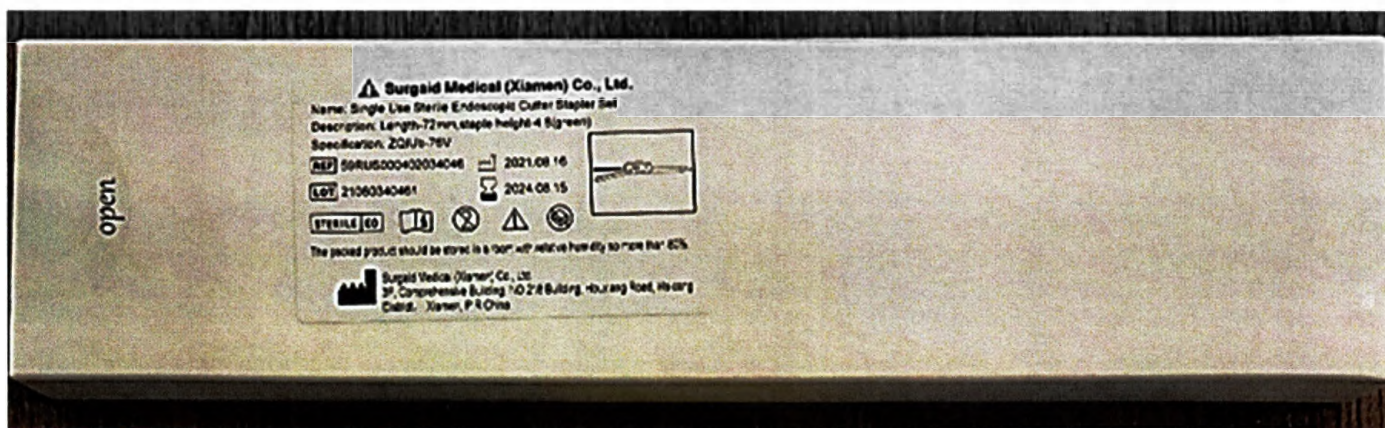


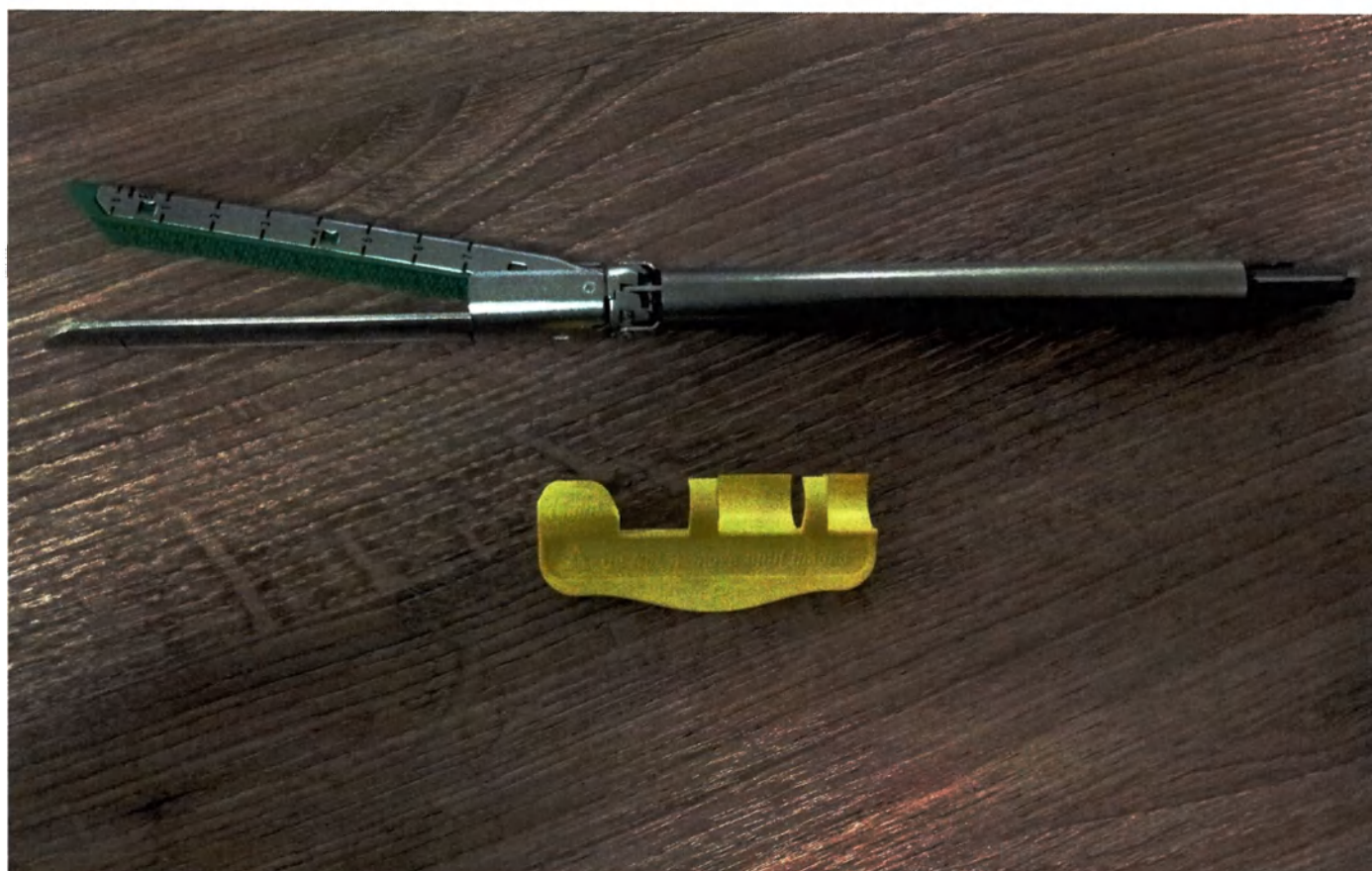
- Картридж для степлера ротационный, прямой: ZQIUb-75G – не более 6 шт. (при необходимости);



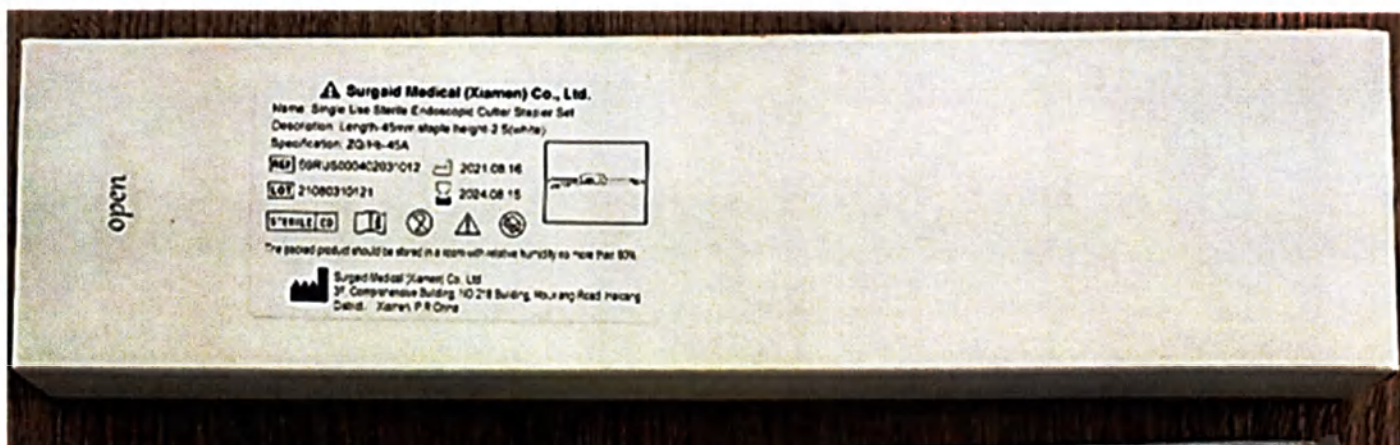


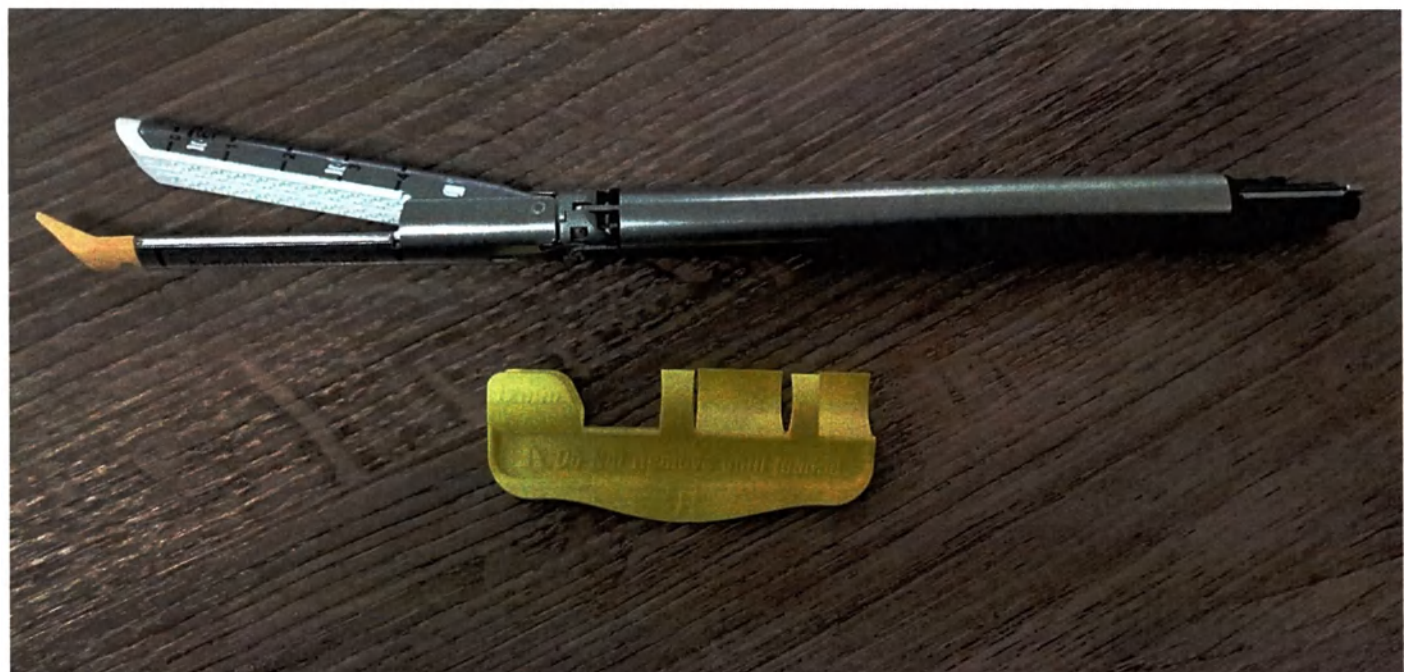
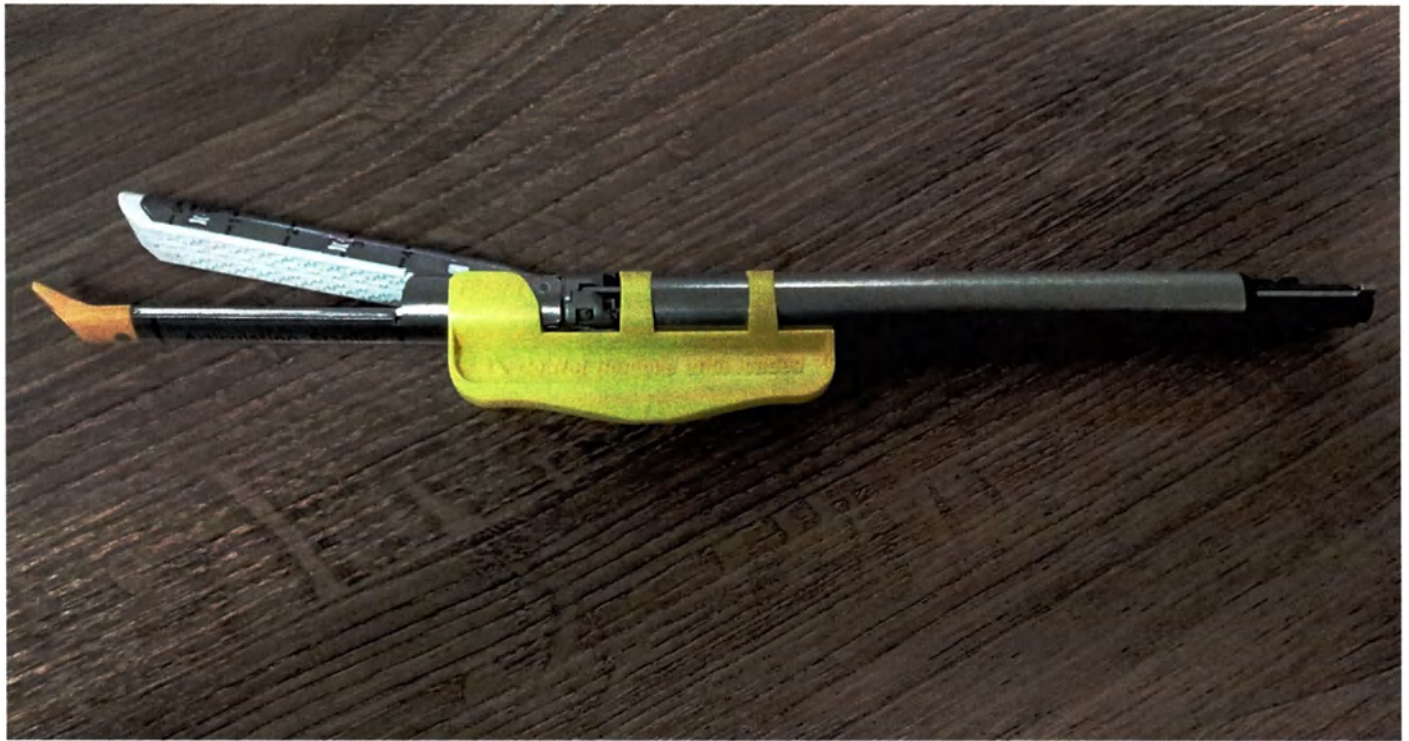
- Картридж для степлера ротационный, прямой: ZQIUb-75V – не более 6 шт. (при необходимости);



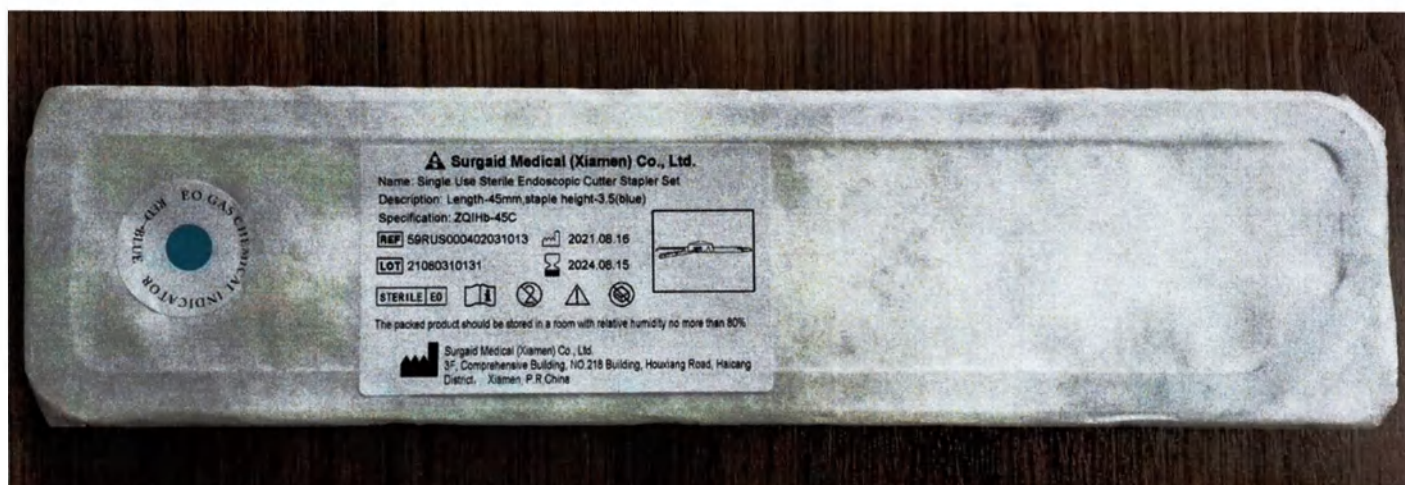
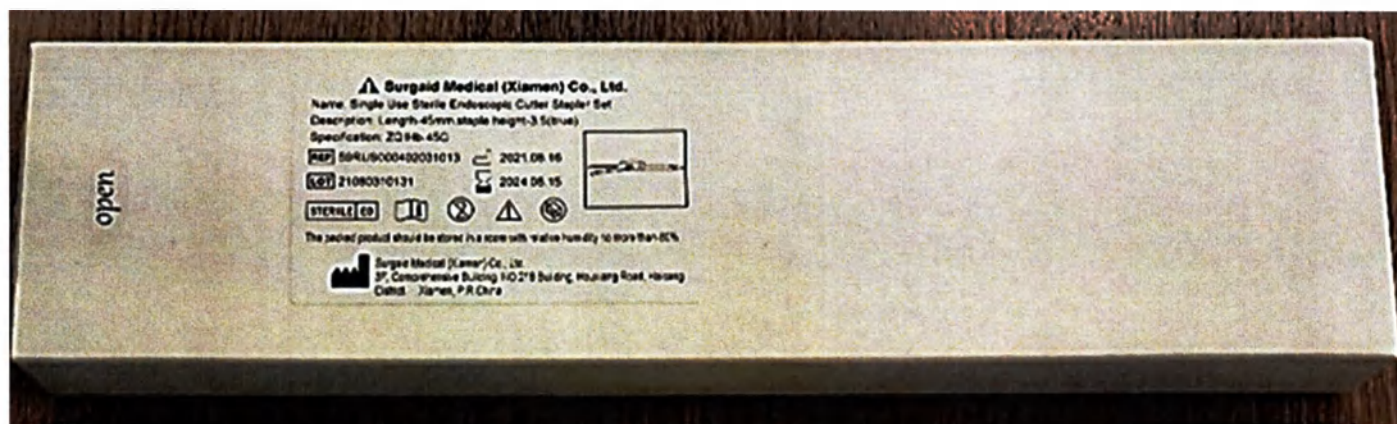


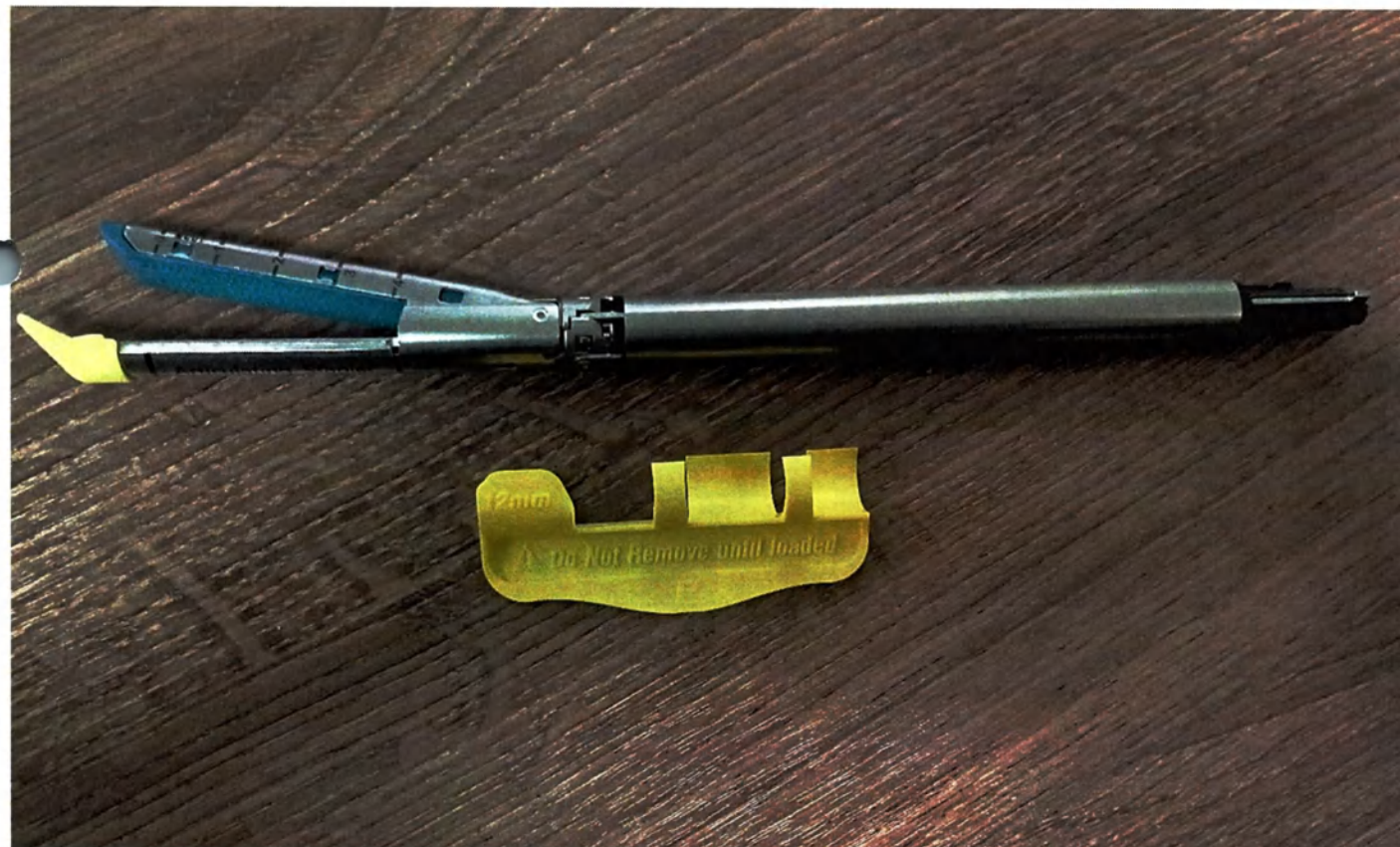
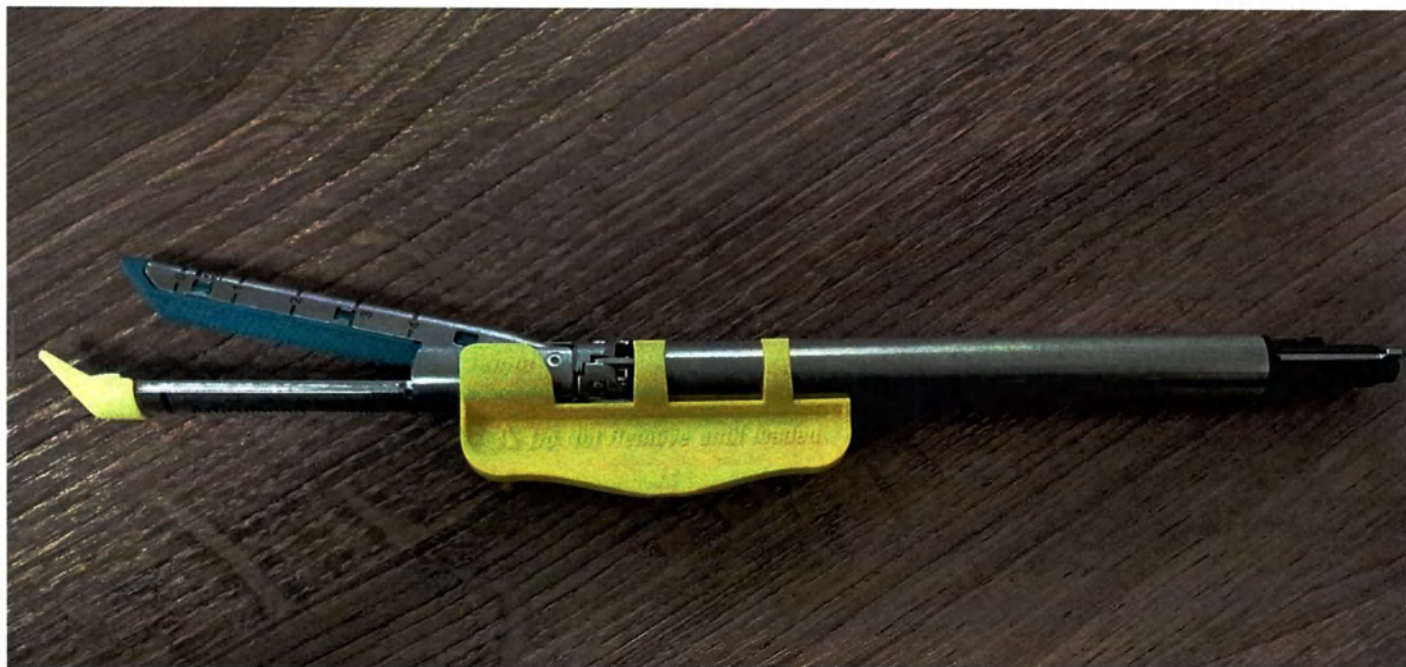
- Картридж для степлера ротационный, с загибом: ZQIHb-45A – не более 6 шт. (при необходимости);



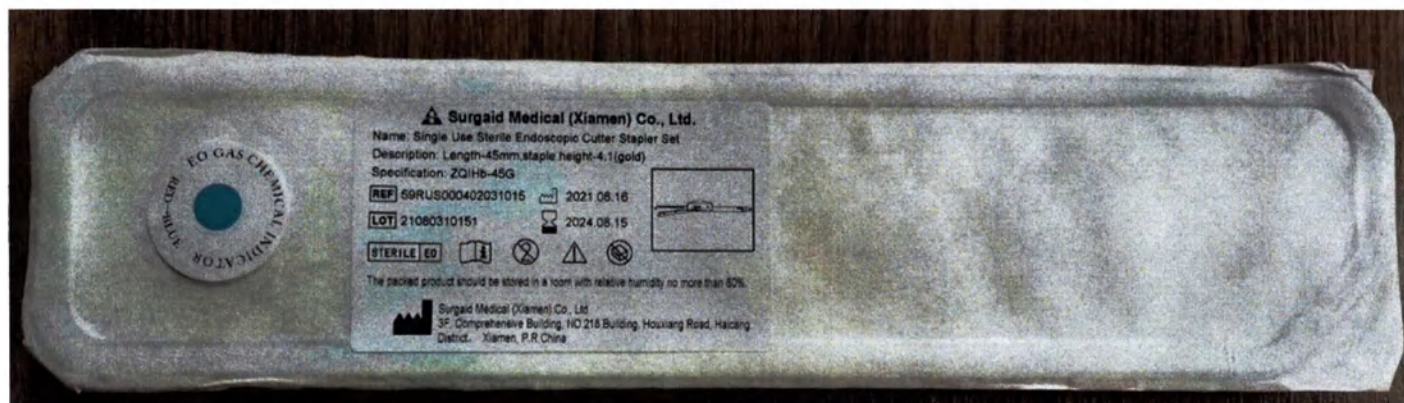


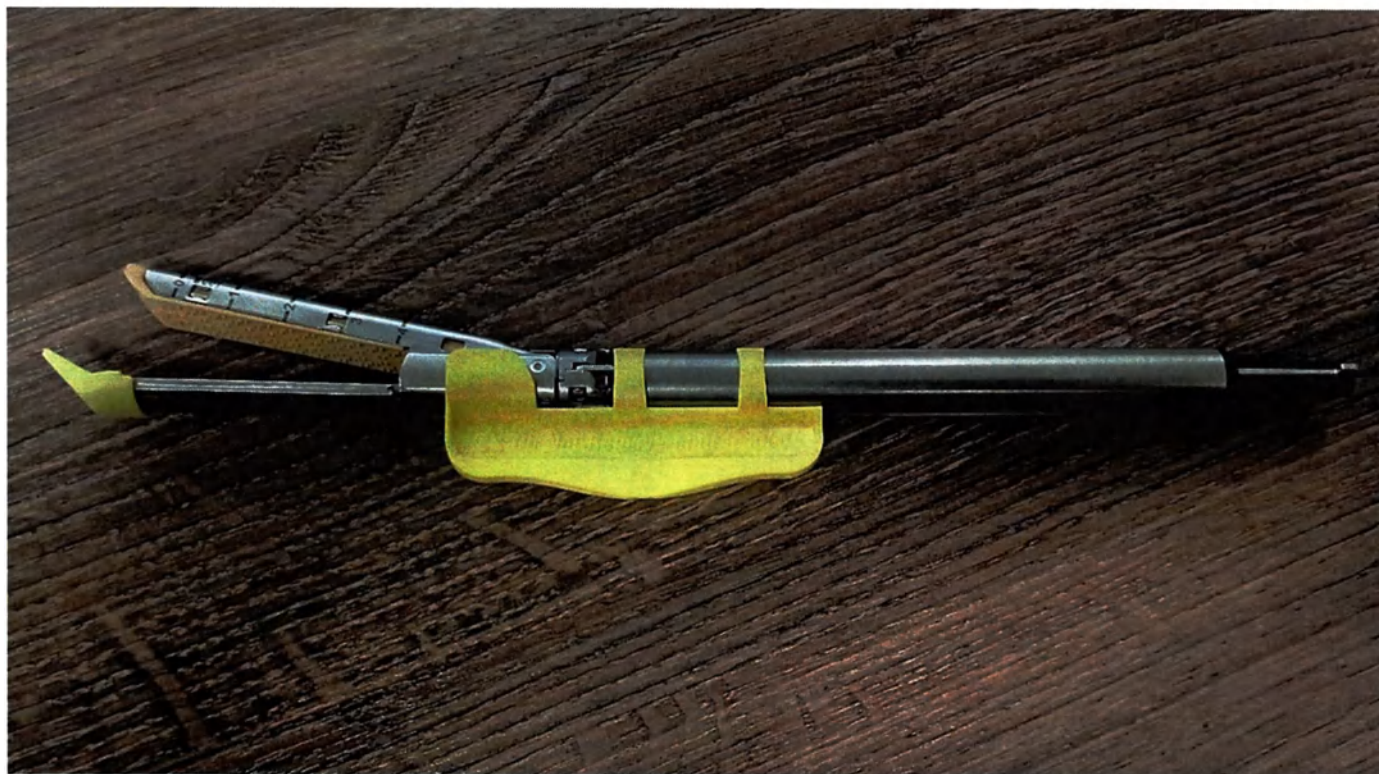
- Картридж для степлера ротационный, с загибом: ZQIHb-45C – не более 6 шт. (при необходимости);



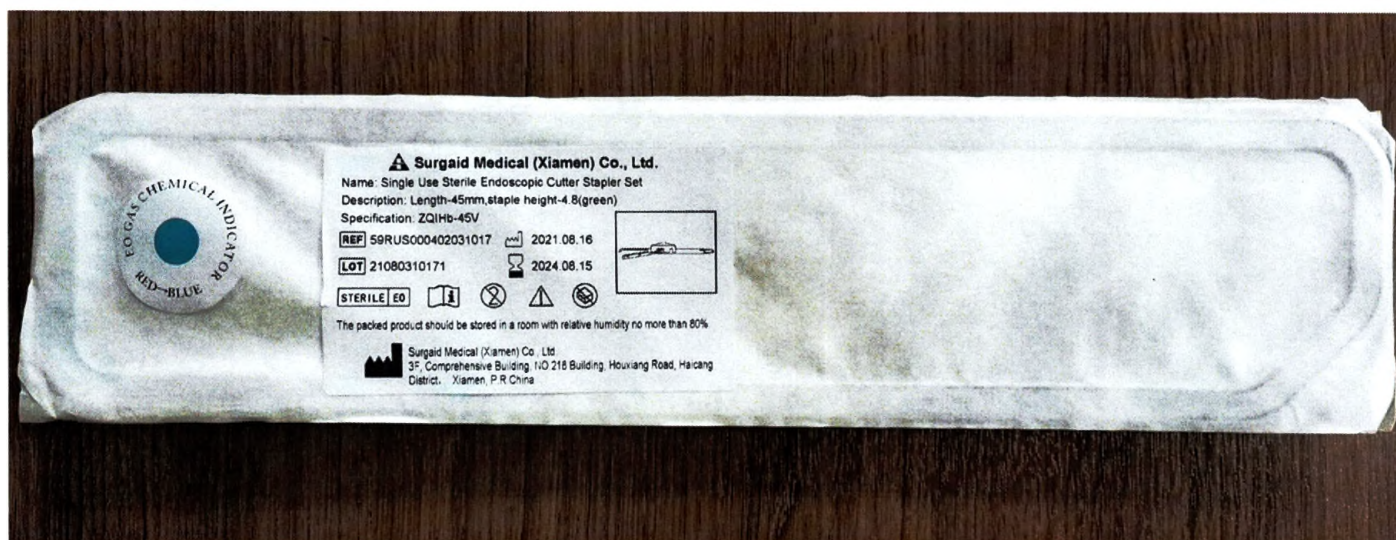
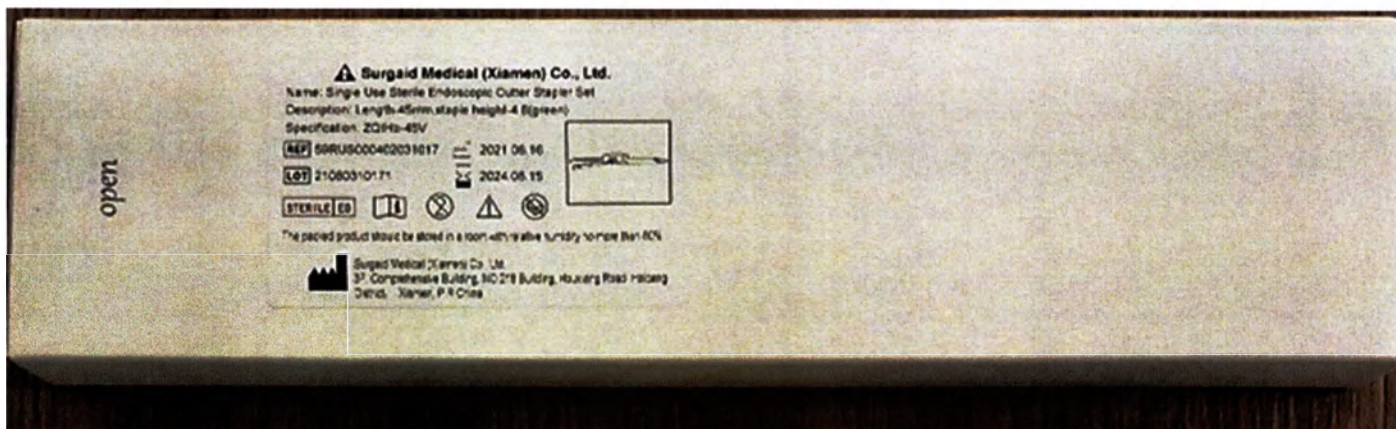


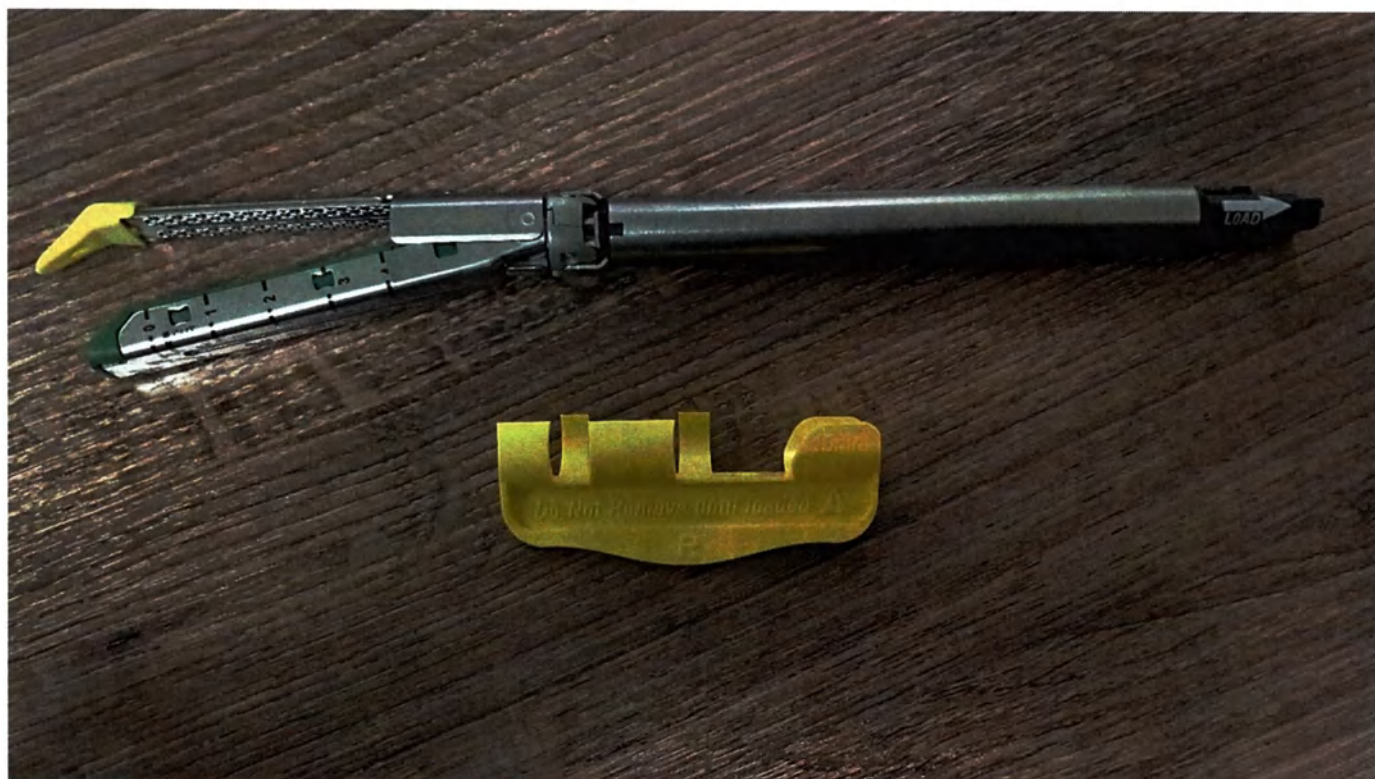
- Картридж для степлера ротационный, с загибом: ZQIHb-45G – не более 6 шт. (при необходимости);



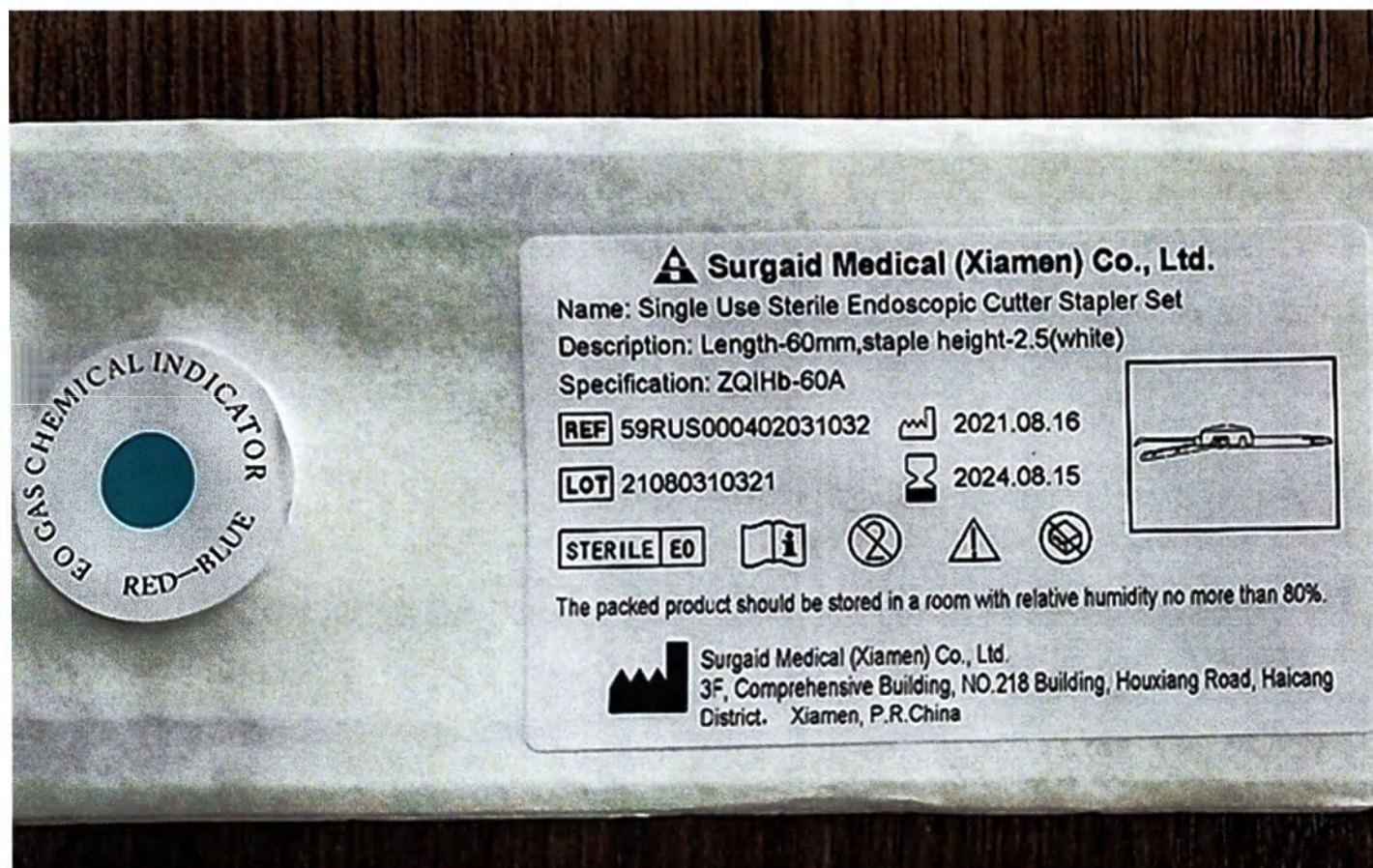
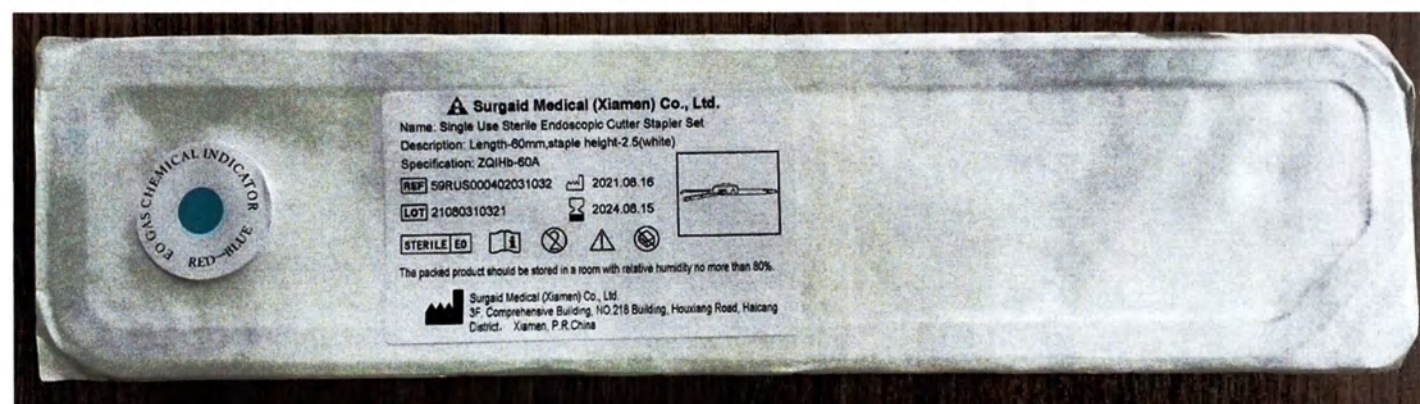
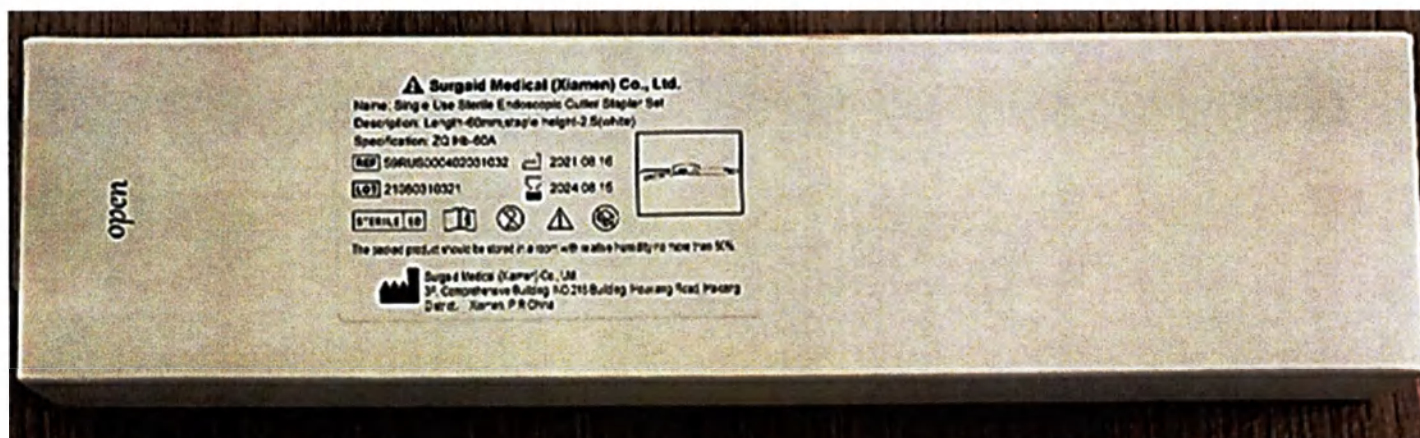


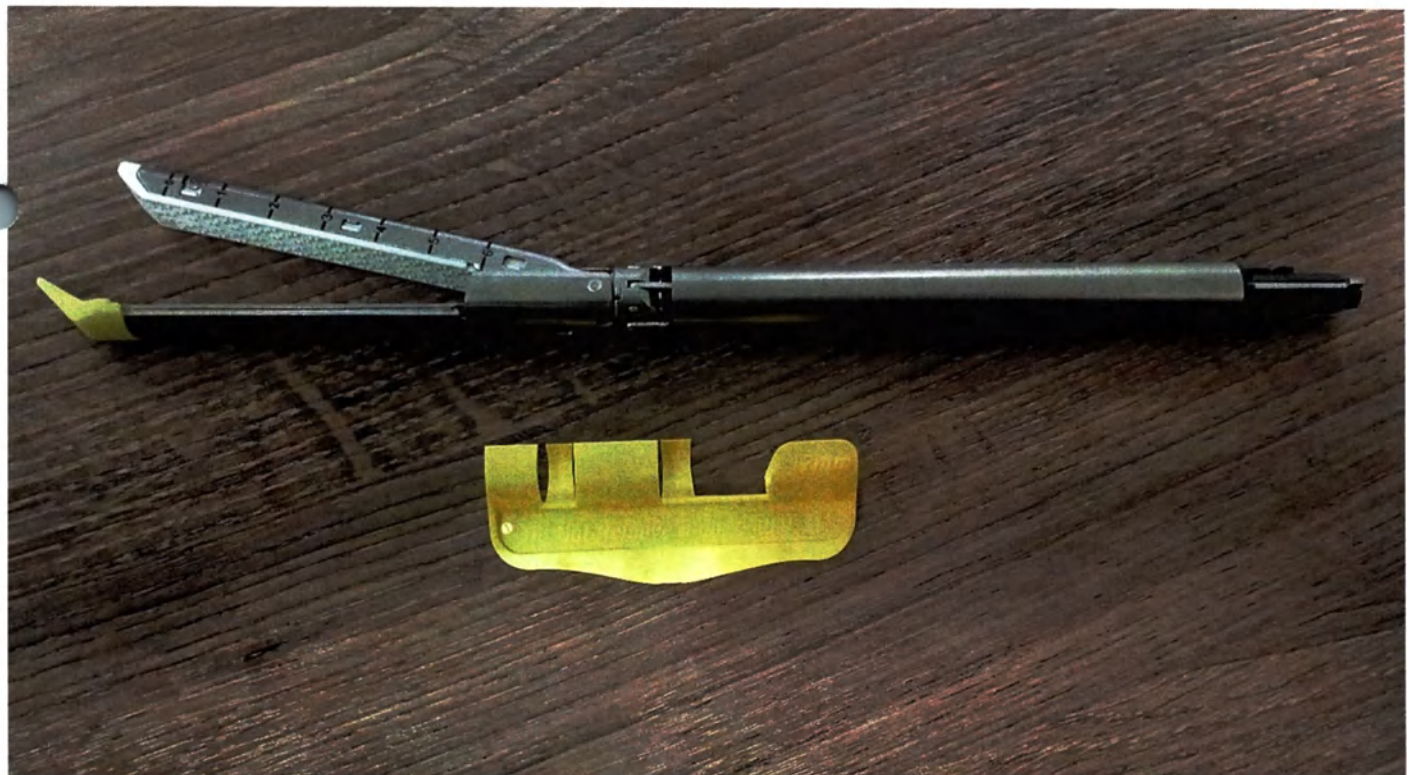
- Картридж для степлера ротационный, с загибом: ZQIHb-45V – не более 6 шт. (при необходимости);



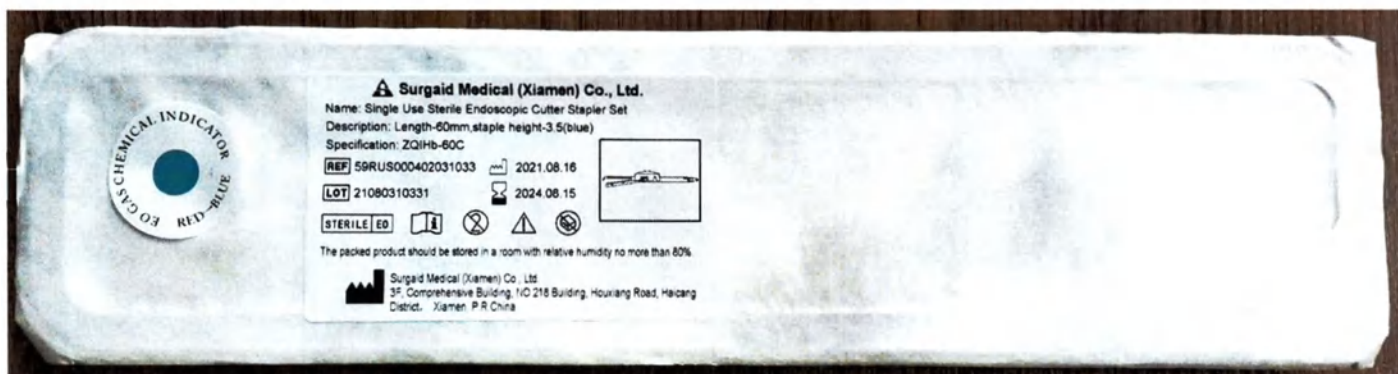
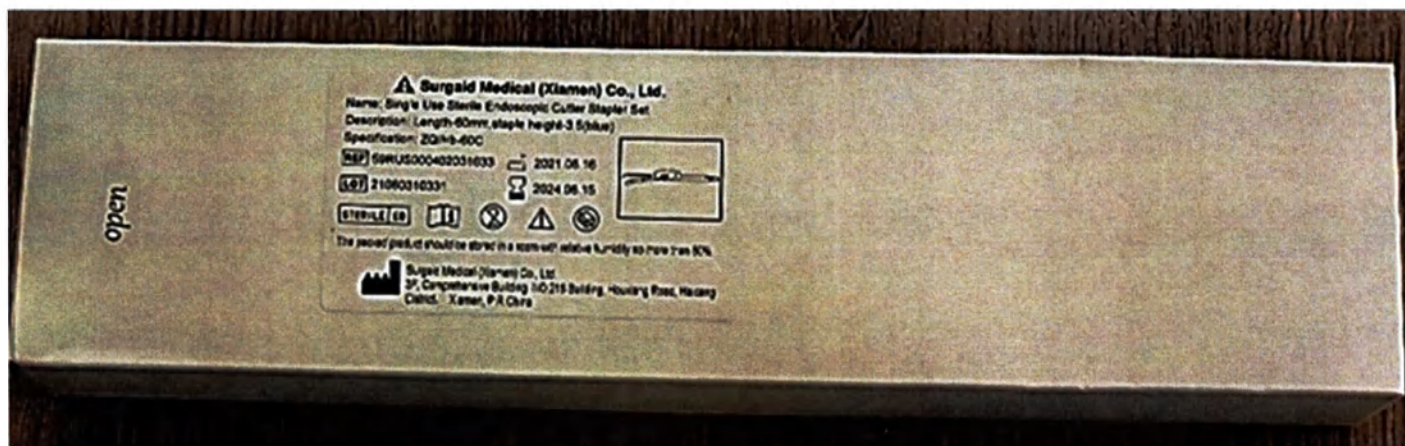


- Картридж для степлера ротационный, с загибом: ZQIHb-60A – не более 6 шт. (при необходимости);



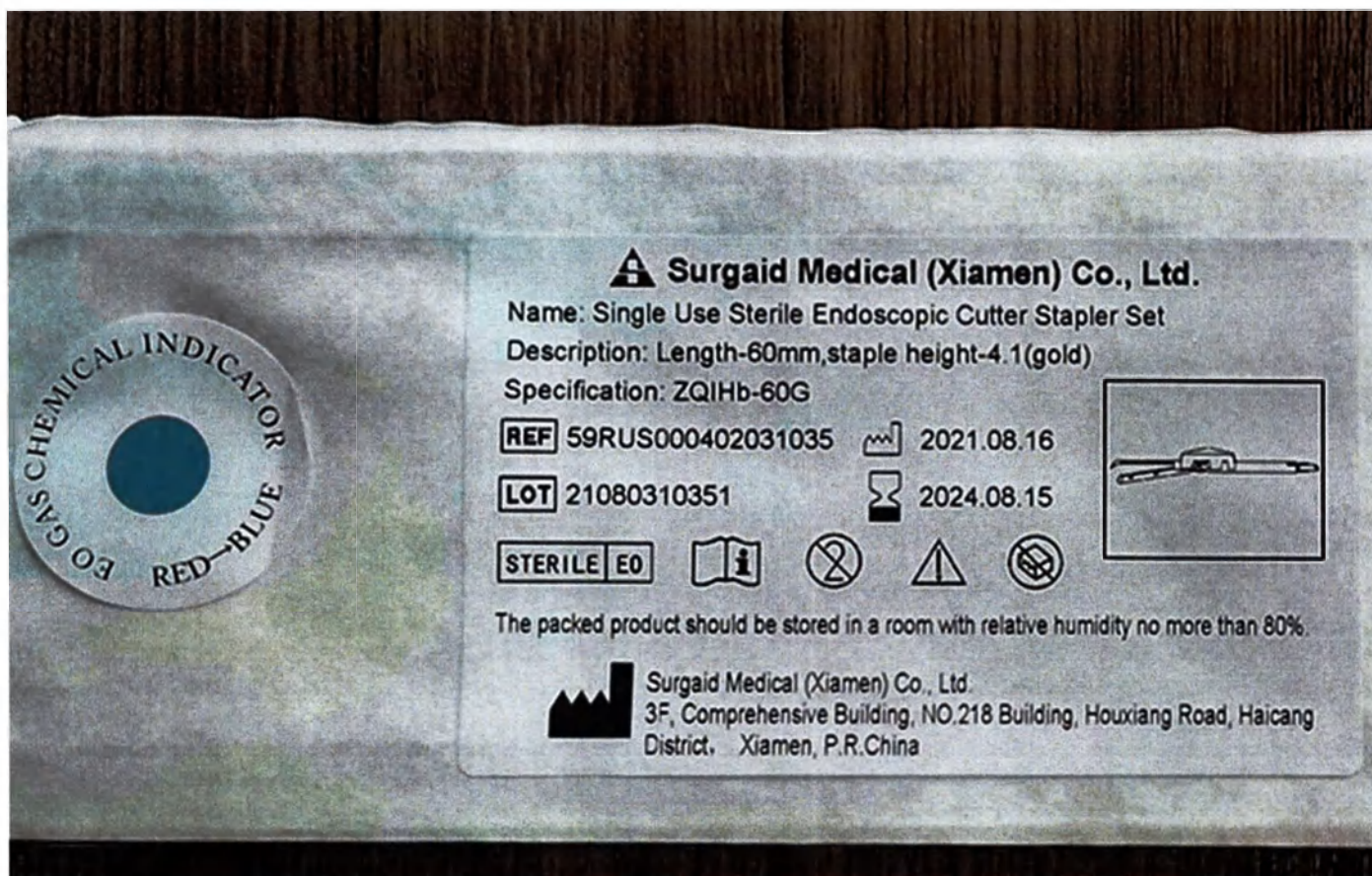
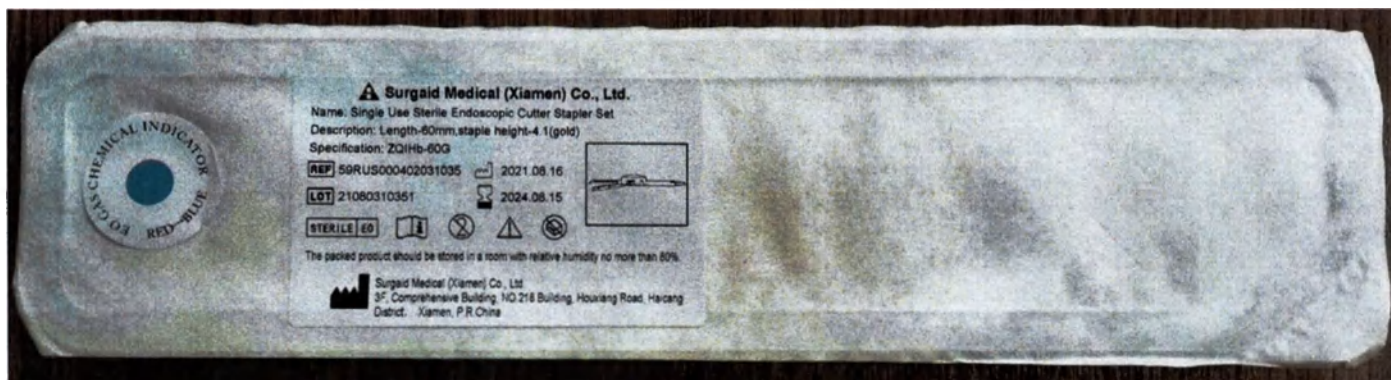
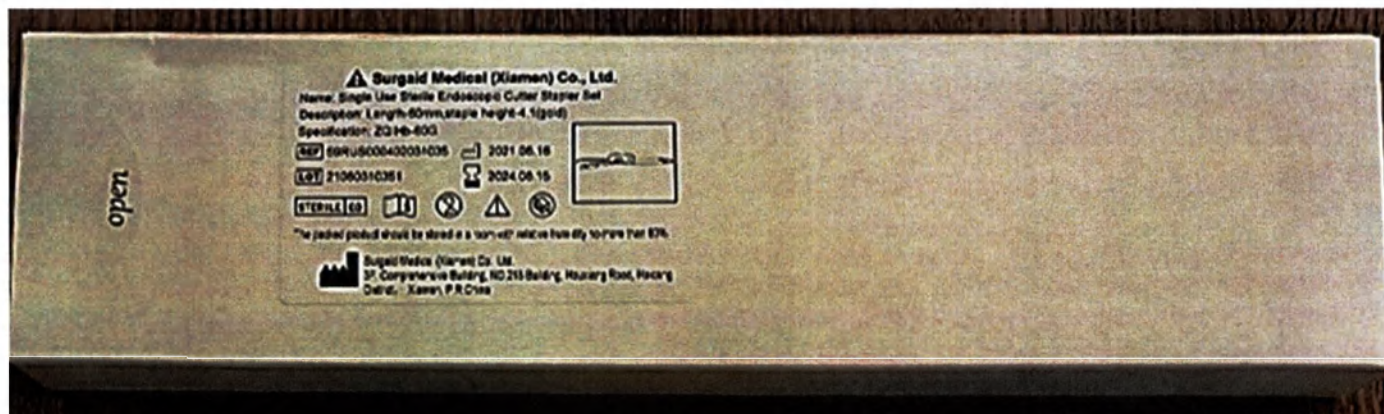


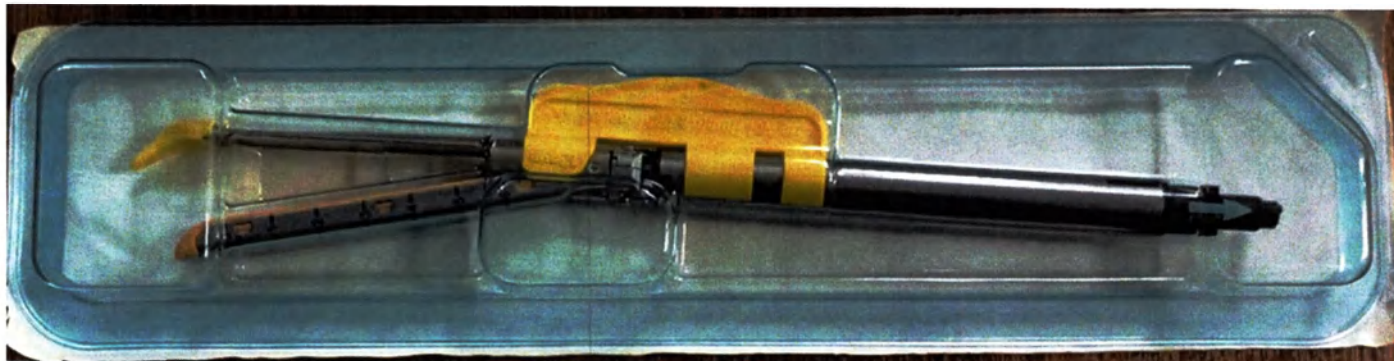
- Картридж для степлера ротационный, с загибом: ZQIHb-60C – не более 6 шт. (при необходимости);



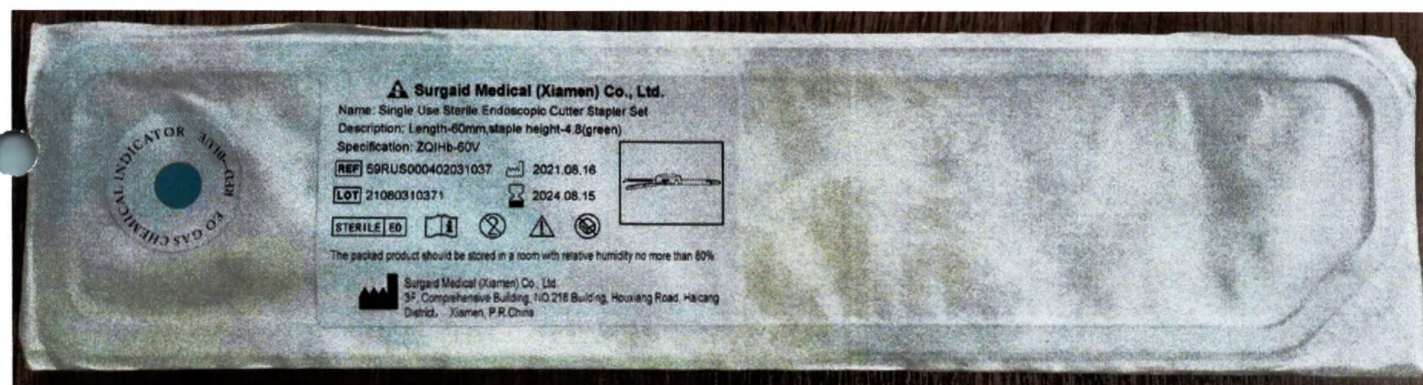
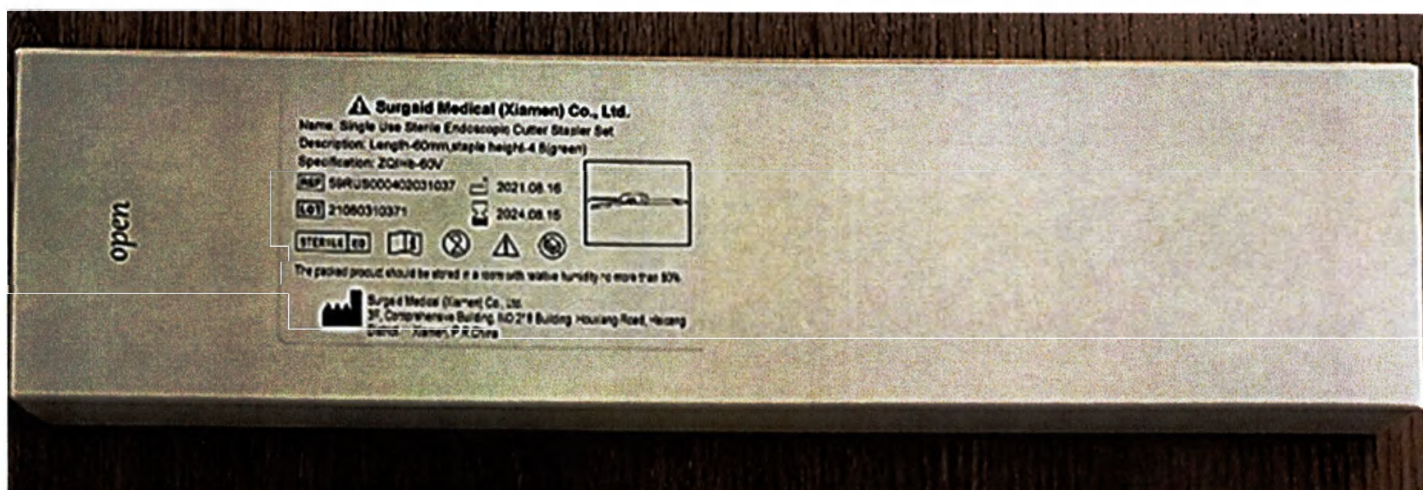


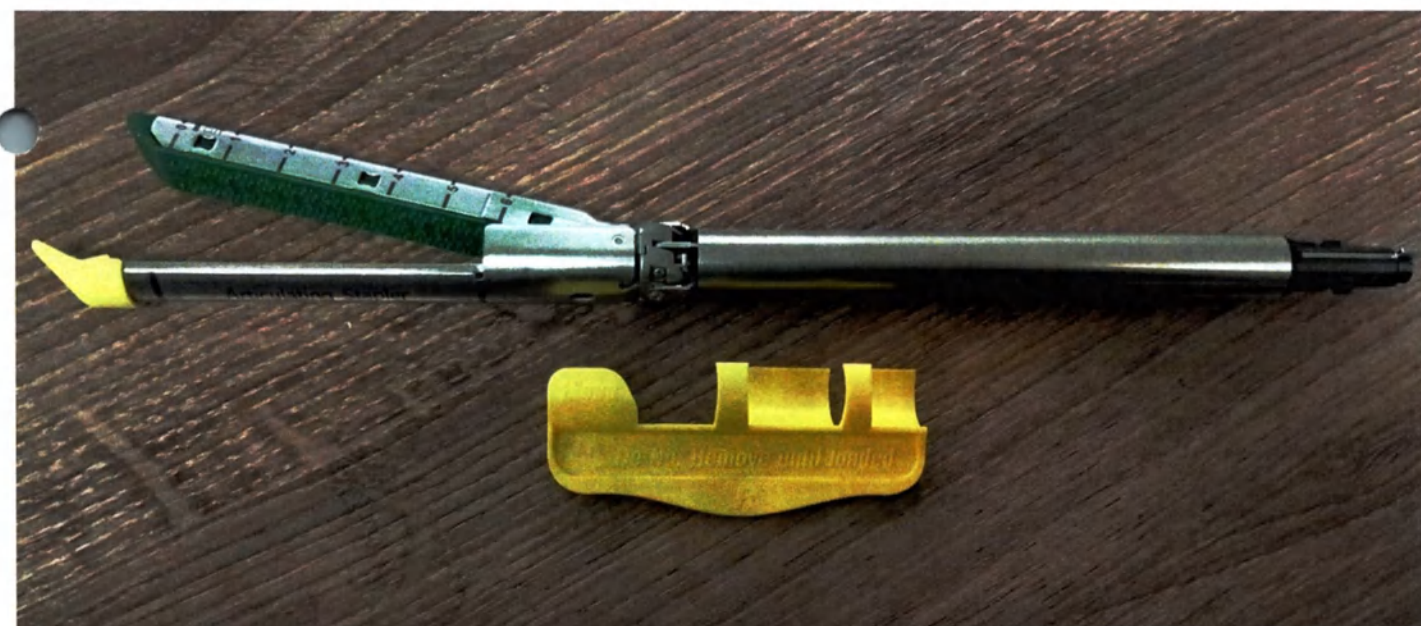
- Картридж для степлера ротационный, с загибом: ZQIHb-60G – не более 6 шт. (при необходимости);



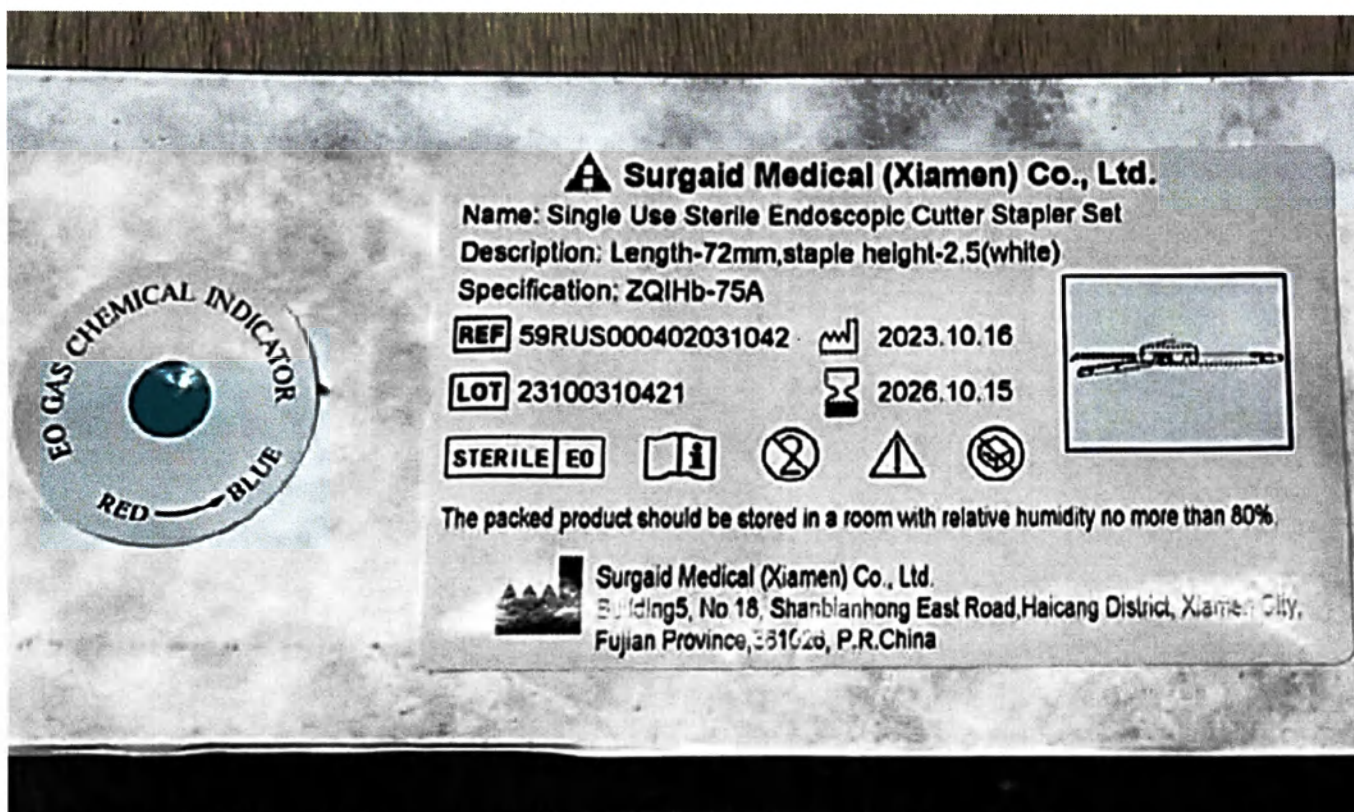
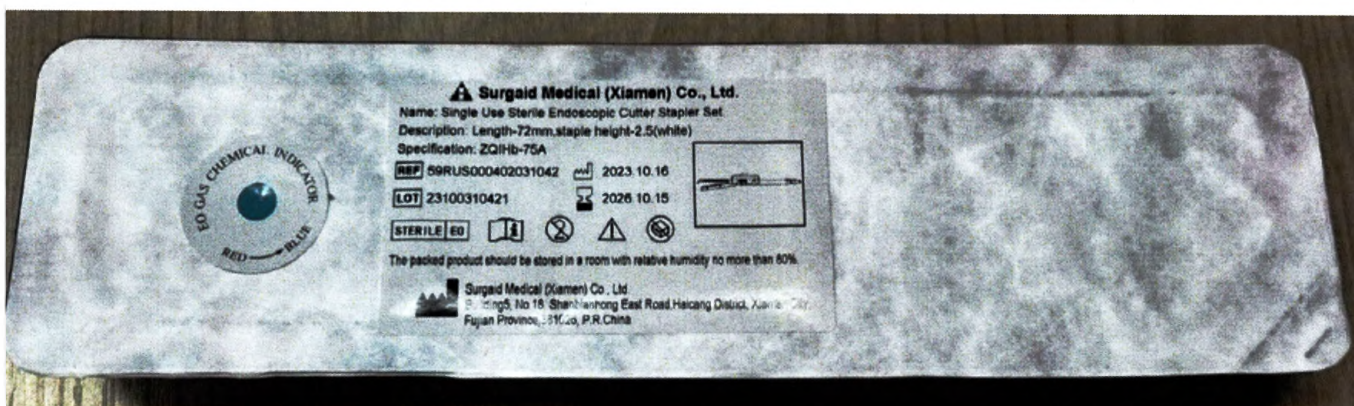
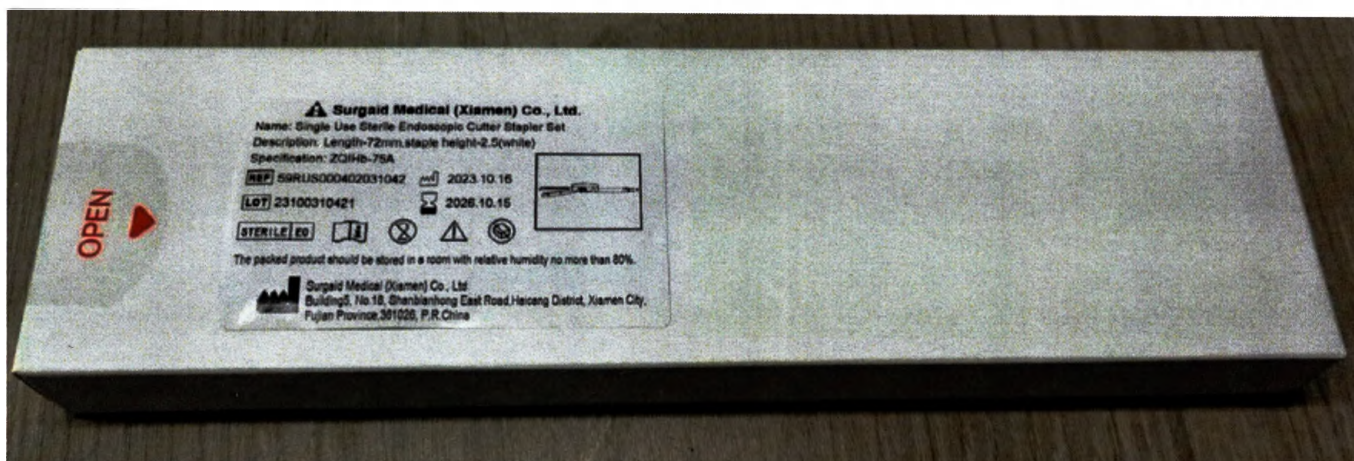


- Картридж для степлера ротационный, с загибом: ZQIHb-60V – не более 6 шт. (при необходимости);



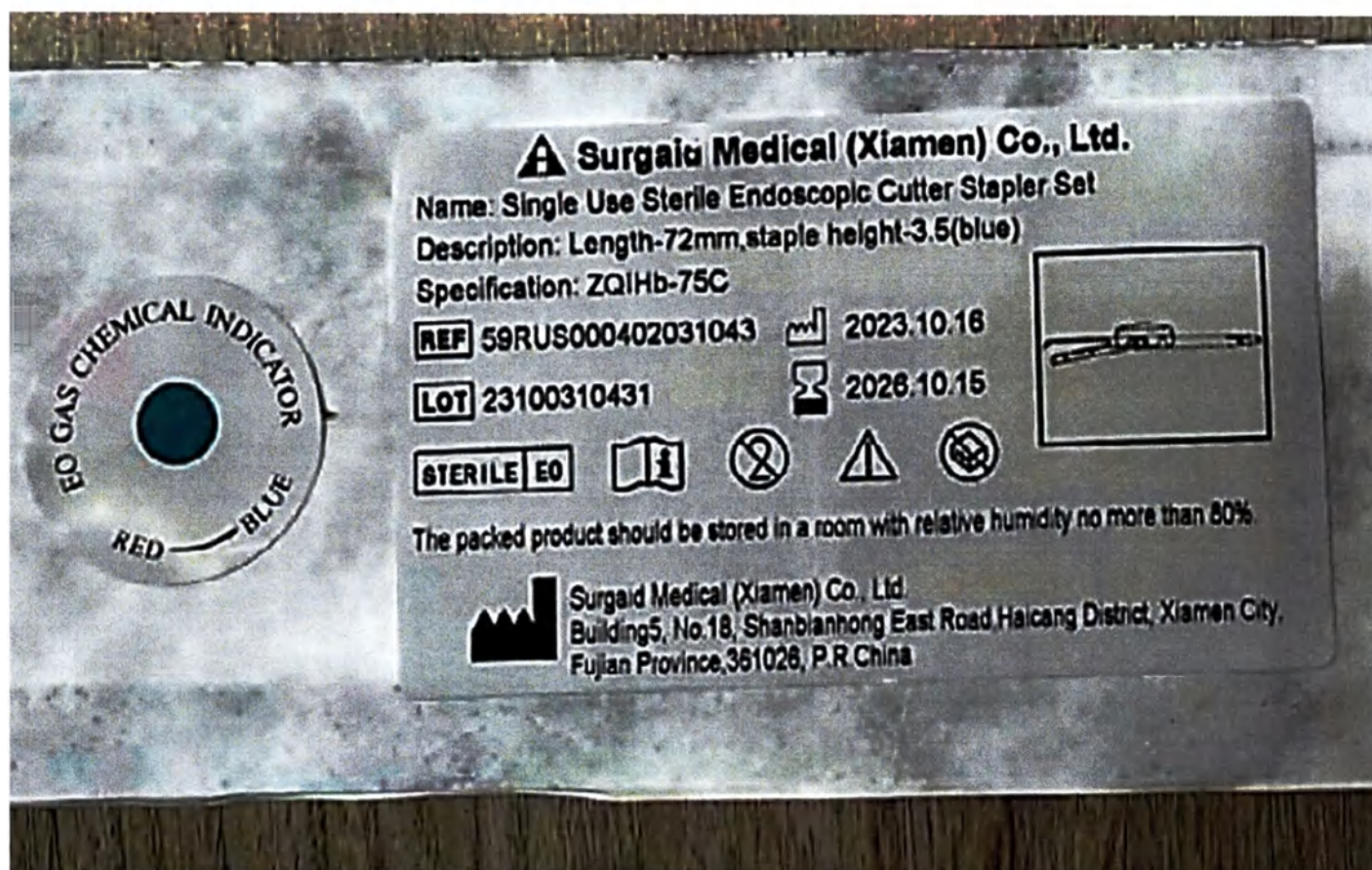
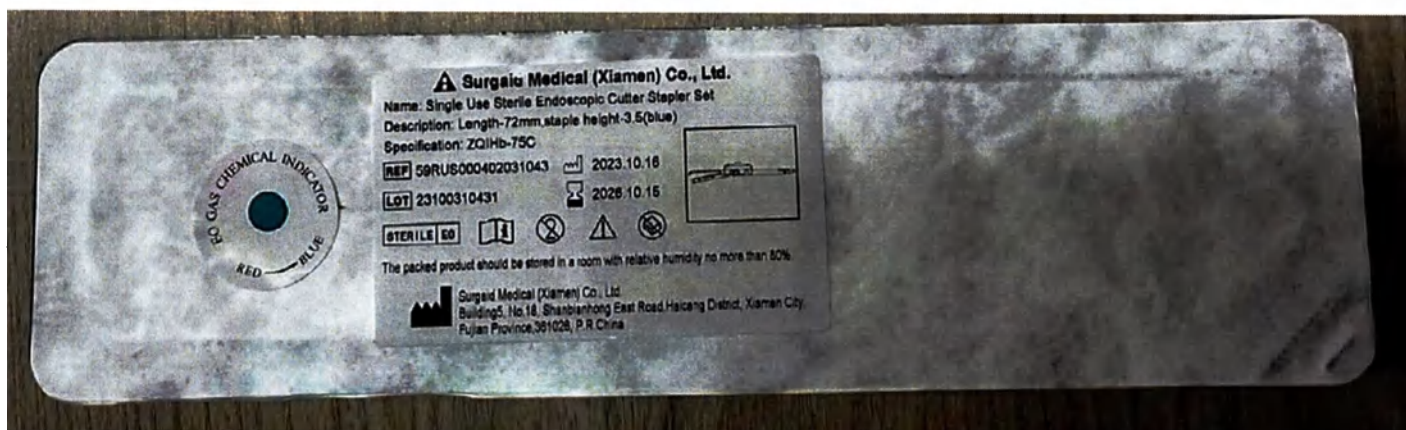
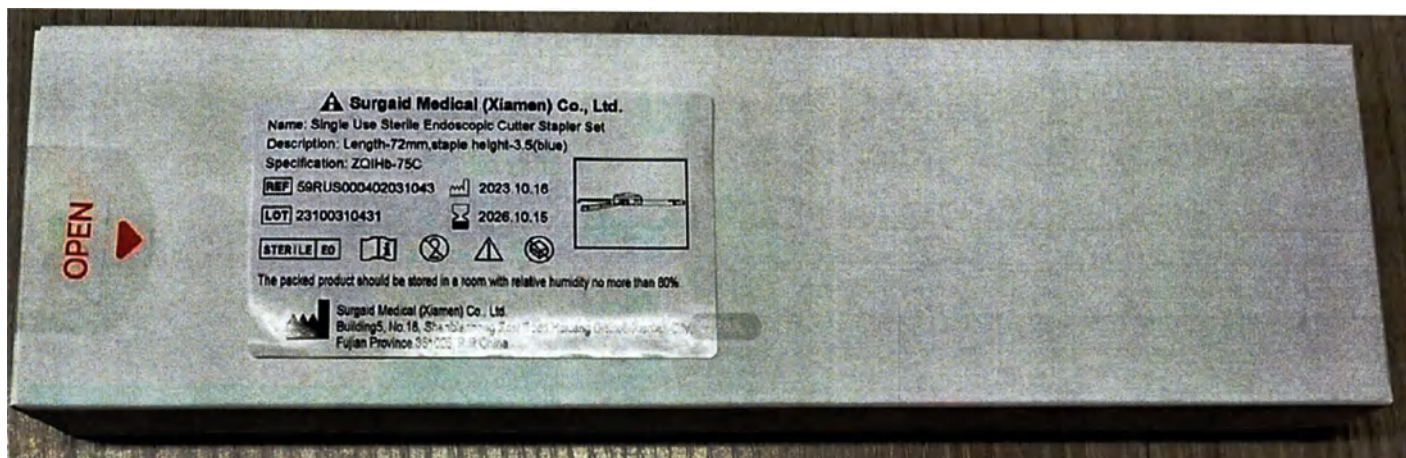


- Картридж для степлера ротационный, с загибом: ZQIHb-75A – не более 6 шт. (при необходимости);



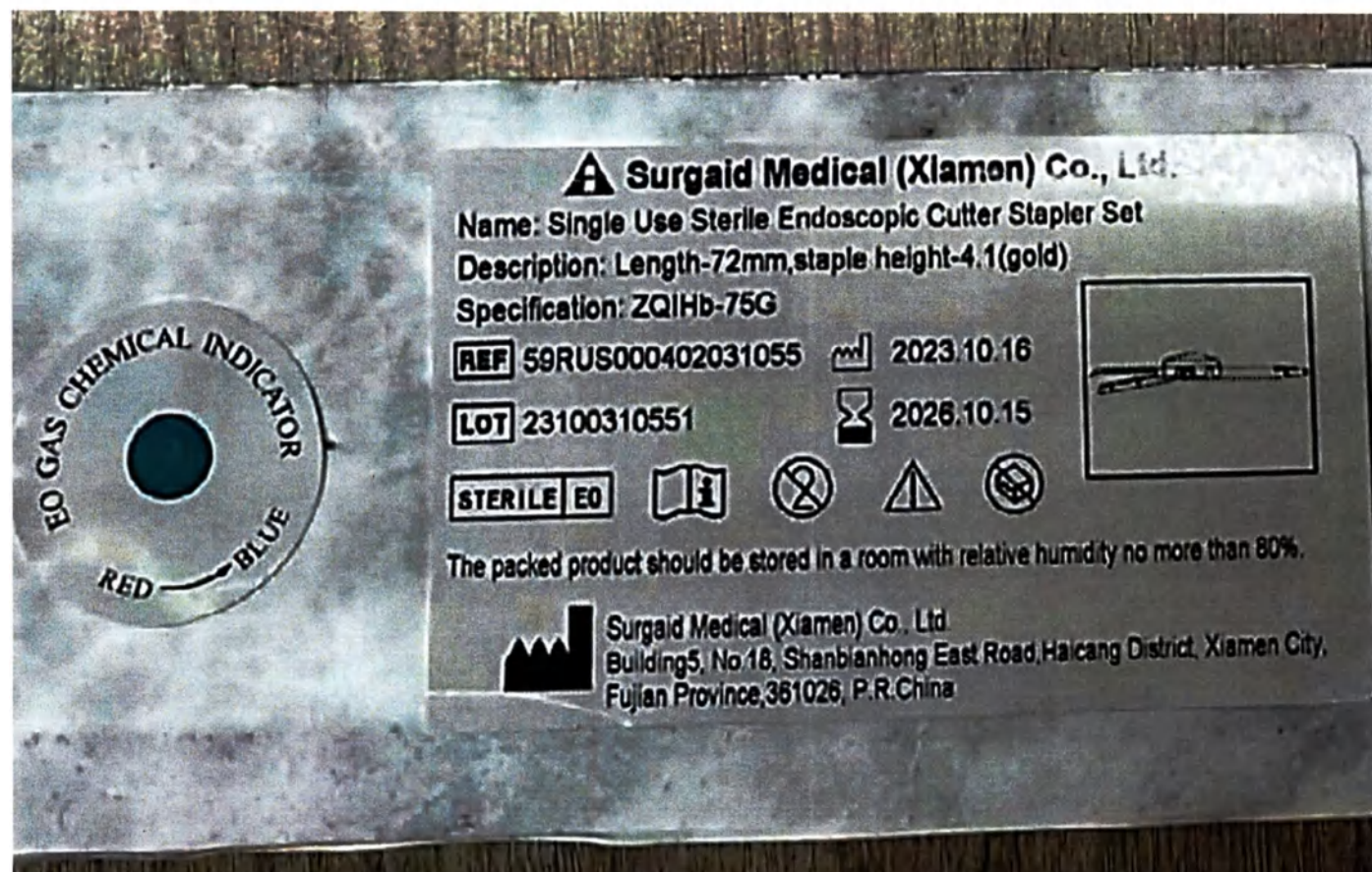
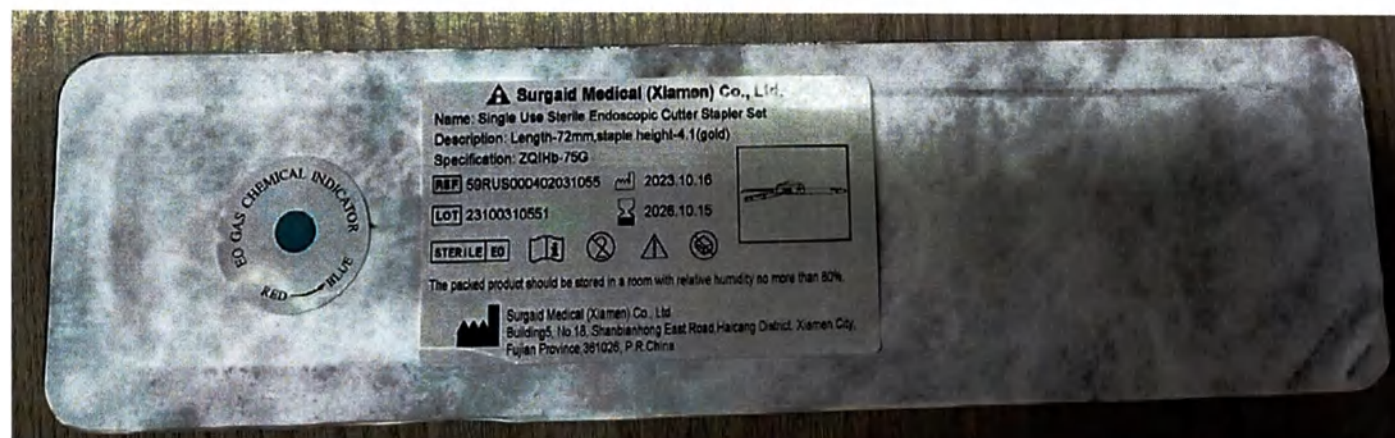
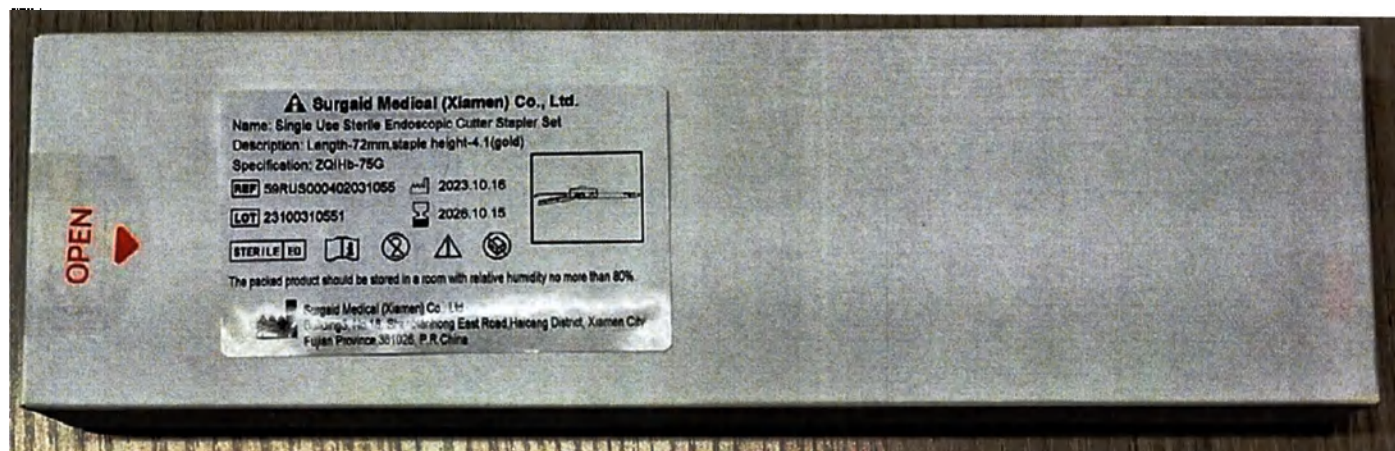


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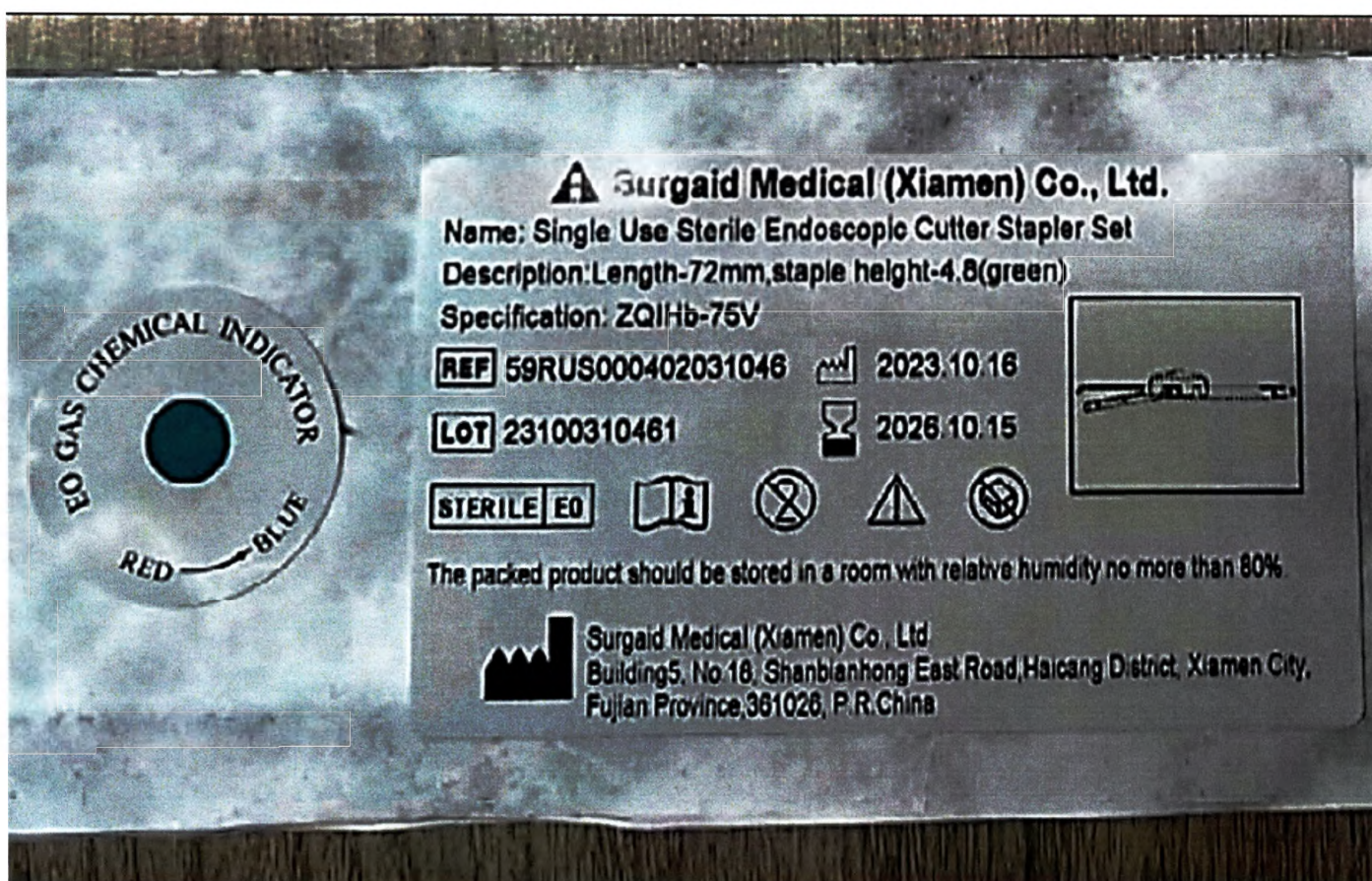
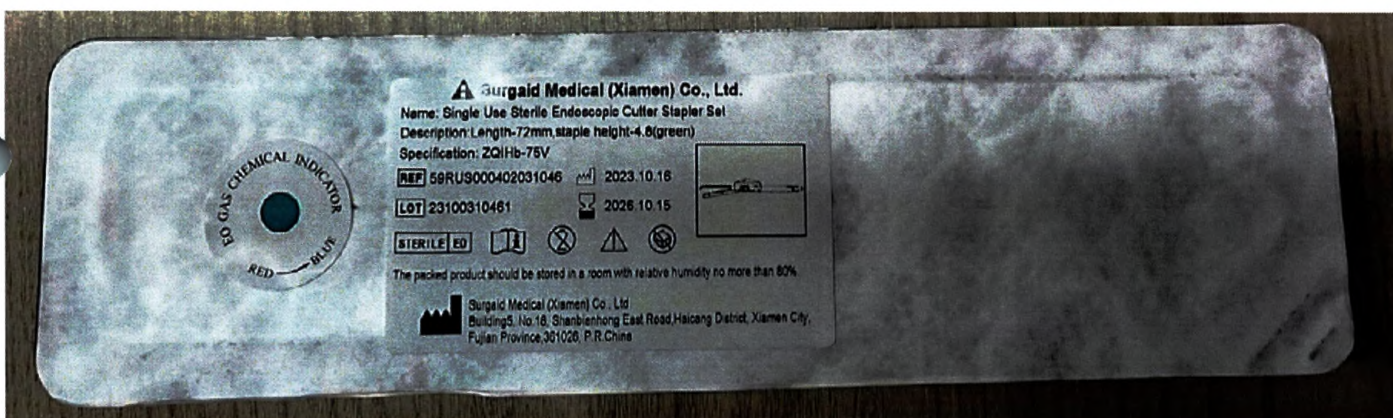
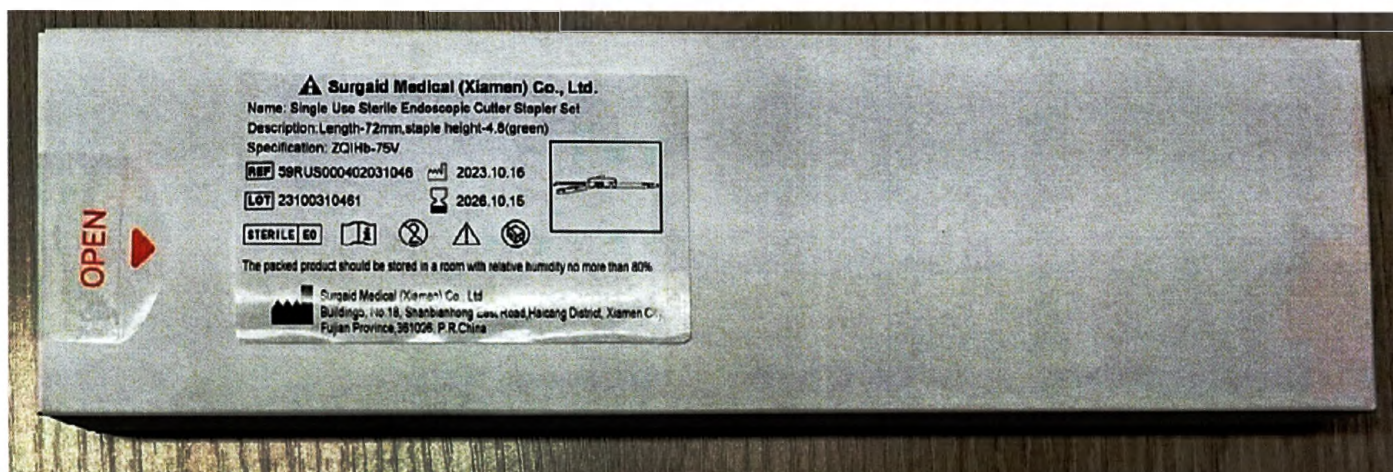


- Картридж для степлера ротационный, с загибом: ZQIHb-75G – не более 6 шт. (при необходимости);





- Картридж для степлера ротационный, с загибом: ZQIHb-75V – не более 6 шт. (при необходимости);





- 3) Инструкция по применению на Степлер хирургический одноразовый эндоскопический с одинарной рукояткой, Степлер хирургический одноразовый эндоскопический с двойной рукояткой – 1 шт.

Instruction for Use

I. Device Name:

Single Use Sterile Endoscopic Cutter Stapler Set

II. Product performance and major components

1. Performance:

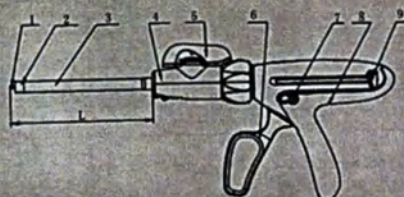
- Appearance:** The Endoscopic Cutter Stapler has smooth surface and well-defined contour without defects such as burrs, scratches or rust. Marks and indications on the outer surface are legible and aligned without malposition. The surface shall not contain any burr or flange.
- Flexibility:** Opening and closure of the stapler shall be flexible without jam. The reset spring shall be elastic enough to ensure complete reset of handle when the reset button is pressed.
- Assemblability:** Replacement of cartridge shall be convenient and positions fixed tightly; the staple shall not project out over the surface of reload when the cartridge is swung.
- Performance of resection and anastomosis:** The product shall perform well in anastomosis and resection for ≥ 5 times. The cartridge is replaceable and a B-shaped staple shall be formed after each anastomosis.
- The anastomotic area shall endure pressure of ≥ 3.6 KPa and no more than 10 drops of water are leaked within 15 seconds.**
- Surface roughness:** The outer surface roughness (Ra) of metal part of stapler shall not exceed $0.8 \mu\text{m}$.
- Corrosion resistance:** The anvil jaw shall have good corrosion resistance.
- The product shall be sterile. The residual ethylene oxide shall not exceed $10 \mu\text{g/g}$.**

2. Major components:

The Endoscopic Cutter Stapler (Model F) is mainly composed of an articulating joint, a shaft sleeve, an outer sleeve, a rotating handle, a swaying handle, a firing handle, a firing insurance, a fixed handle and a reset knob.

The Endoscopic Cutter Stapler (Model D) is mainly composed of reload unit, anvil jaw, cartridge jaw, cutter, outer sleeve, rotating handle, blade direction switch, blade direction indicator, fixed handle, reset button, locking handle and firing handle.

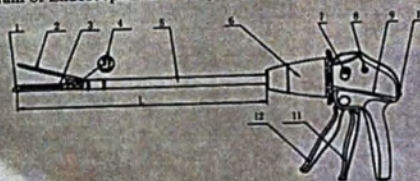
The cartridge is mainly composed of anvil jaw, reload, cutter, outer sleeve, and retaining cap. The structural diagrams of Endoscopic Cutter Stapler (Model F) are listed below:



1. Articulating joint; 2. Shaft sleeve; 3. Outer sleeve; 4. Rotating handle; 5. Swaying handle; 6. Firing handle; 7. Firing insurance; 8. Fixed handle 9. Reset knob

Figure 1. Structural diagram of Model F

The structural diagram of Endoscopic Cutter Stapler (Model with D) is listed below:

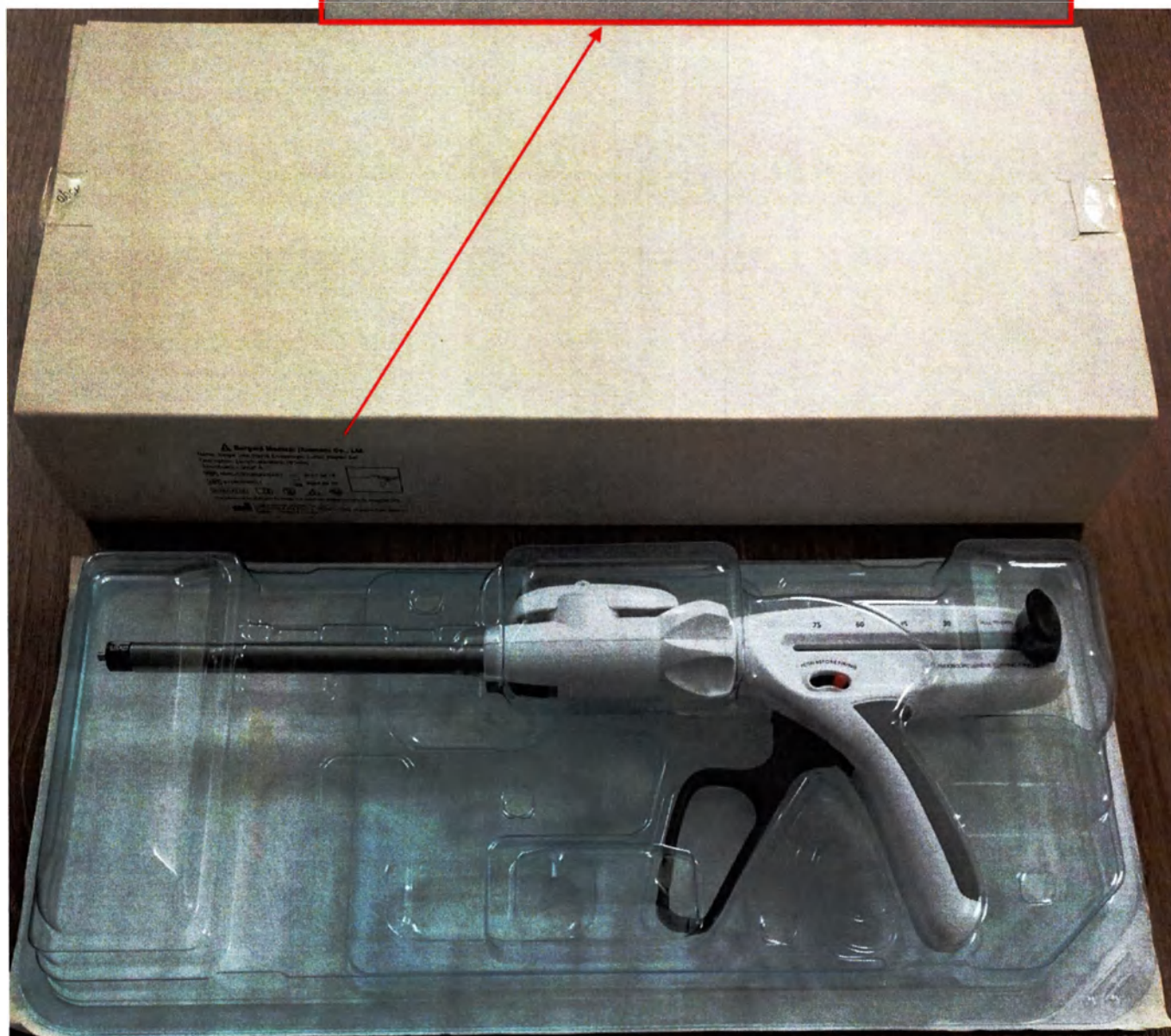
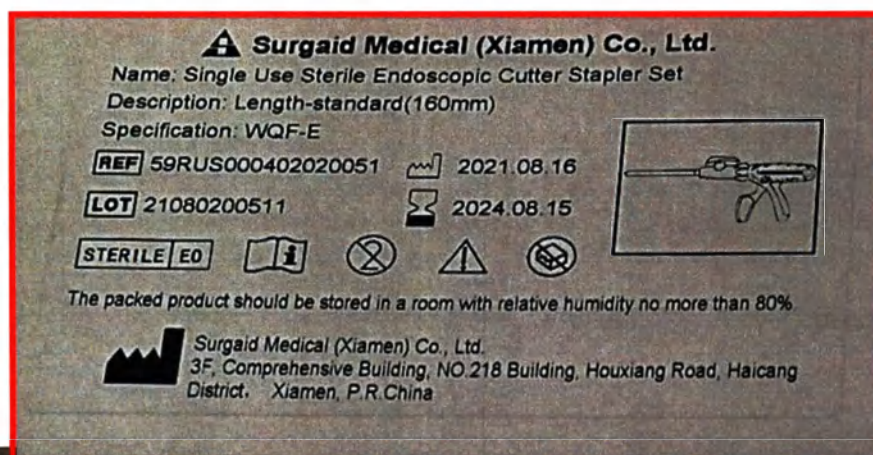


1. Reload 2. Anvil 3. Cartridge jaw 4. Cutter 5. Outer sleeve 6. Rotating handle 7. Blade direction switch 8. Blade direction indicator 9. Fixed handle 10. Reset button 11. Locking handle 12. Firing handle

Figure 2. Structural diagram of Model with D

Степлер хирургический одноразовый эндоскопический с одинарной рукояткой: WQF-E, в составе:

1) Степлер хирургический одноразовый эндоскопический с одинарной рукояткой: WQF-E – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Endoscopic Cutter Stapler Set
Description: Length-standard(160mm)
Specification: WQF-E
REF 59RUS000402020051 2021.08.16
LOT 21080200511 2024.08.15
STERILE E0
The packed product should be stored in a room with relative humidity no more than 80%.
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

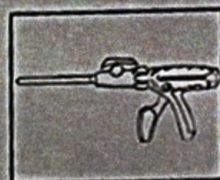
Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Endoscopic Cutter Stapler Set
Description: Length-standard(160mm)
Specification: WQF-E

REF 59RUS000402020051 2021.08.16

LOT 21080200511 2024.08.15

STERILE E0



The packed product should be stored in a room with relative humidity no more than 80%.

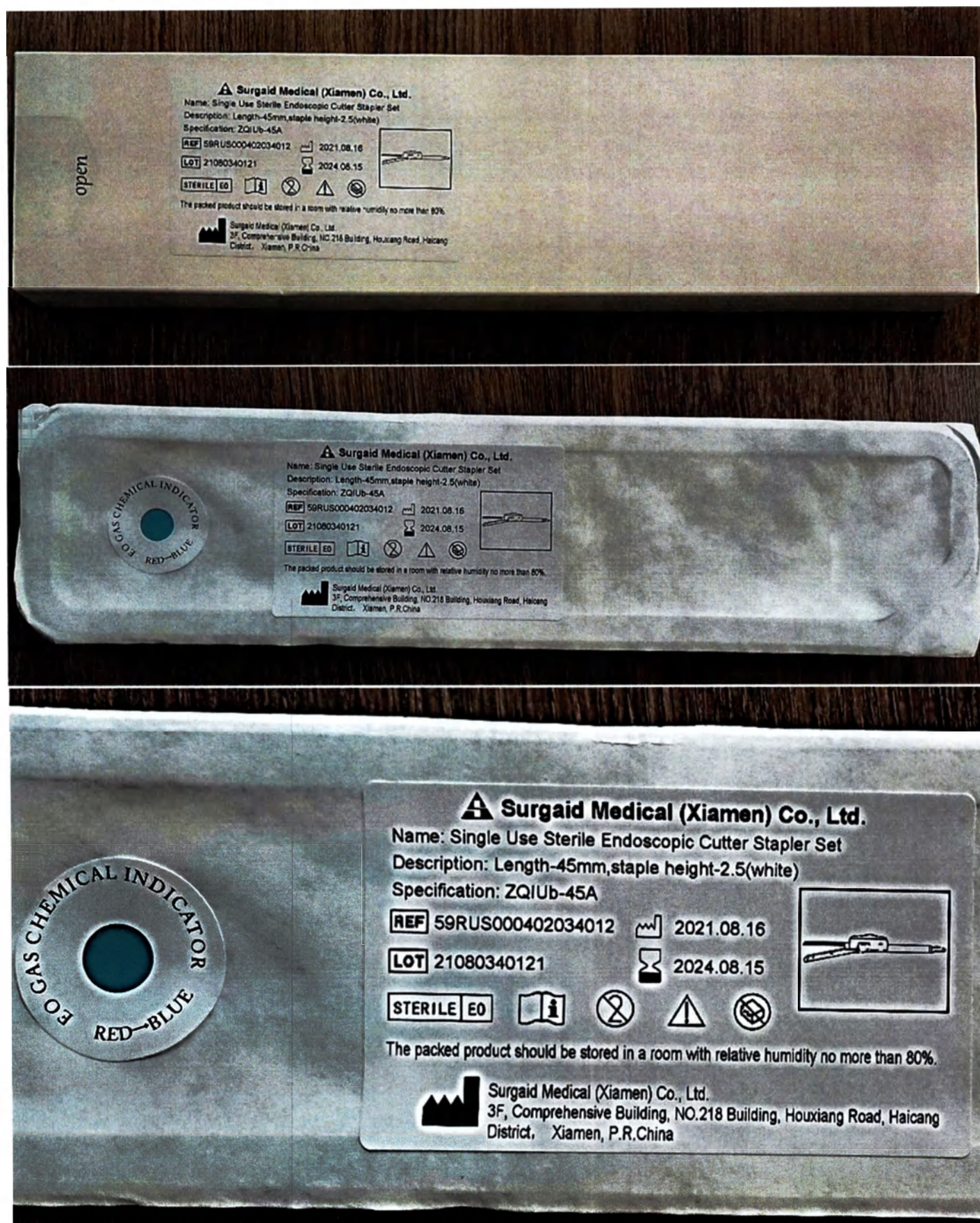


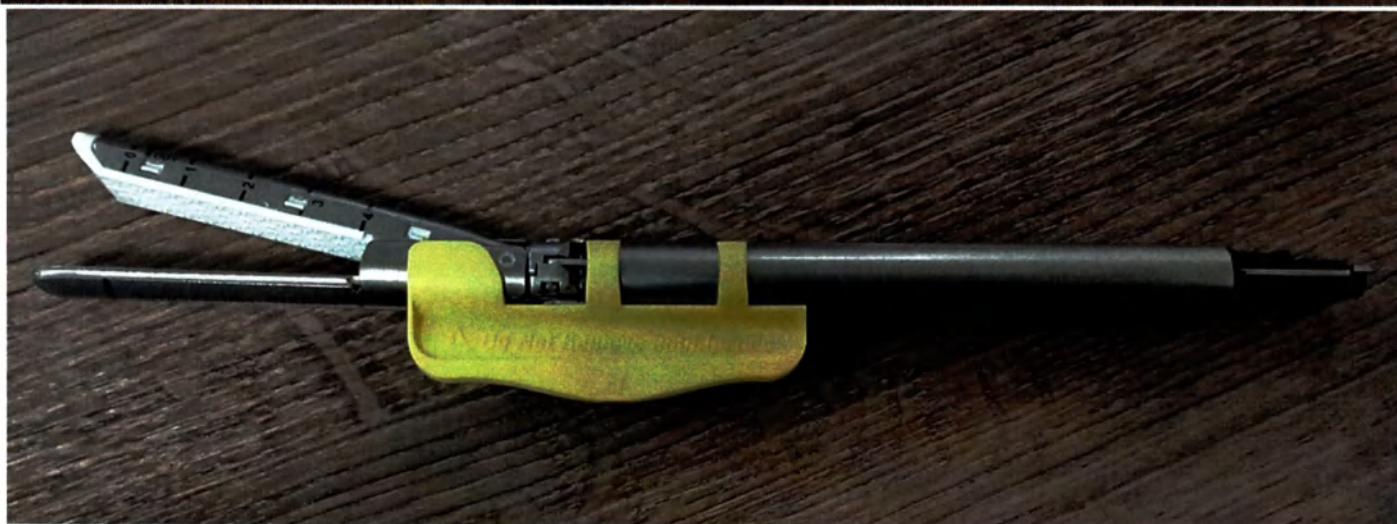
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



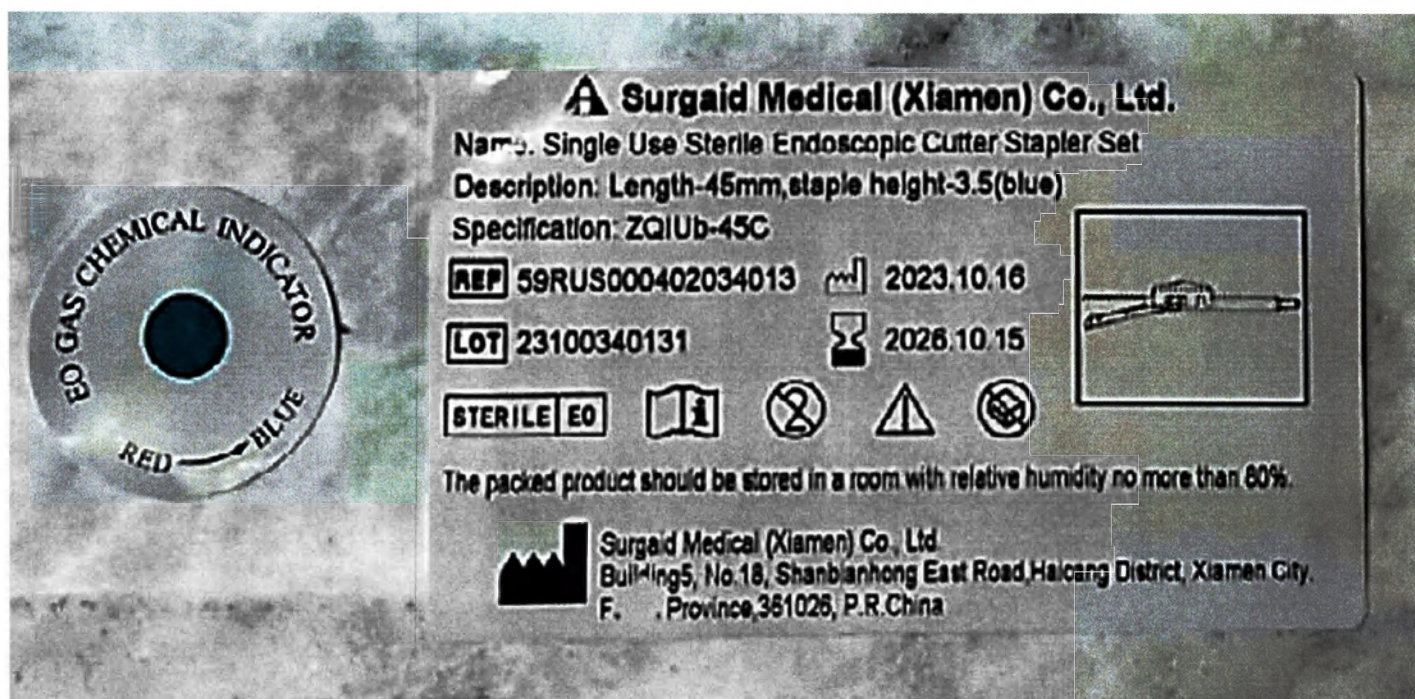
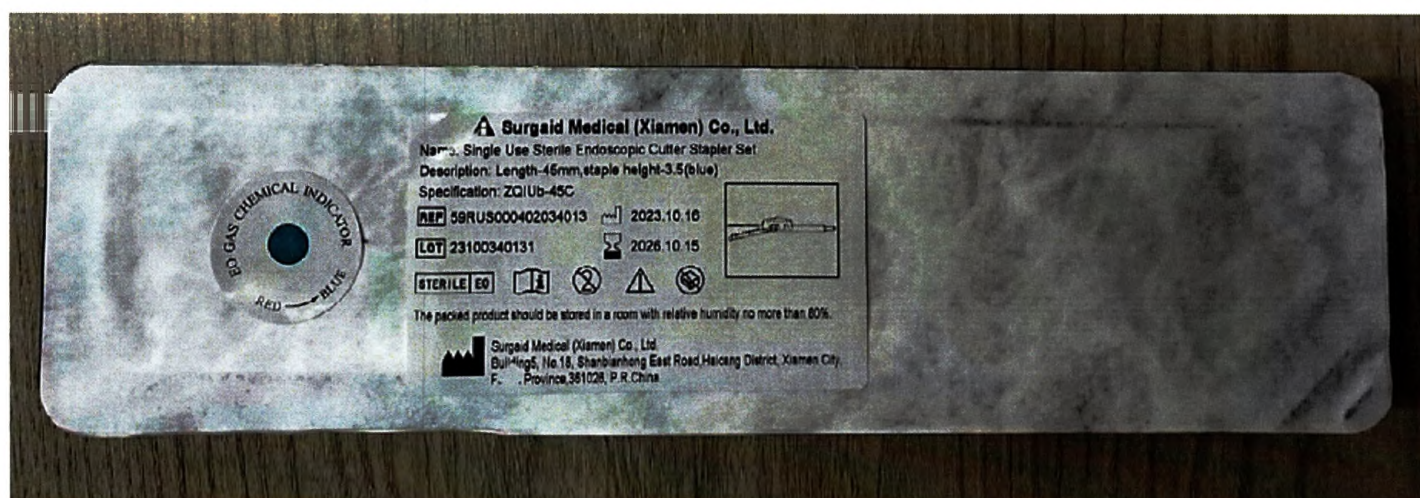
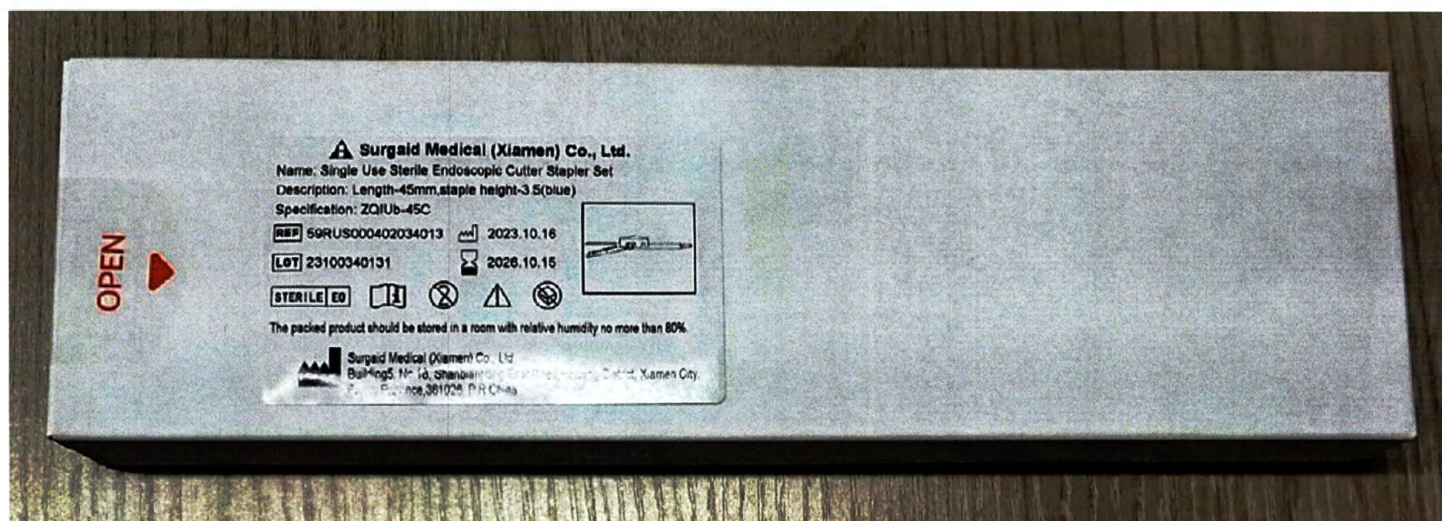
2) Картридж для степлера ротационный, в одном из вариантов исполнения:

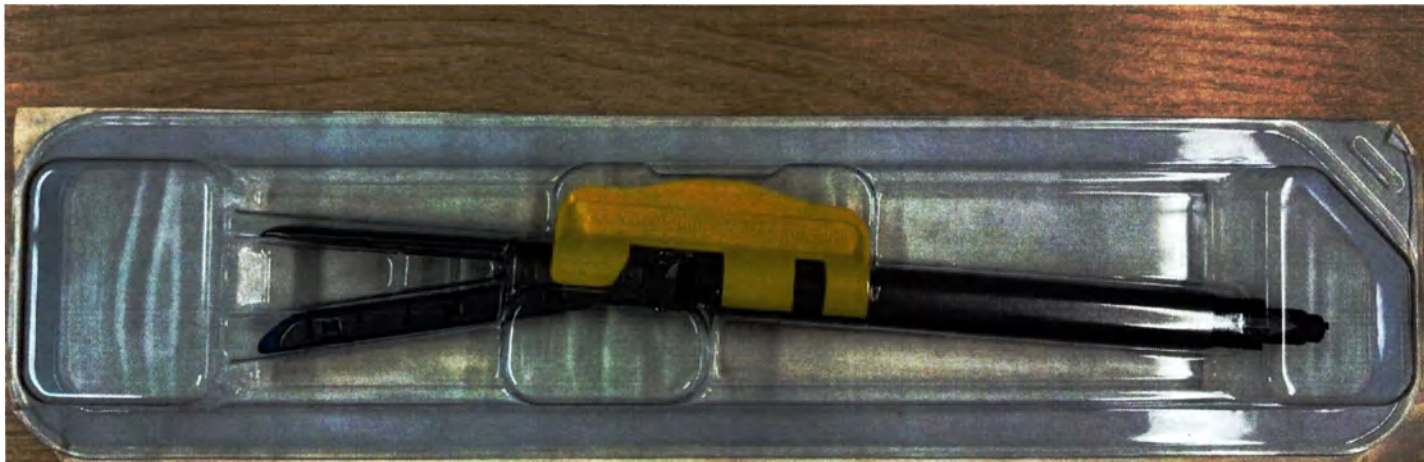
- Картридж для степлера ротационный, прямой: ZQIUb-45A – не более 6 шт. (при необходимости);



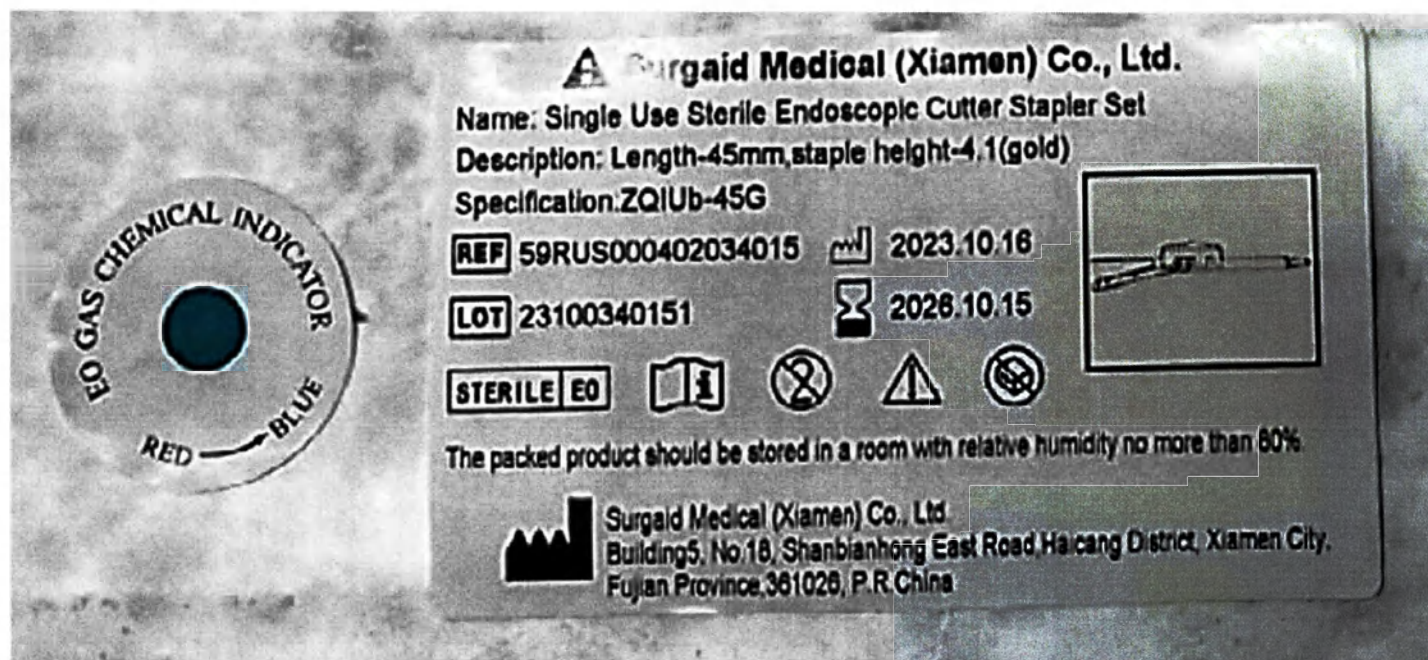
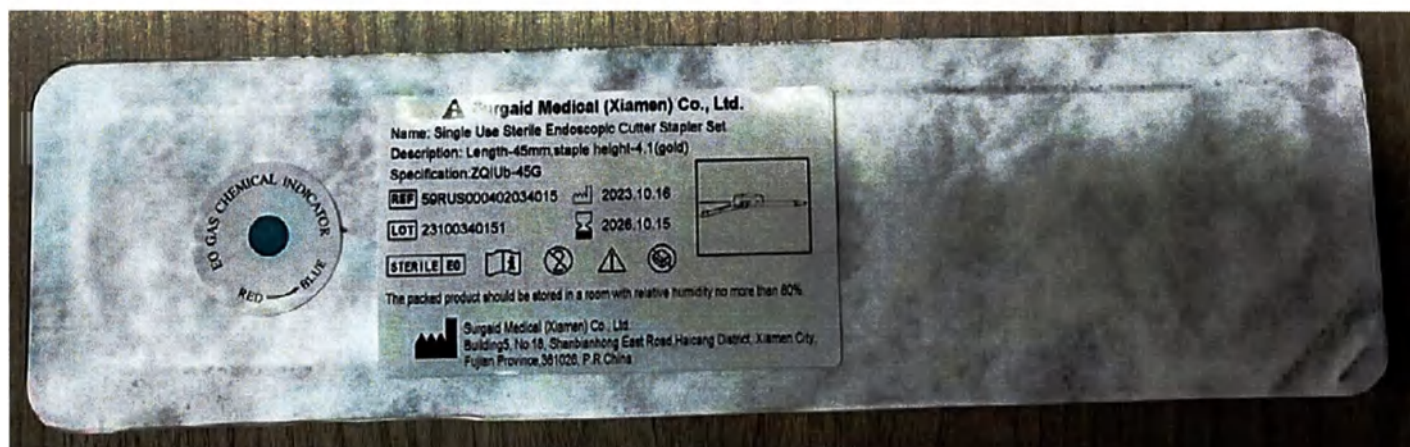
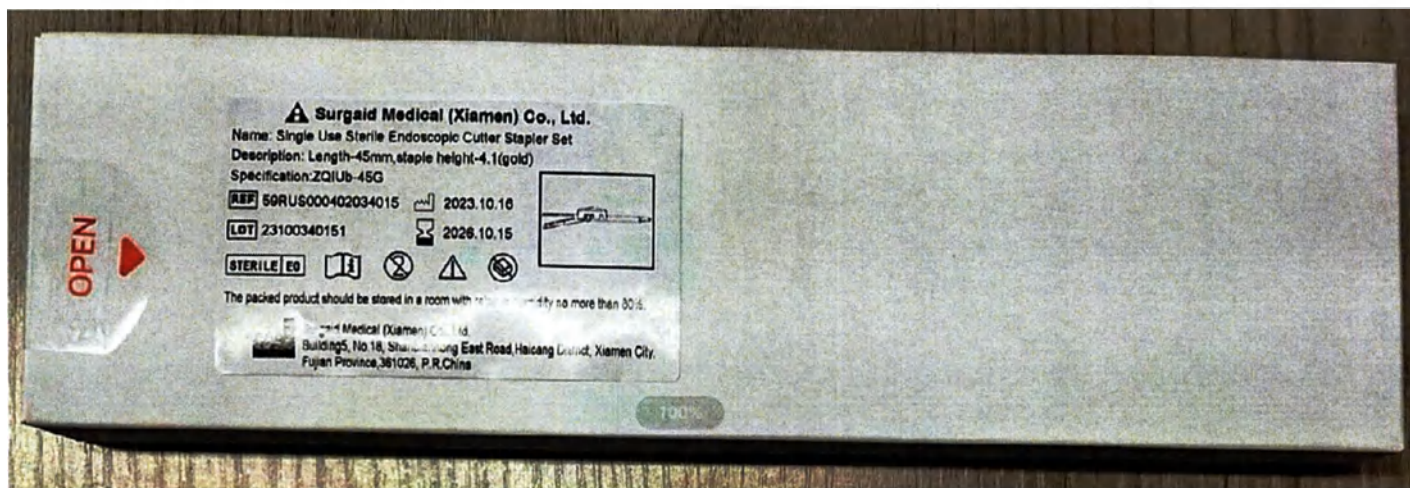


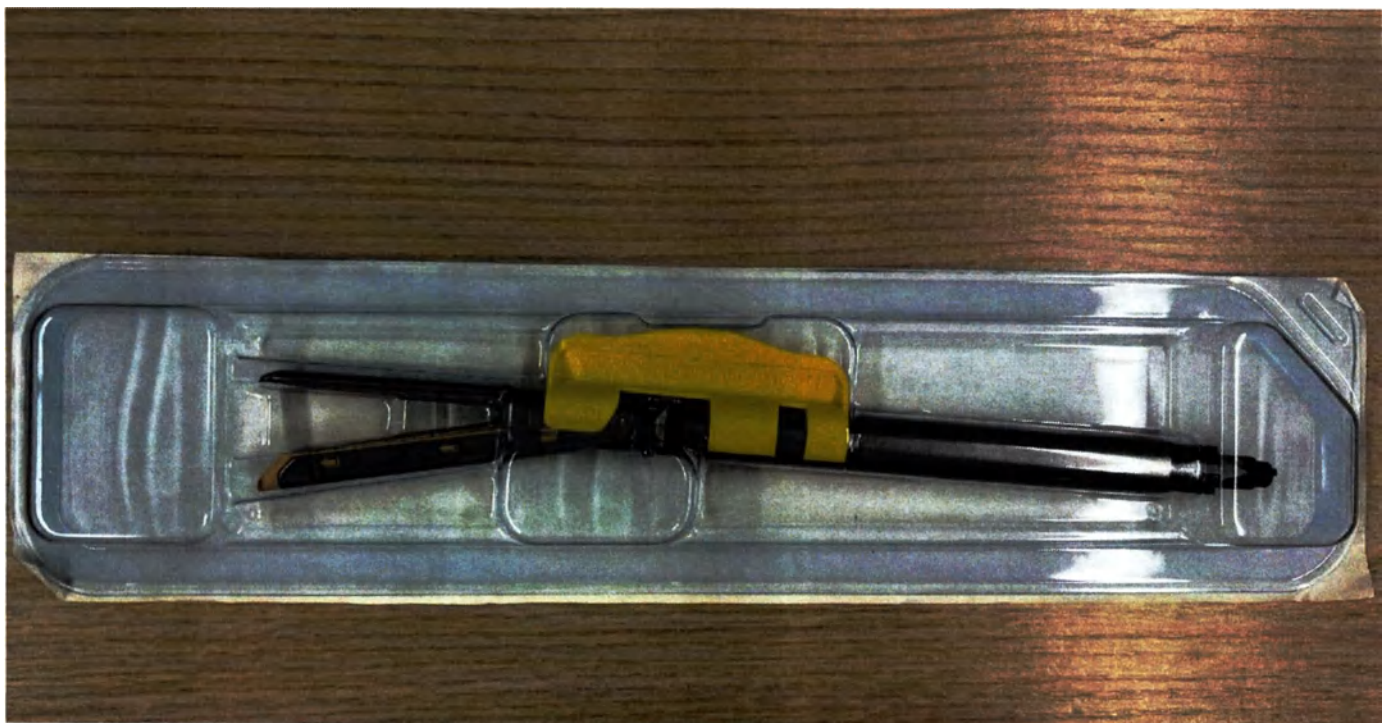
- Картридж для степлера ротационный, прямой: ZQIUb-45C – не более 6 шт. (при необходимости);



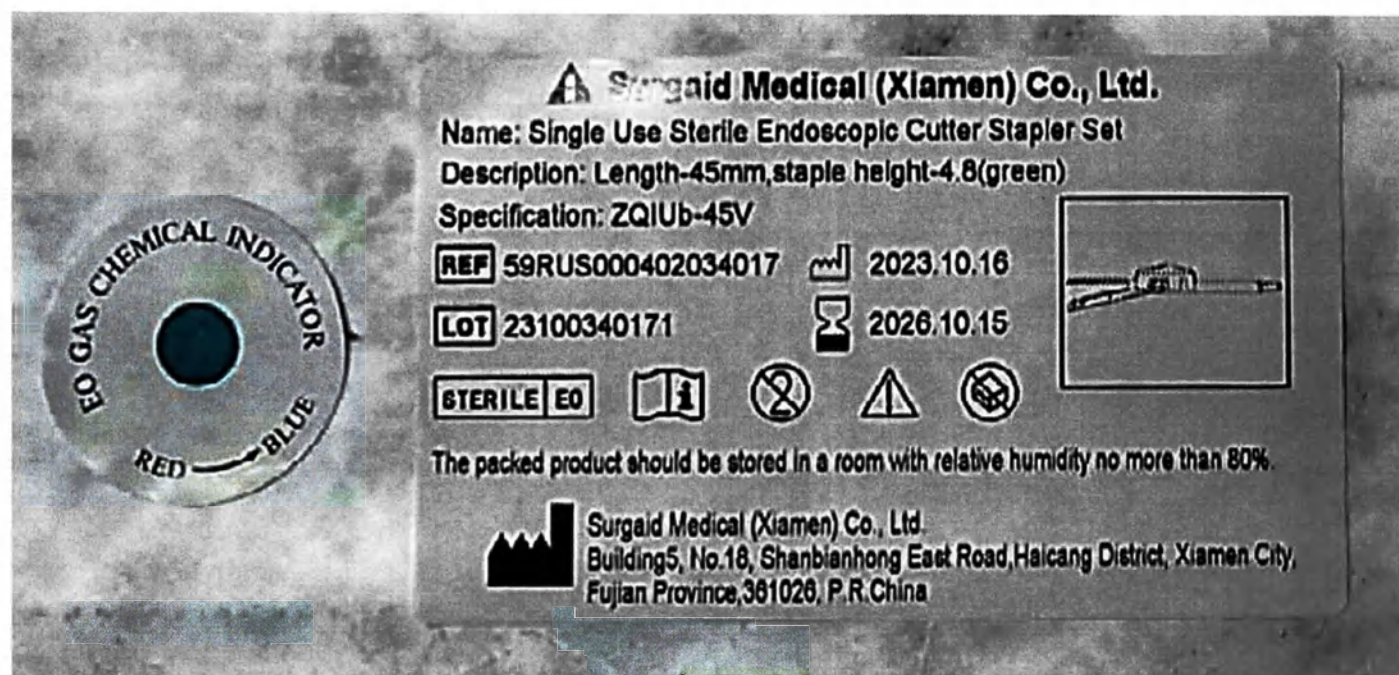
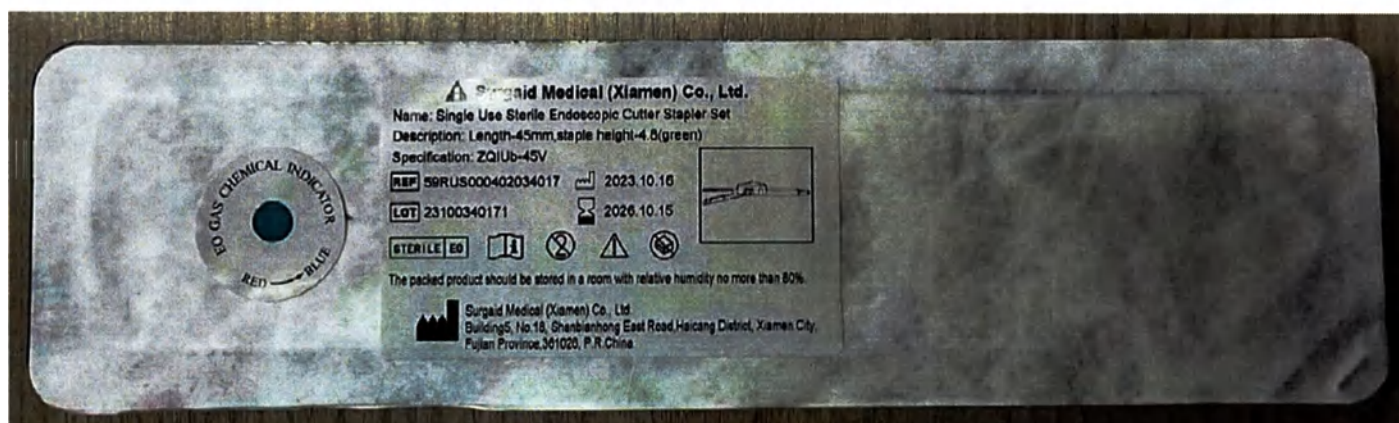
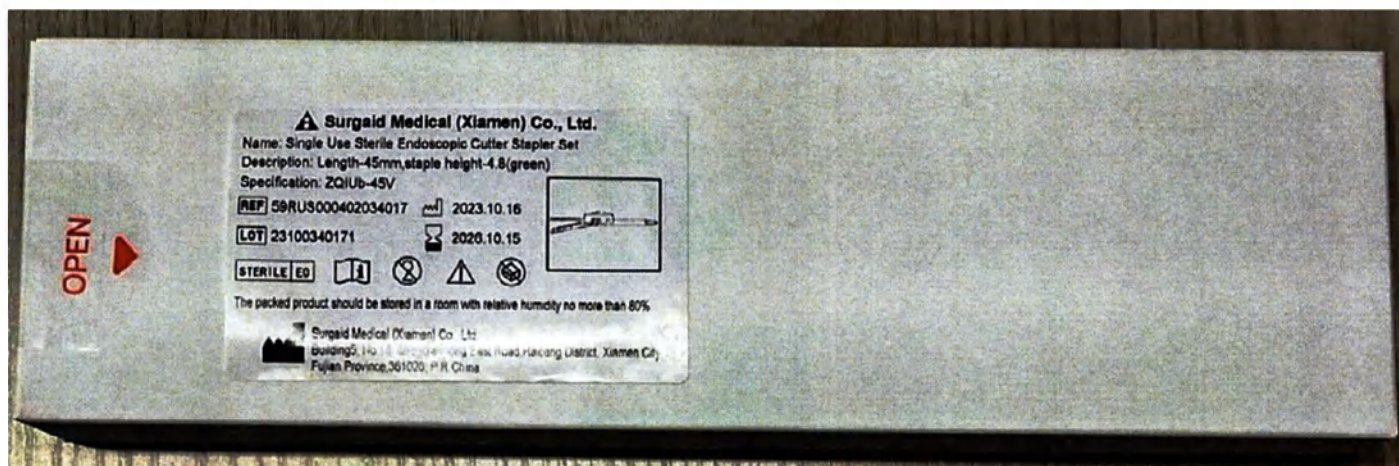


- Картридж для степлера ротационный, прямой: ZQIUb-45G – не более 6 шт. (при необходимости);



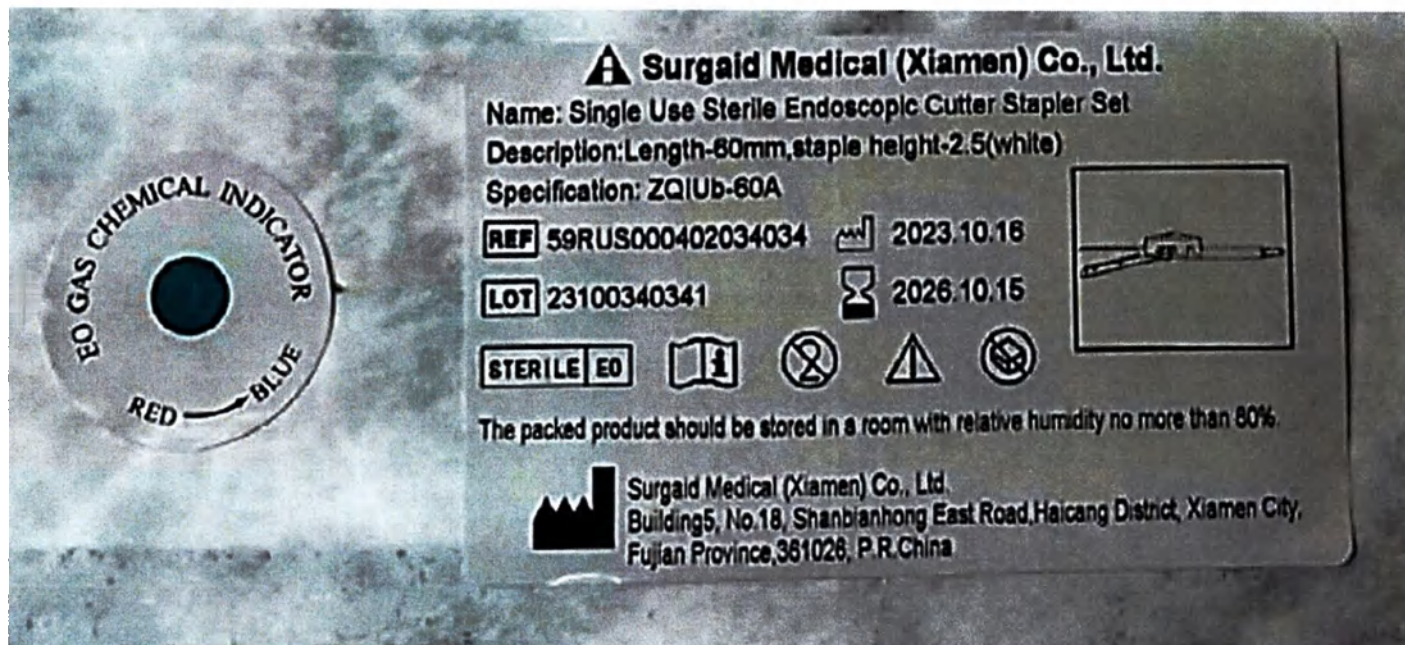
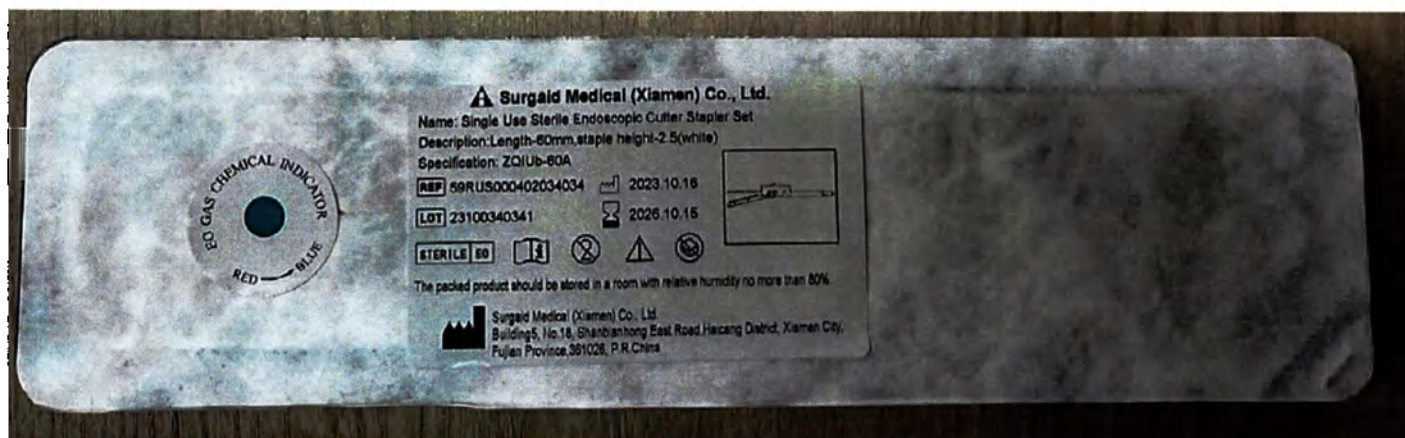
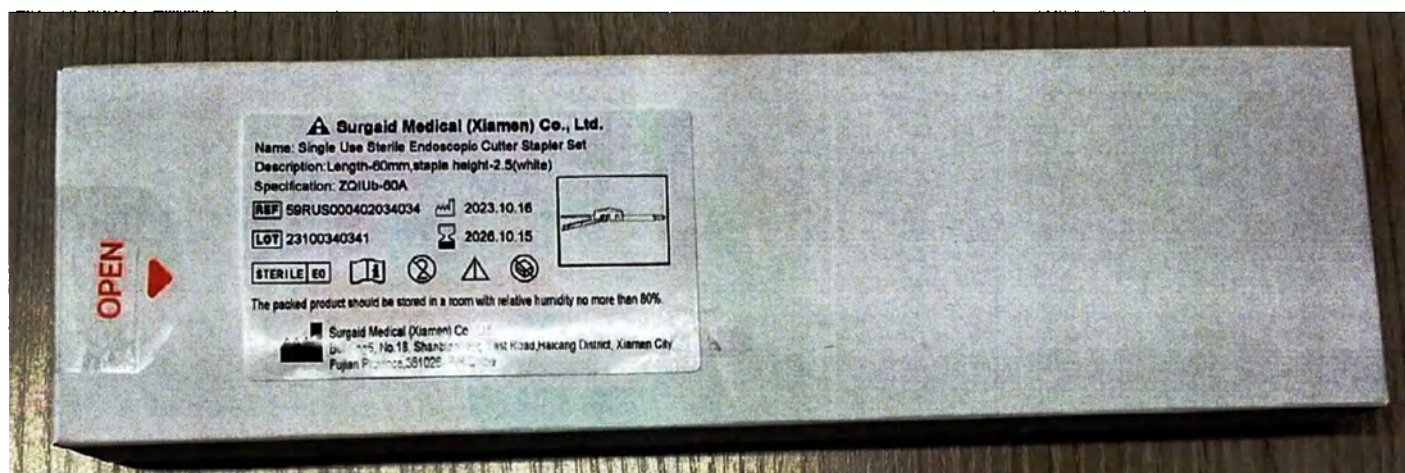


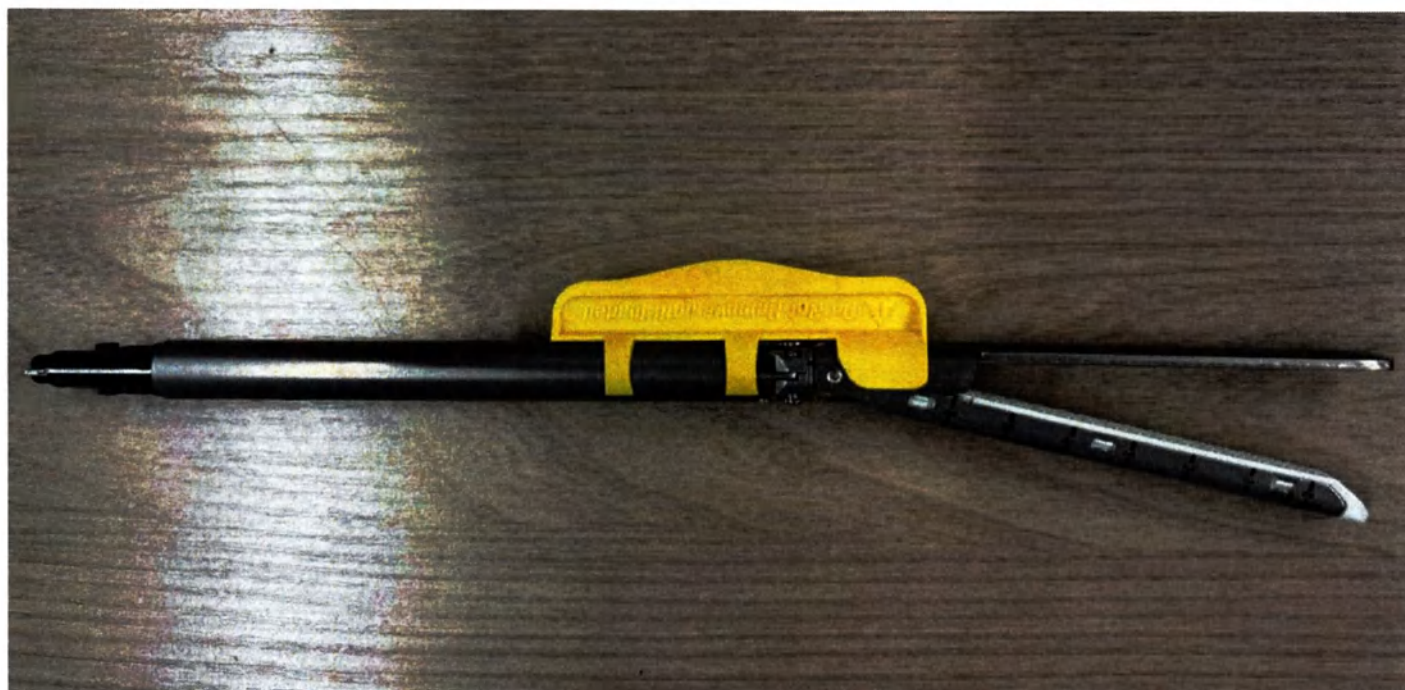
- Картридж для степлера ротационный, прямой: ZQIUb-45V – не более 6 шт. (при необходимости);



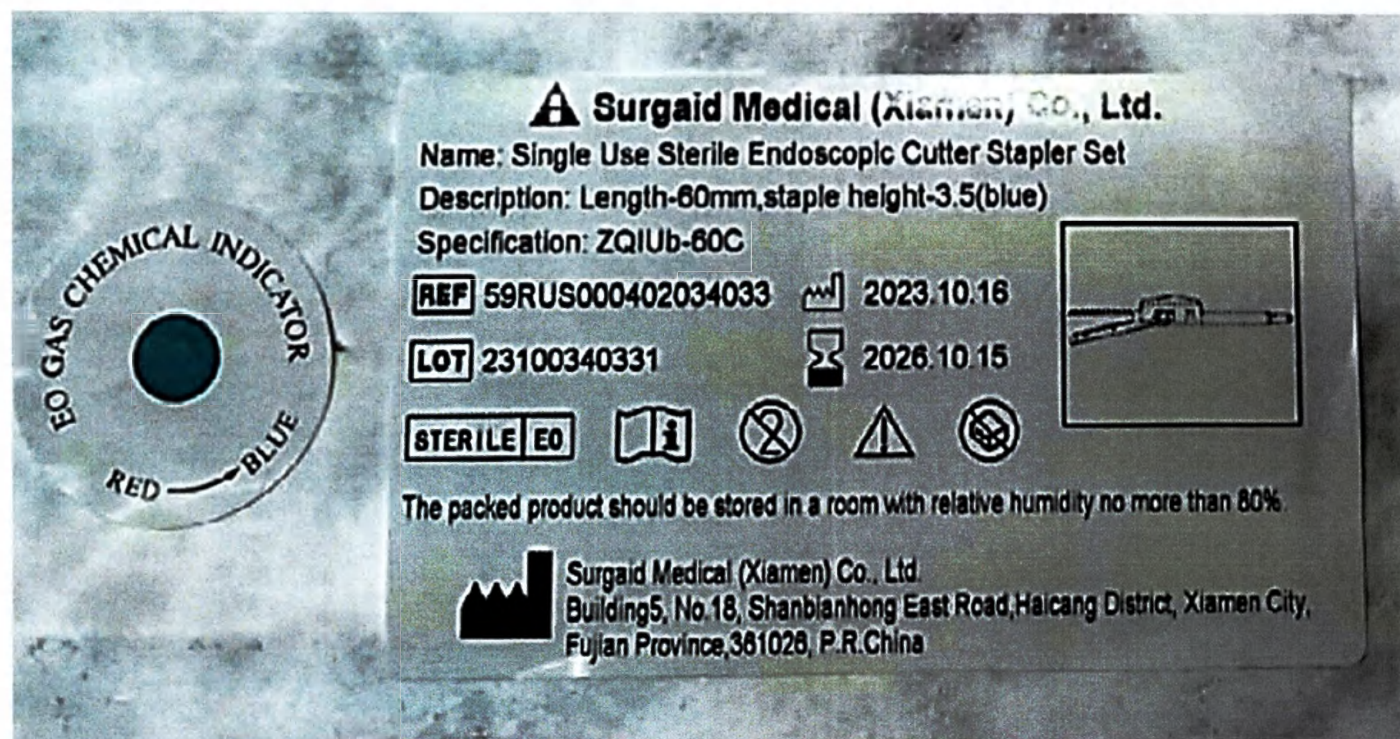
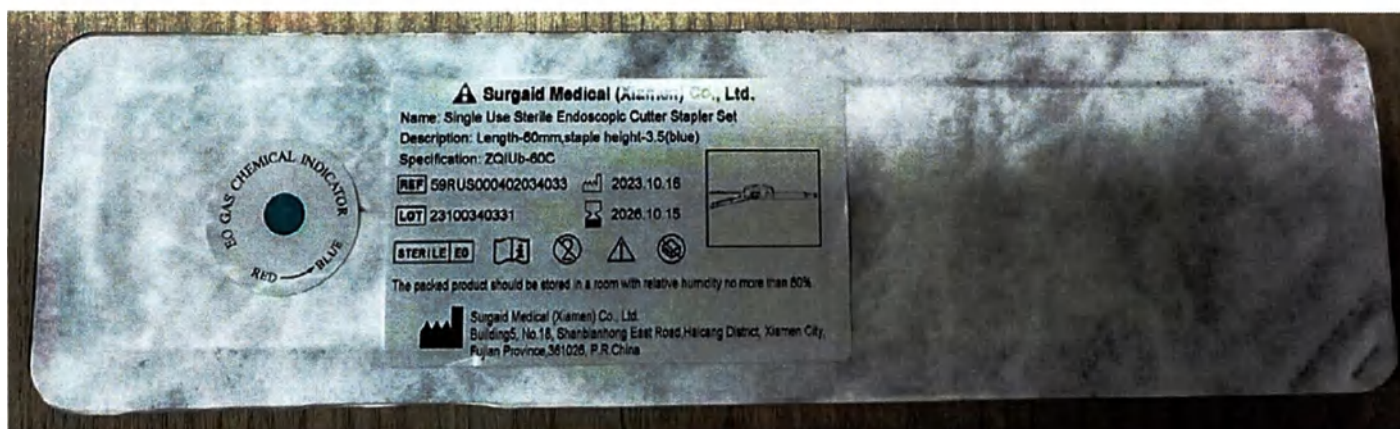
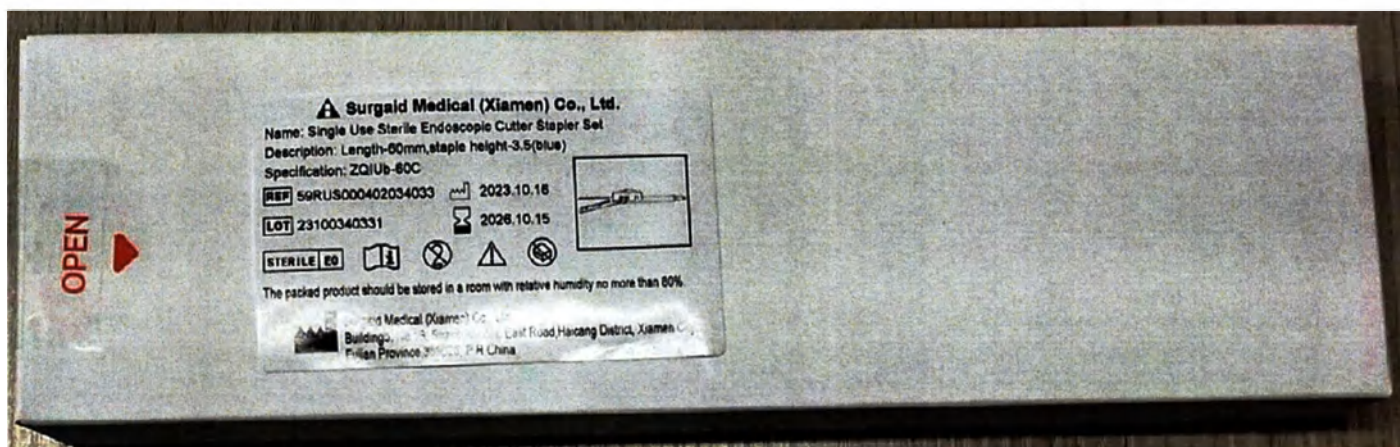


- Картридж для степлера ротационный, прямой: ZQIUb-60A – не более 6 шт. (при необходимости);



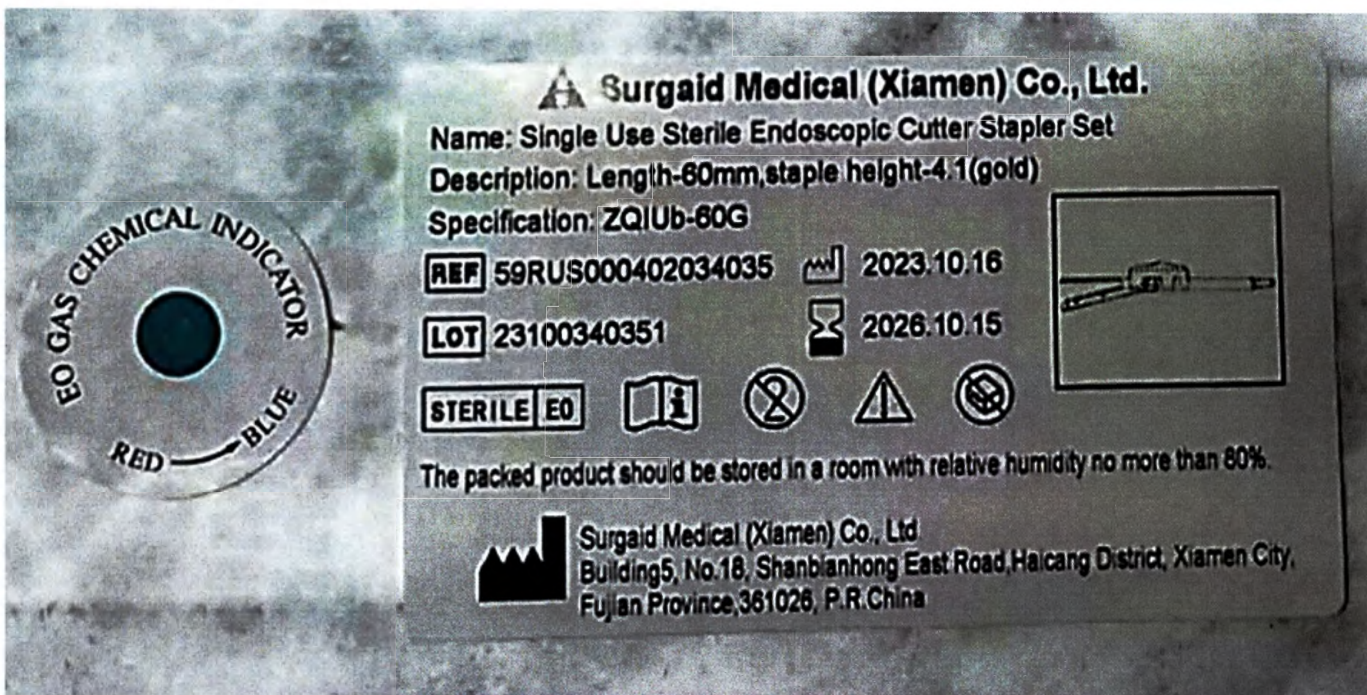
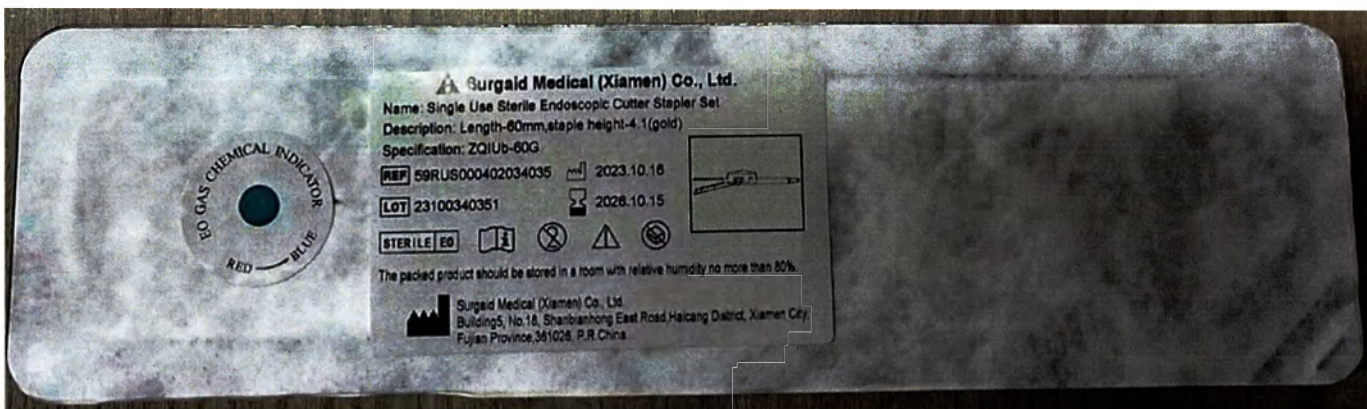
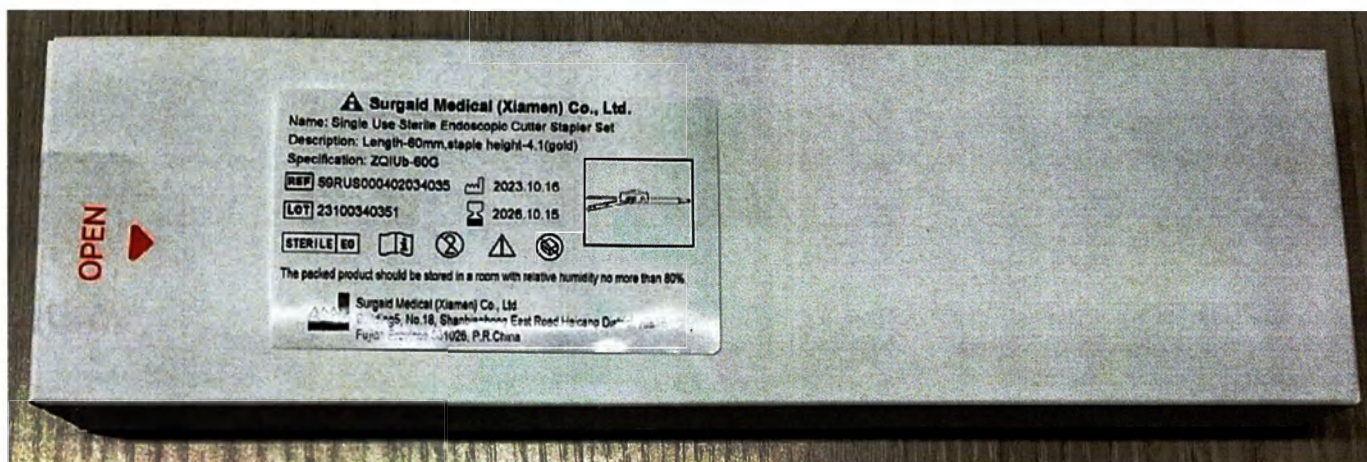


- Картридж для степлера ротационный, прямой: ZQIUb-60C – не более 6 шт. (при необходимости);



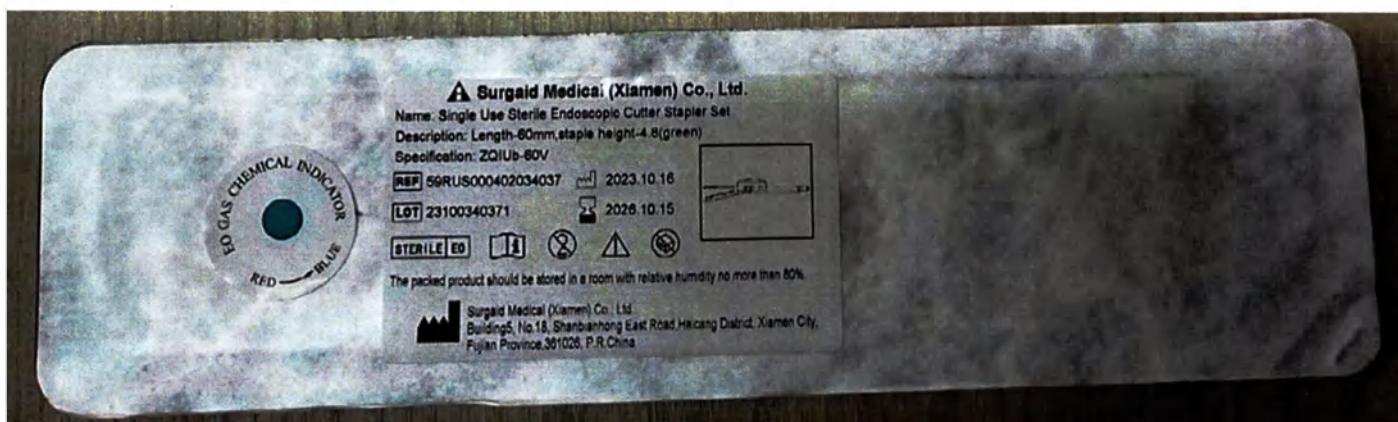
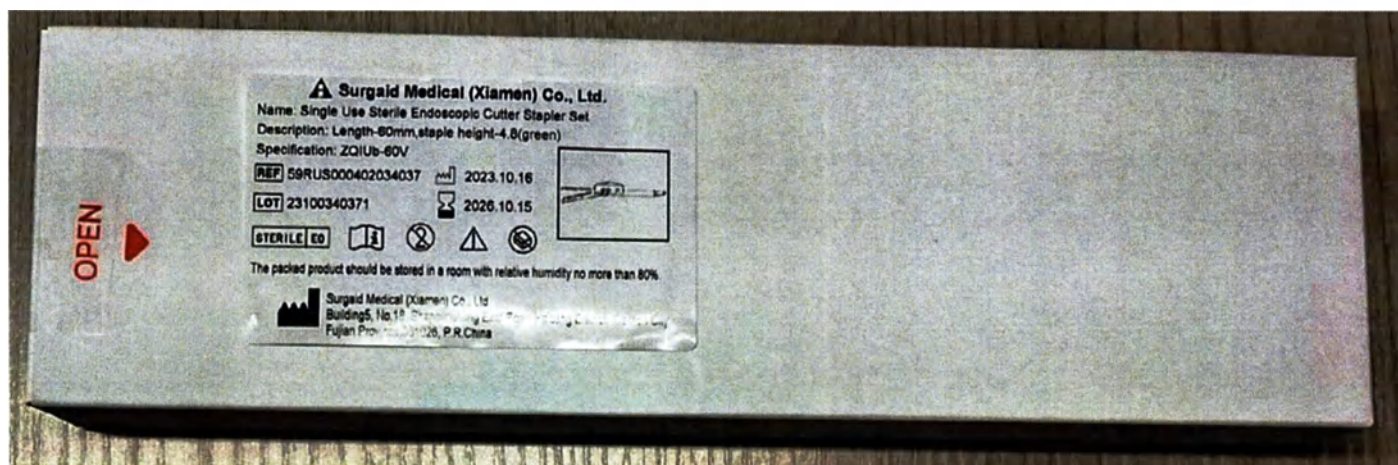


- Картридж для степлера ротационный, прямой: ZQIUb-60G – не более 6 шт. (при необходимости);



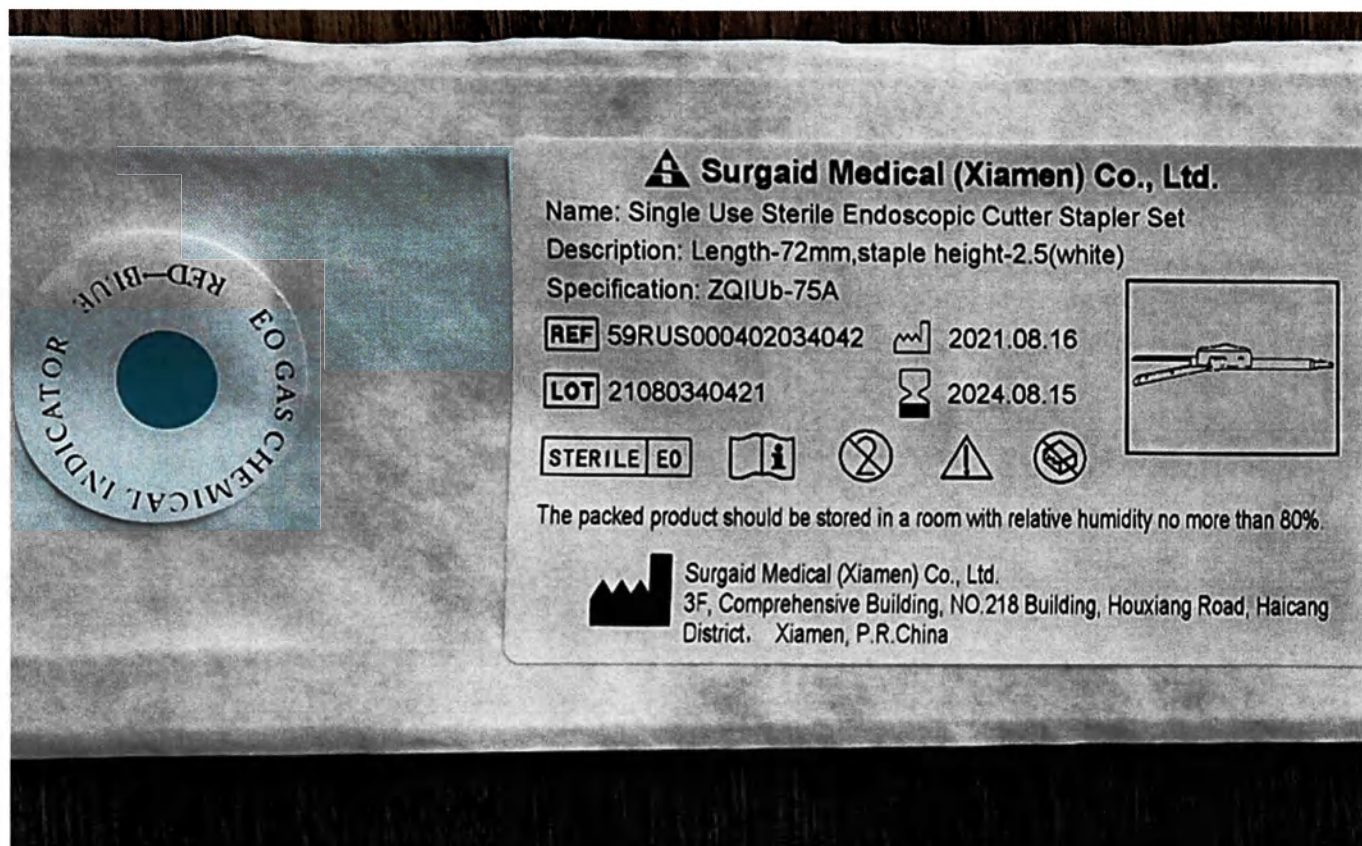
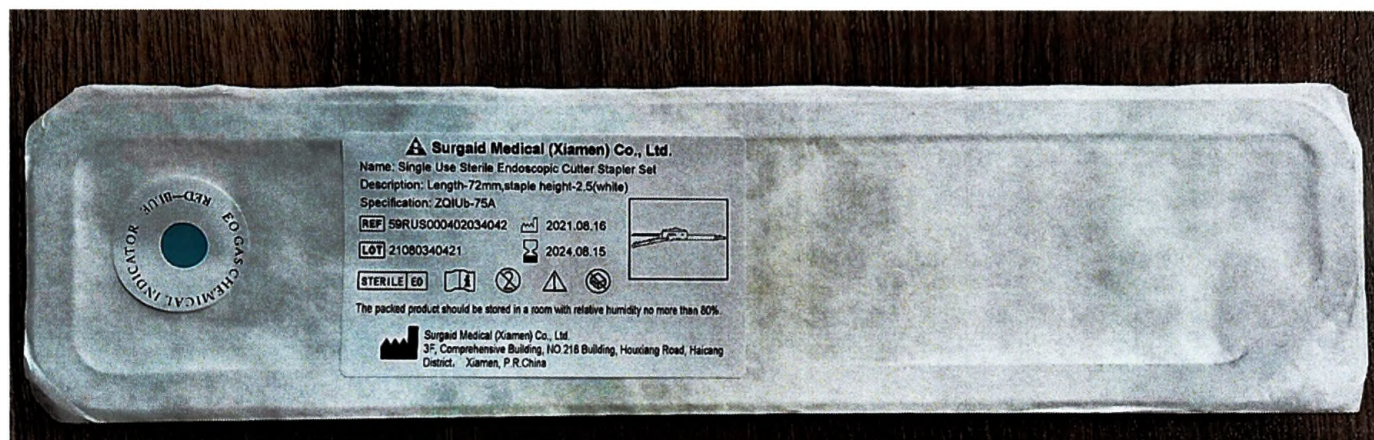
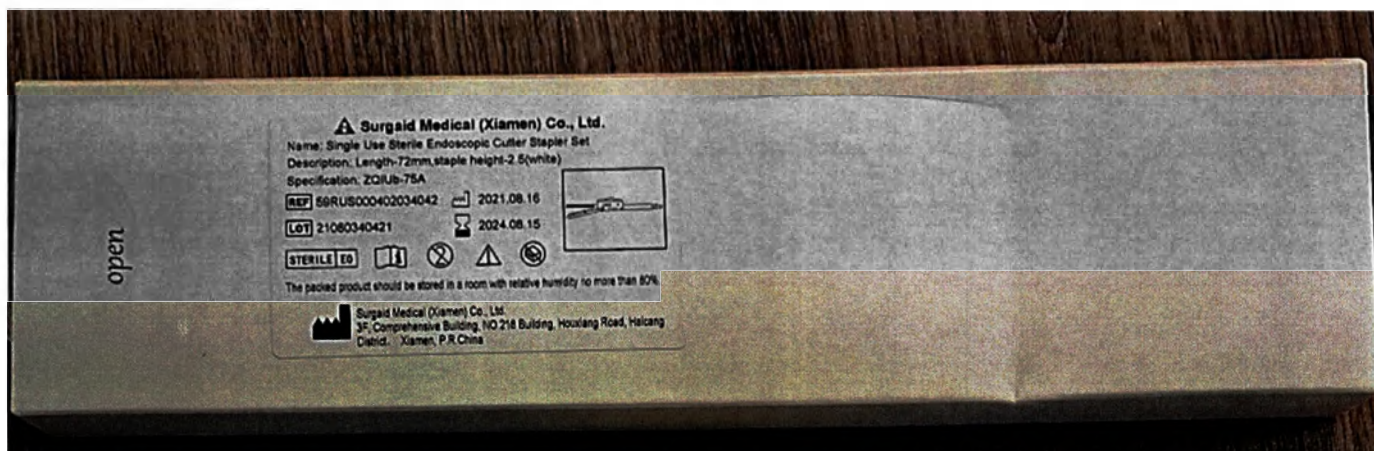


- Картридж для степлера ротационный, прямой: ZQIUb-60V – не более 6 шт. (при необходимости);



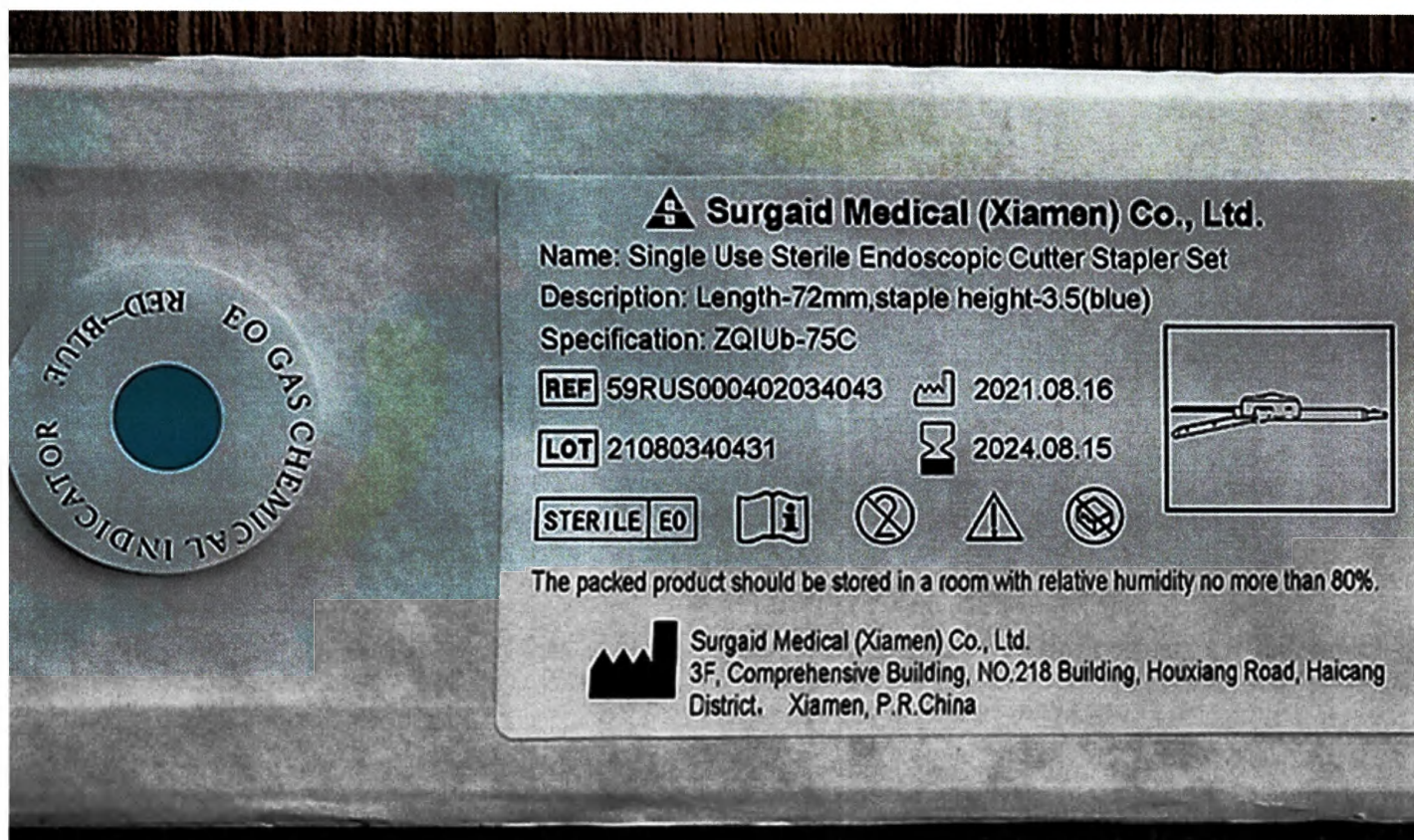
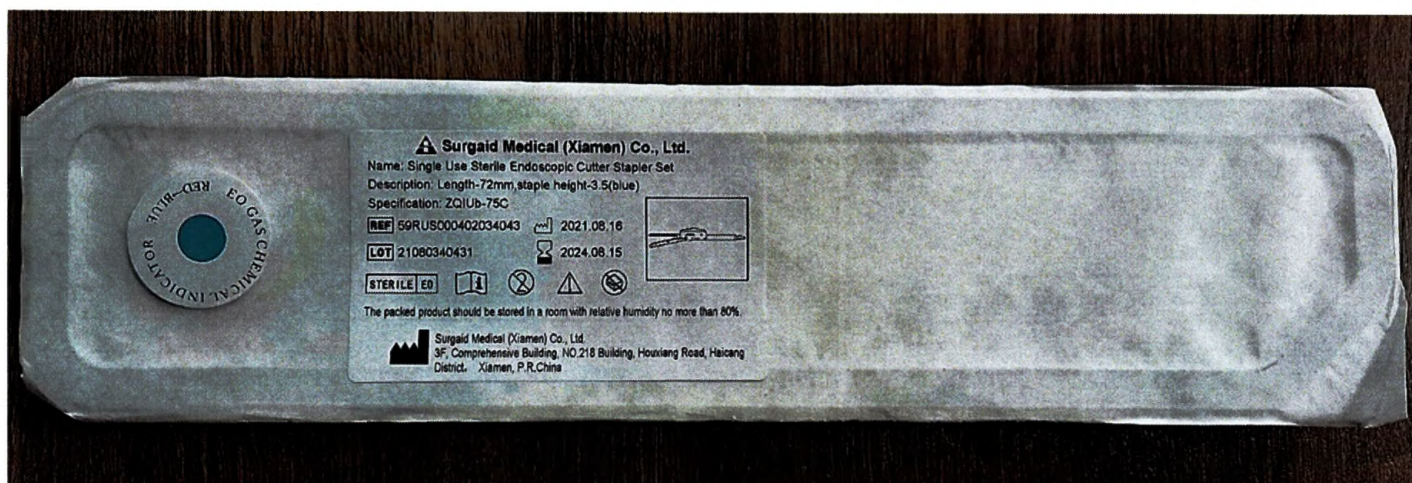
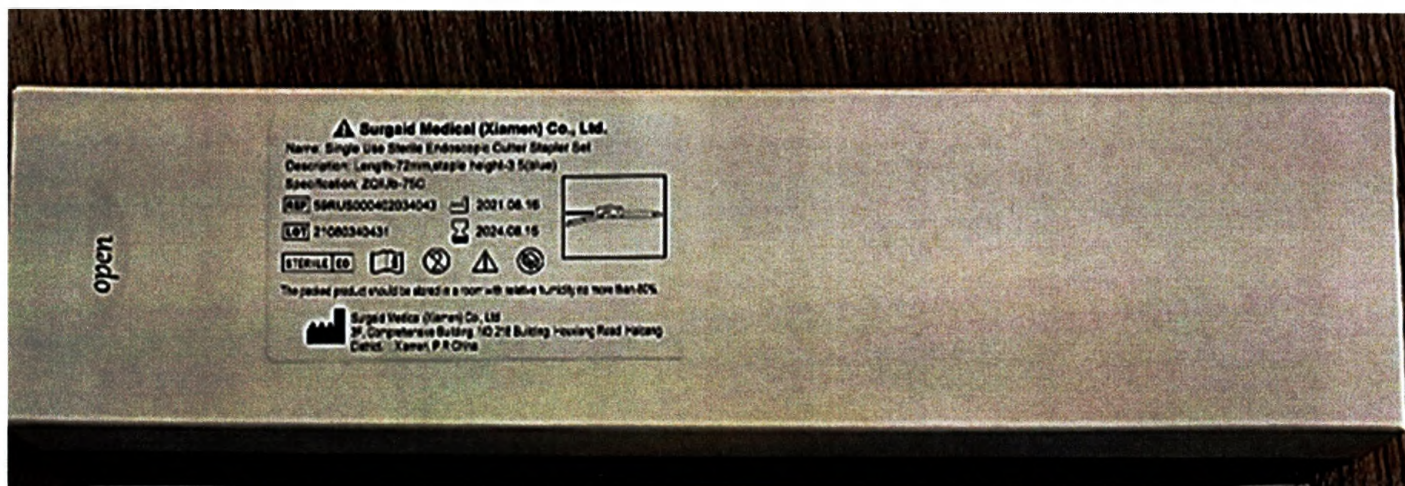


- Картридж для степлера ротационный, прямой: ZQIUb-75A – не более 6 шт. (при необходимости);



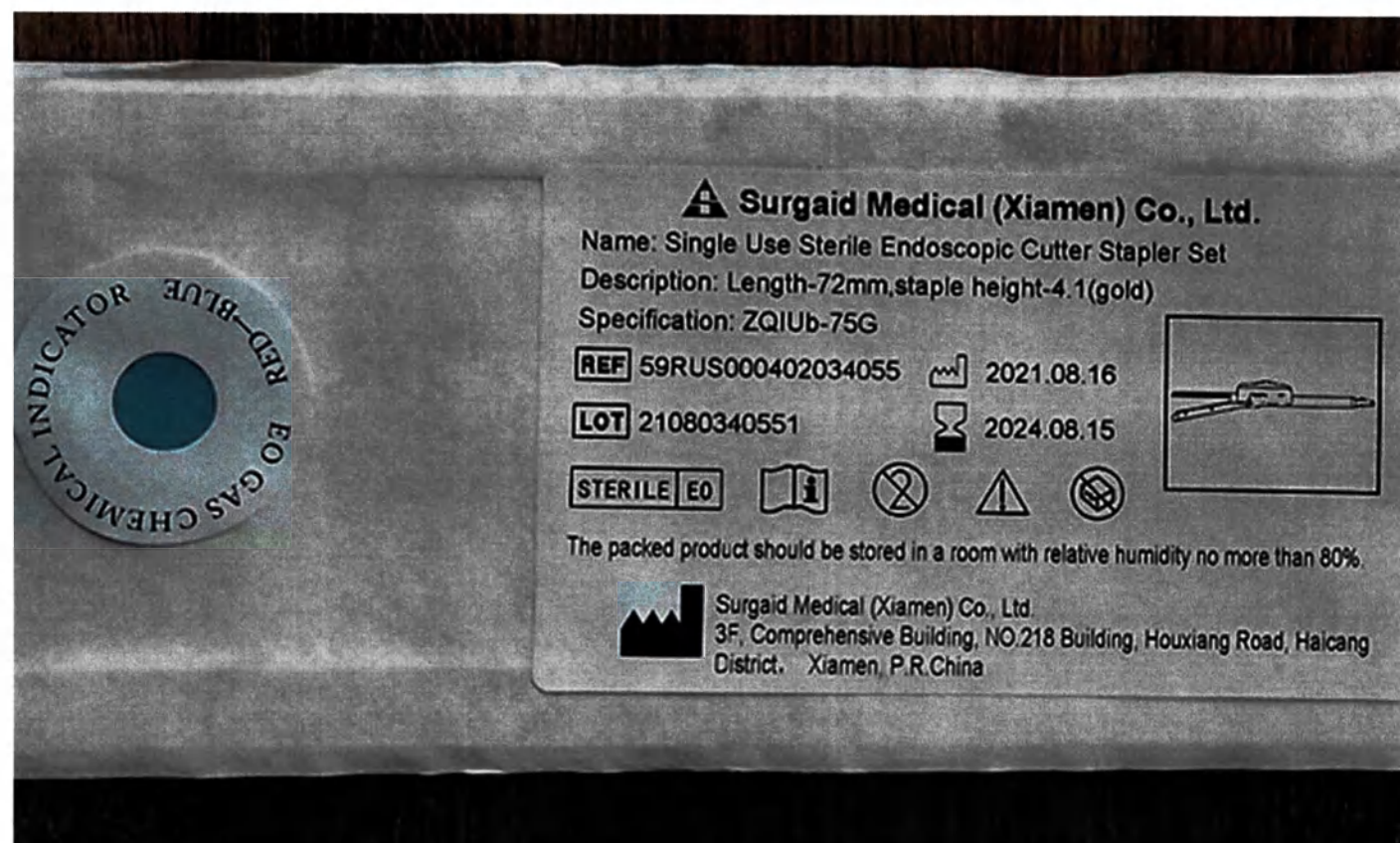
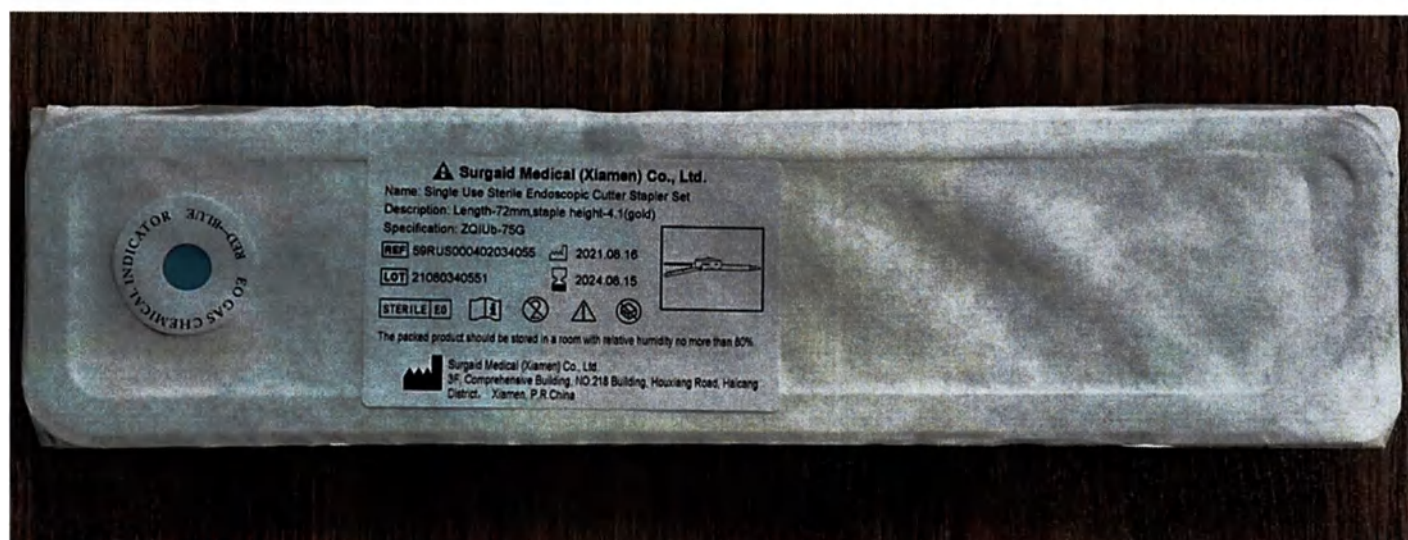
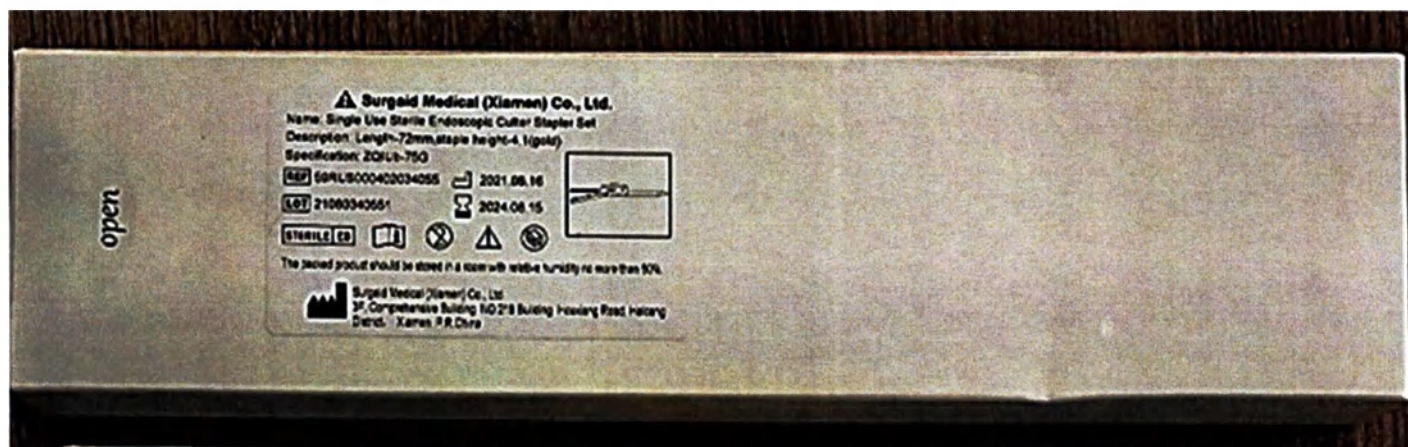


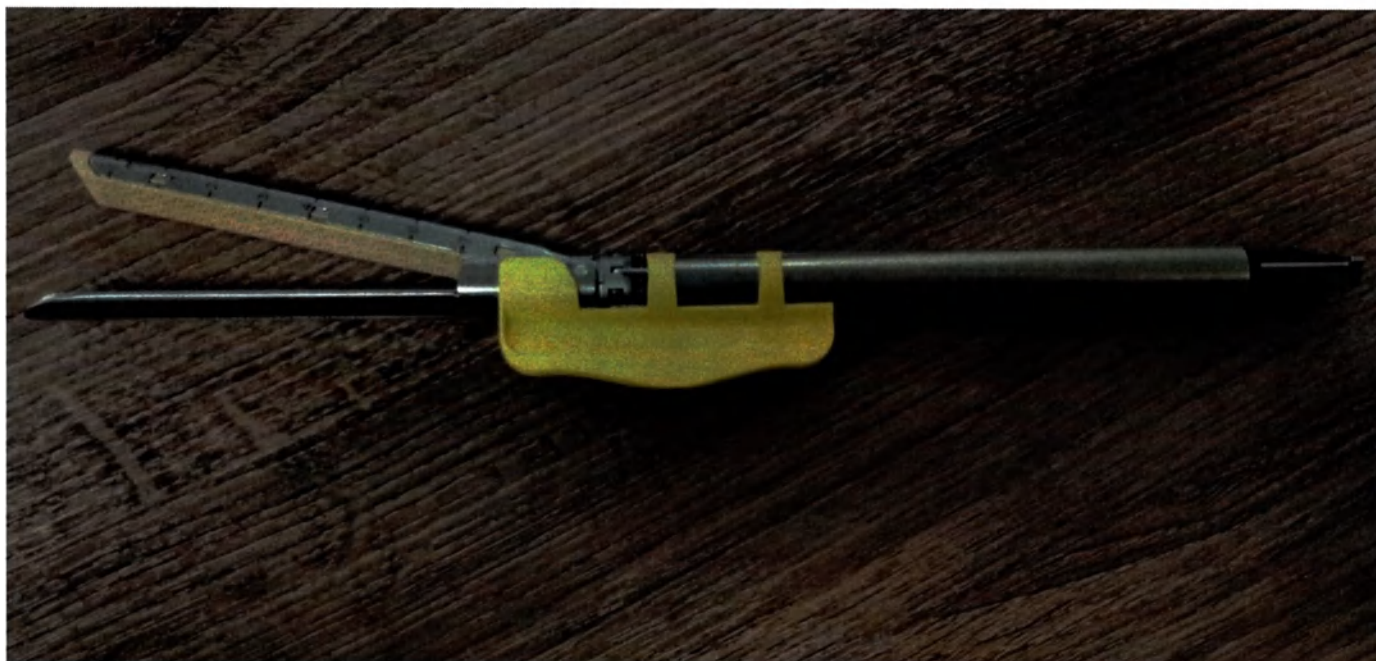
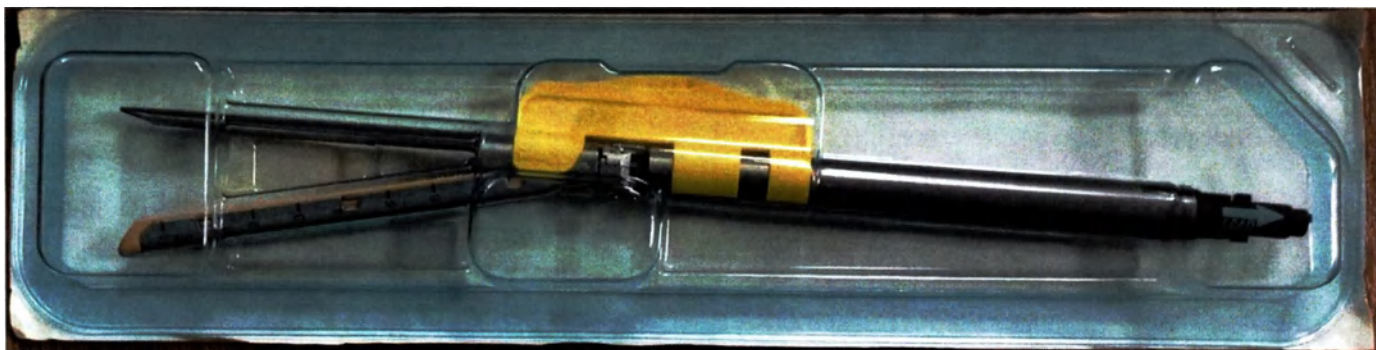
- Картридж для степлера ротационный, прямой: ZQIUb-75C – не более 6 шт. (при необходимости);



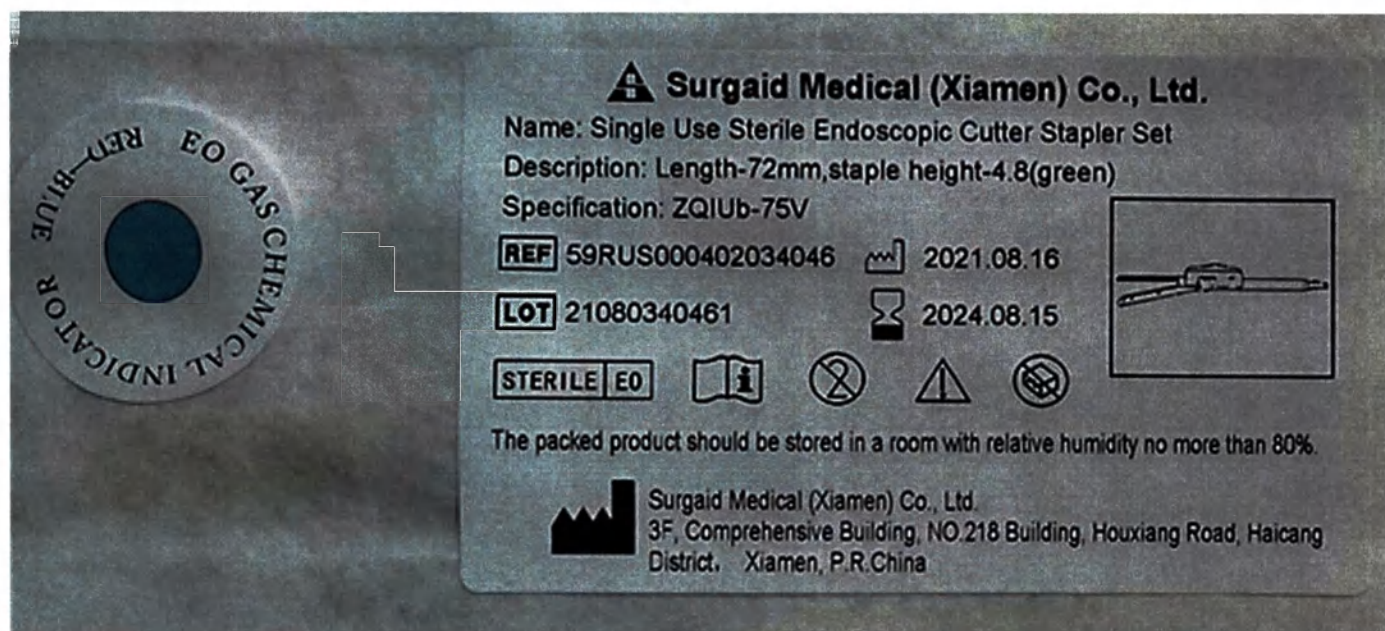


- Картридж для степлера ротационный, прямой: ZQIUb-75G – не более 6 шт. (при необходимости);



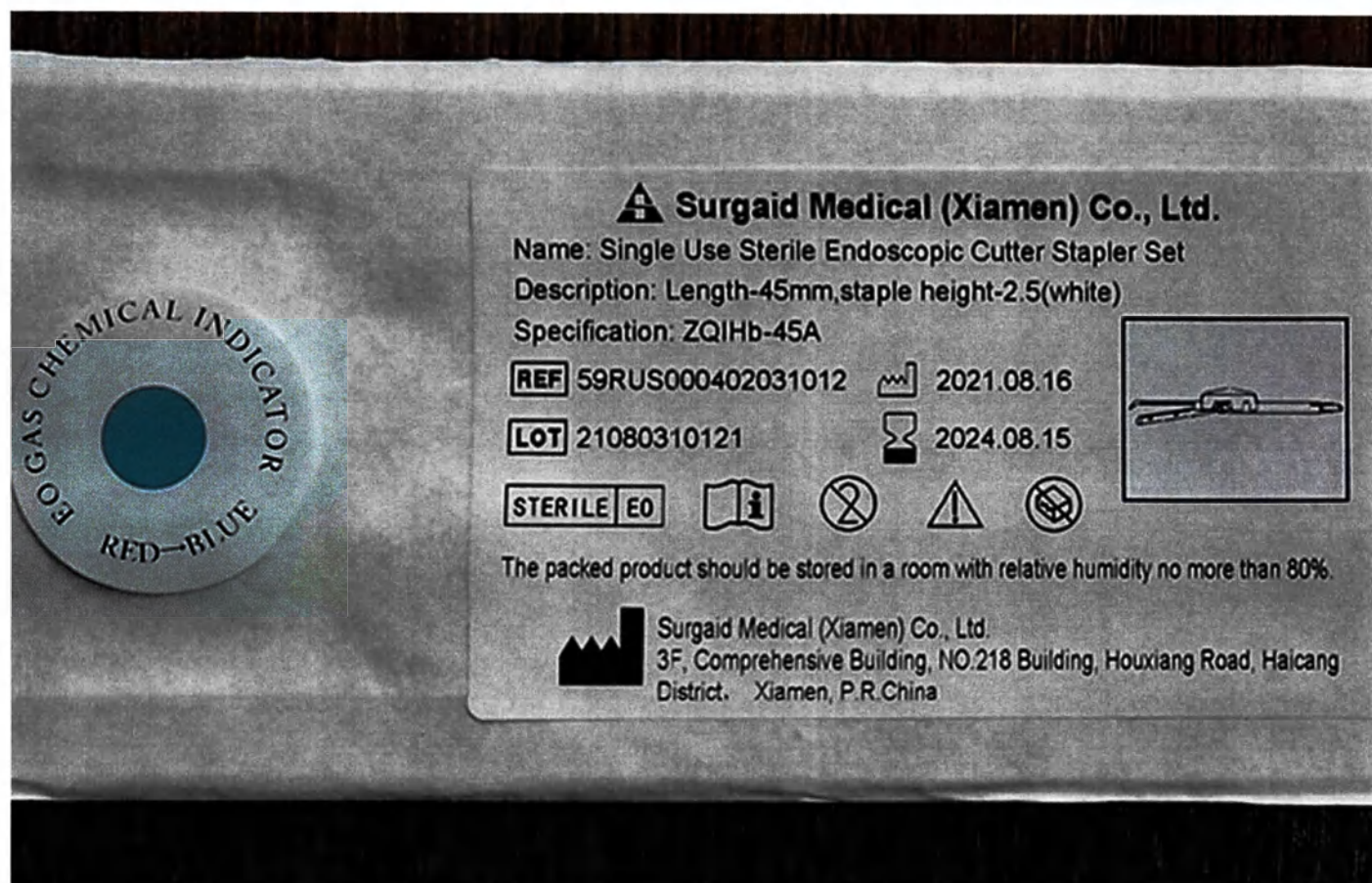
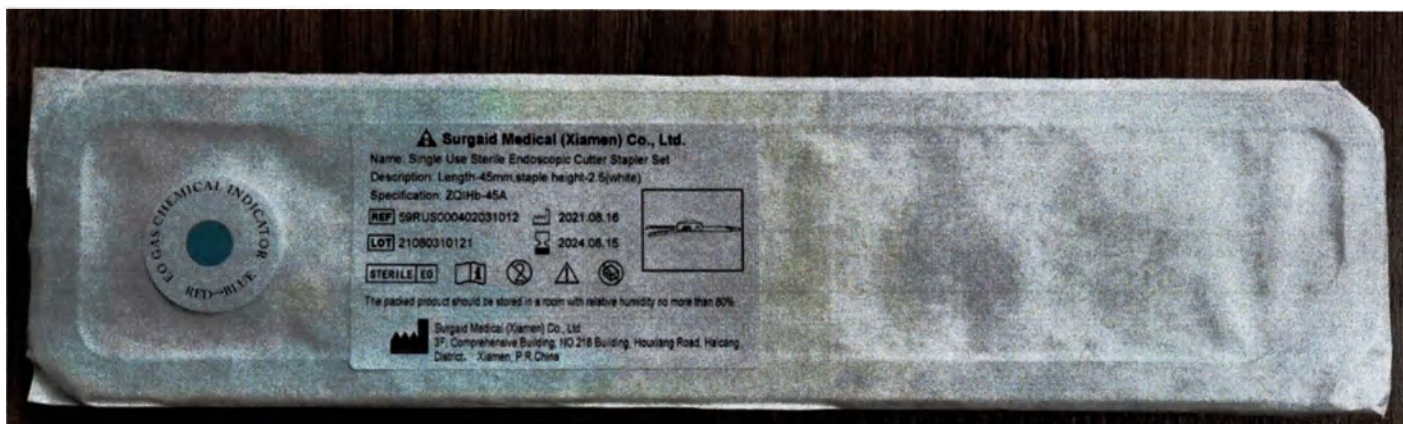
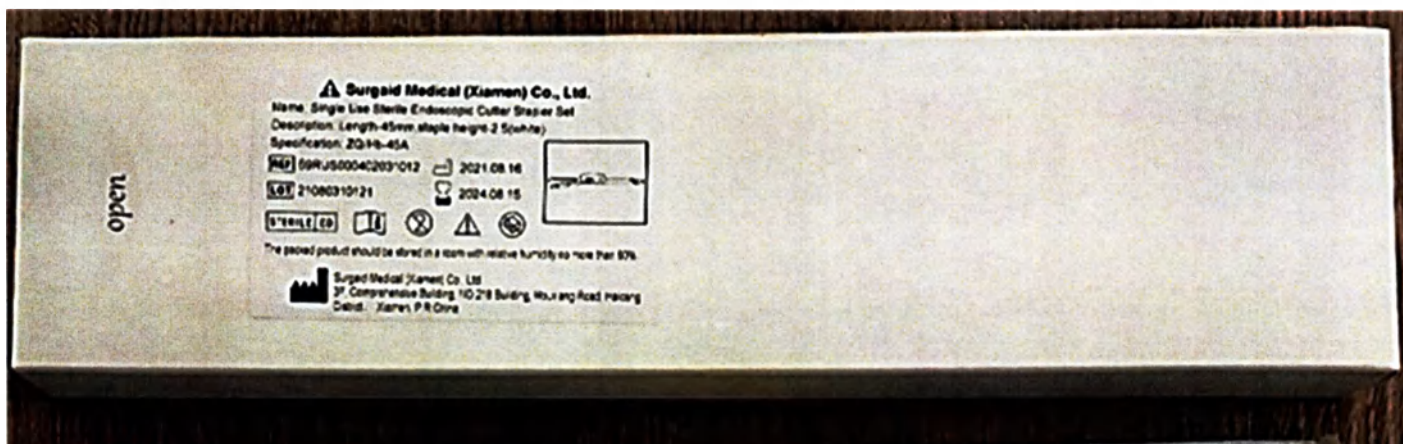


- Картридж для степлера ротационный, прямой: ZQIUb-75V – не более 6 шт. (при необходимости);



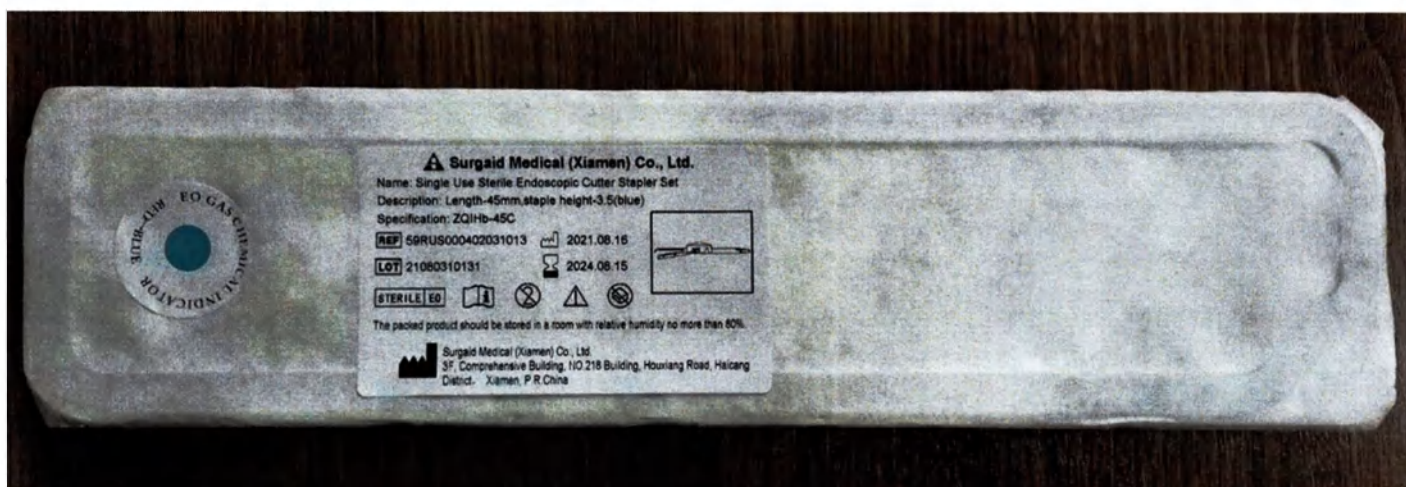
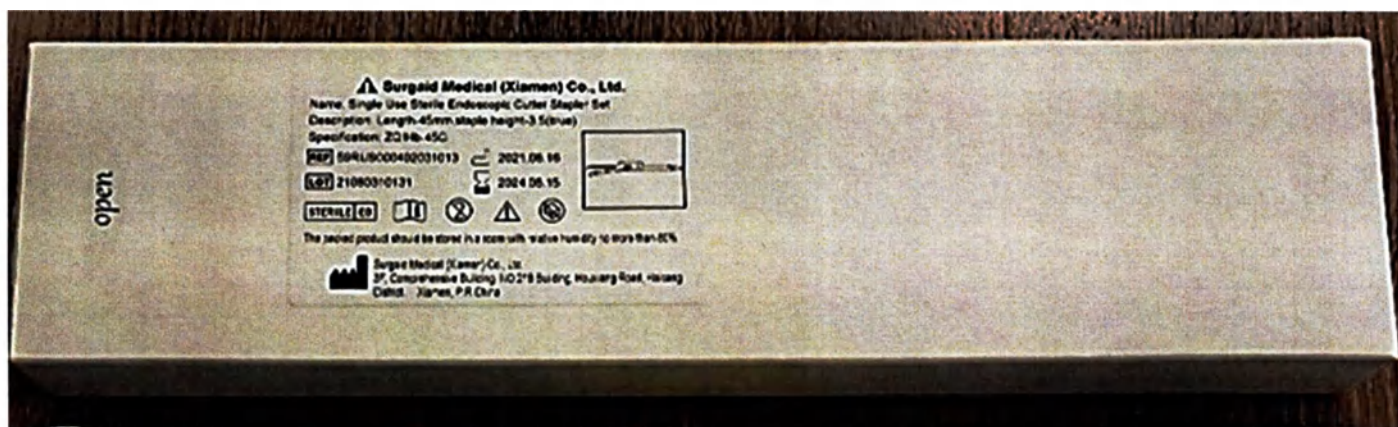


- Картридж для степлера ротационный, с загибом: ZQIHb-45A – не более 6 шт. (при необходимости);



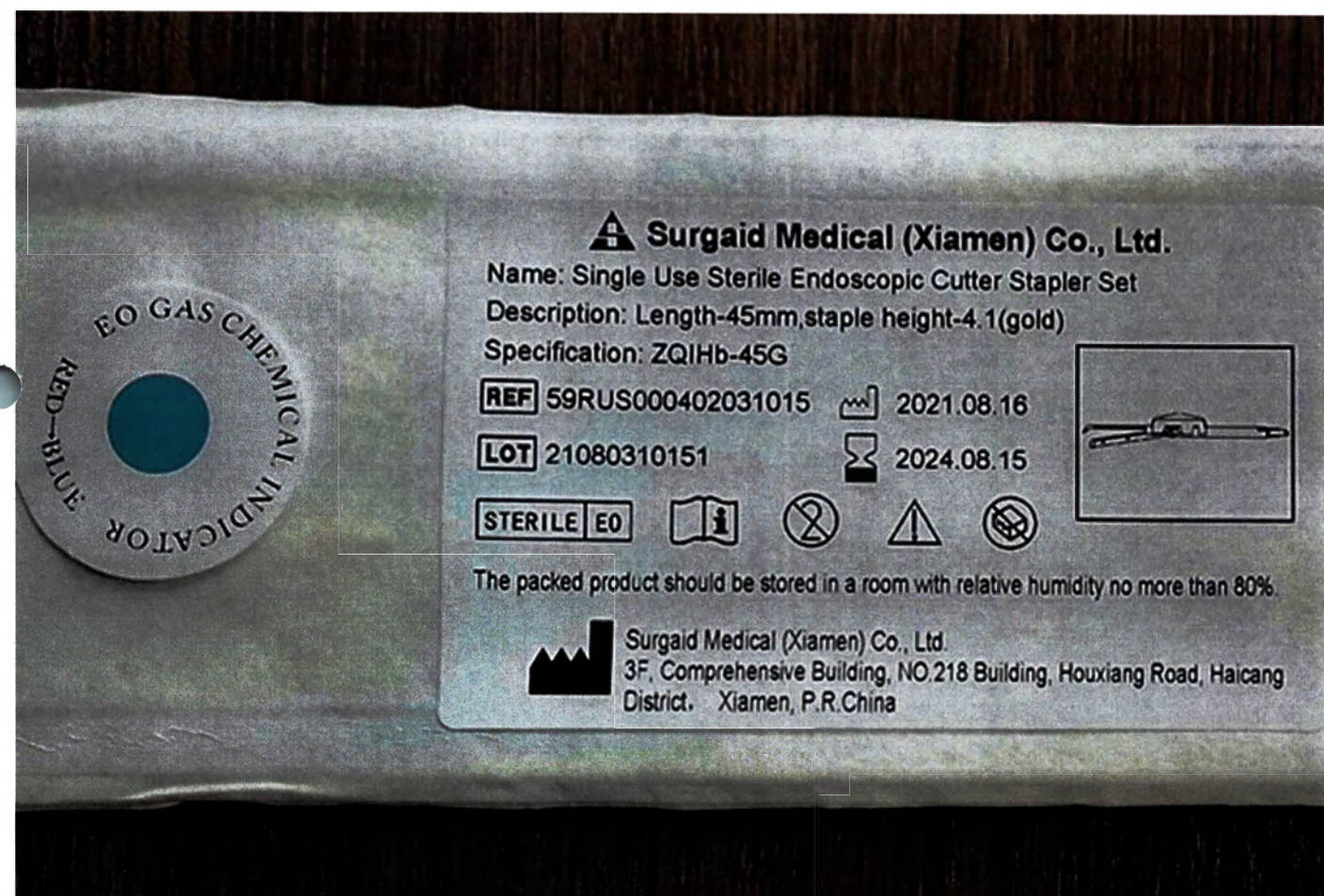
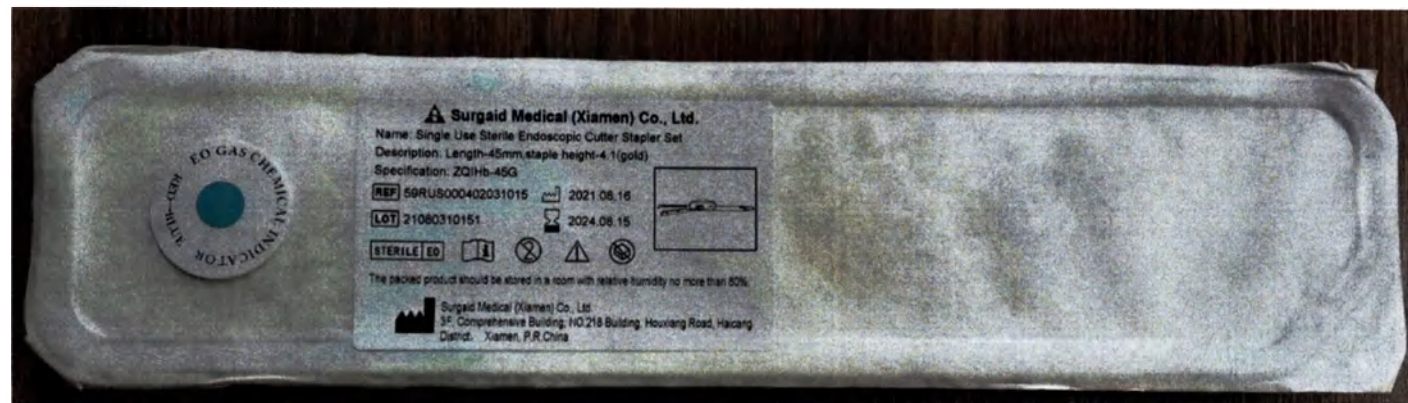
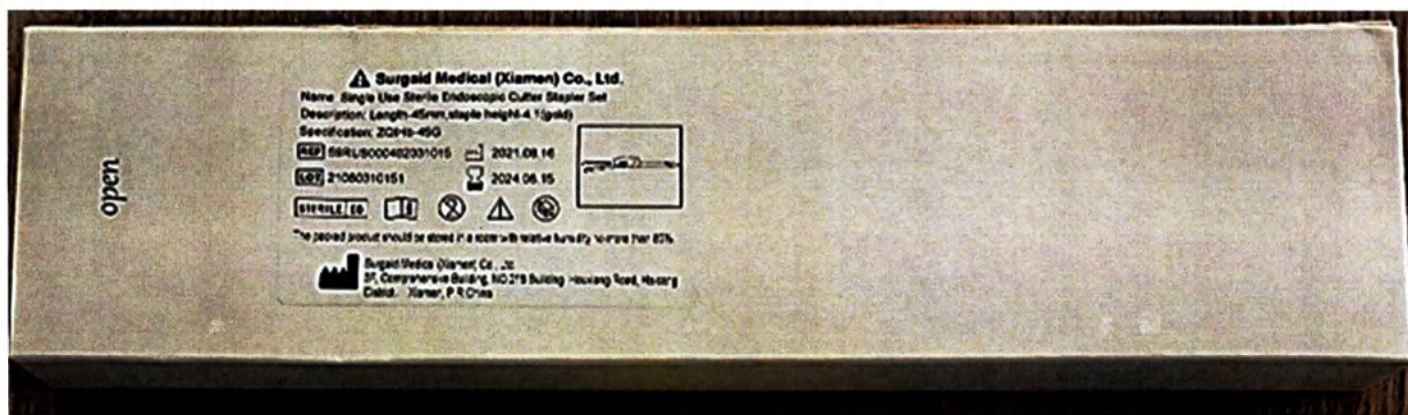


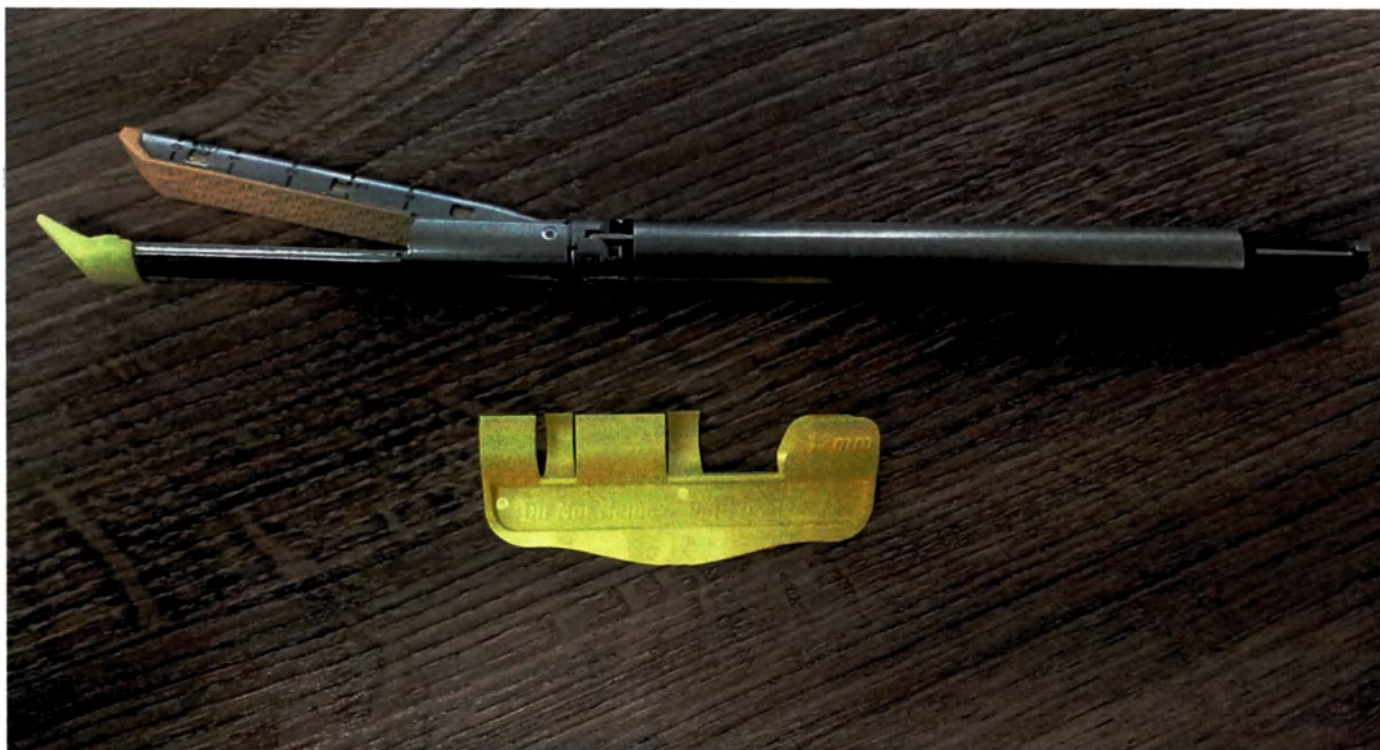
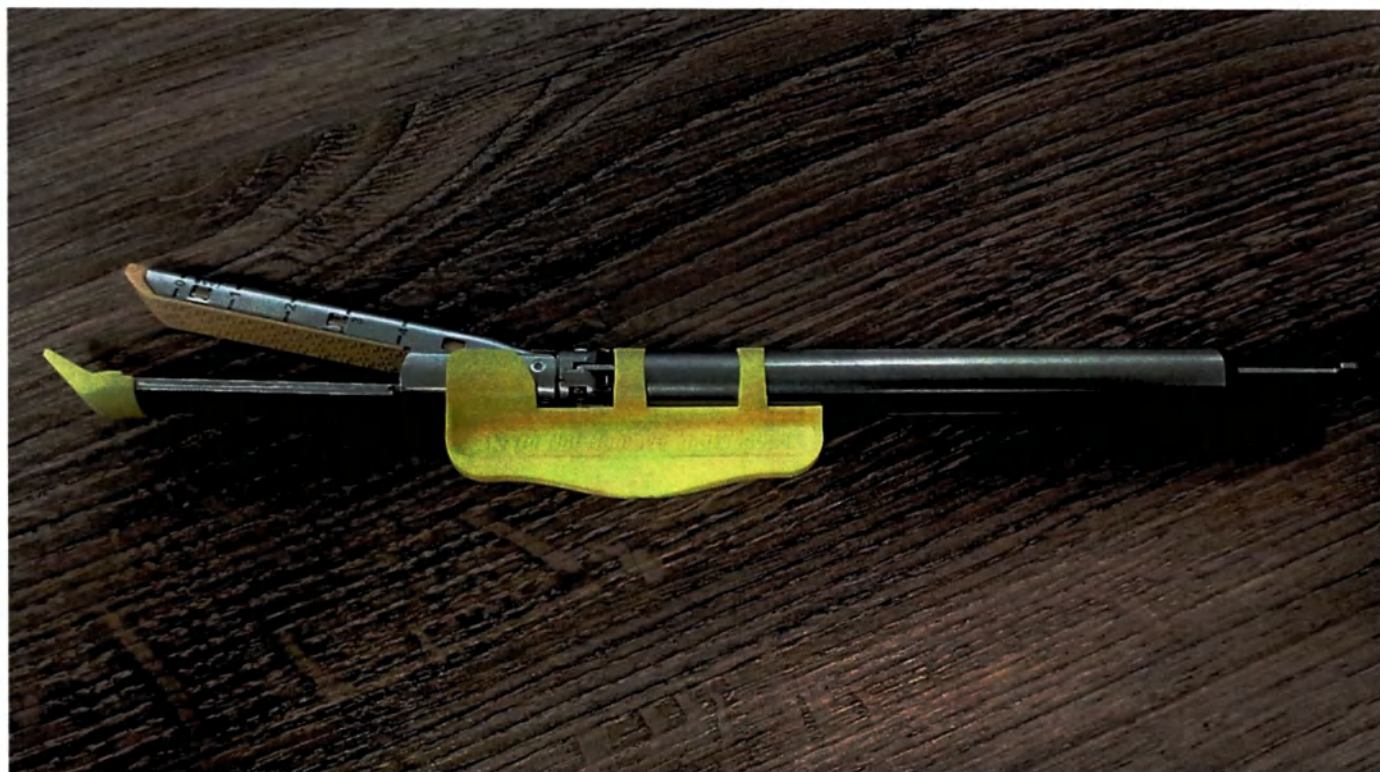
- Картридж для степлера ротационный, с загибом: ZQIHb-45C – не более 6 шт. (при необходимости);



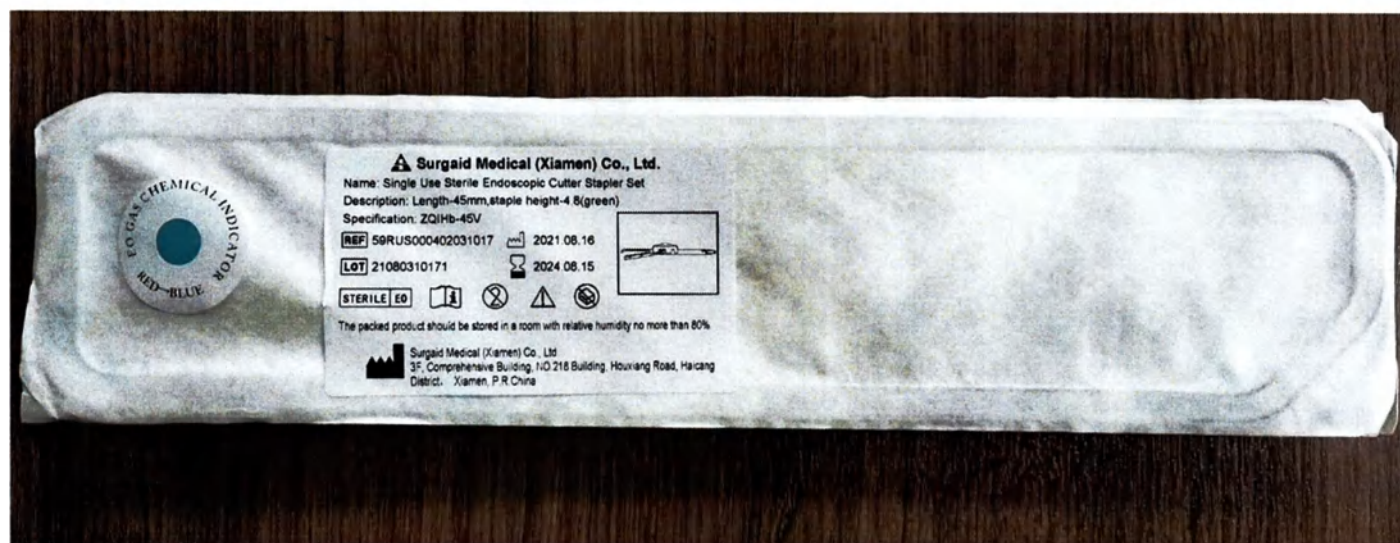
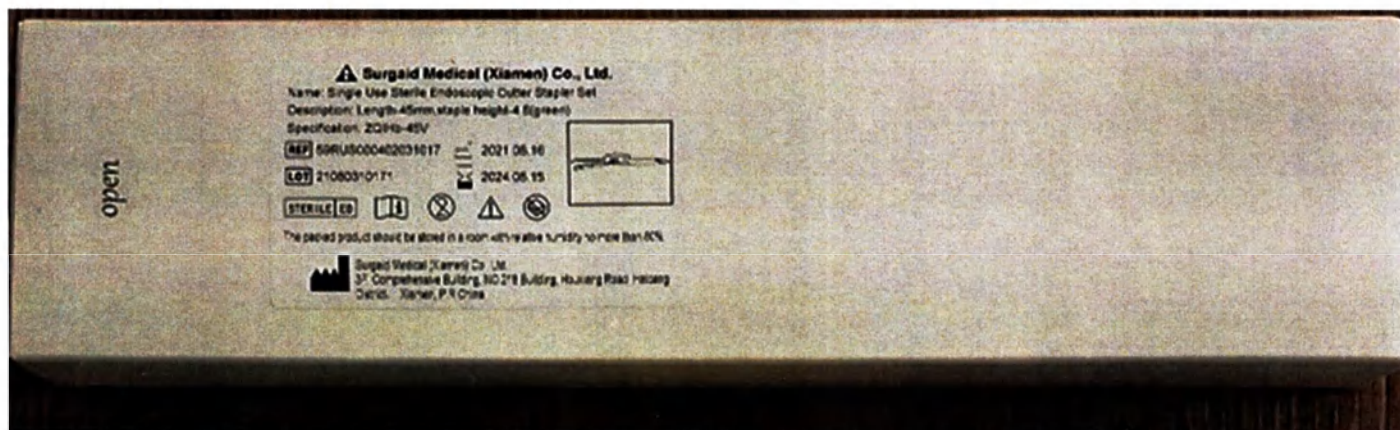


- Картридж для степлера ротационный, с загибом: ZQIHb-45G – не более 6 шт. (при необходимости);



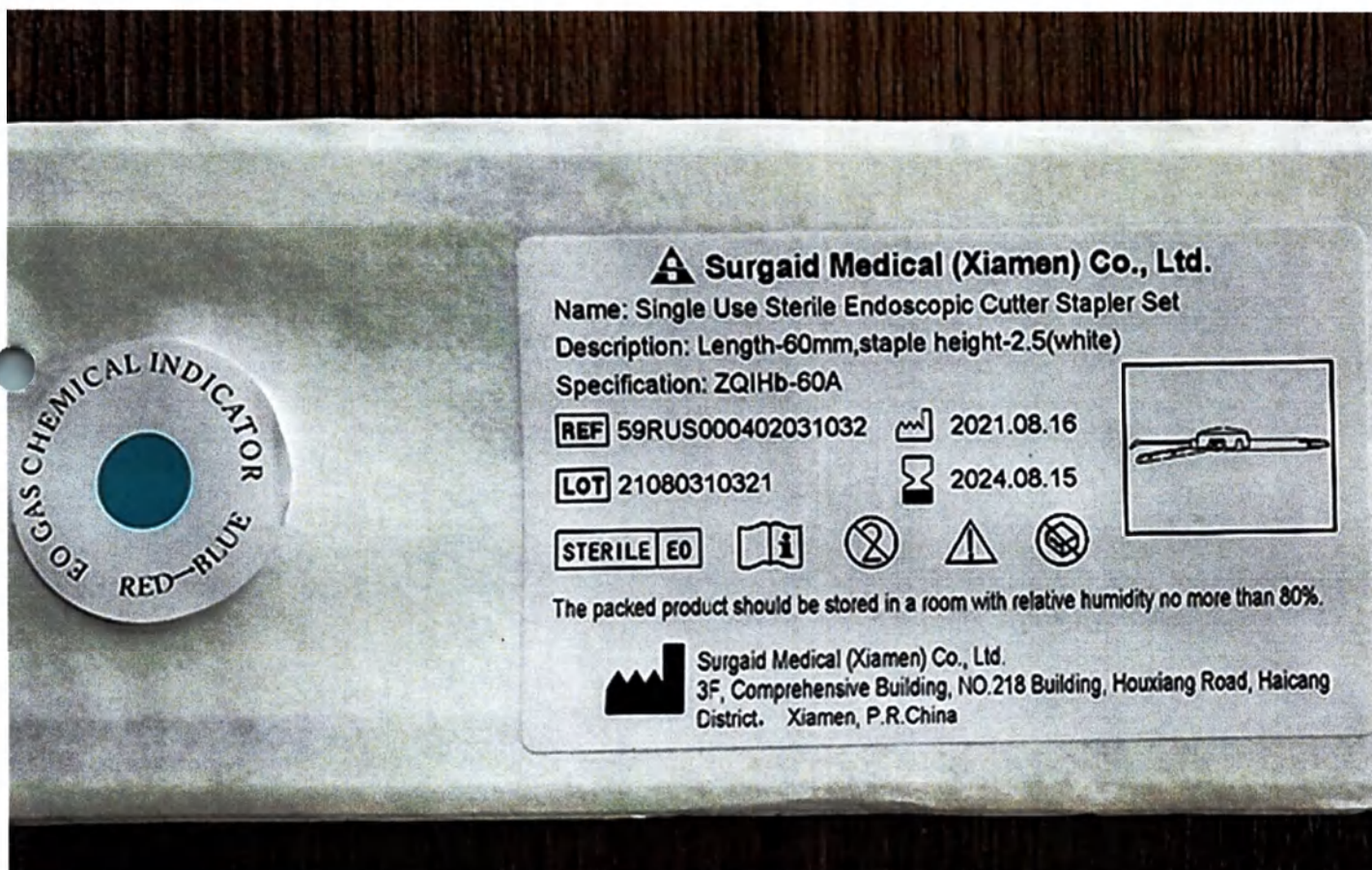
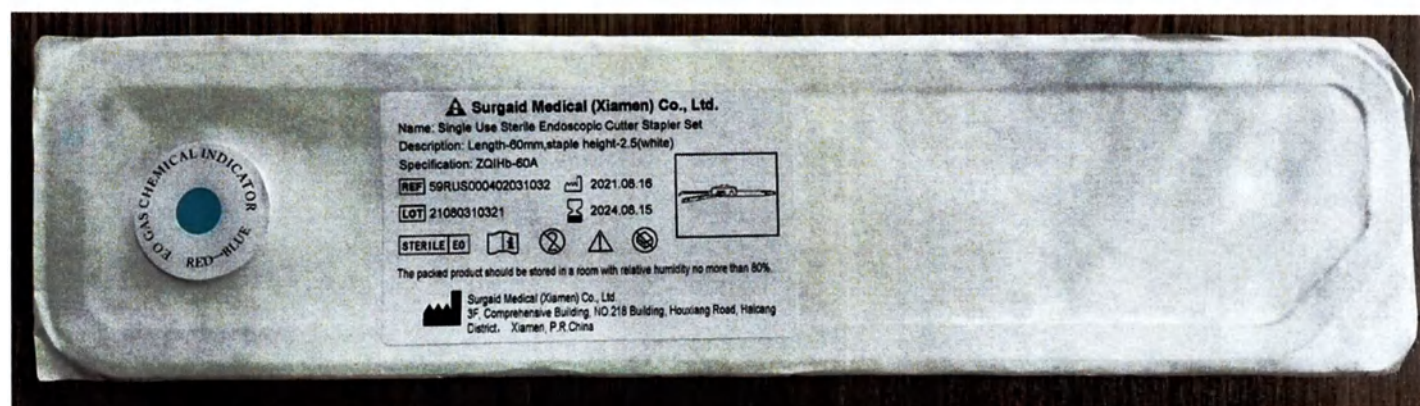
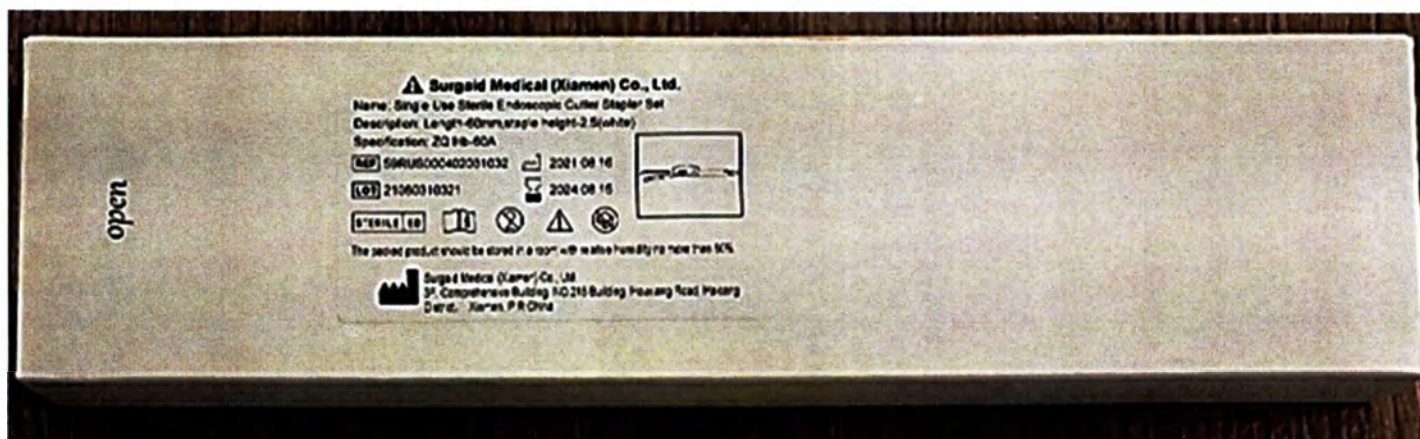


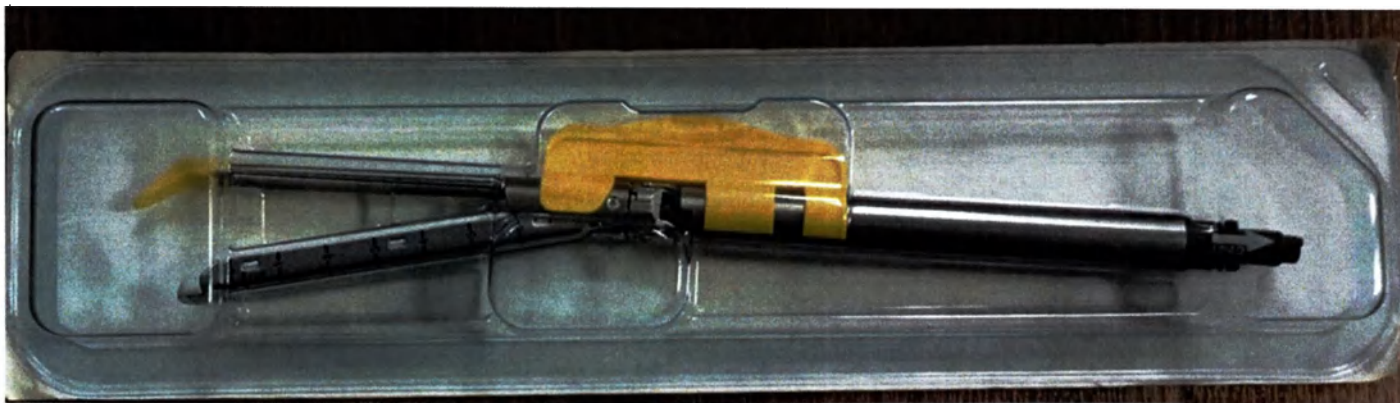
- Картридж для степлера ротационный, с загибом: ZQIHb-45V – не более 6 шт. (при необходимости);



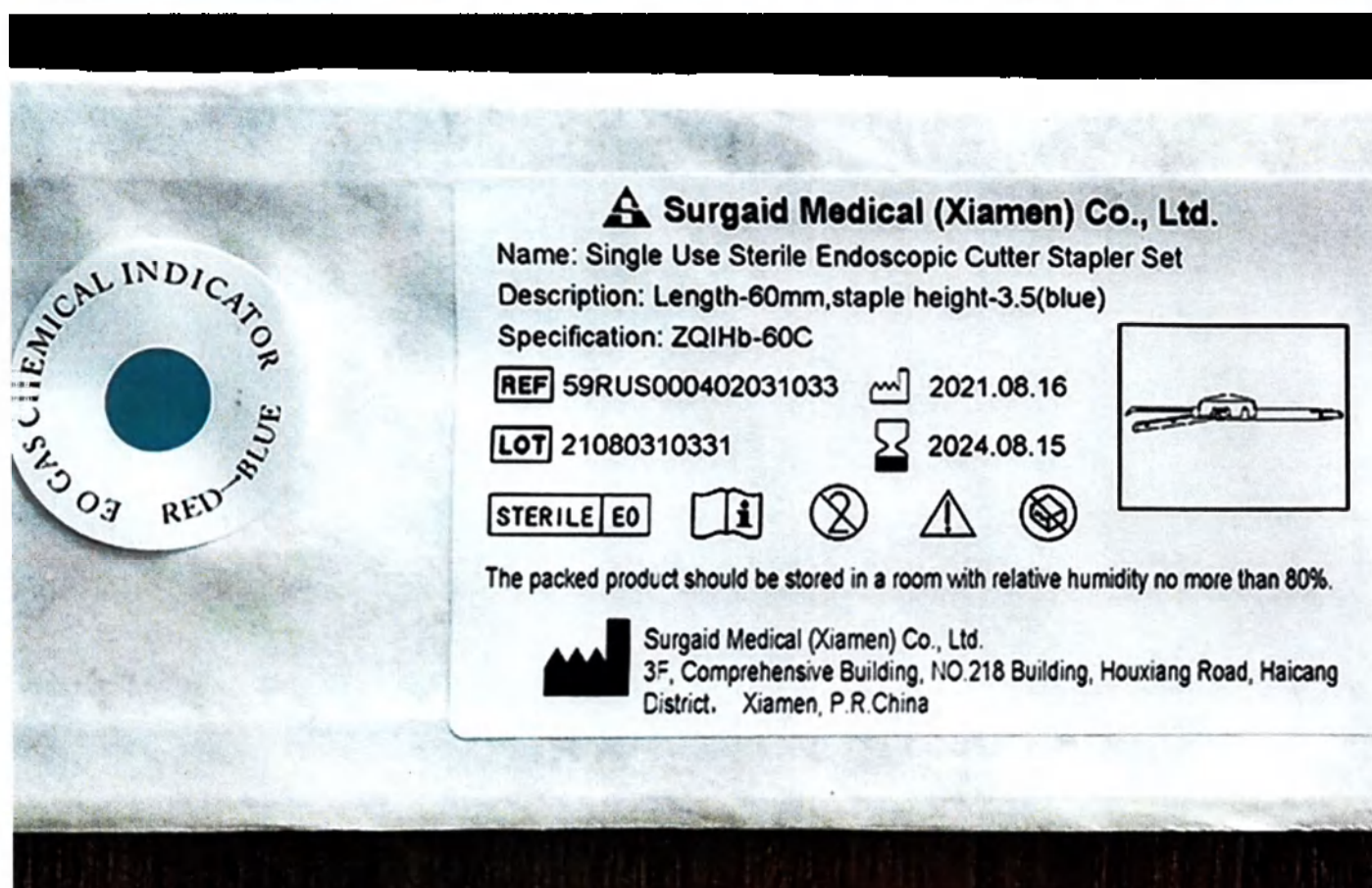
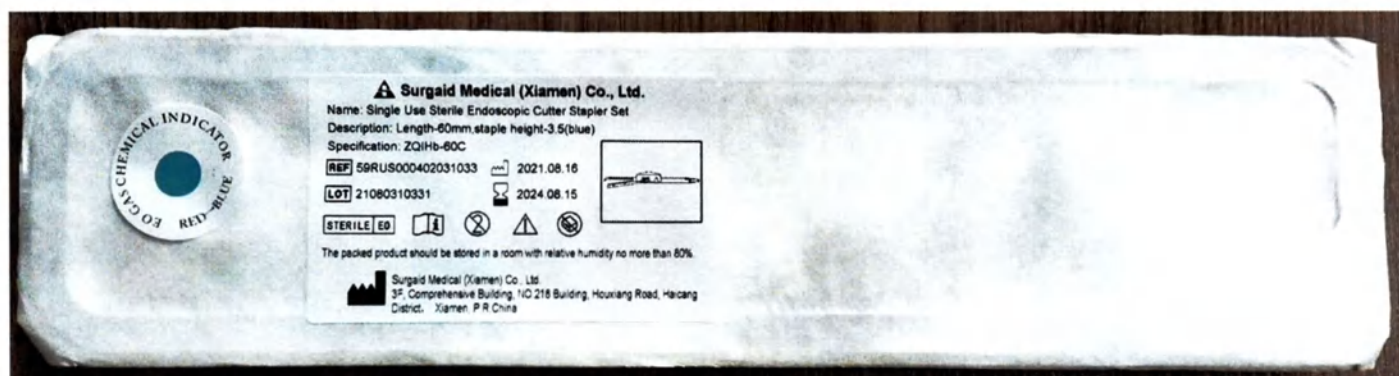
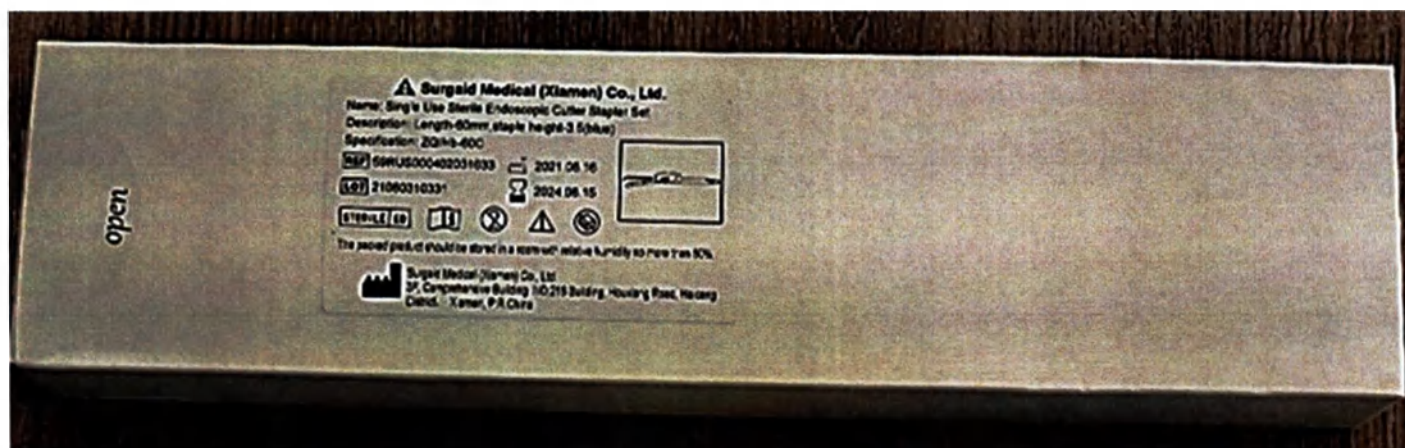


- Картридж для степлера ротационный, с загибом: ZQIHb-60A – не более 6 шт. (при необходимости);



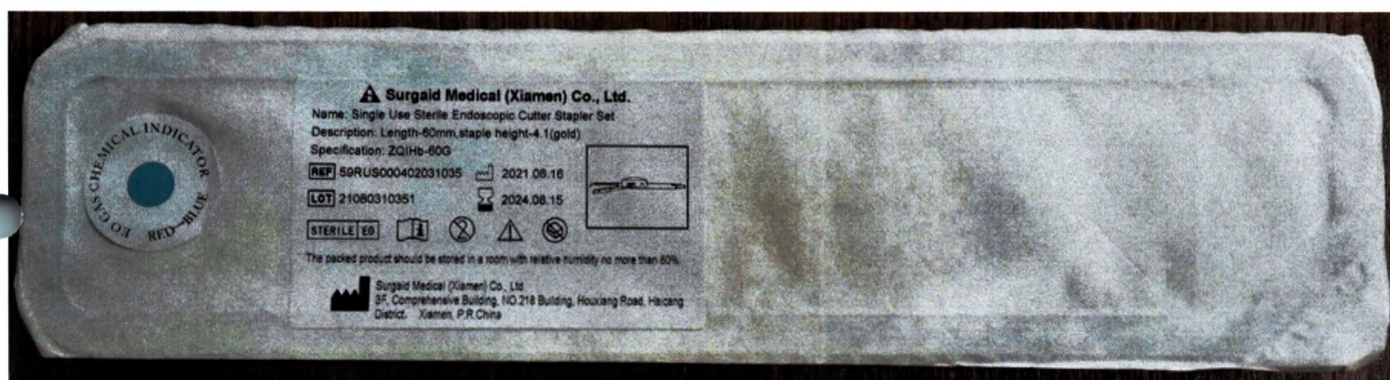
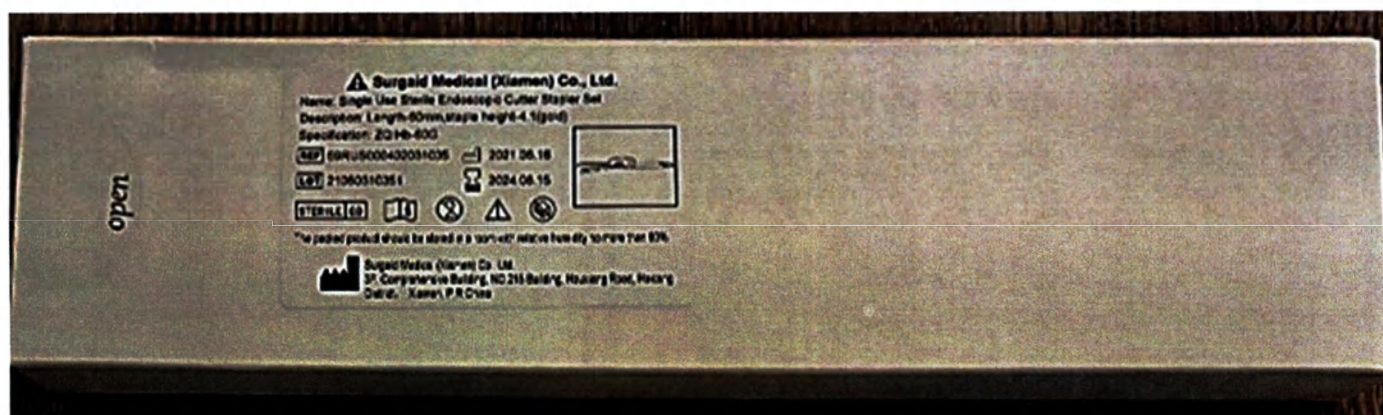


- Картридж для степлера ротационный, с загибом: ZQIHb-60C– не более 6 шт. (при необходимости);



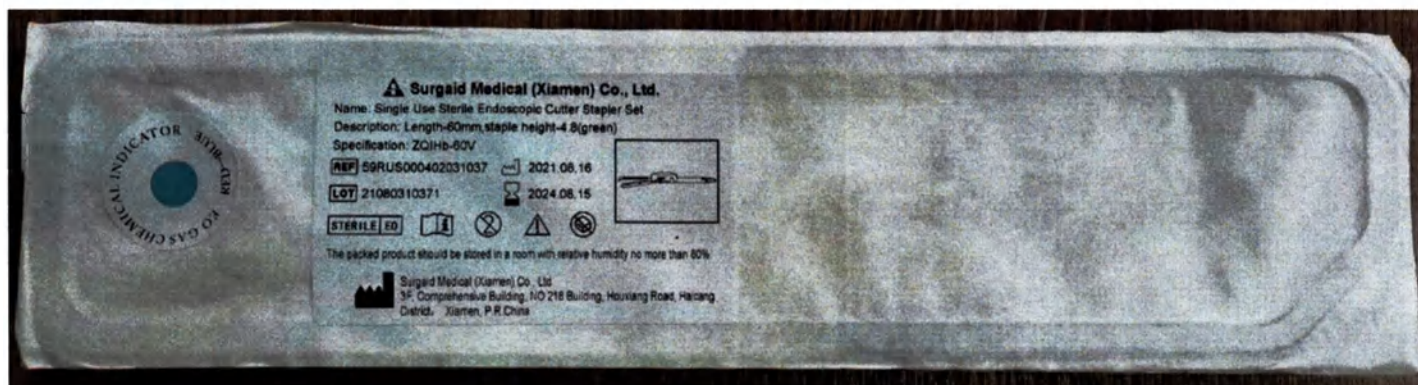
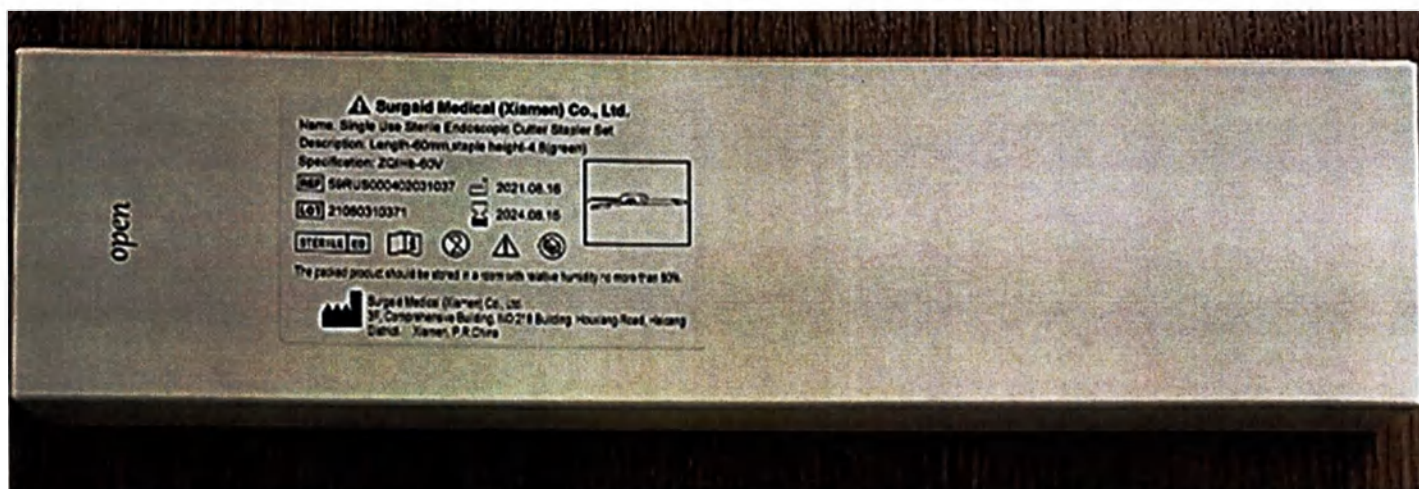


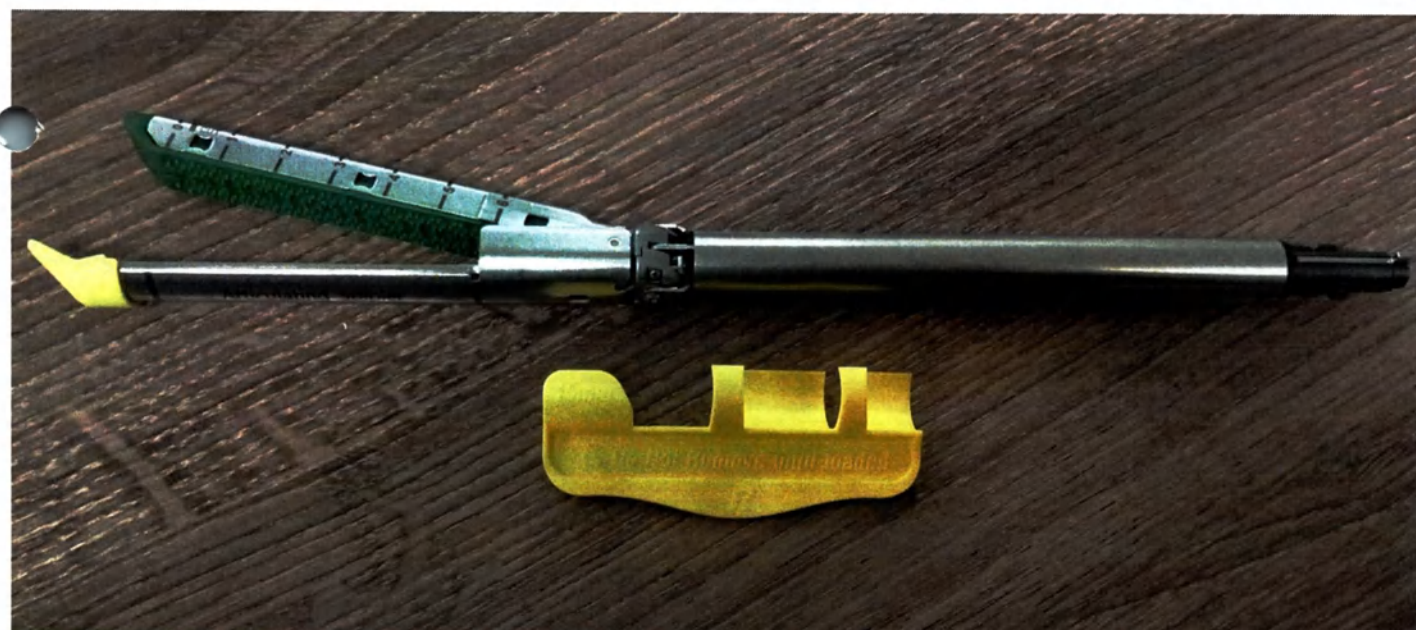
- Картридж для степлера ротационный, с загибом: ZQIHb-60G – не более 6 шт. (при необходимости);



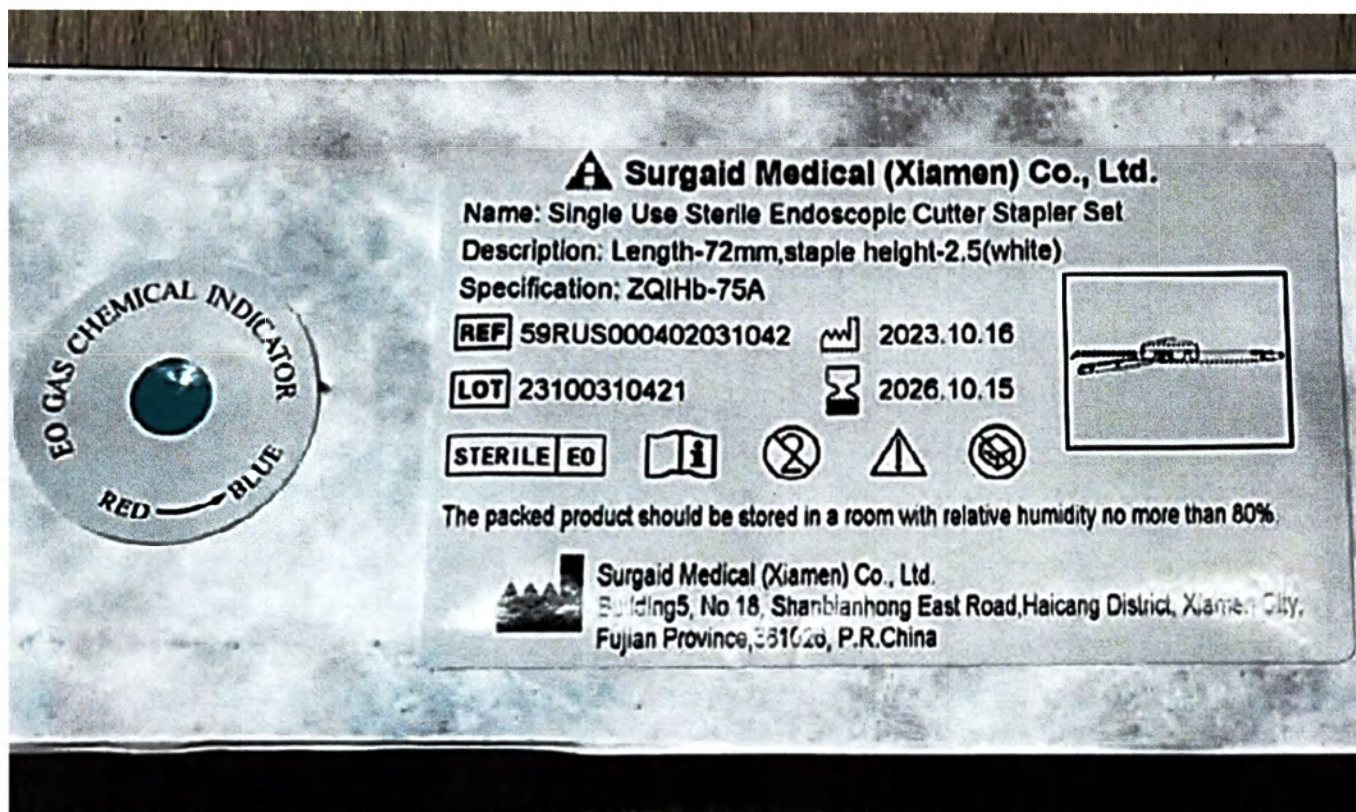
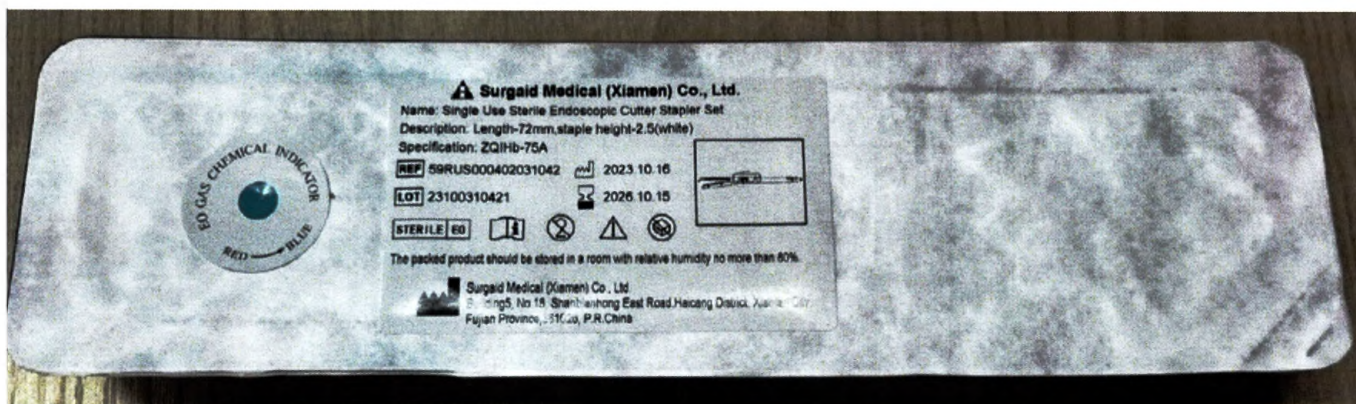
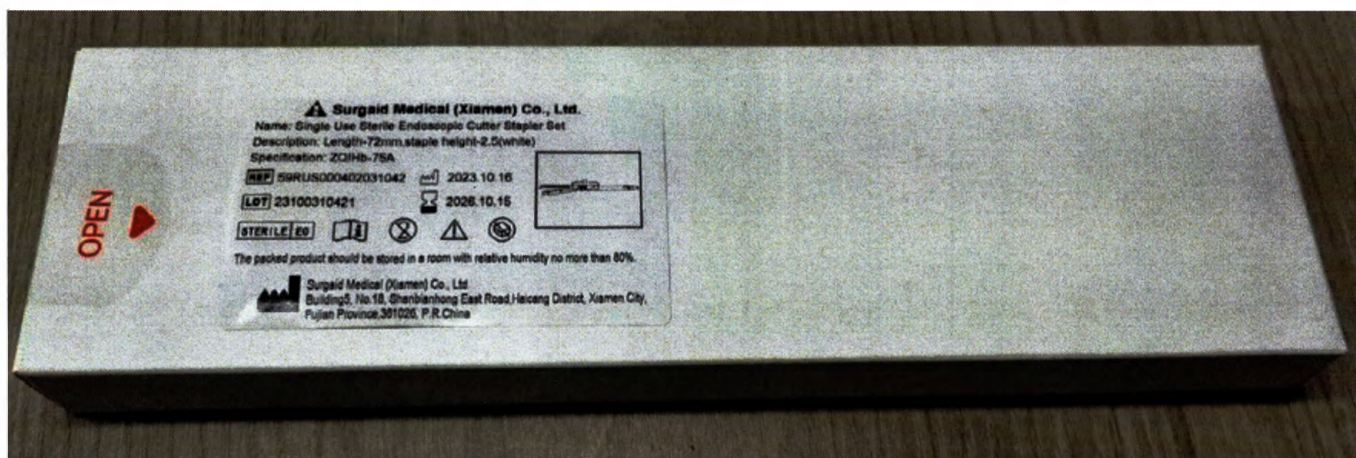


- Картридж для степлера ротационный, с загибом: ZQIHb-60V– не более 6 шт. (при необходимости);



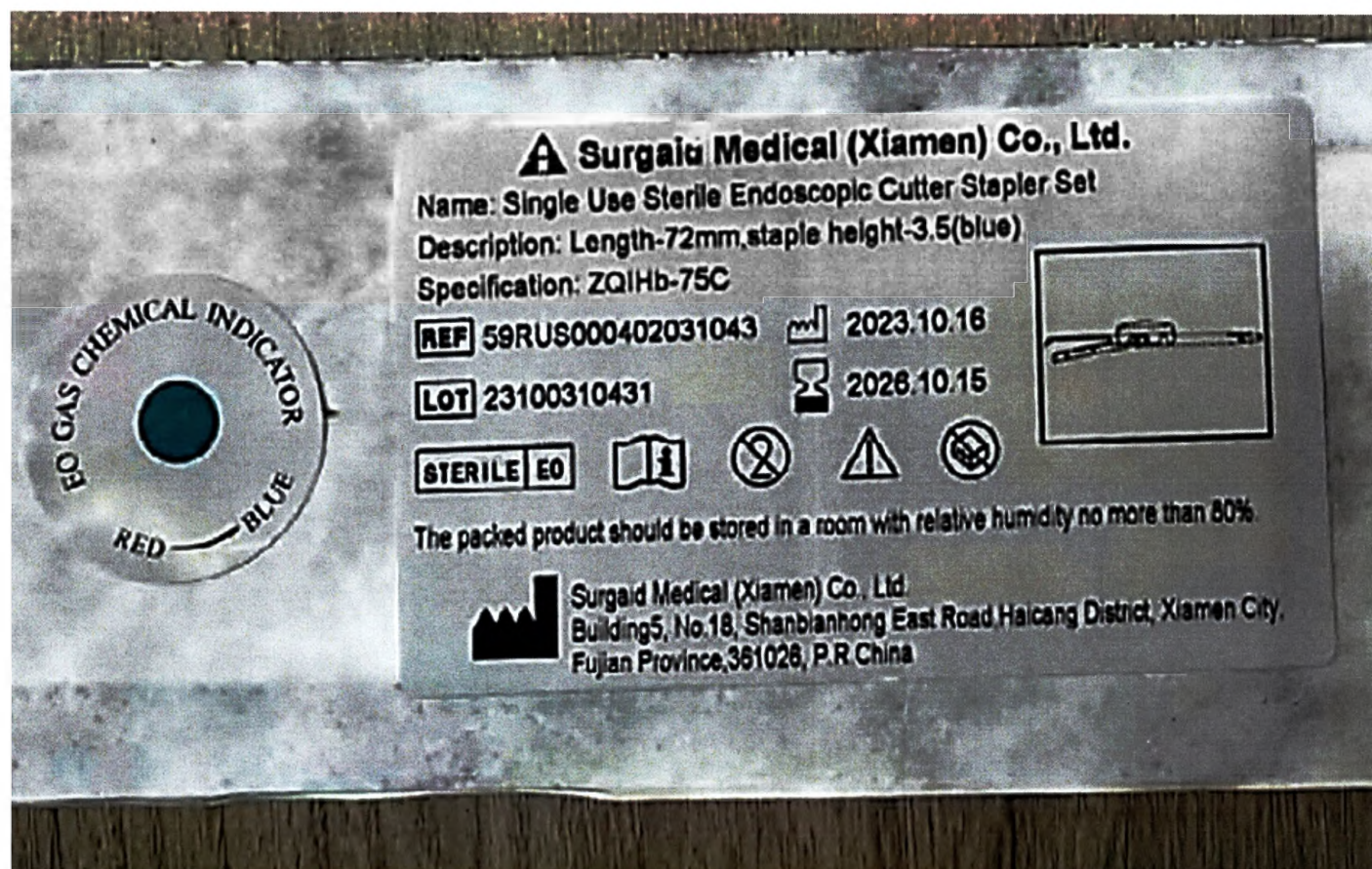
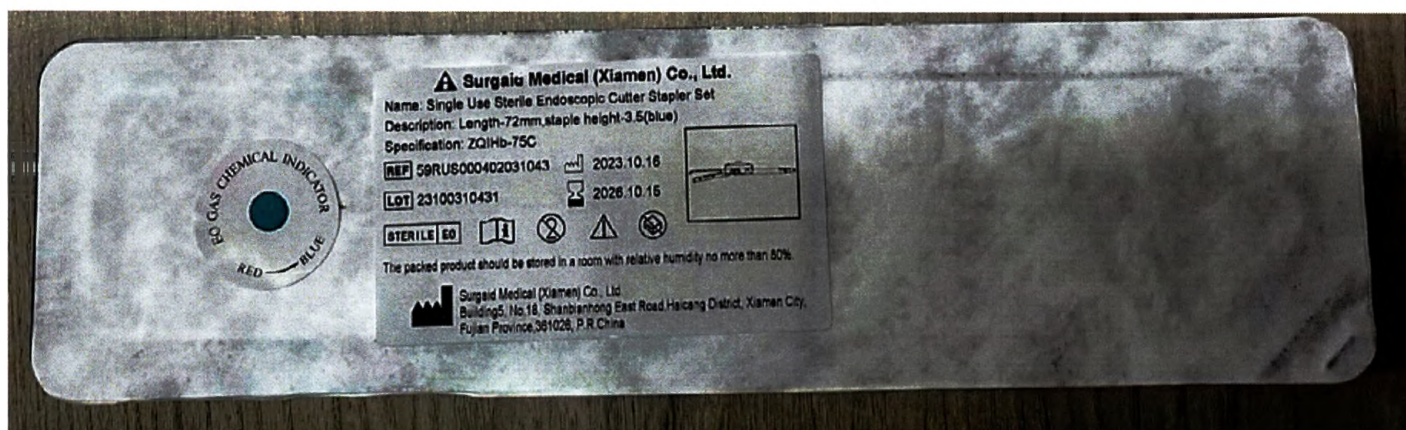
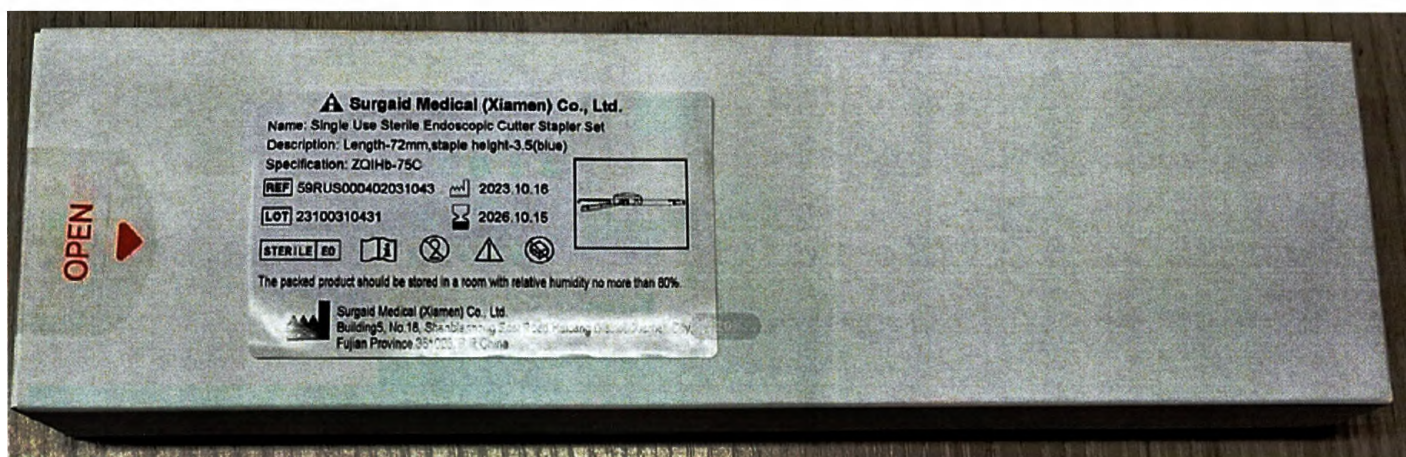


- Картридж для степлера ротационный, с загибом: ZQIHb-75A – не более 6 шт. (при необходимости);



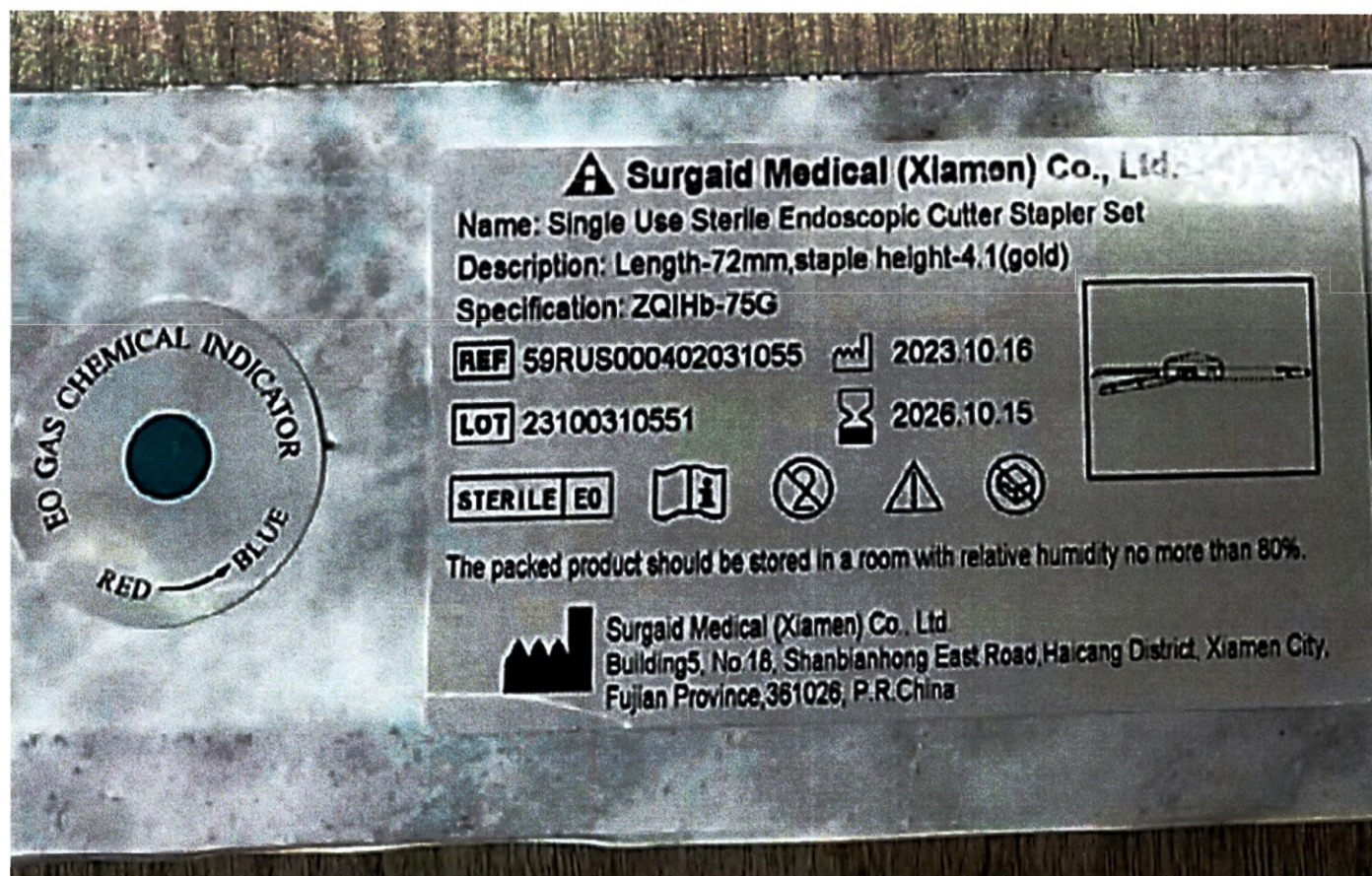
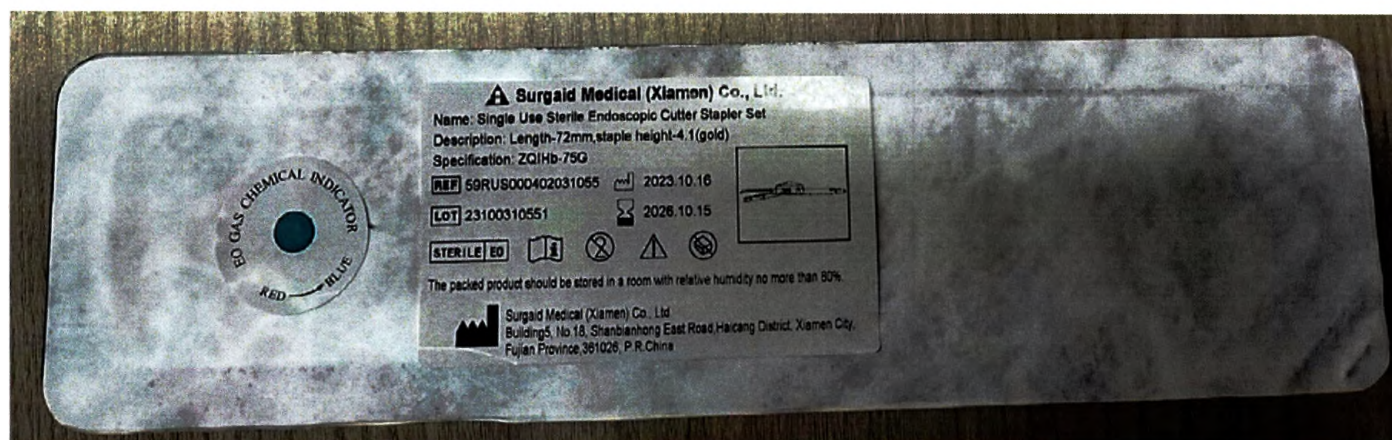
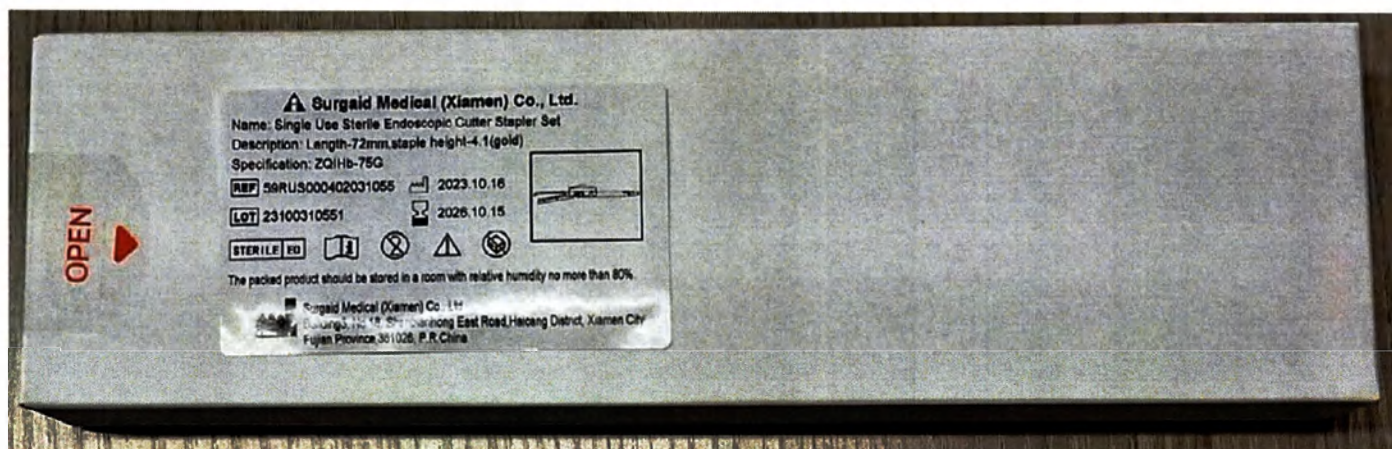


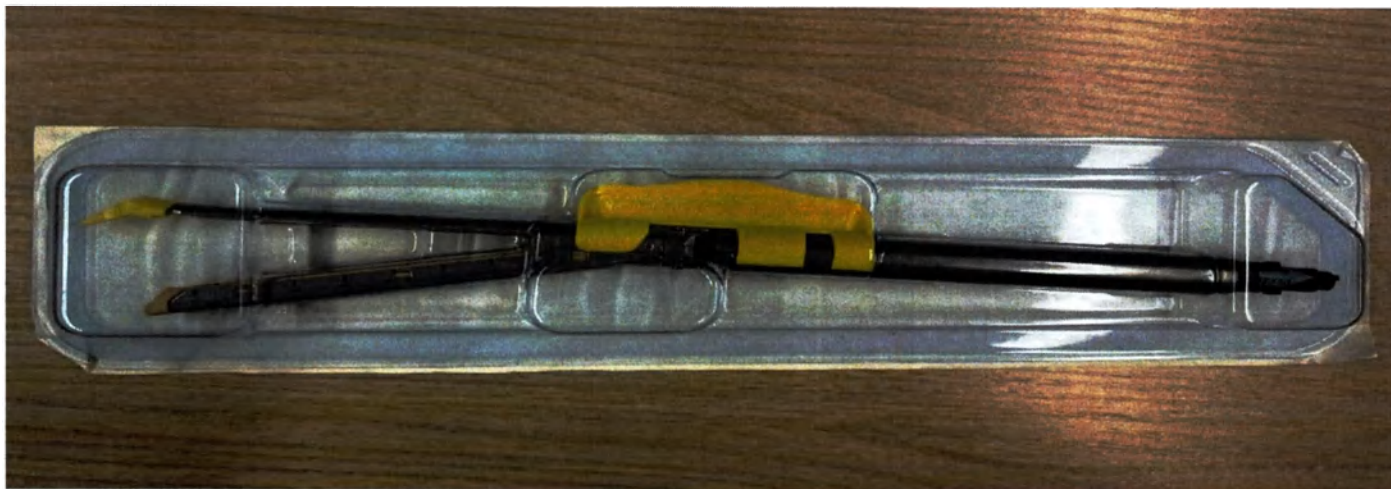
- Картридж для степлера ротационный, с загибом: ZQIHb-75C – не более 6 шт. (при необходимости);



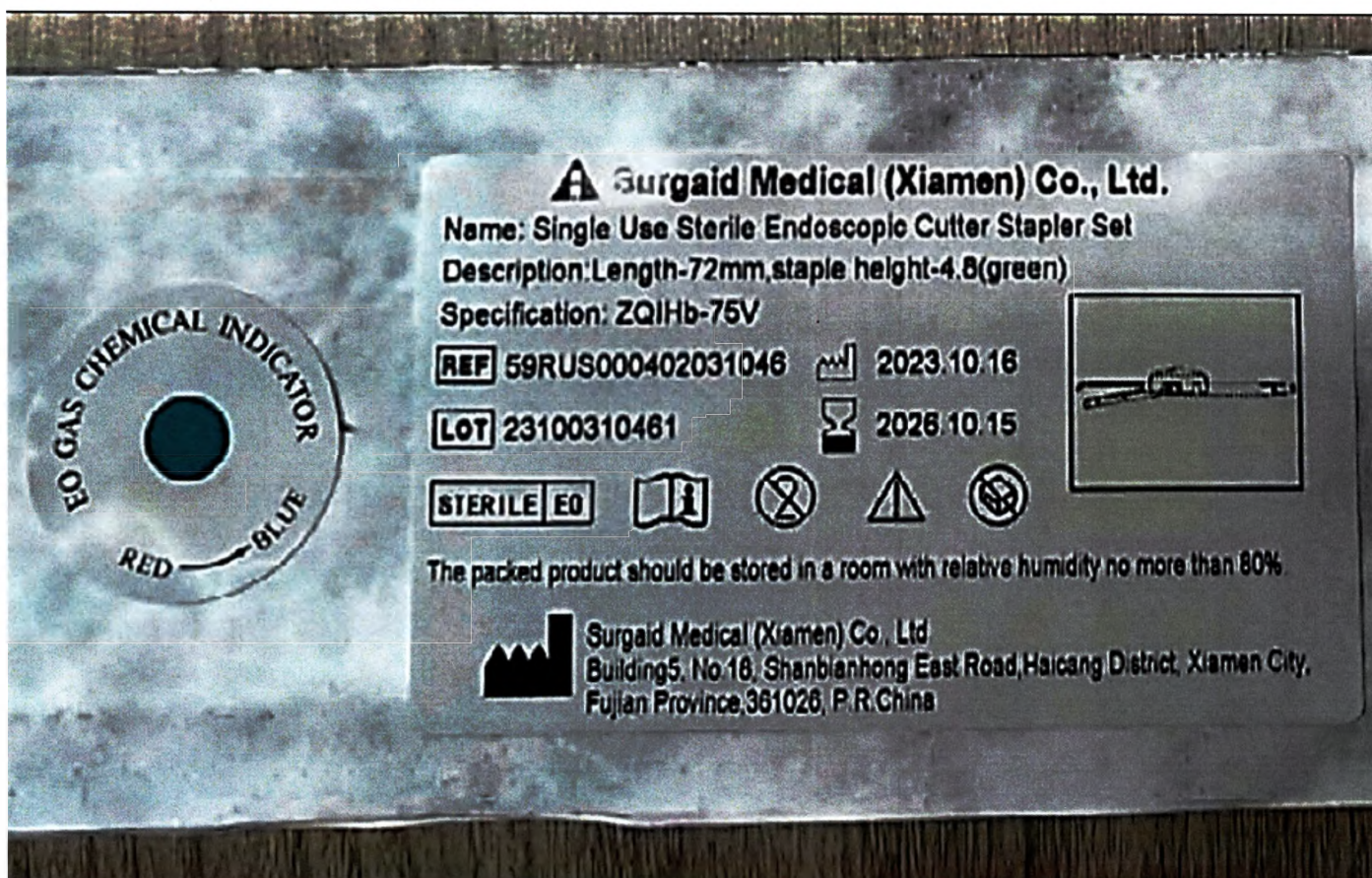
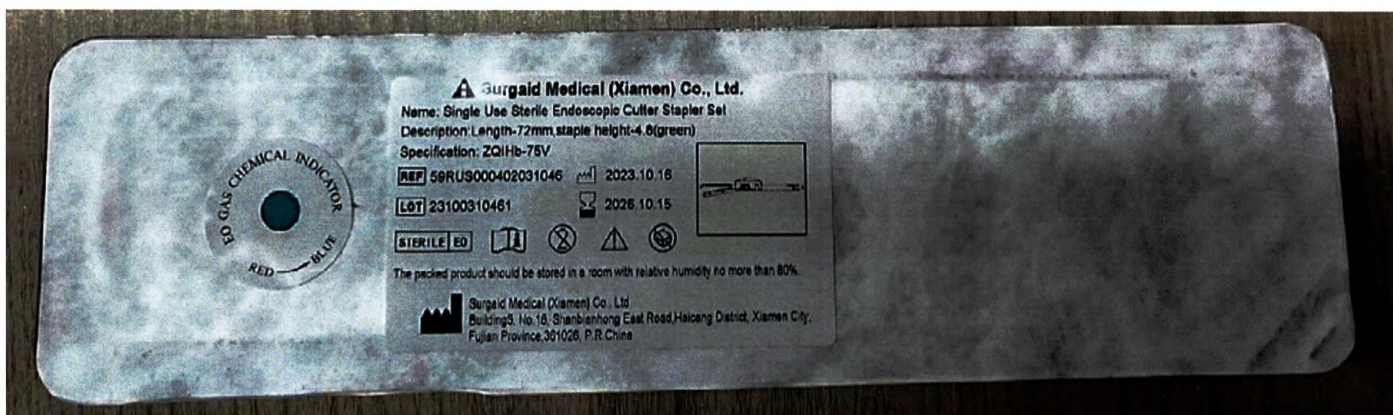
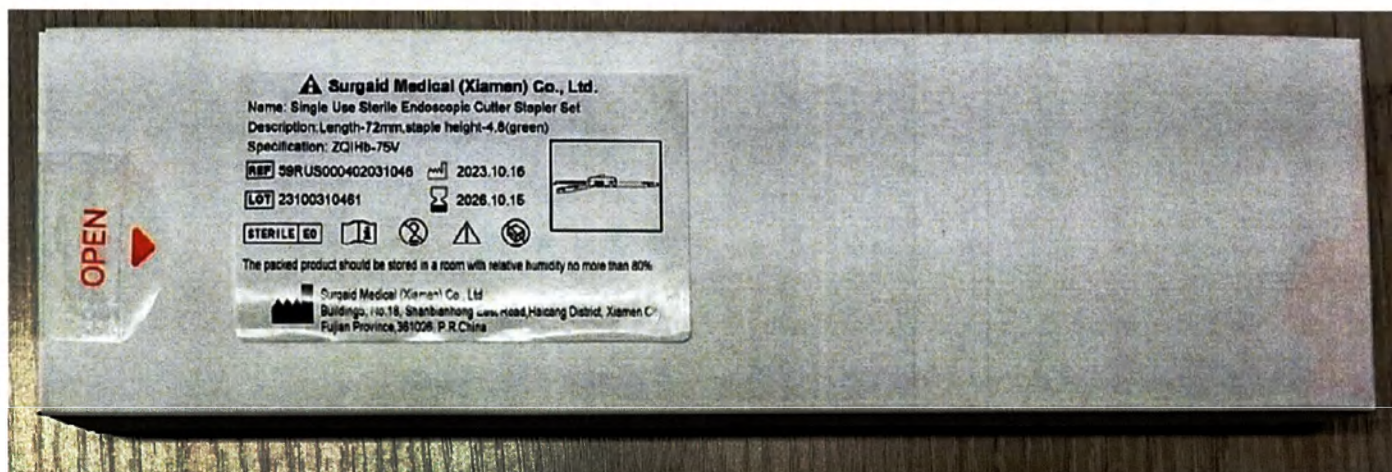


- Картридж для степлера ротационный, с загибом: ZQIHb-75G – не более 6 шт. (при необходимости);



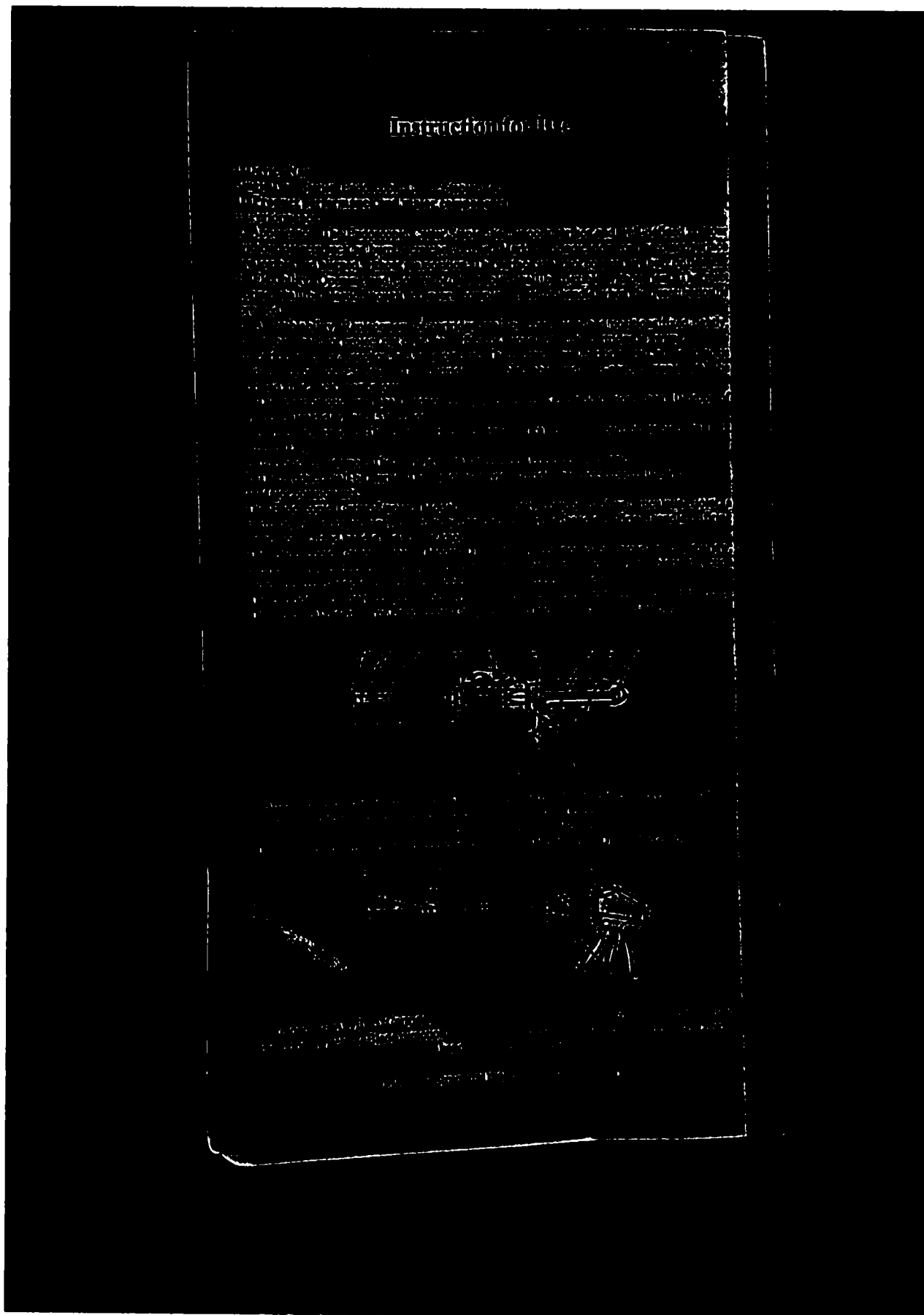


- Картридж для степлера ротационный, с загибом: ZQIHb-75V – не более 6 шт. (при необходимости);



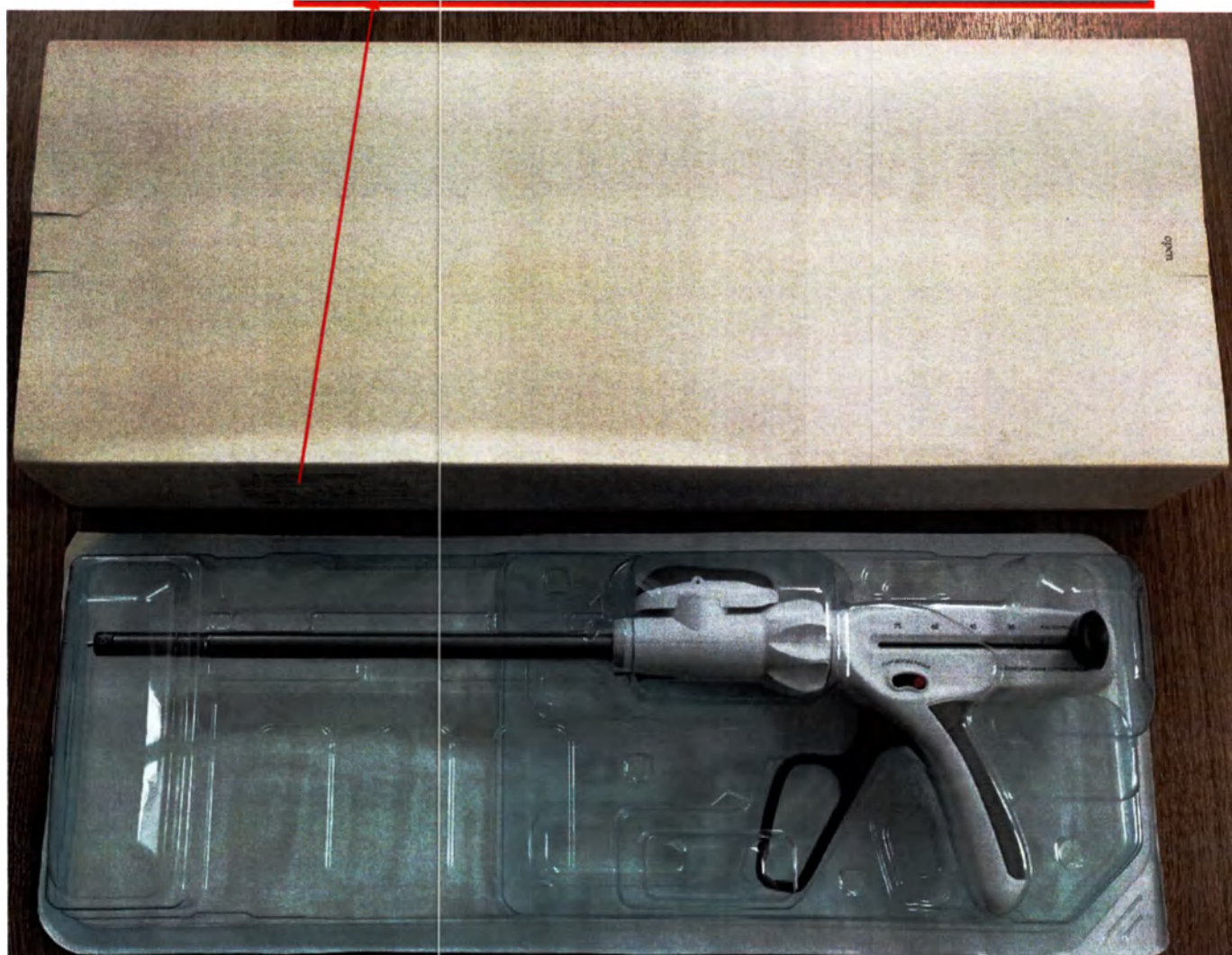
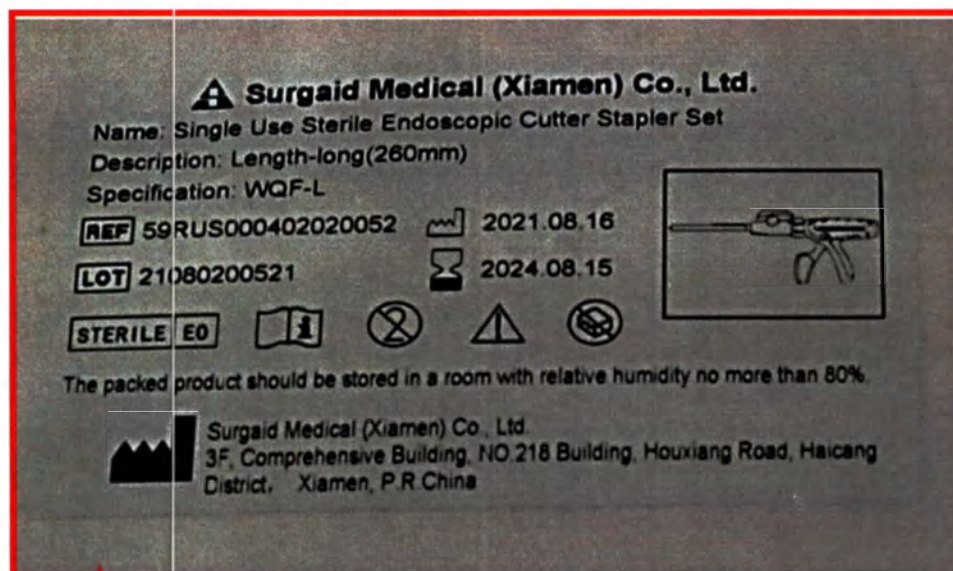


- 3) Инструкция по применению на Степлер хирургический одноразовый эндоскопический с одинарной рукояткой, Степлер хирургический одноразовый эндоскопический с двойной рукояткой – 1 шт.



Степлер хирургический одноразовый эндоскопический с одинарной рукояткой: WQF-L, в составе:

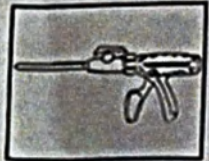
1) Степлер хирургический одноразовый эндоскопический с одинарной рукояткой: WQF-L – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Endoscopic Cutter Stapler Set
Description: Length-long(260mm)
Specification: WQF-L
REF 59RUS000402020052 2021.08.16
LOT 21080200521 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

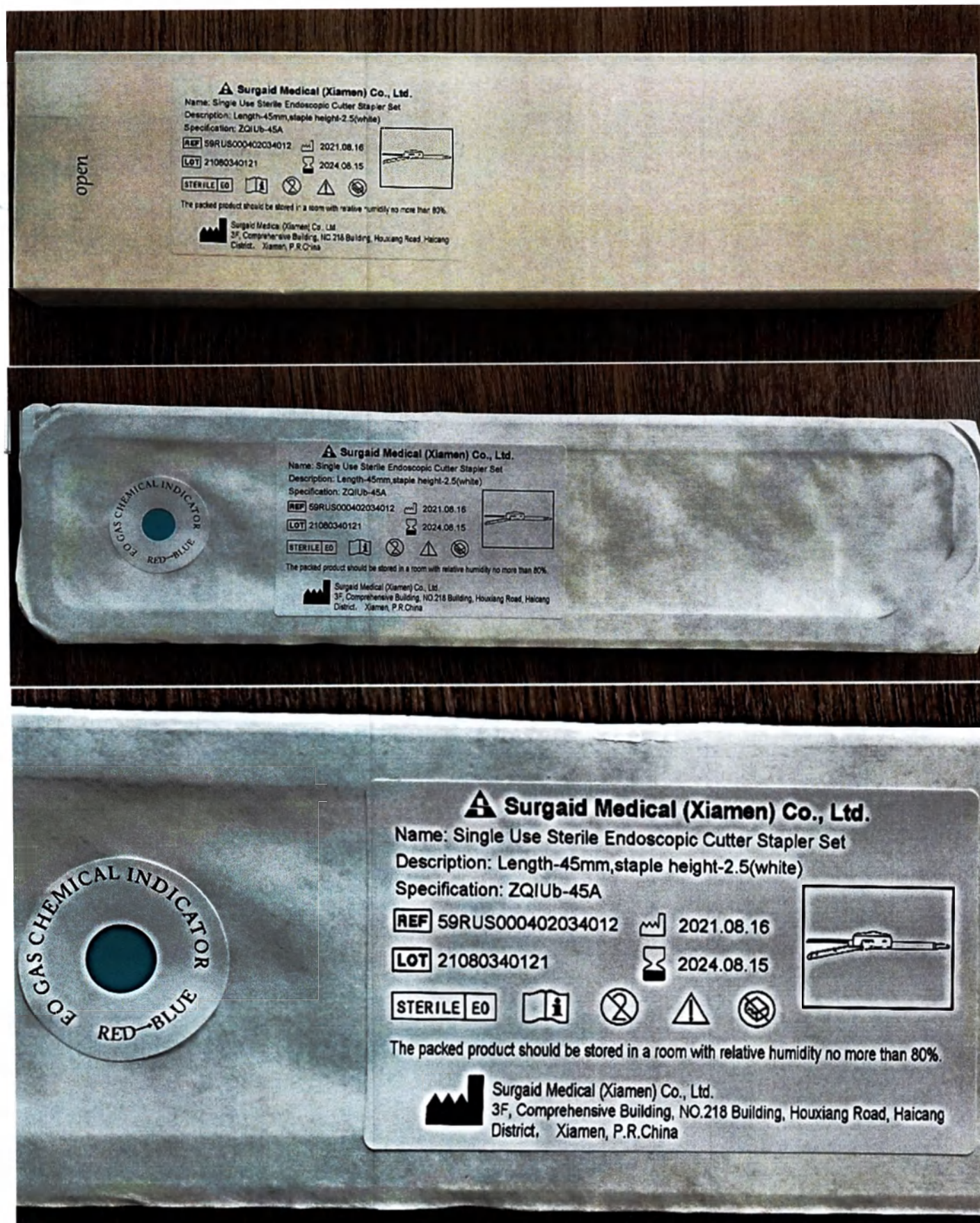
Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Endoscopic Cutter Stapler Set
Description: Length-long(260mm)
Specification: WQF-L
REF 59RUS000402020052 2021.08.16
LOT 21080200521 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

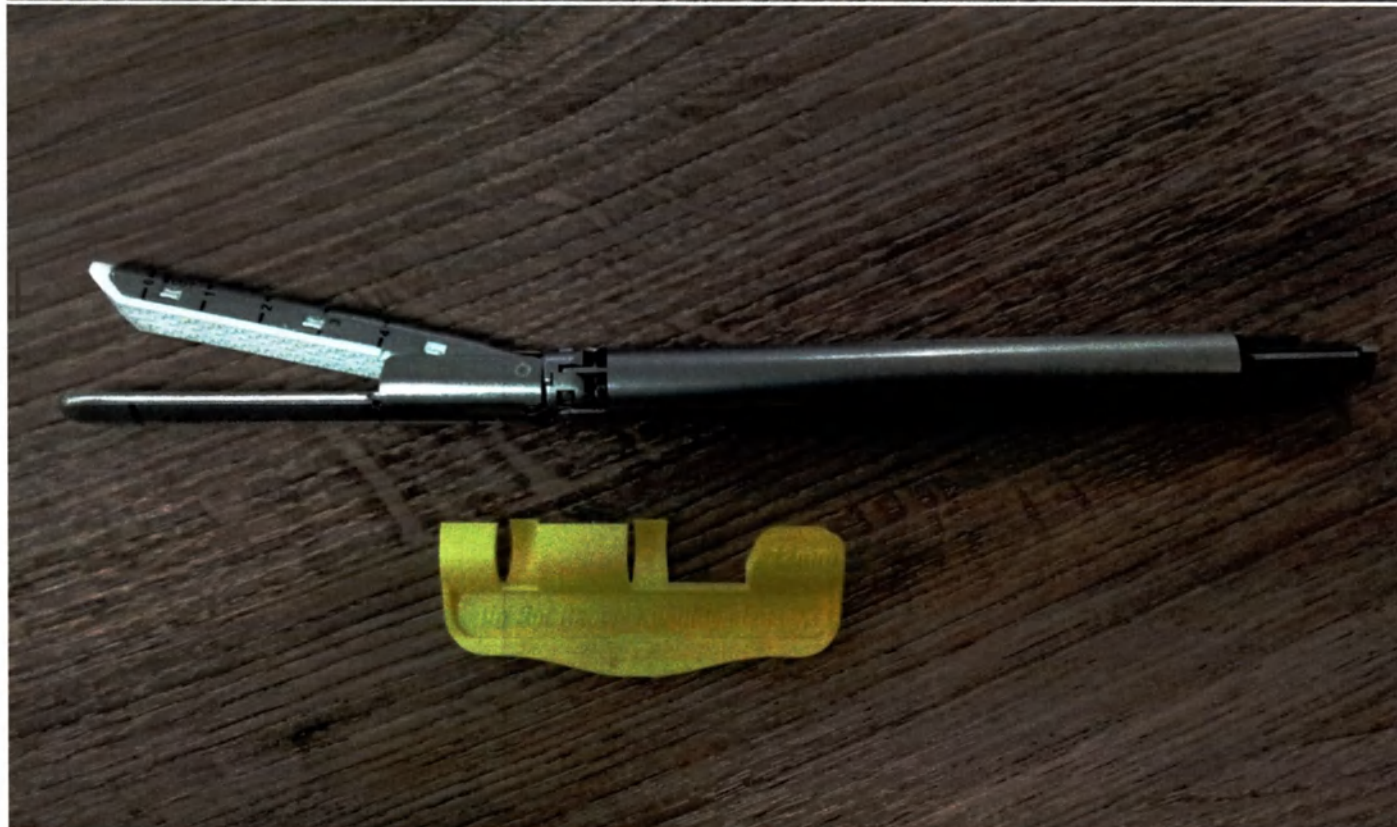
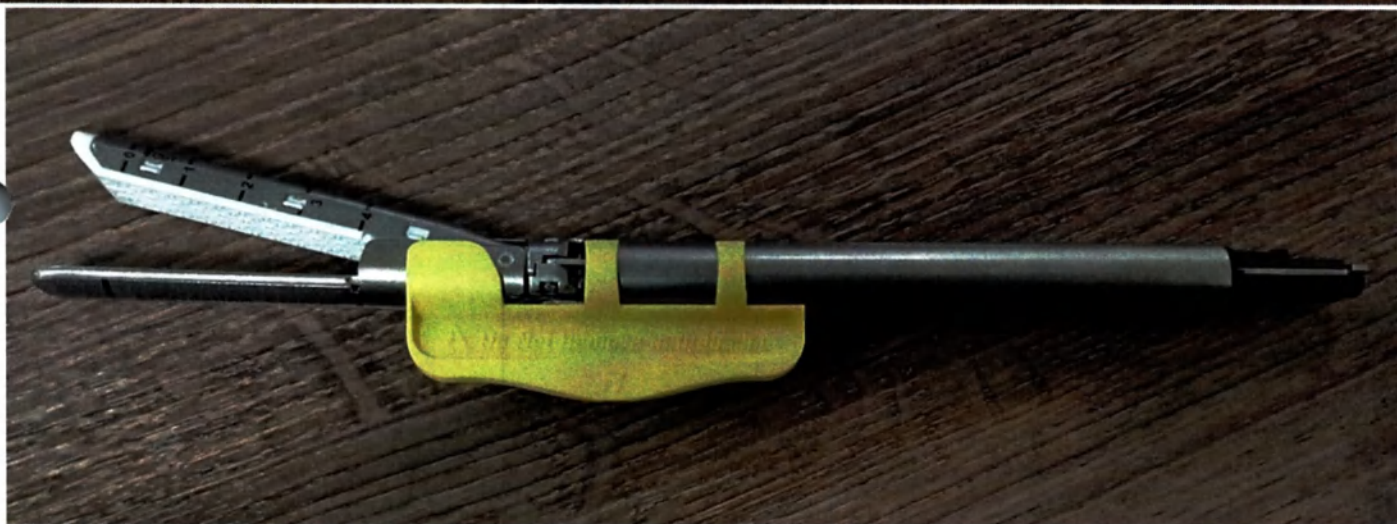




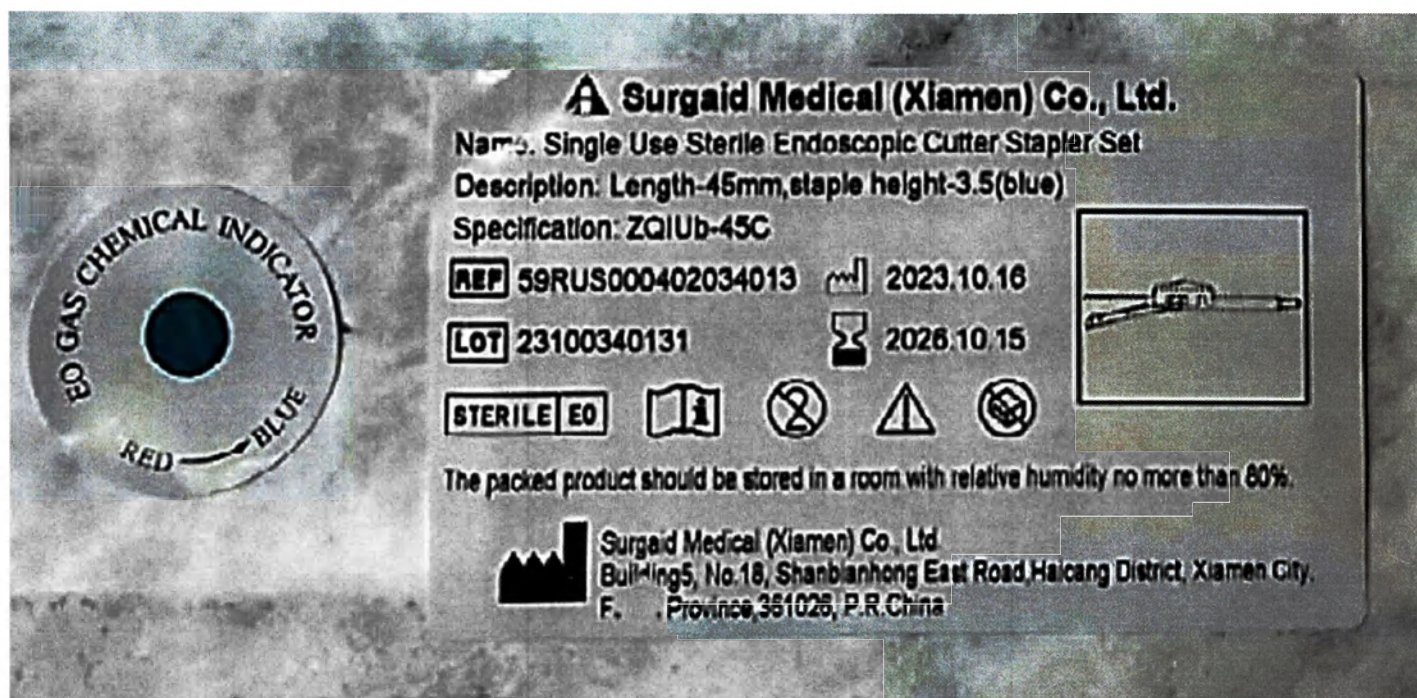
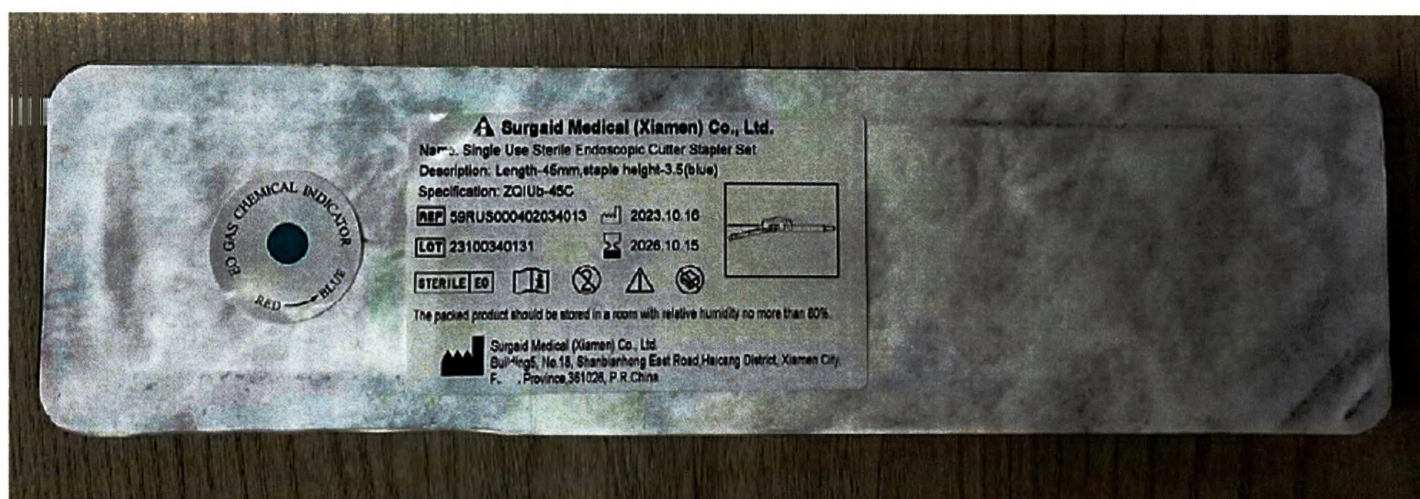
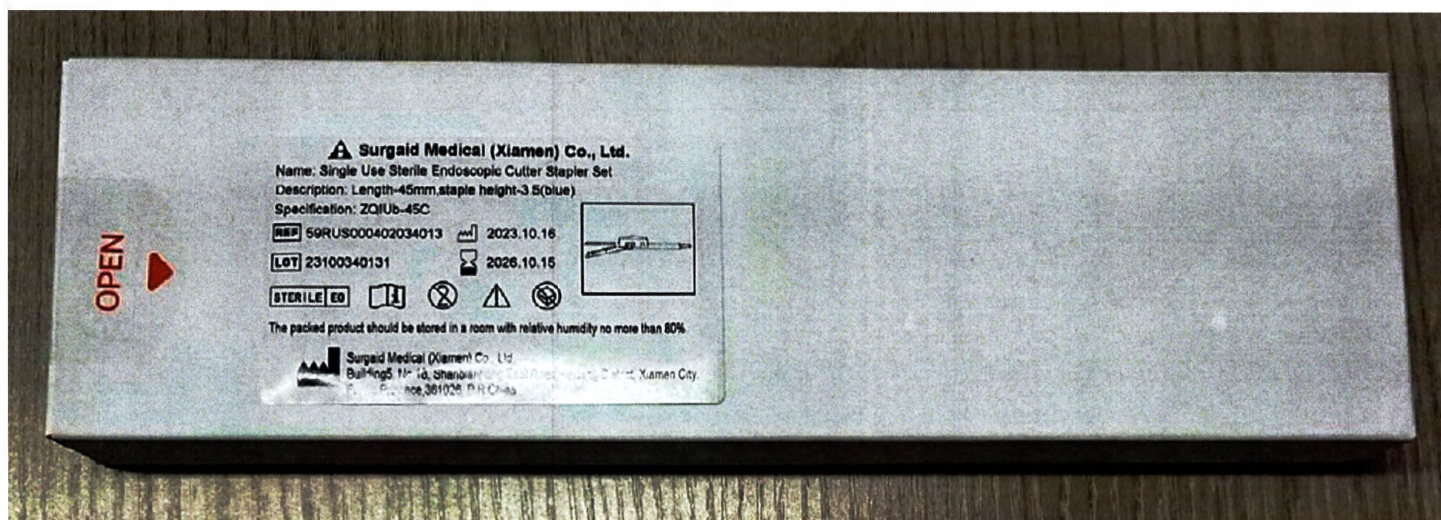
2) Картридж для степлера ротационный, в одном из вариантов исполнения:

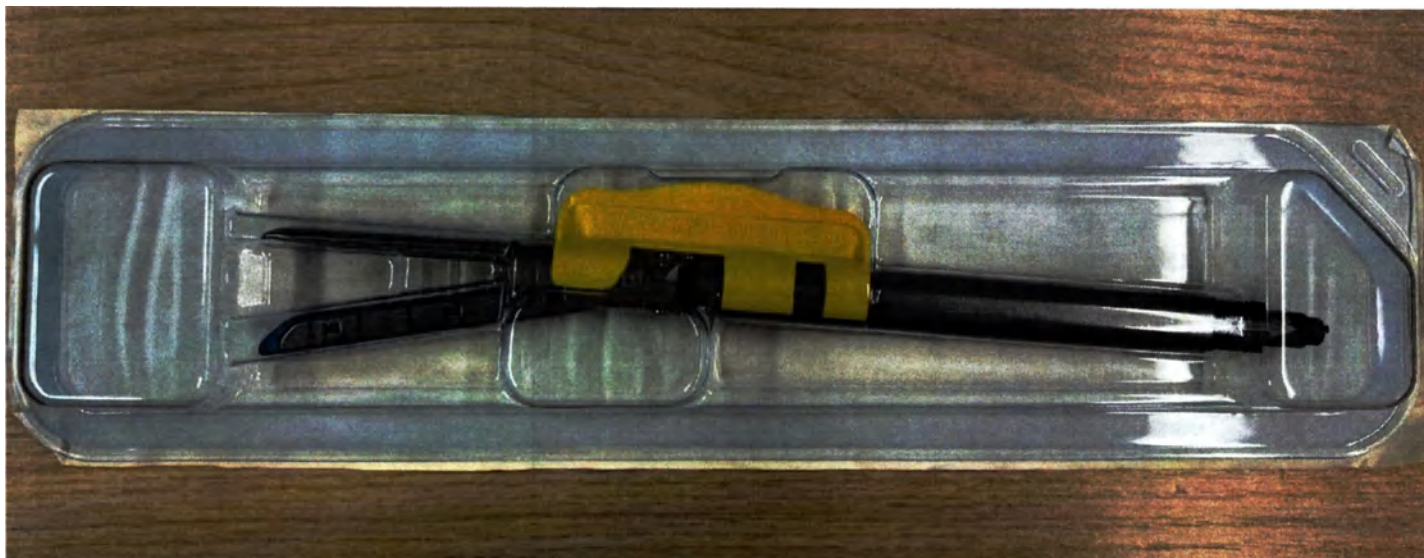
- Картридж для степлера ротационный, прямой: ZQIUb-45A – не более 6 шт. (при необходимости);



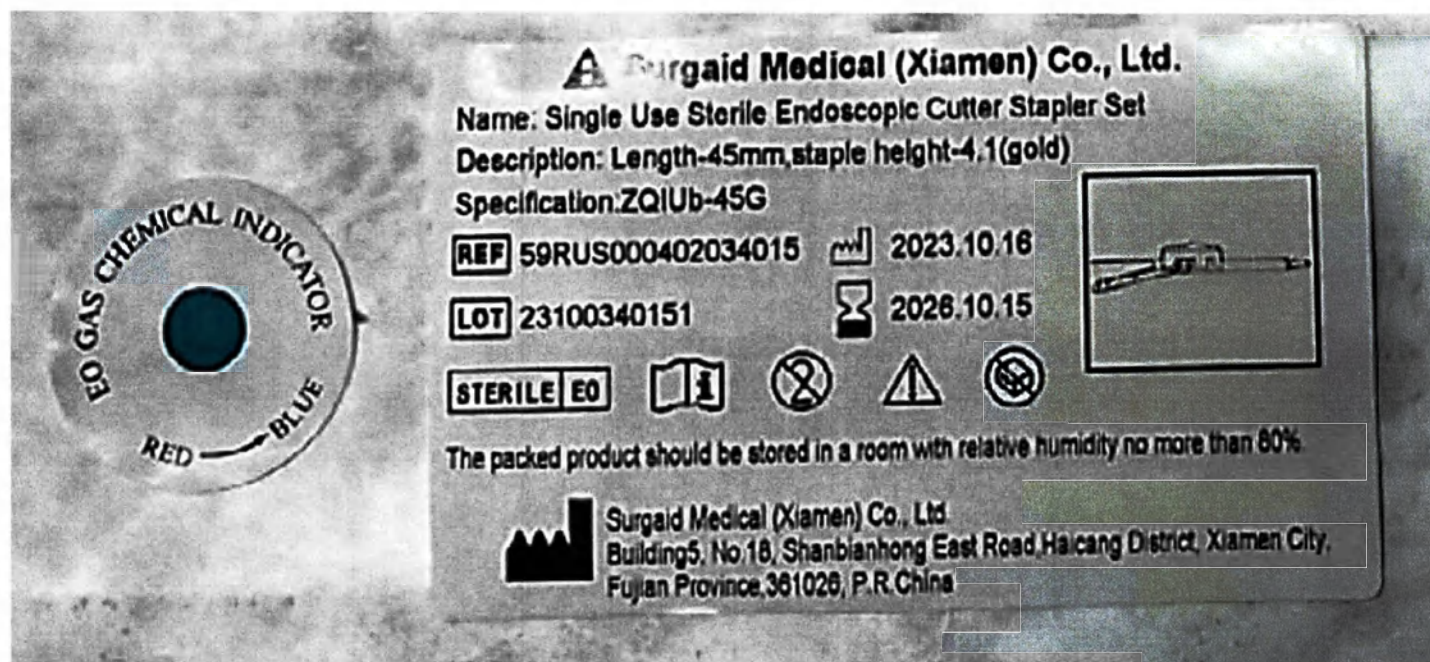
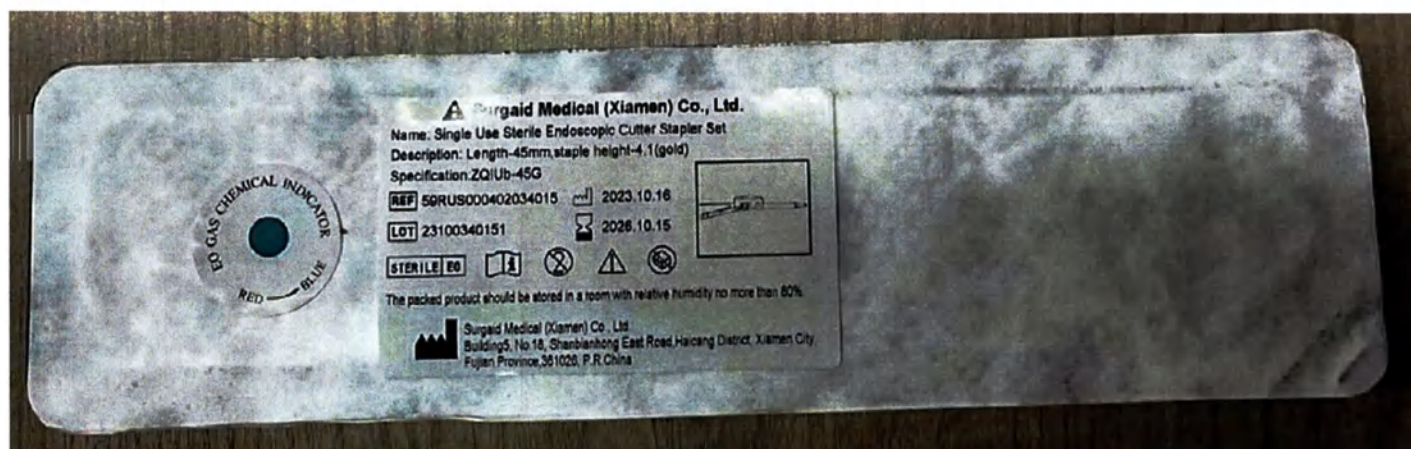
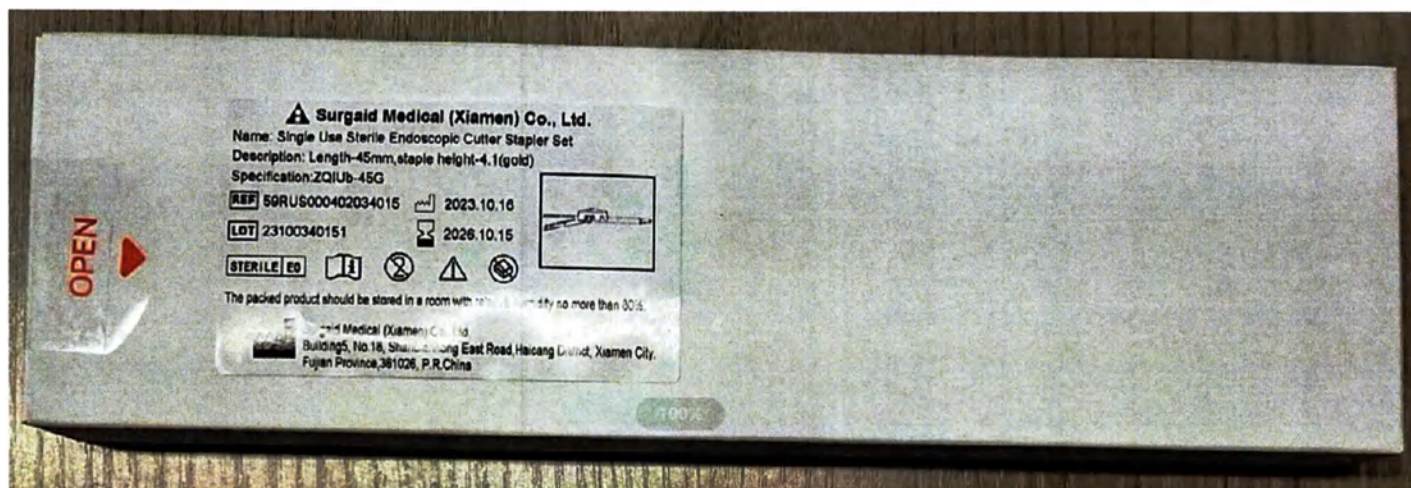


- Картридж для степлера ротационный, прямой: ZQIUb-45C – не более 6 шт. (при необходимости);



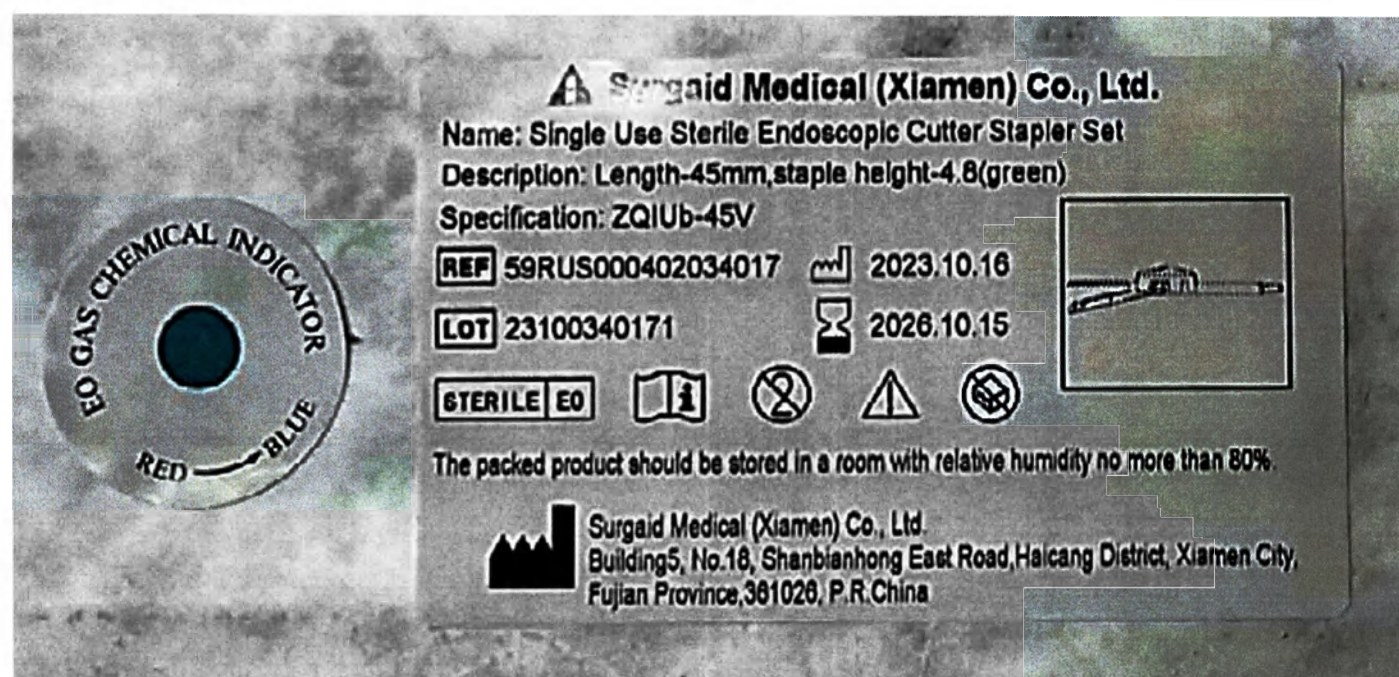
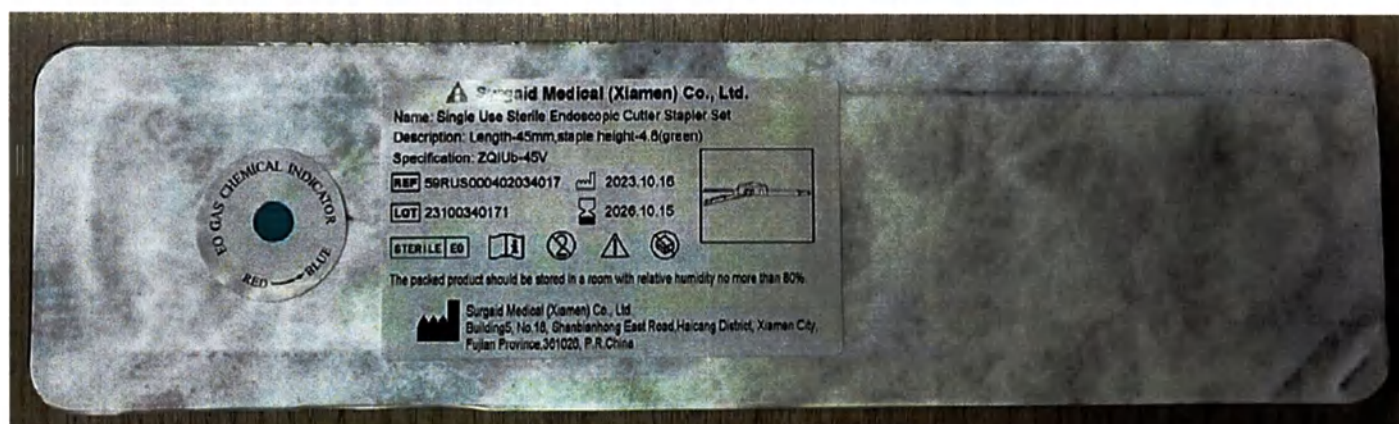
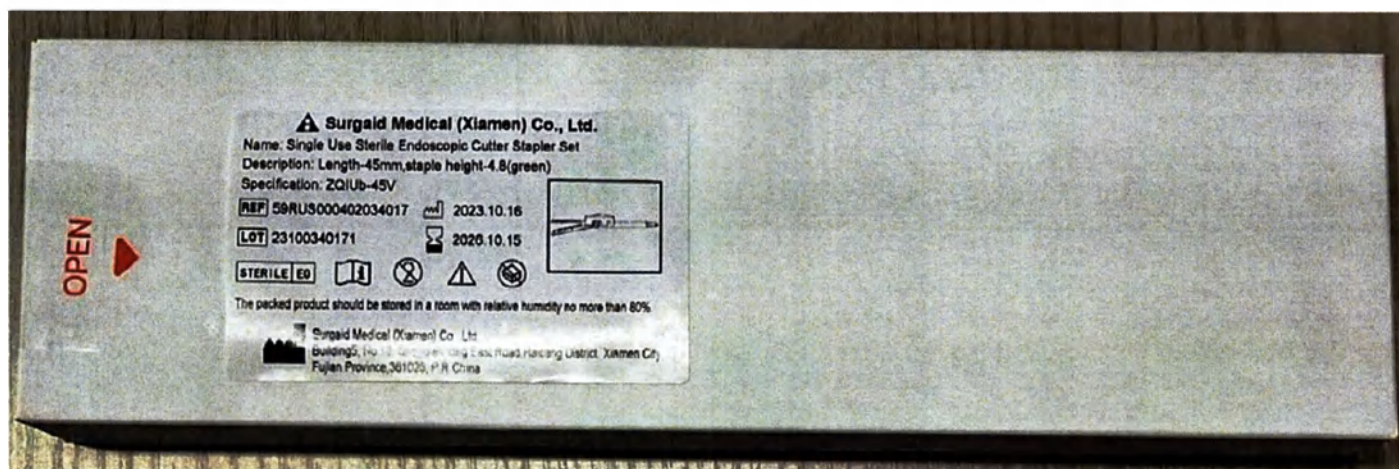


- Картридж для степлера ротационный, прямой: ZQIUb-45G – не более 6 шт. (при необходимости);



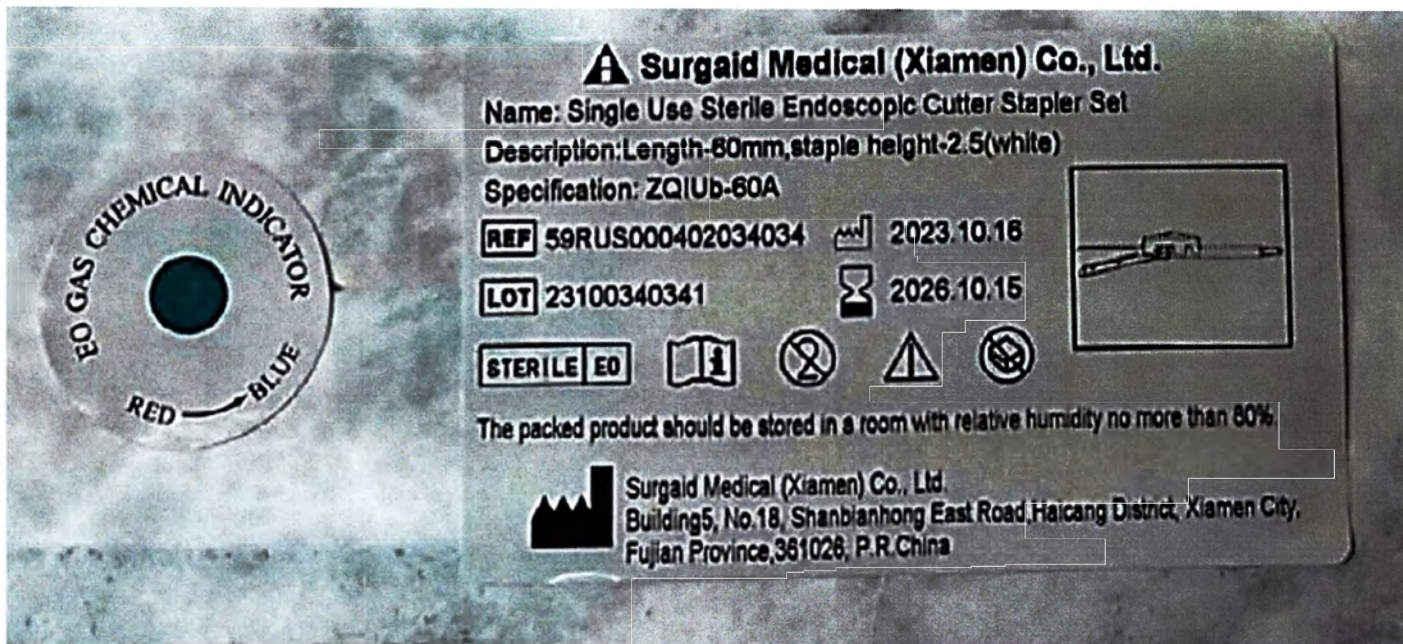
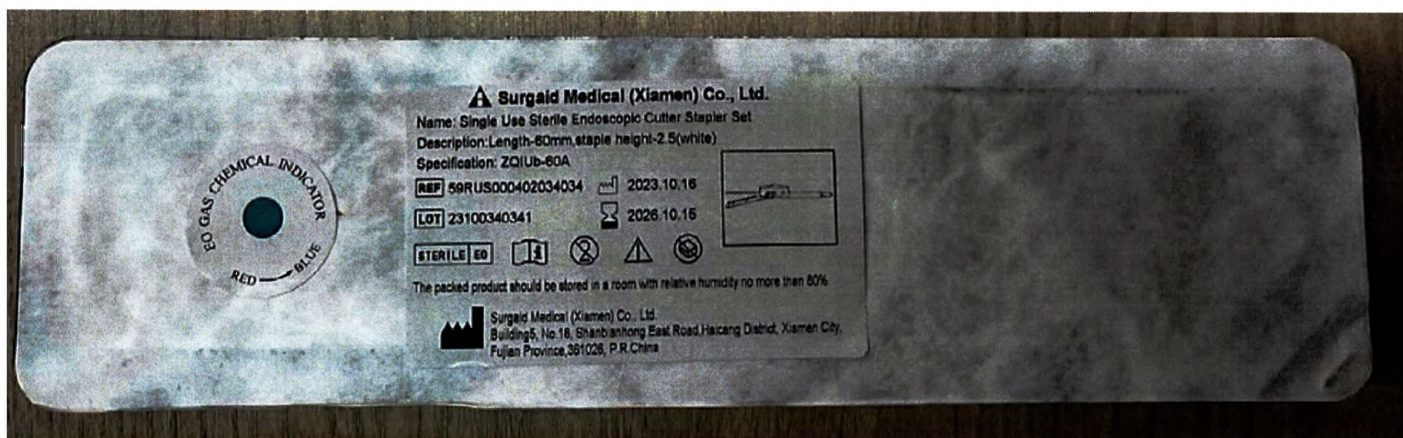
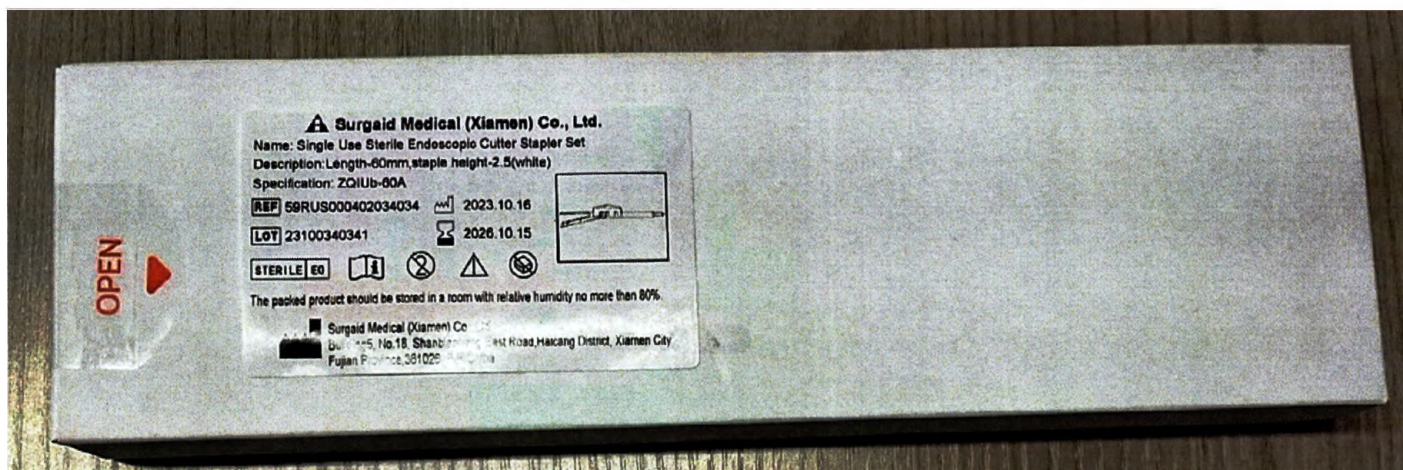


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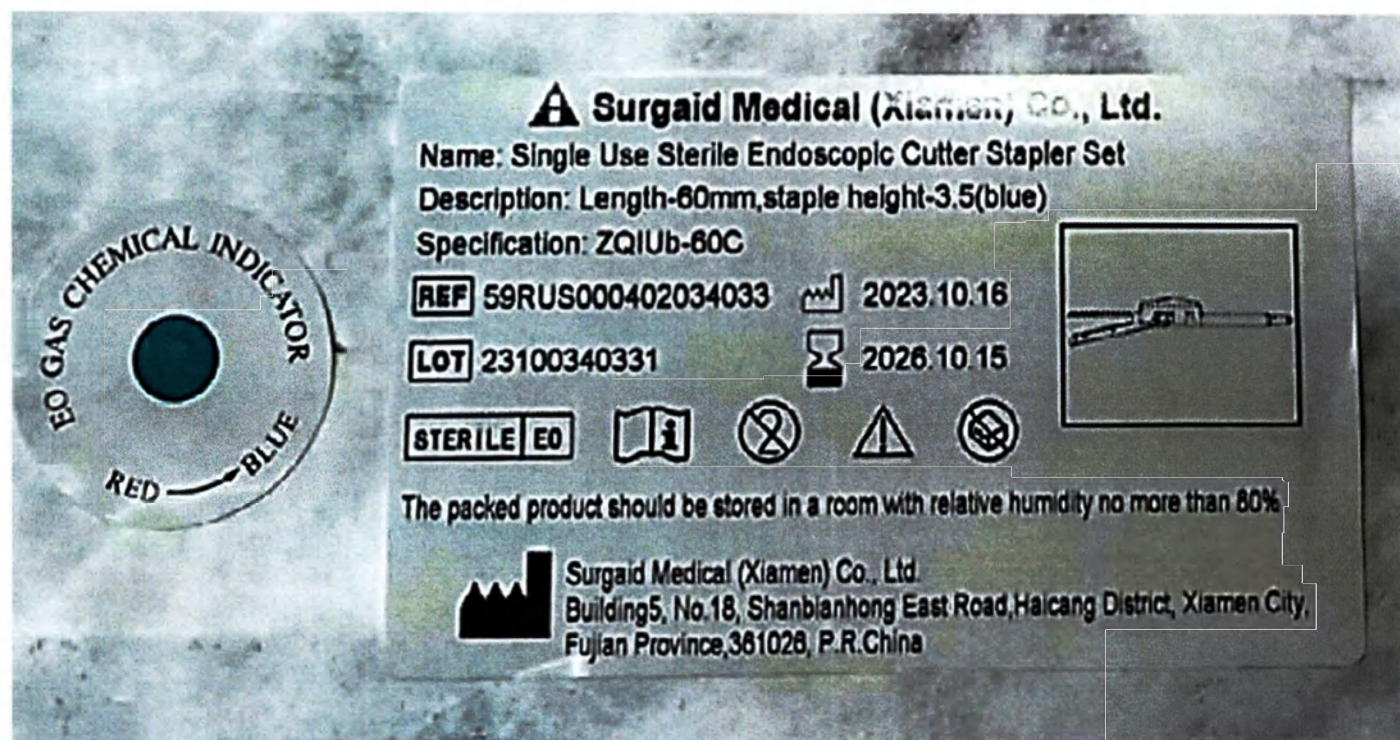
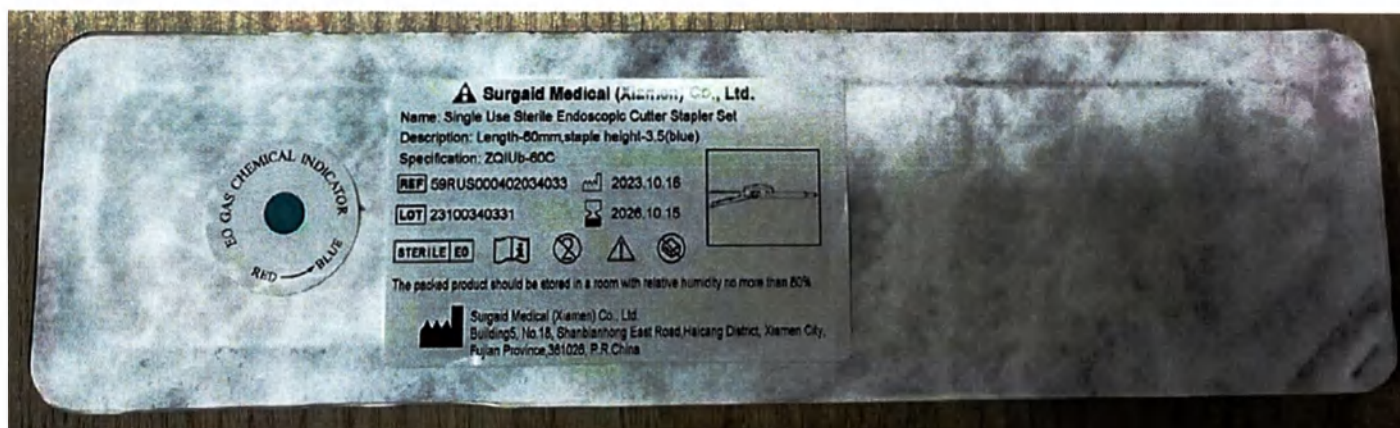
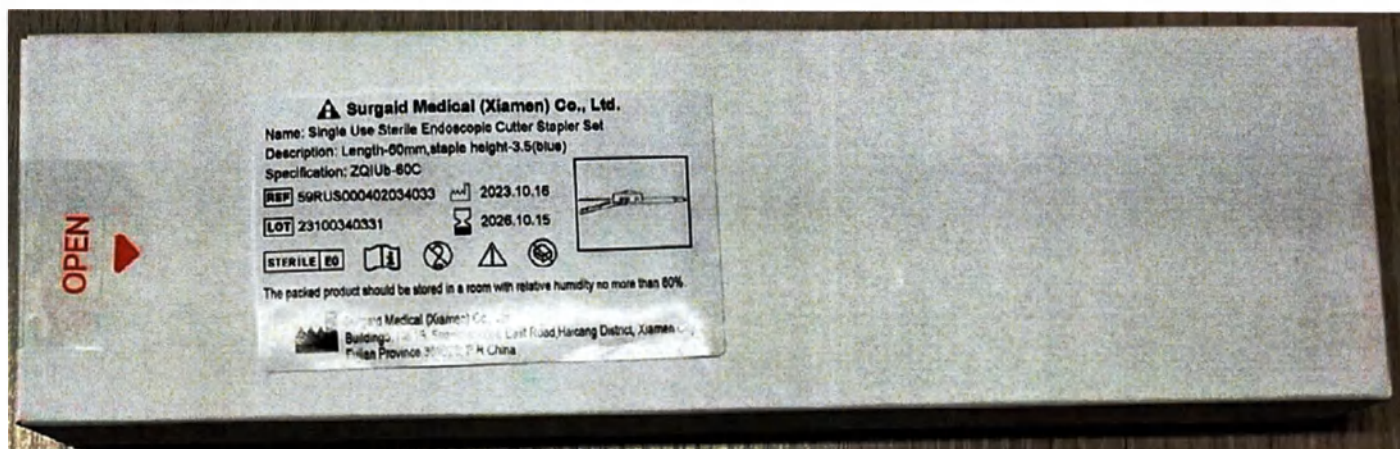


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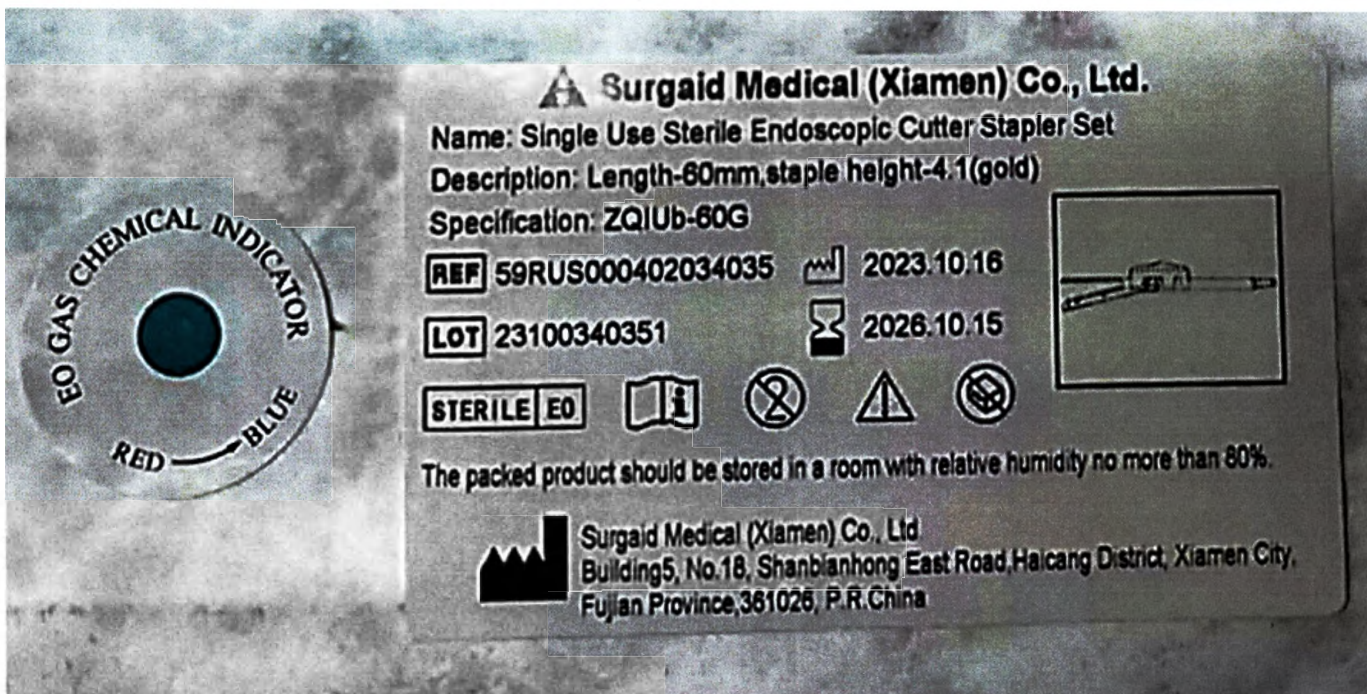
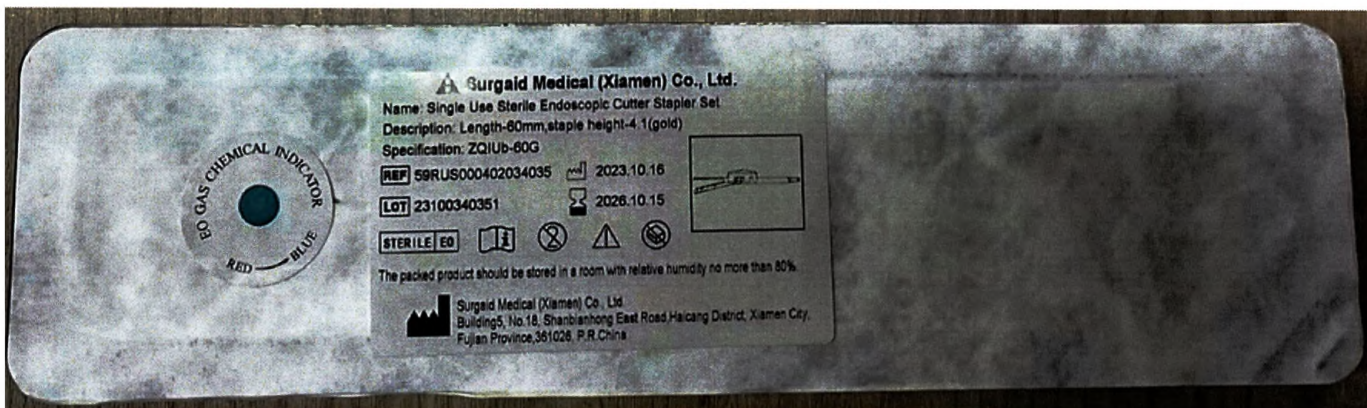
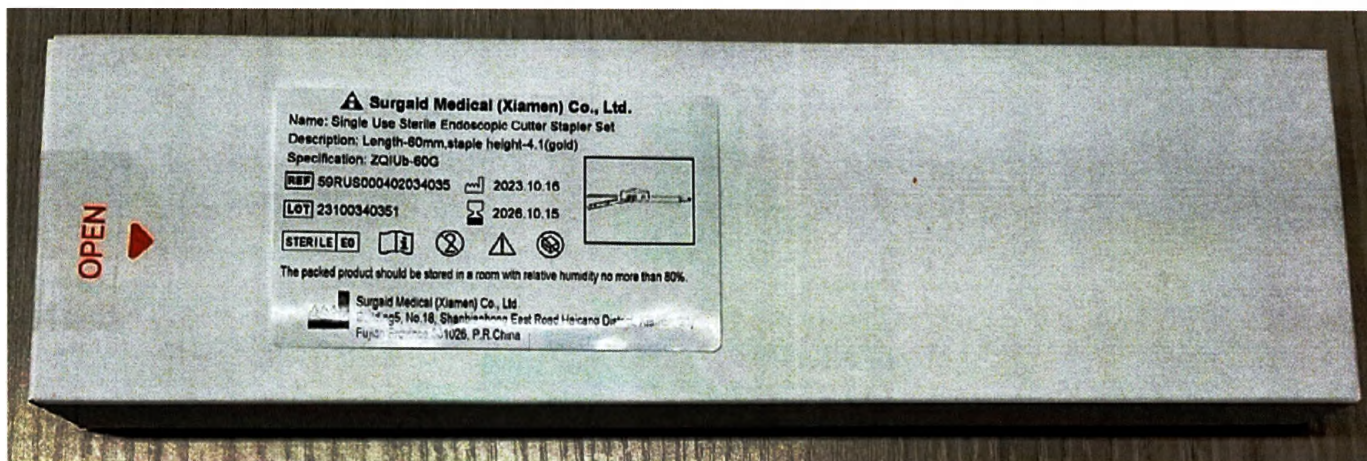


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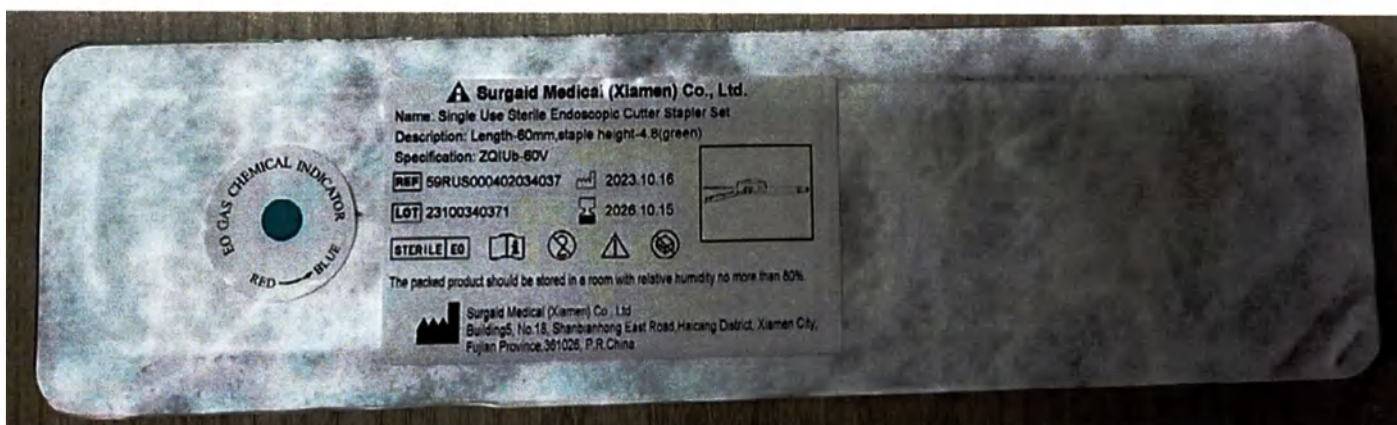
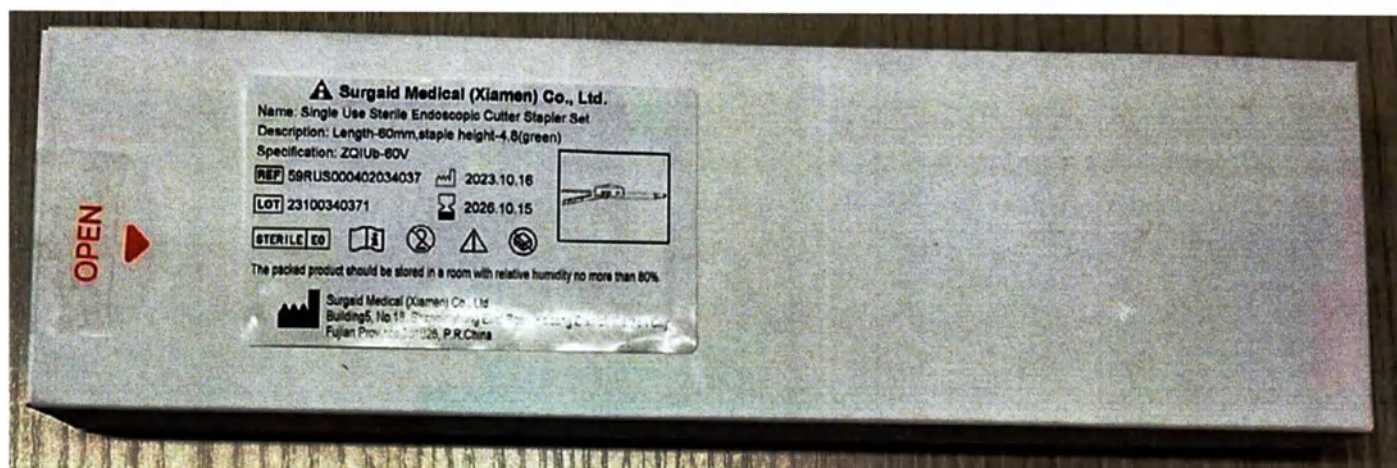


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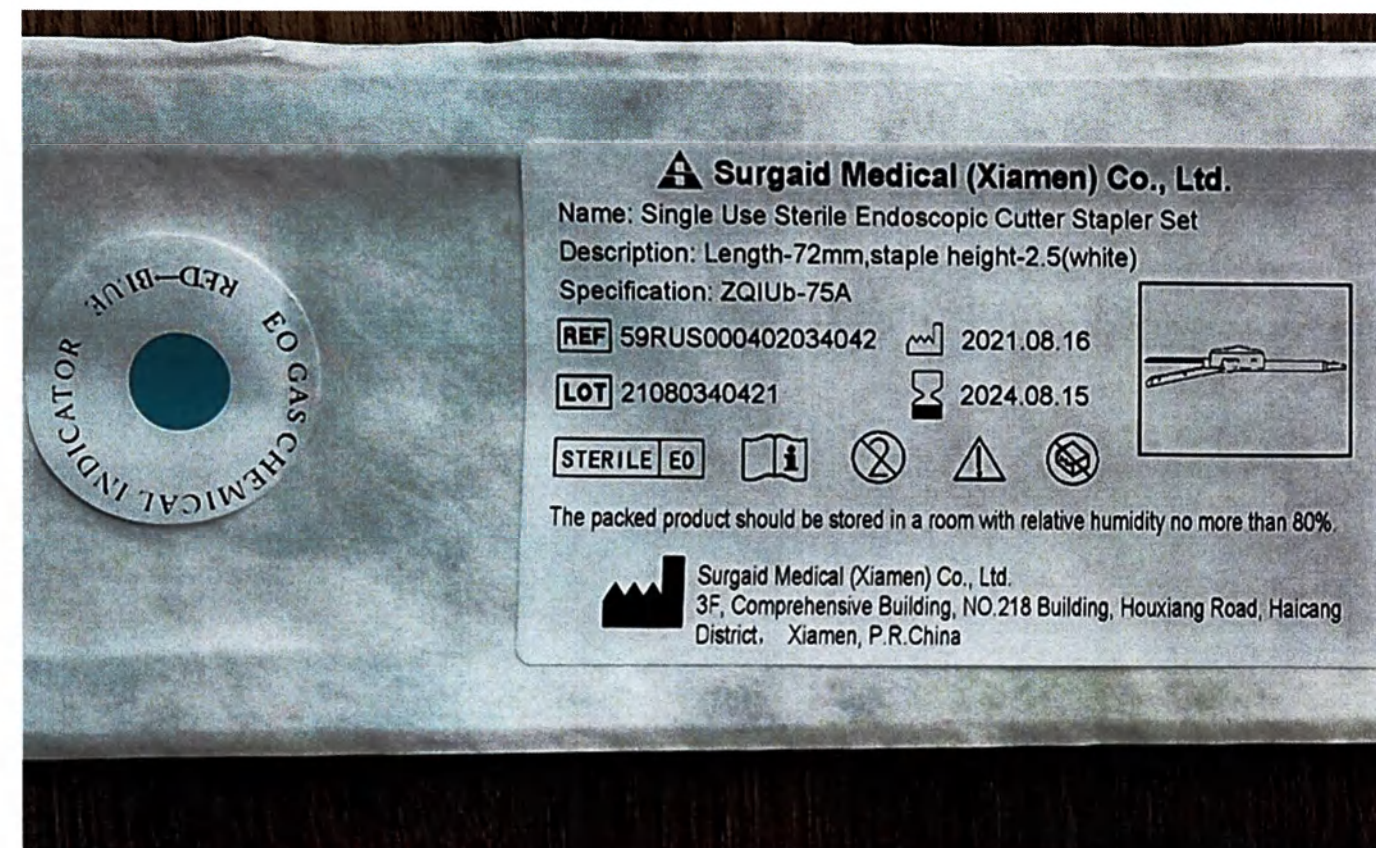
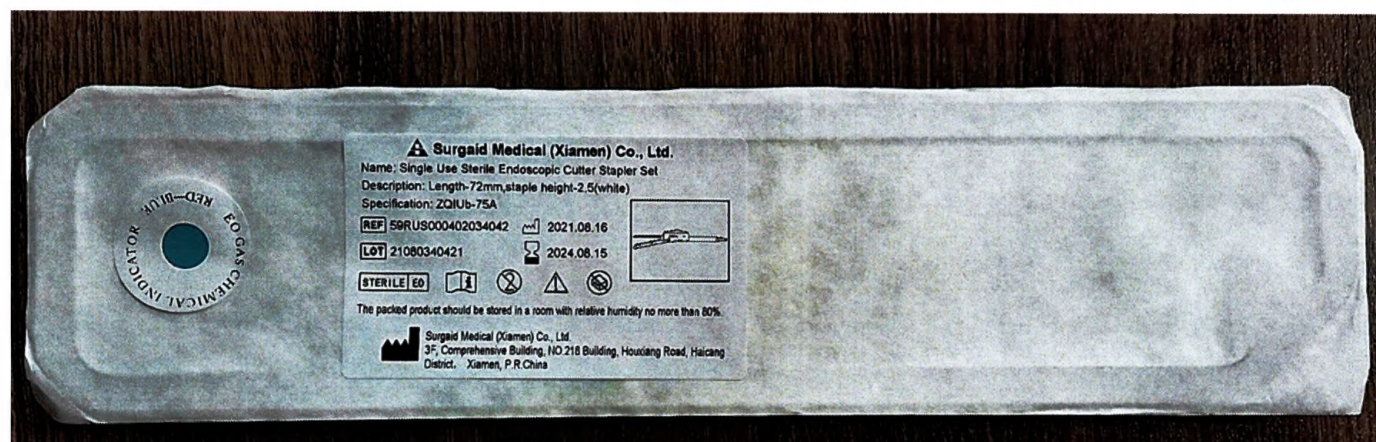
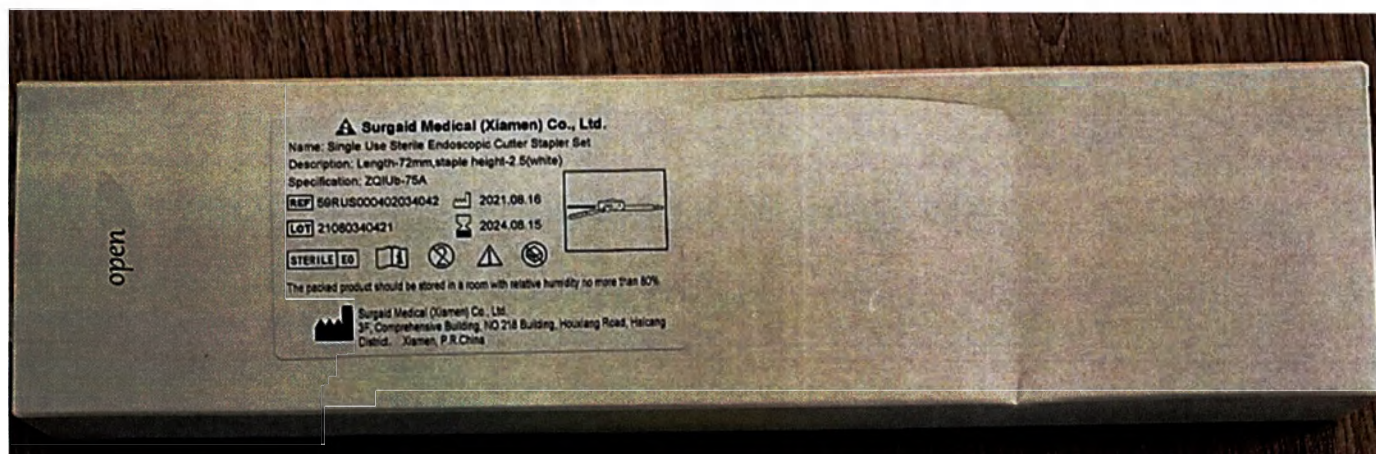


- Картридж для степлера ротационный, прямой: ZQIUb-60V – не более 6 шт. (при необходимости);



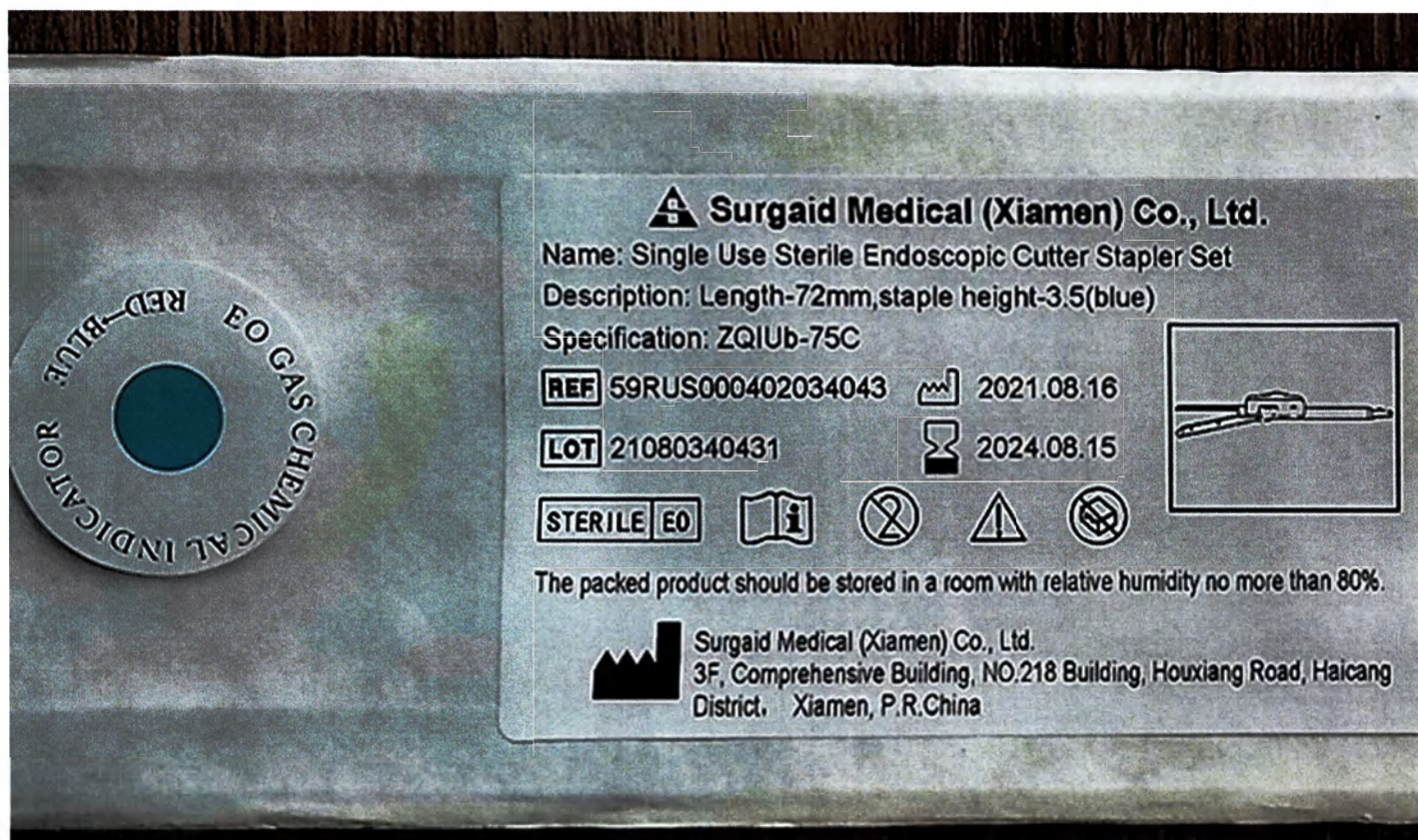
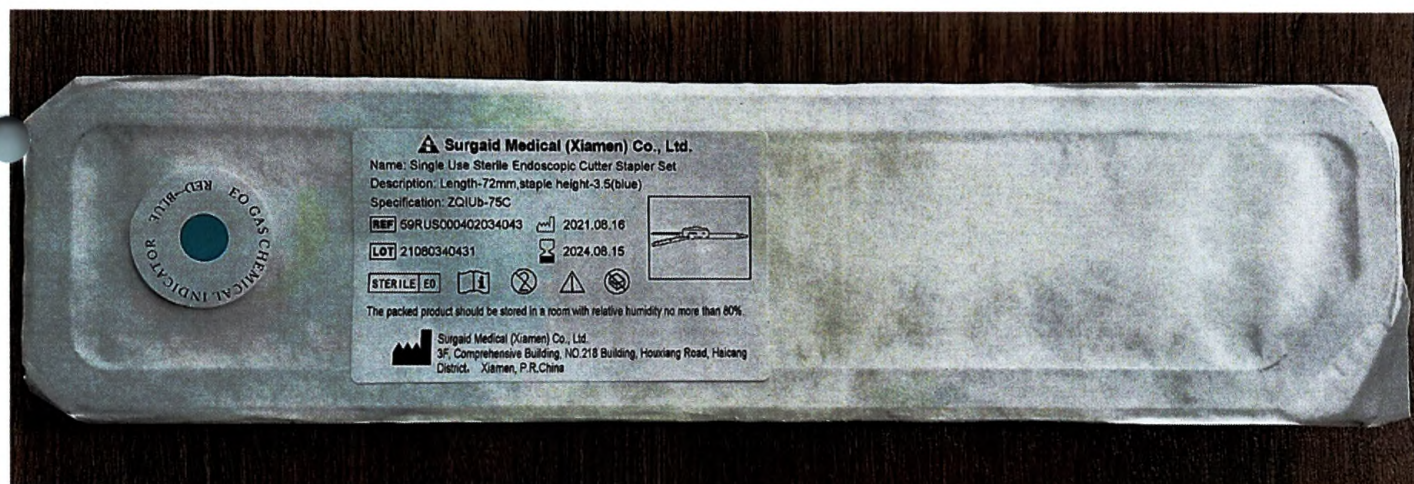
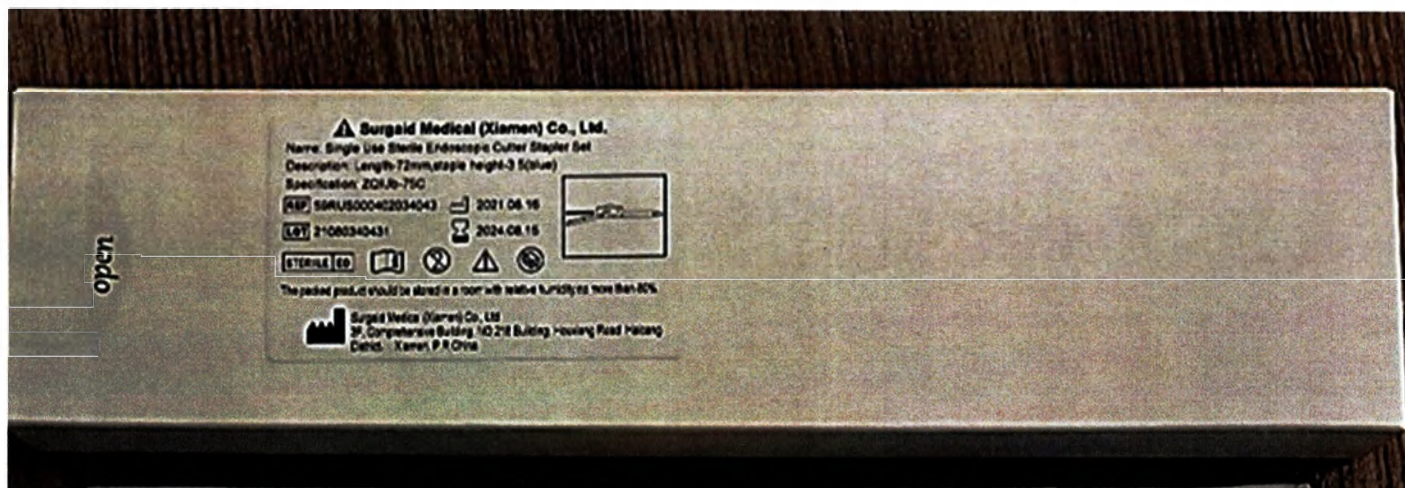


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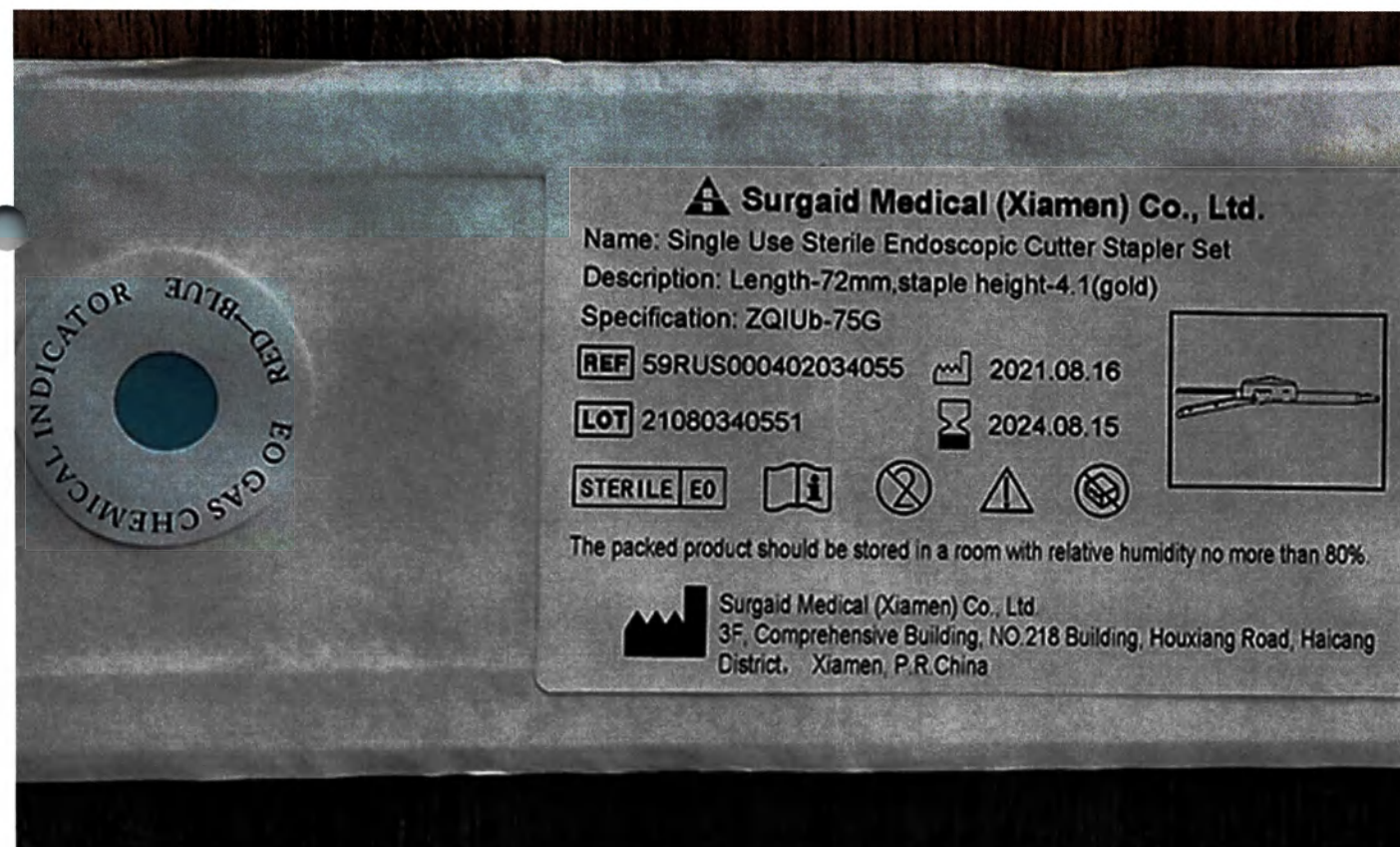
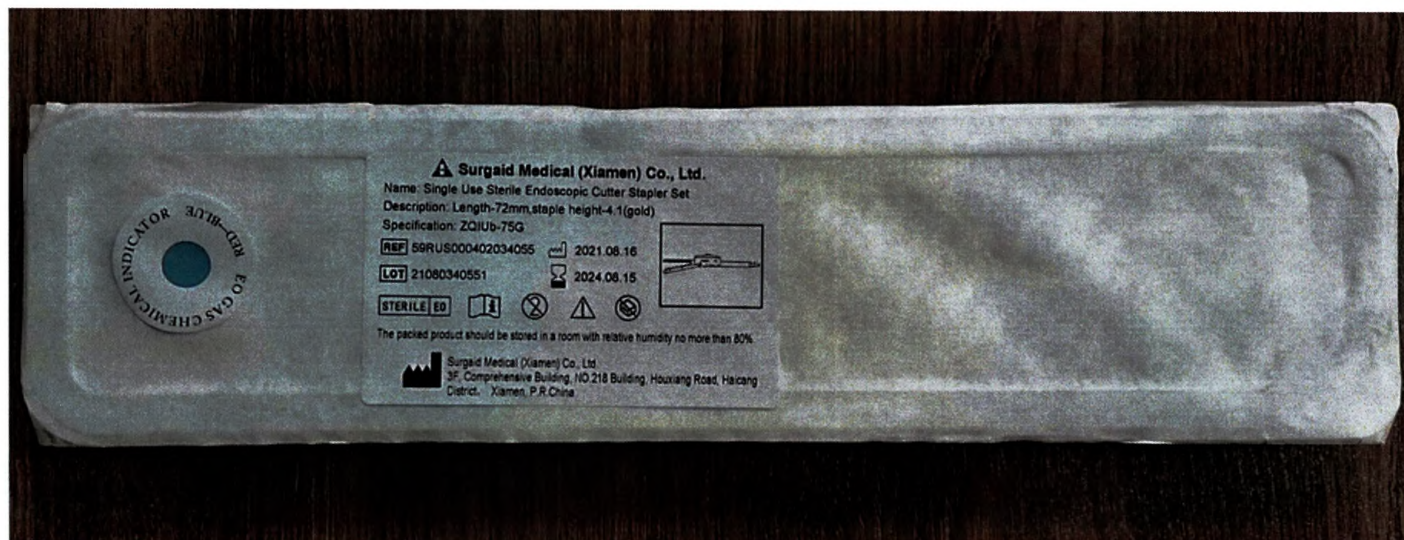
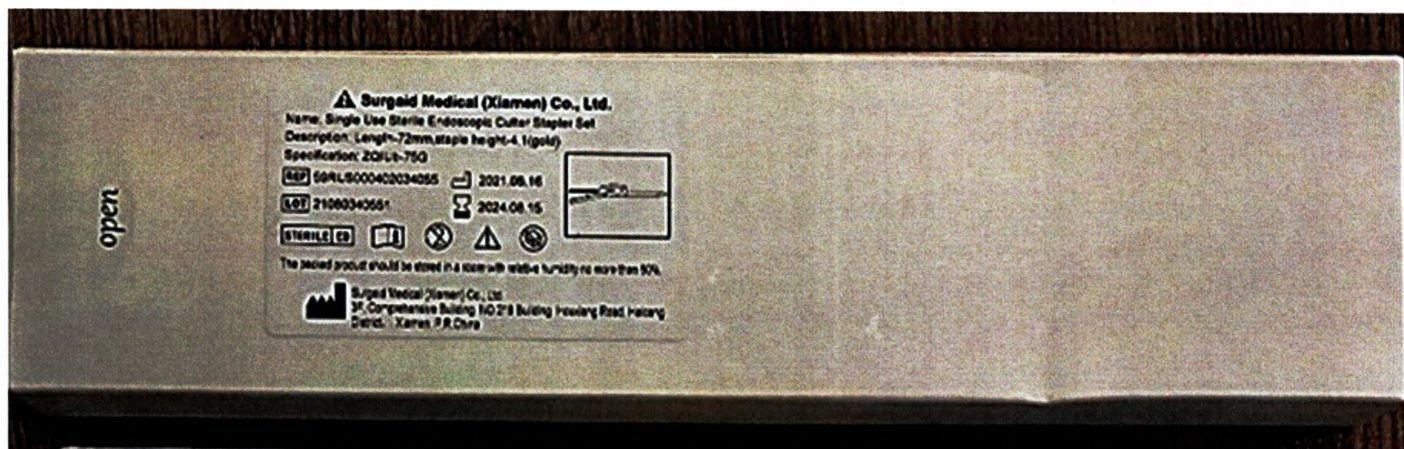


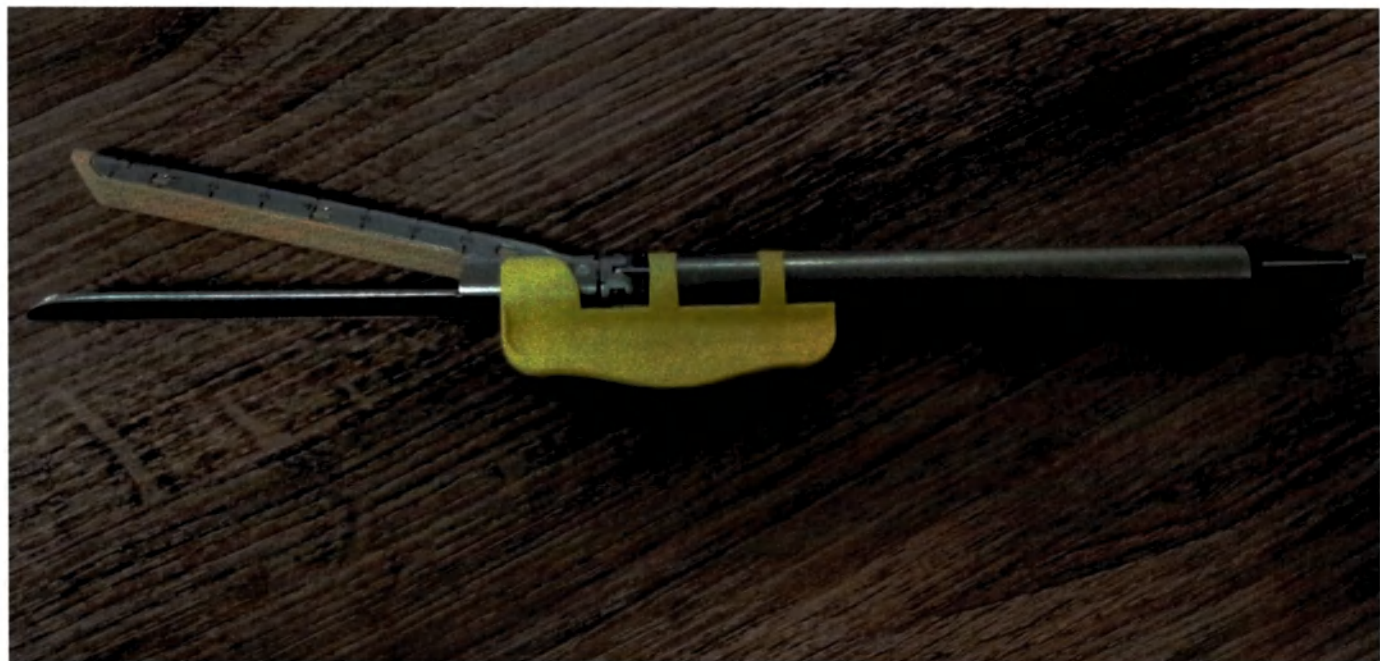
- Картридж для степлера ротационный, прямой: ZQIUb-75C – не более 6 шт. (при необходимости);



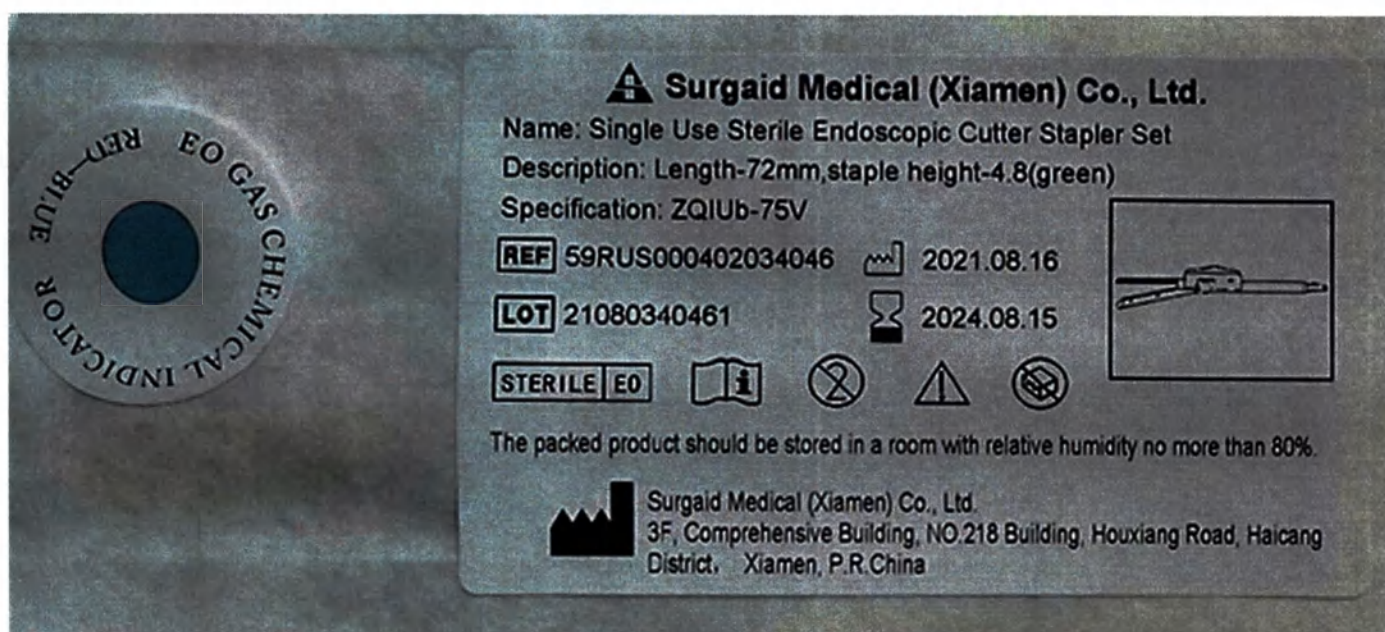
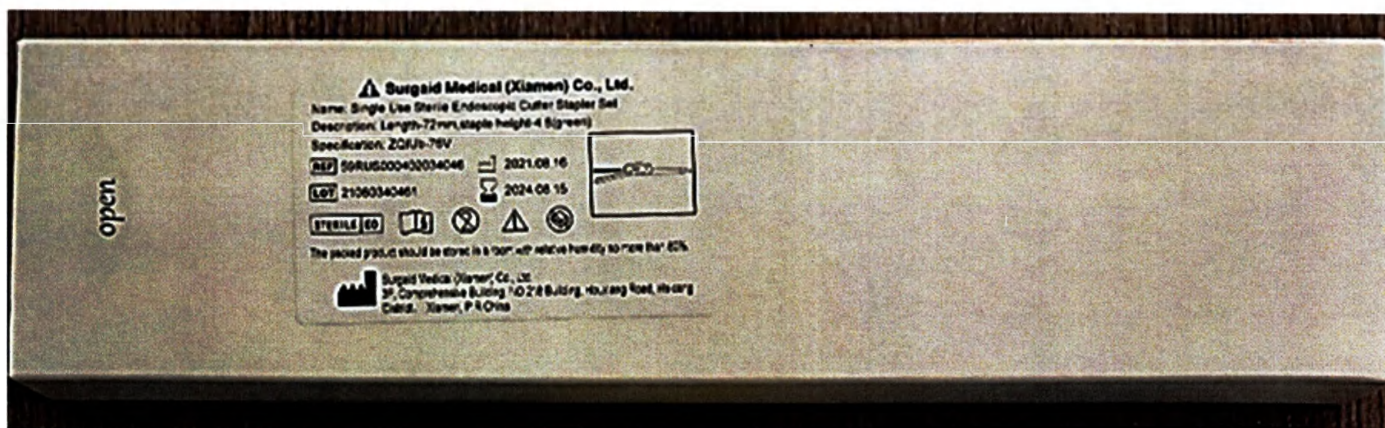


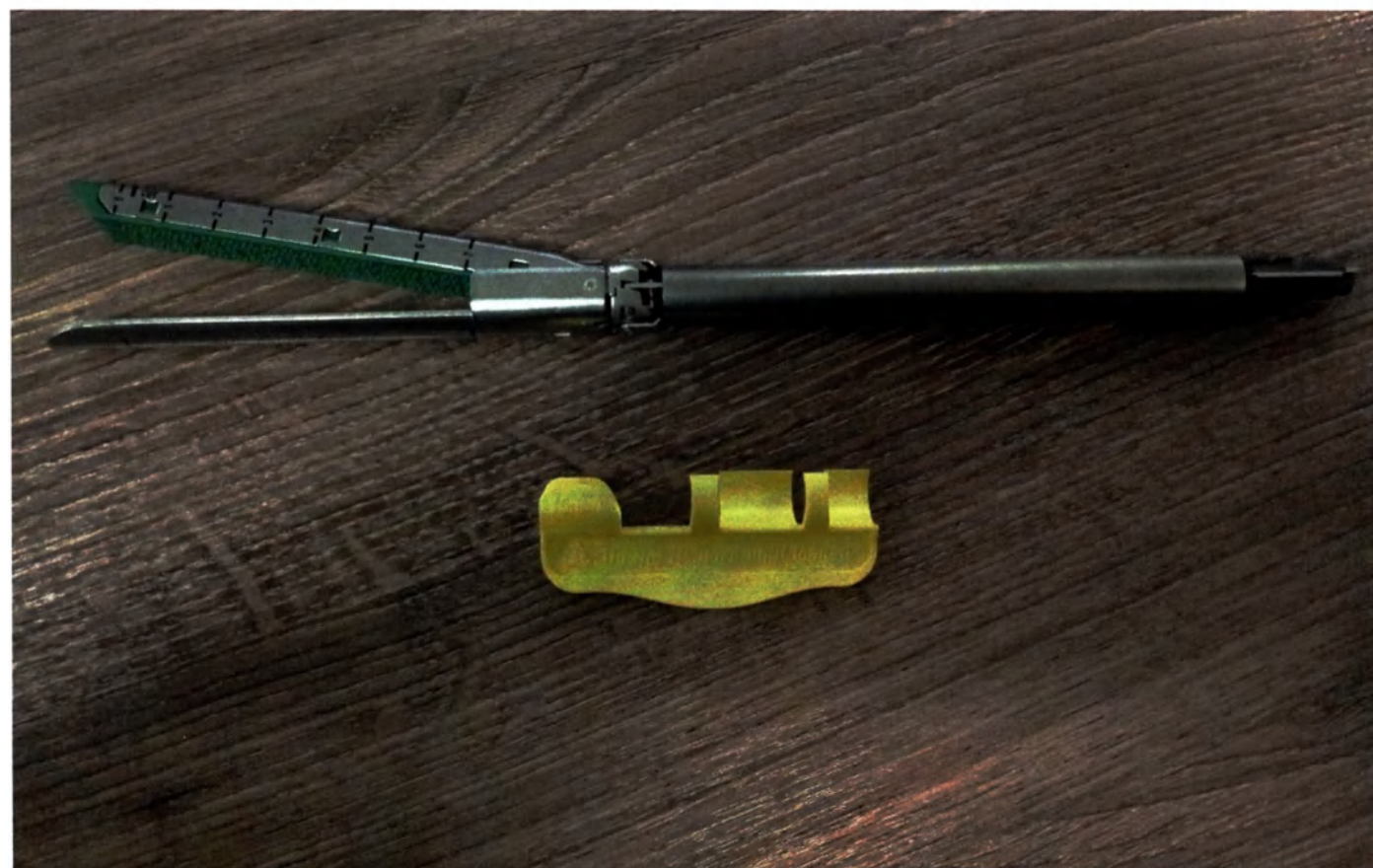
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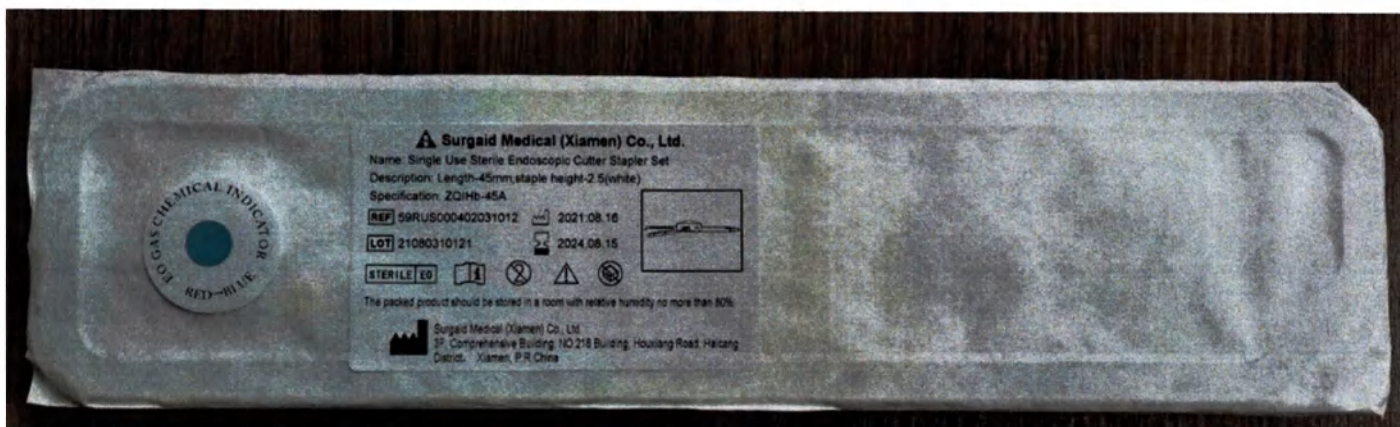


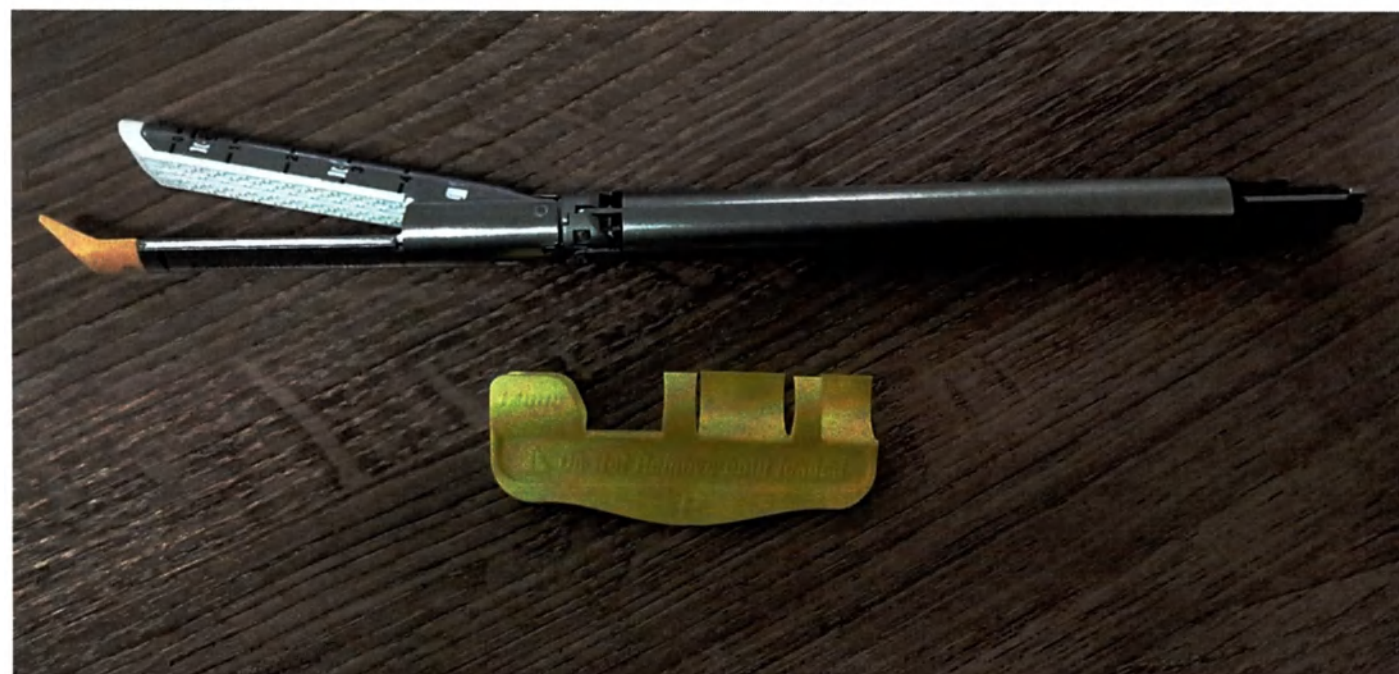
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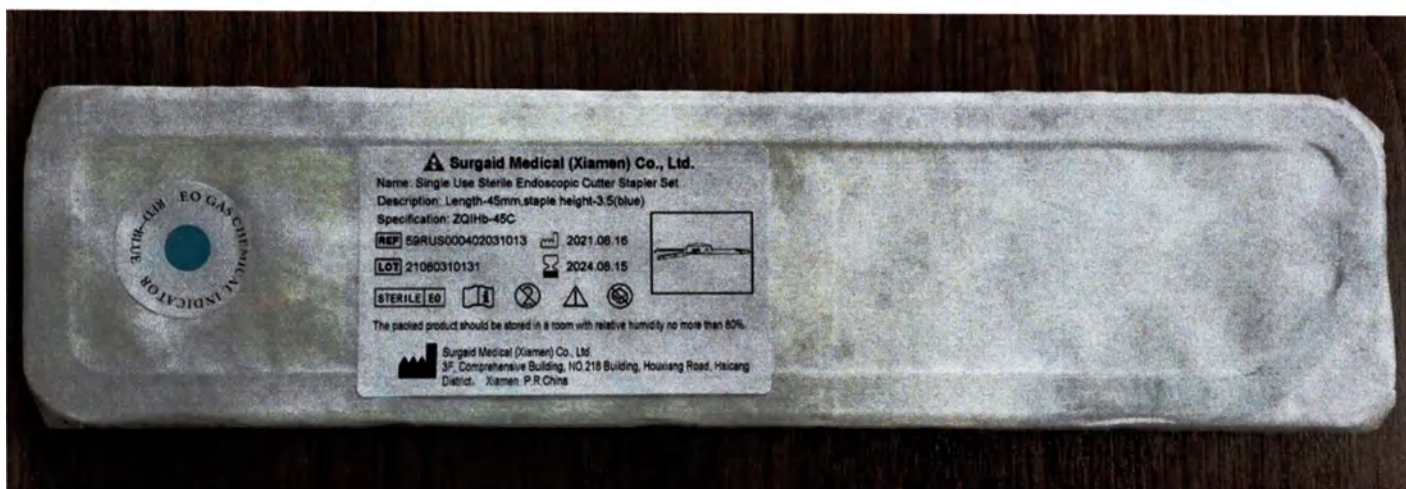
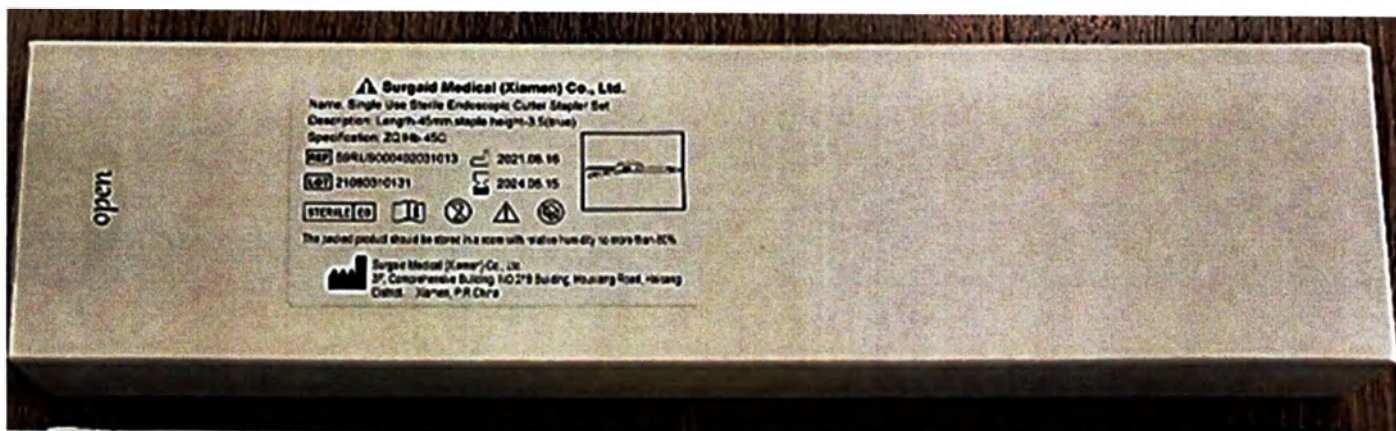


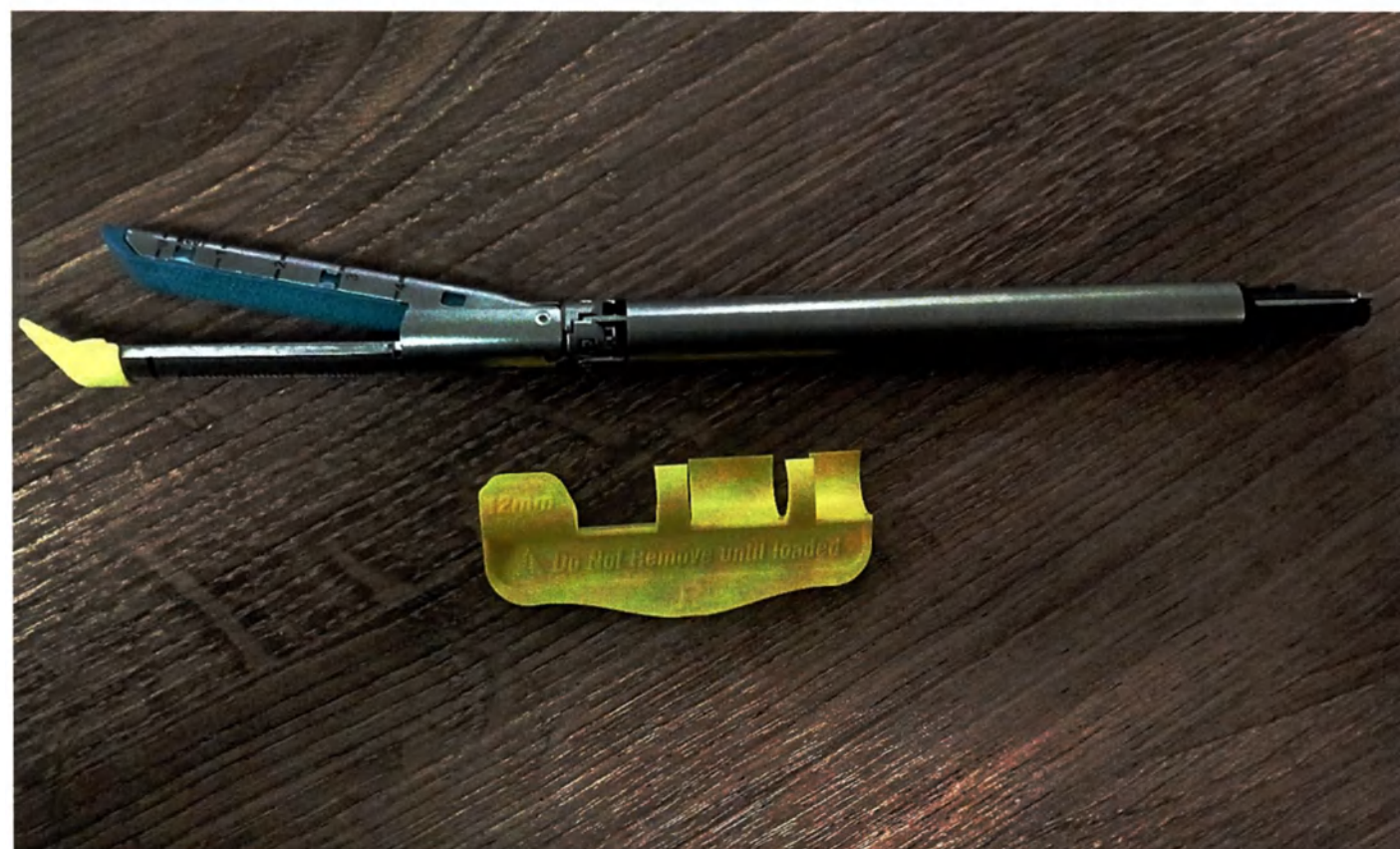
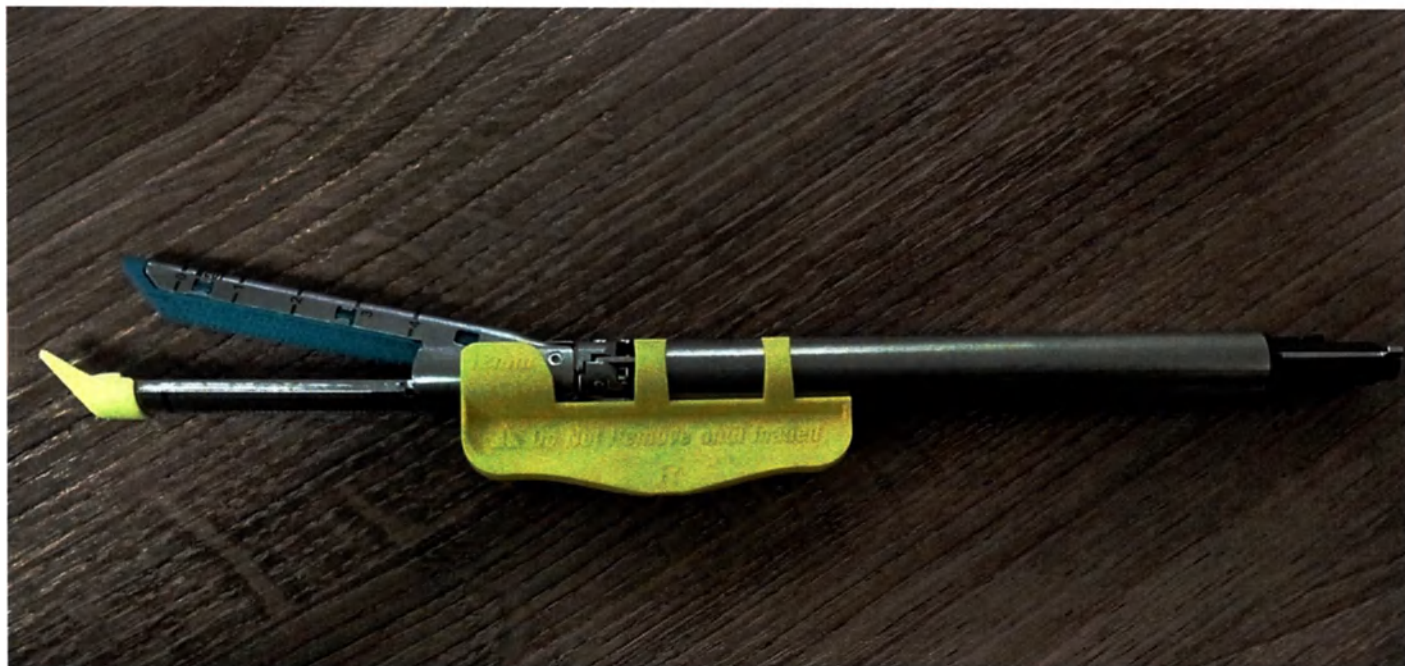
- Картридж для степлера ротационный, с загибом: ZQIHb-45A– не более 6 шт. (при необходимости);



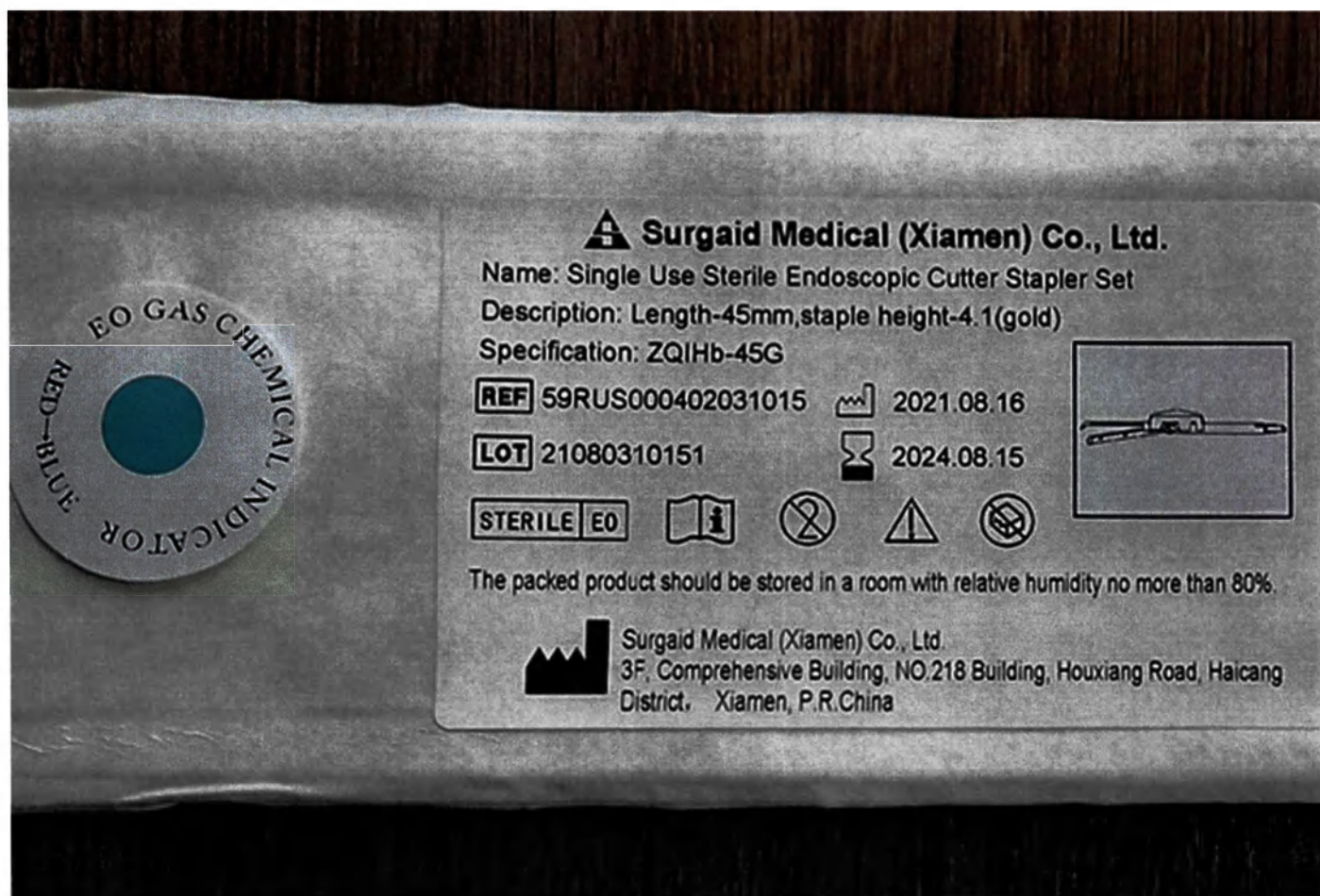
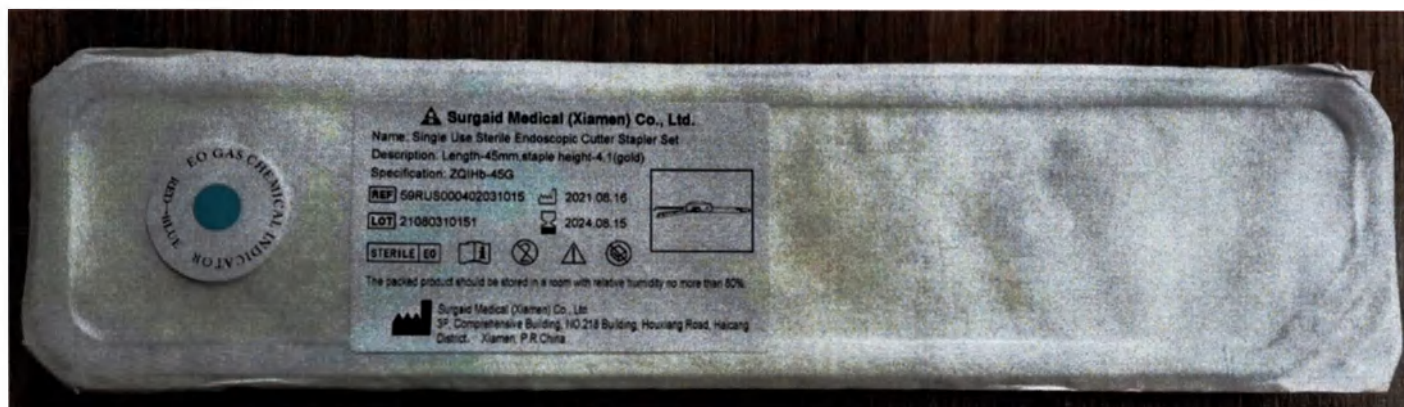


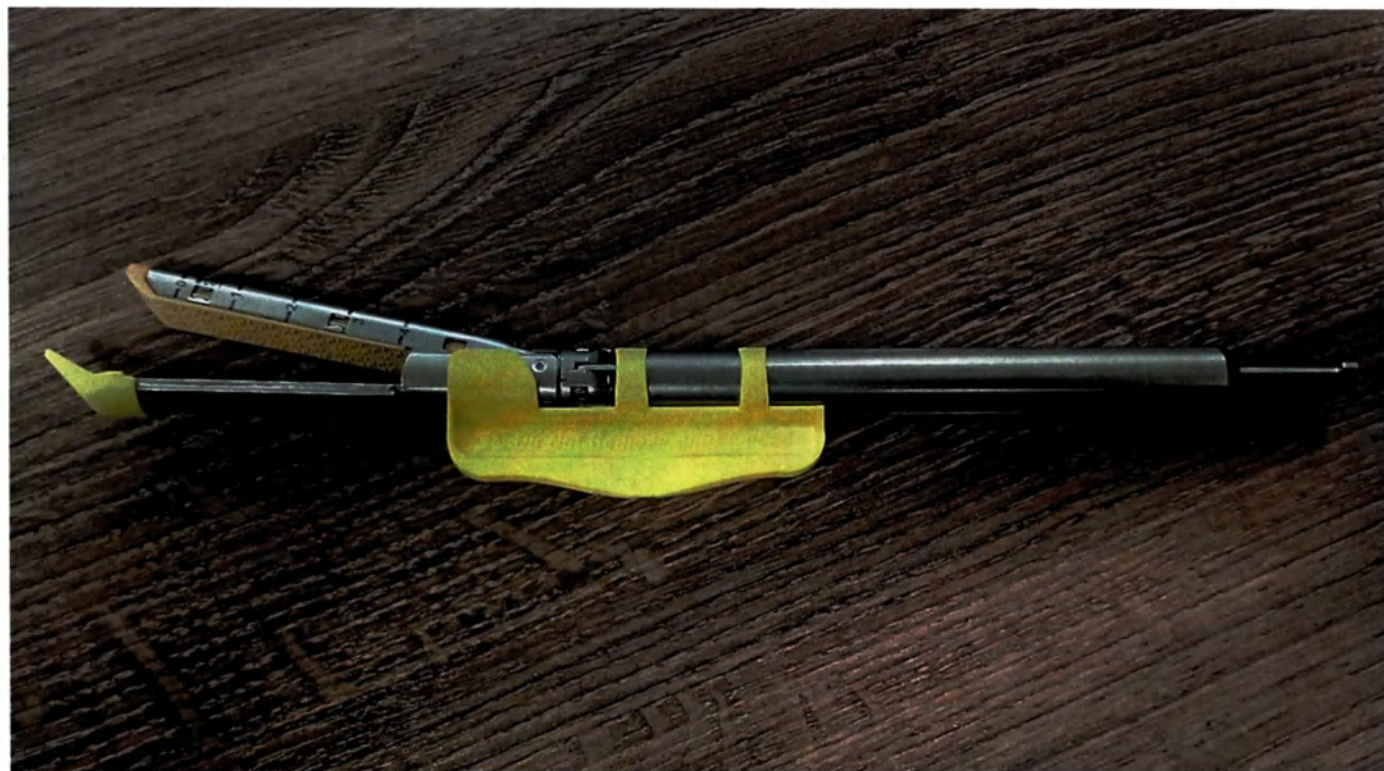
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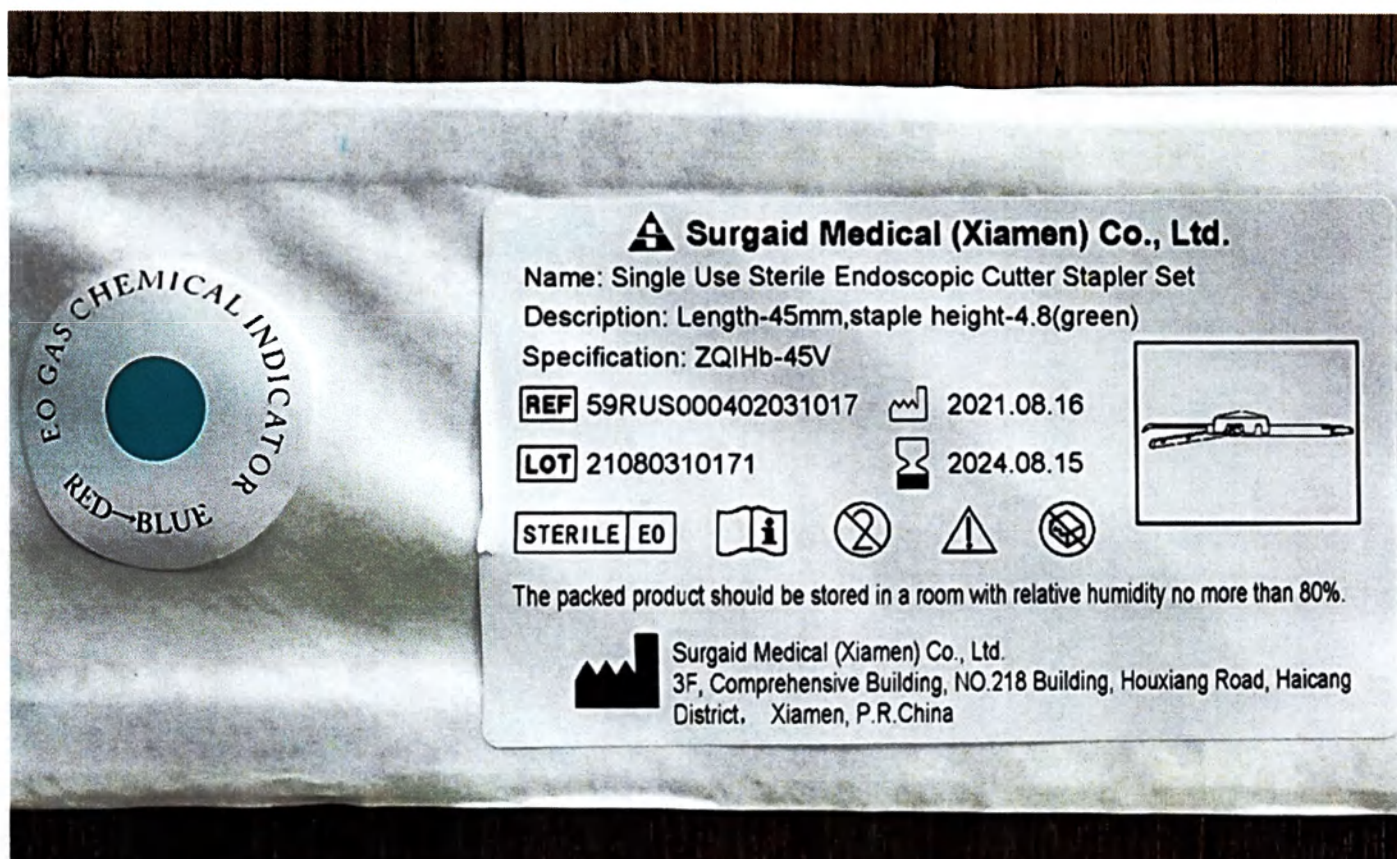
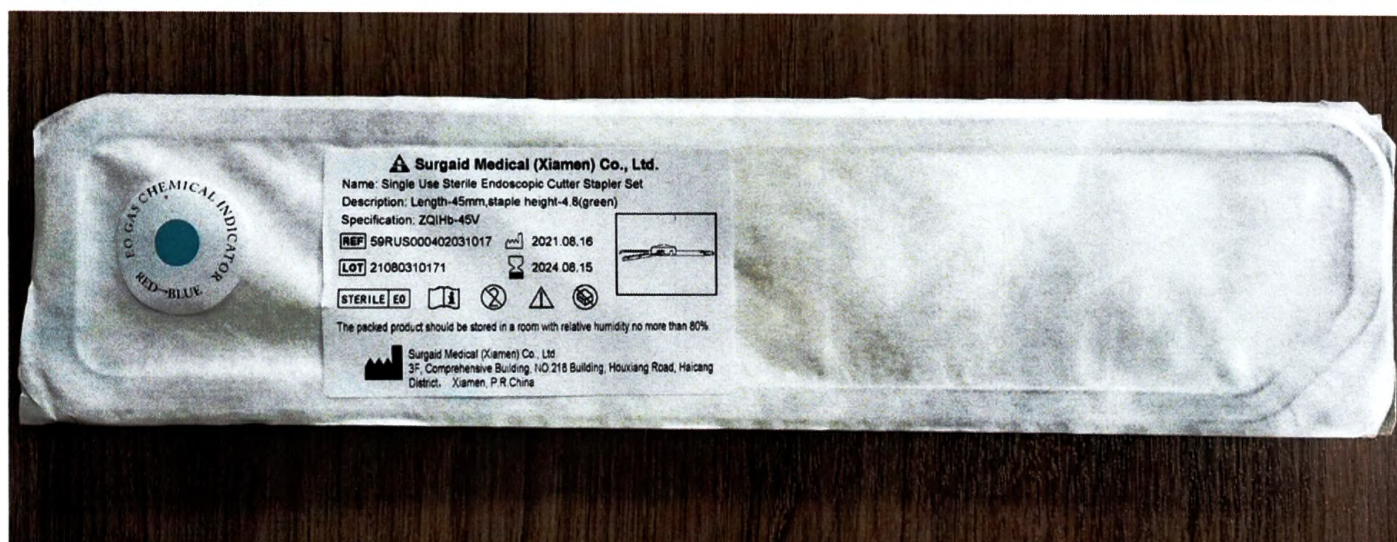
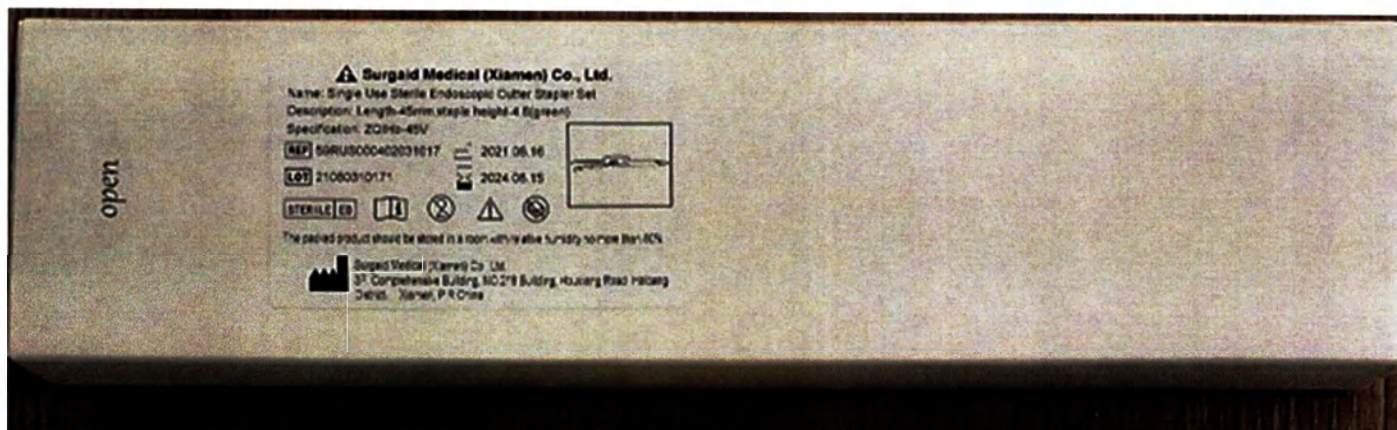


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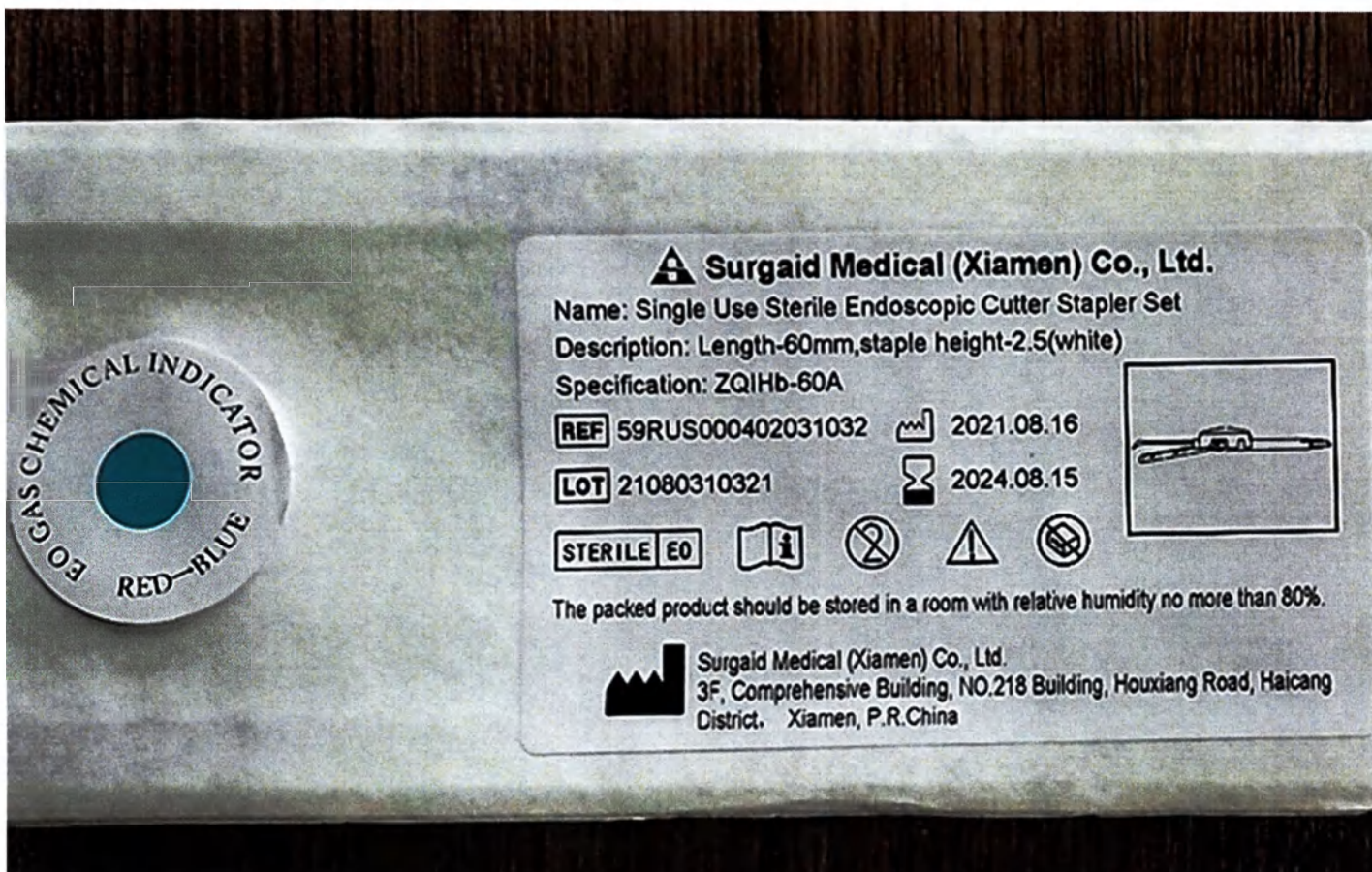
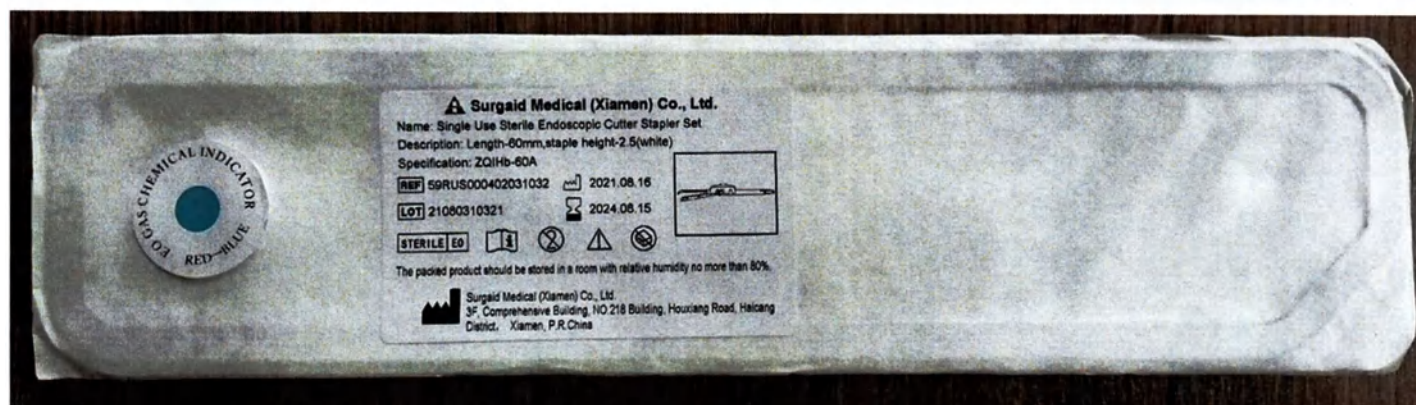
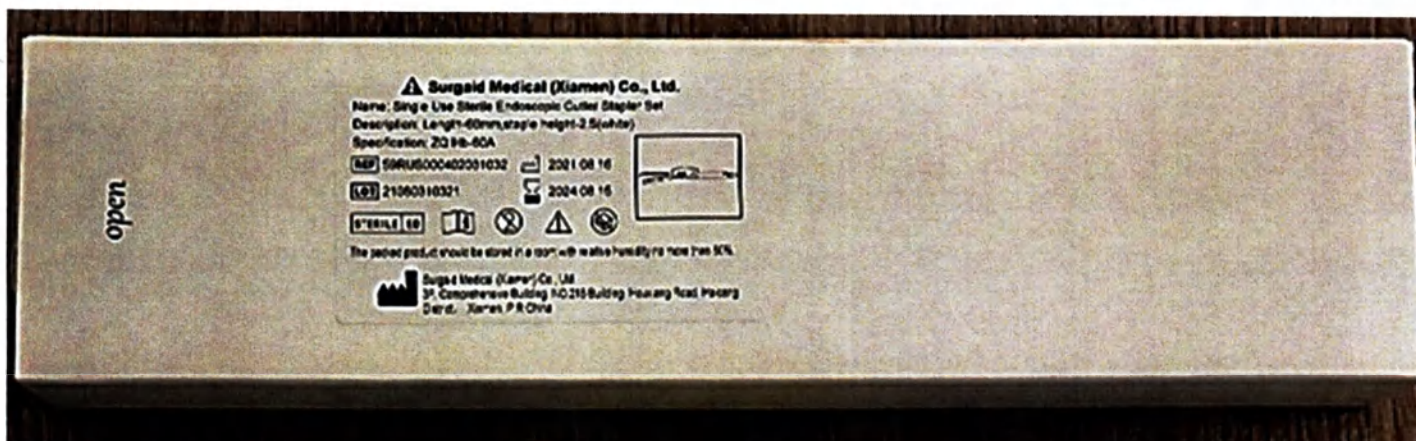


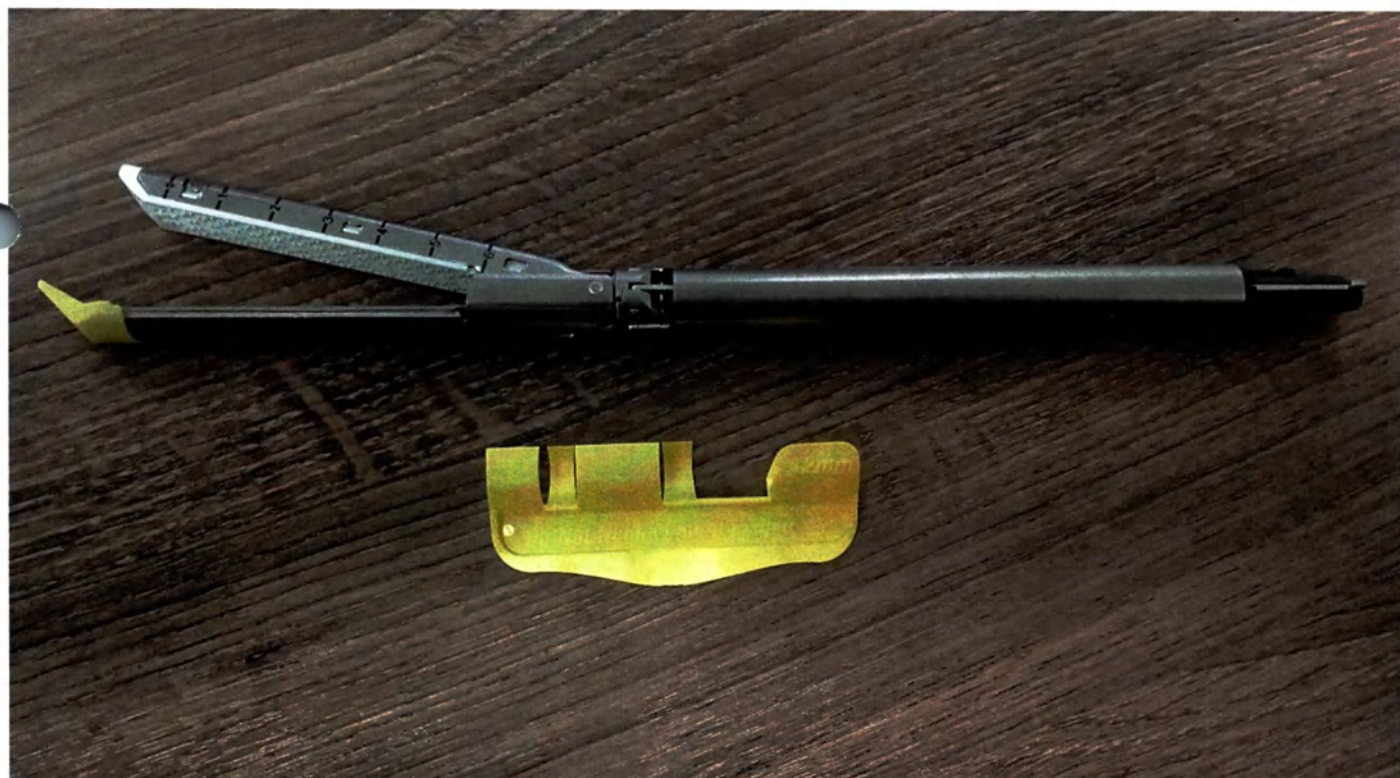
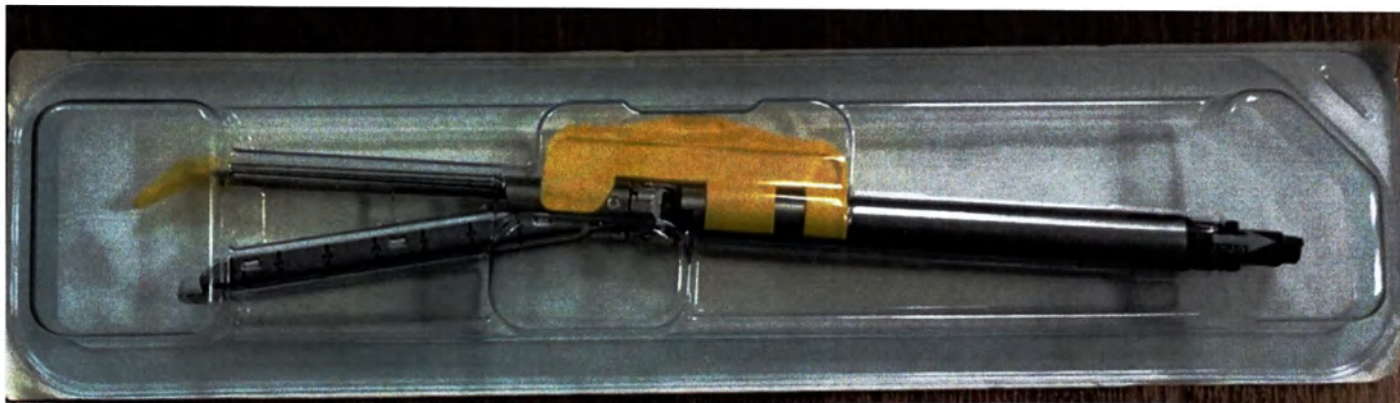
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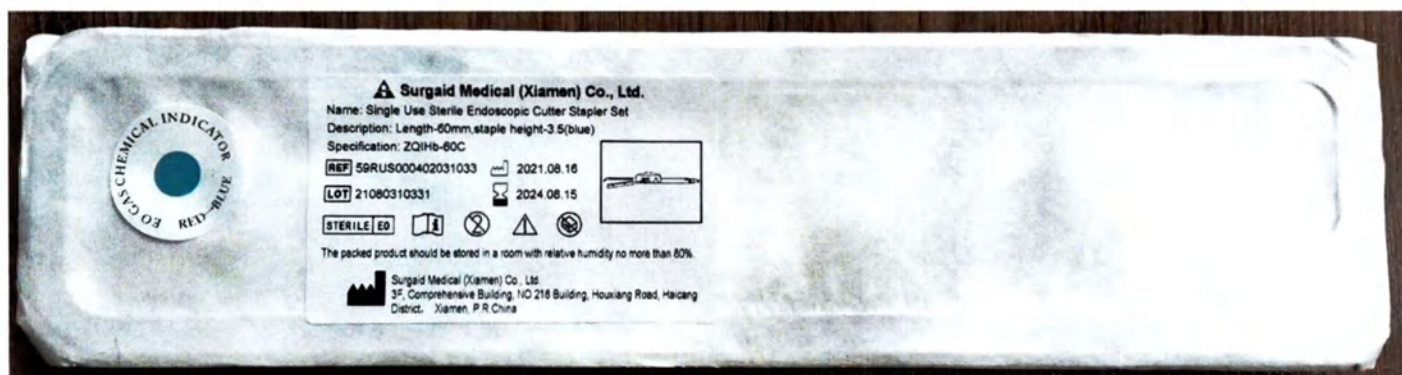


- Картридж для степлера ротационный, с загибом: ZQIHb-60A – не более 6 шт. (при необходимости);



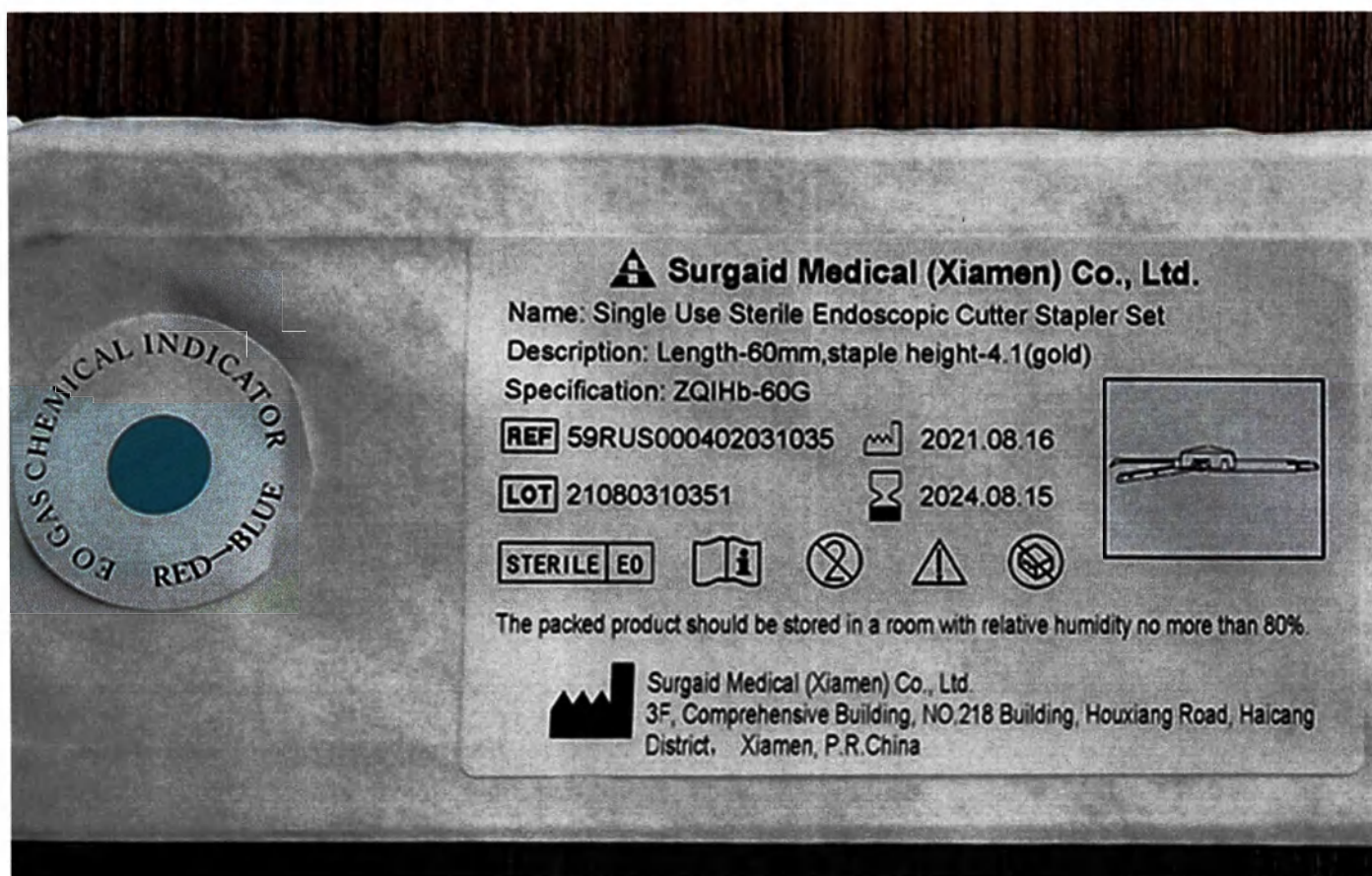
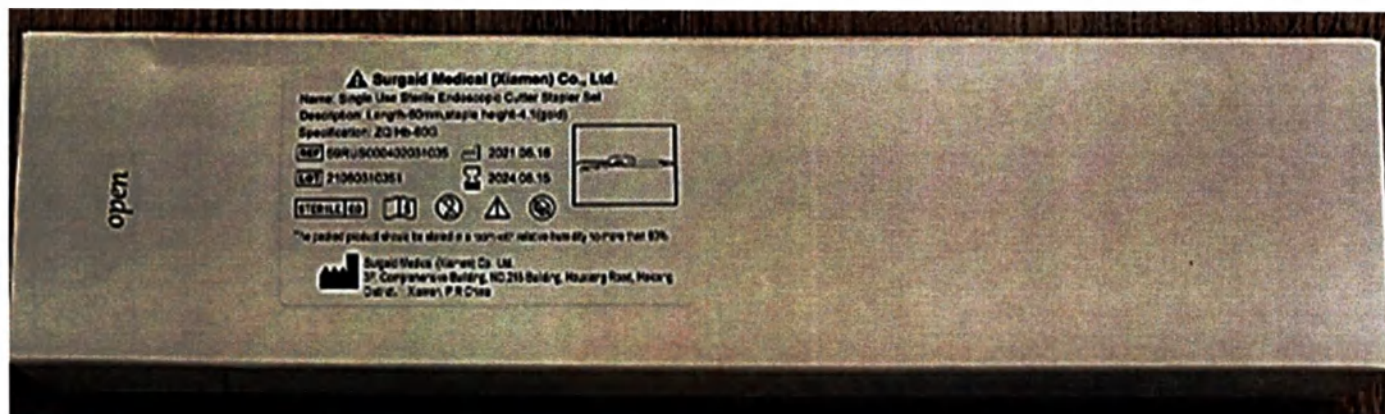


- Картридж для степлера ротационный, с загибом: ZQIHb-60C– не более 6 шт. (при необходимости);



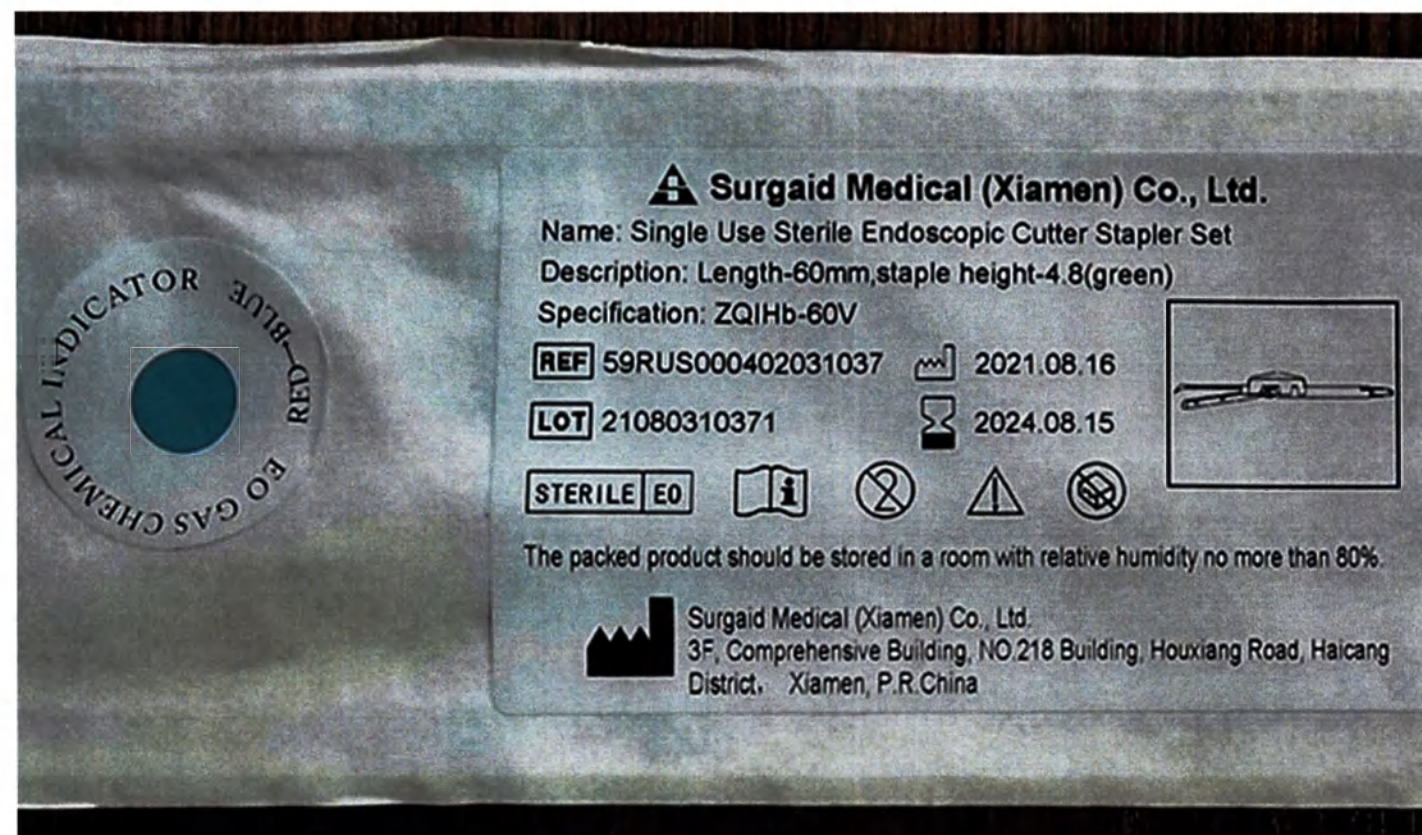
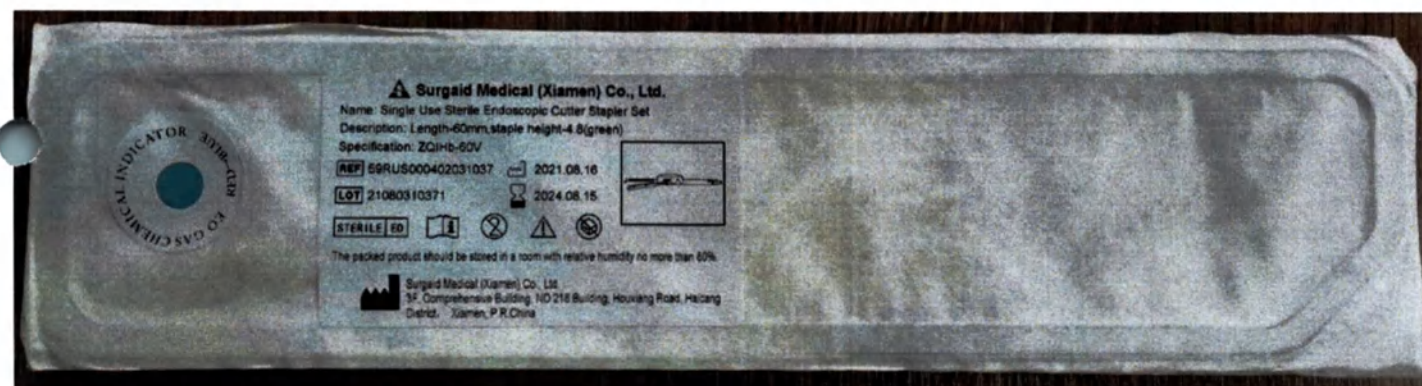
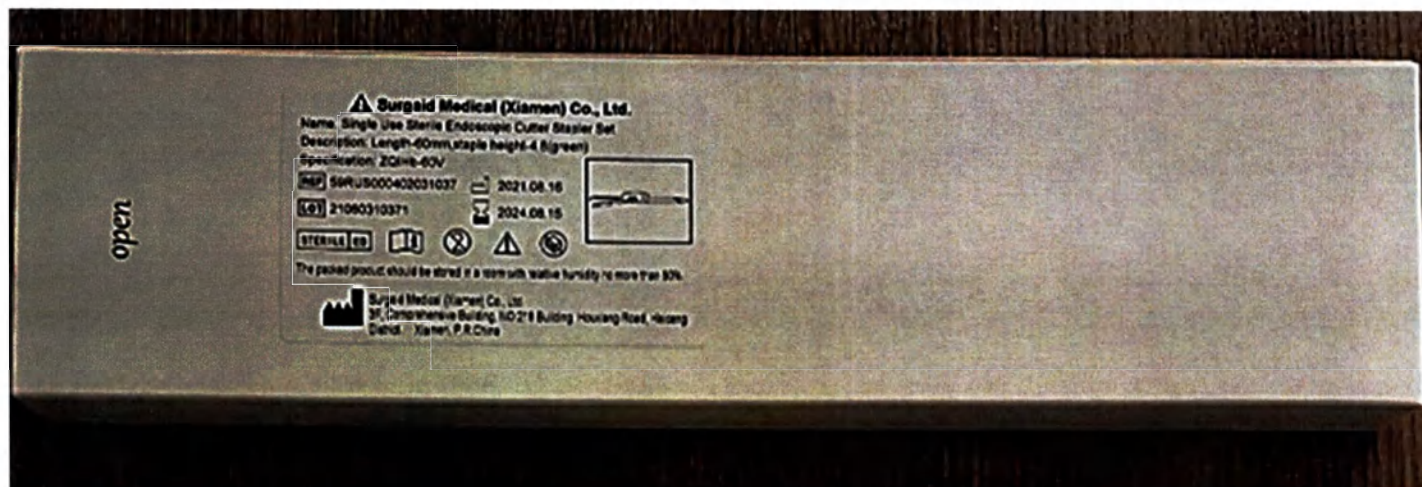


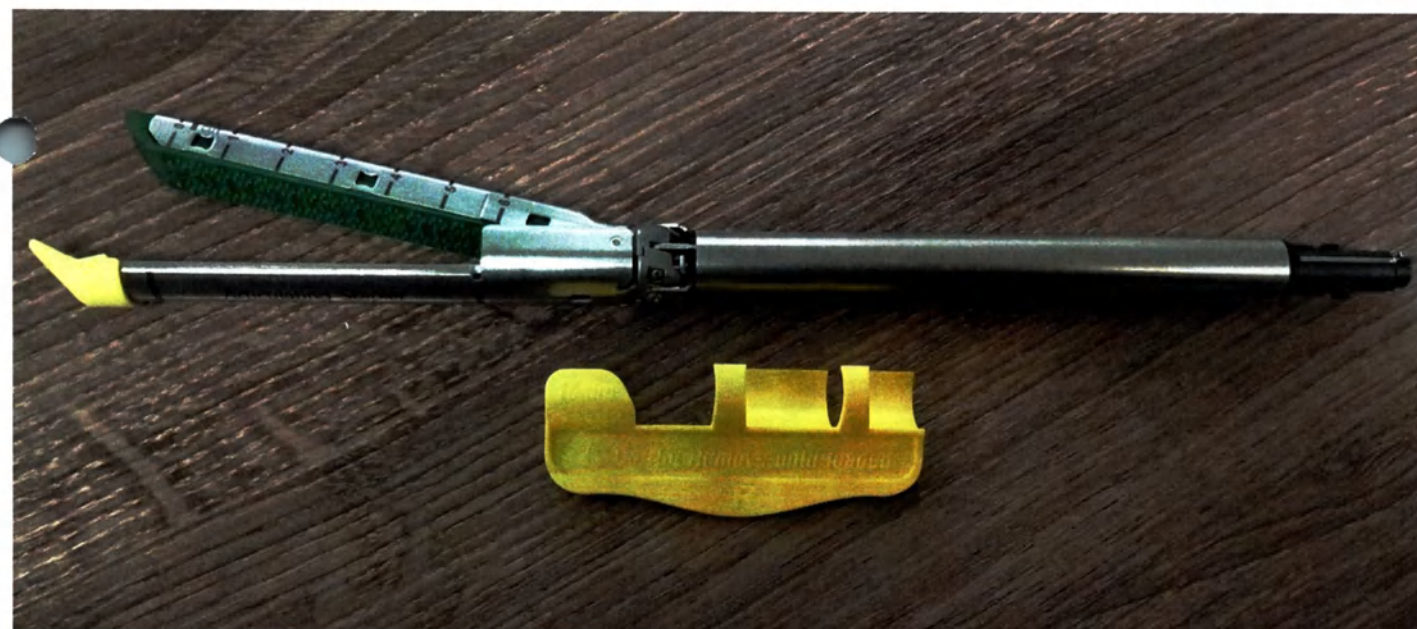
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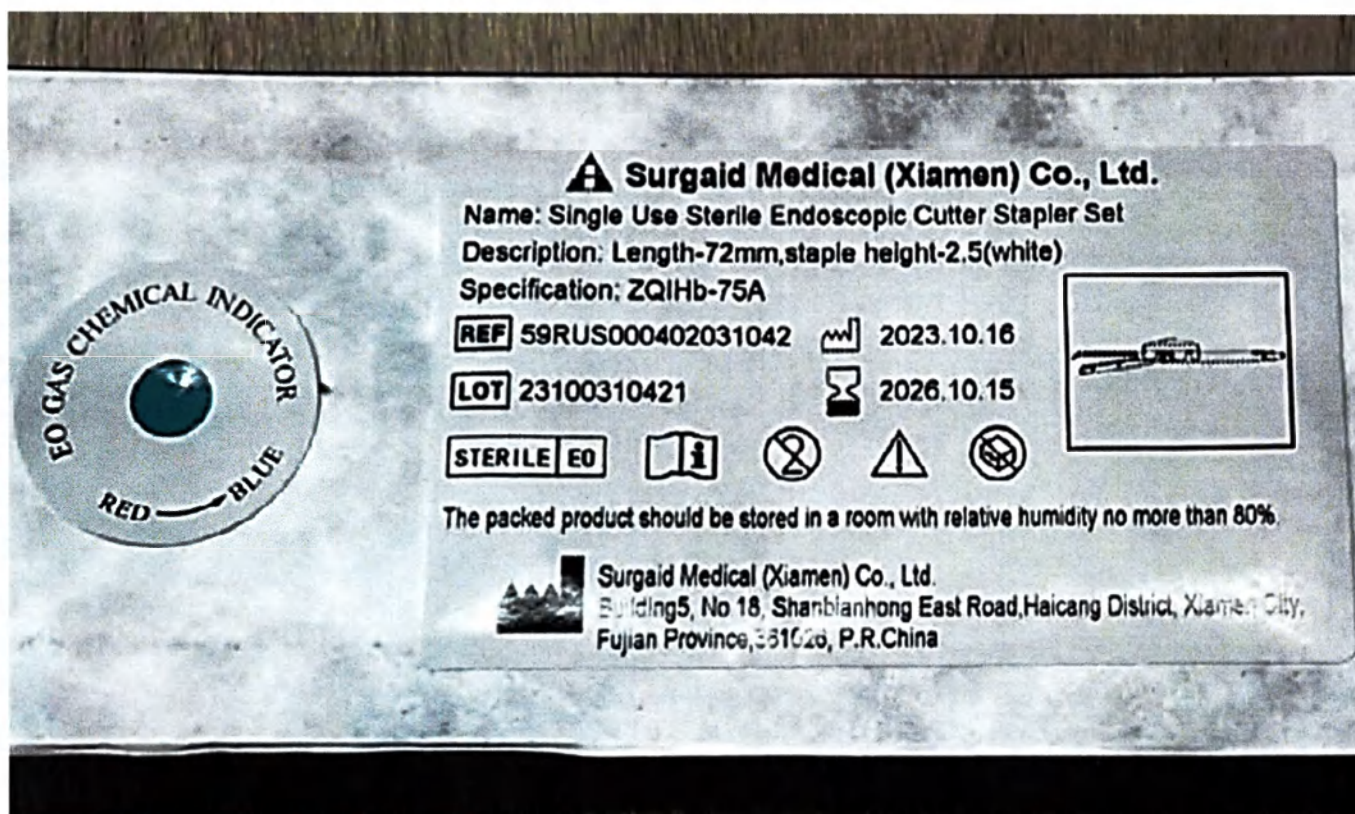
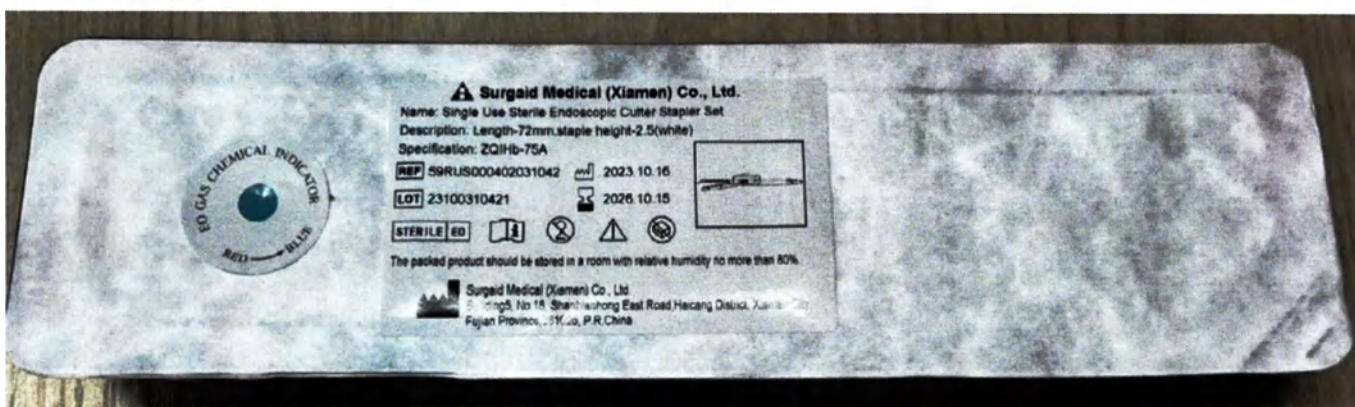
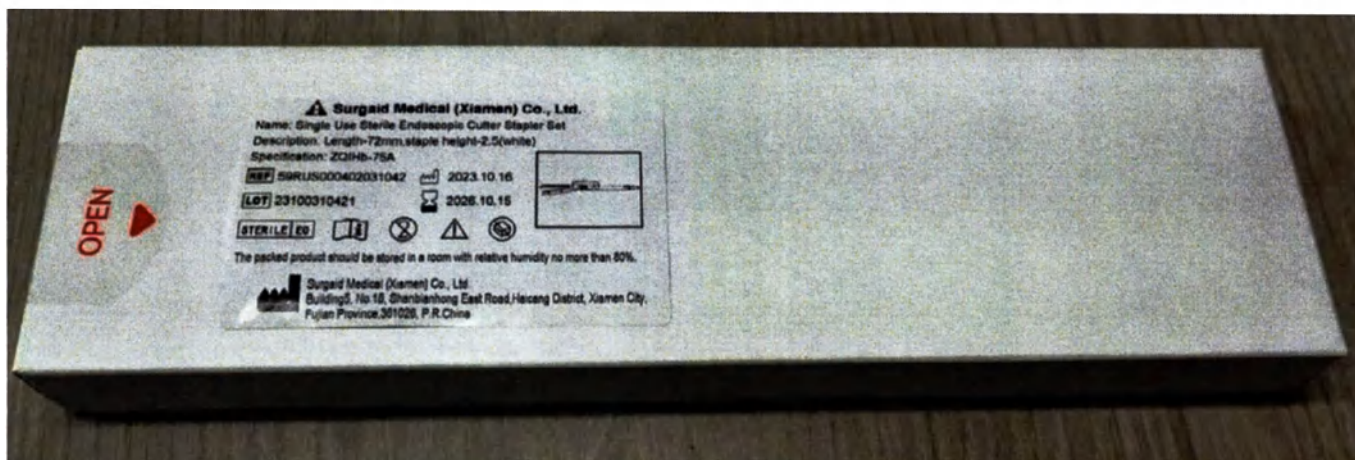


- Картридж для степлера ротационный, с загибом: ZQIHb-60V – не более 6 шт. (при необходимости);



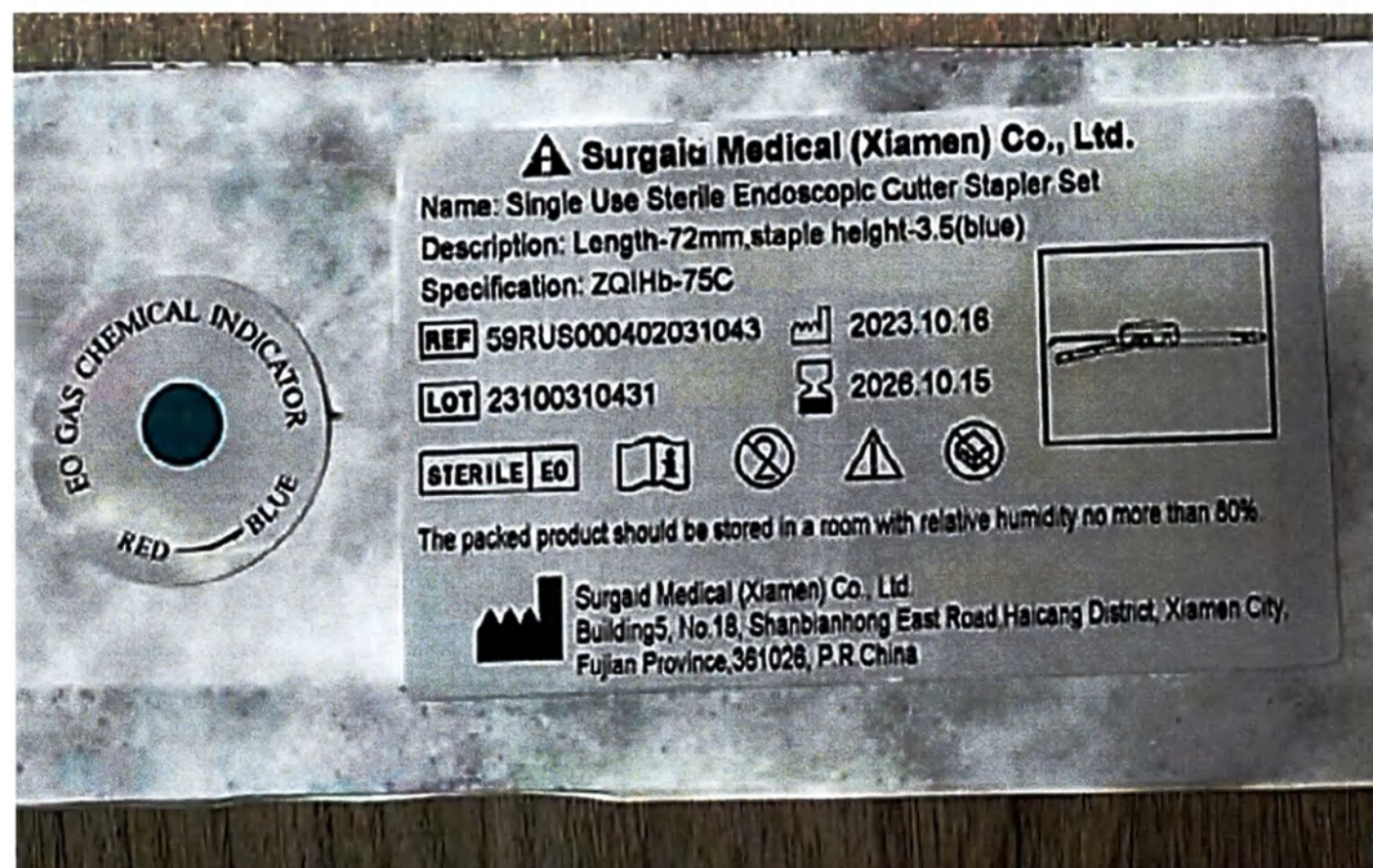
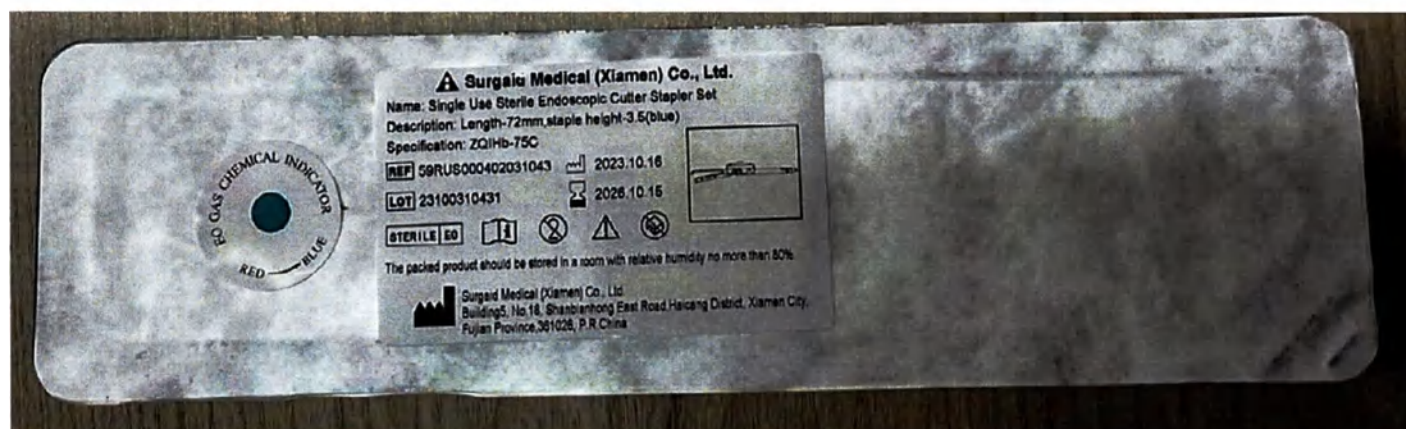
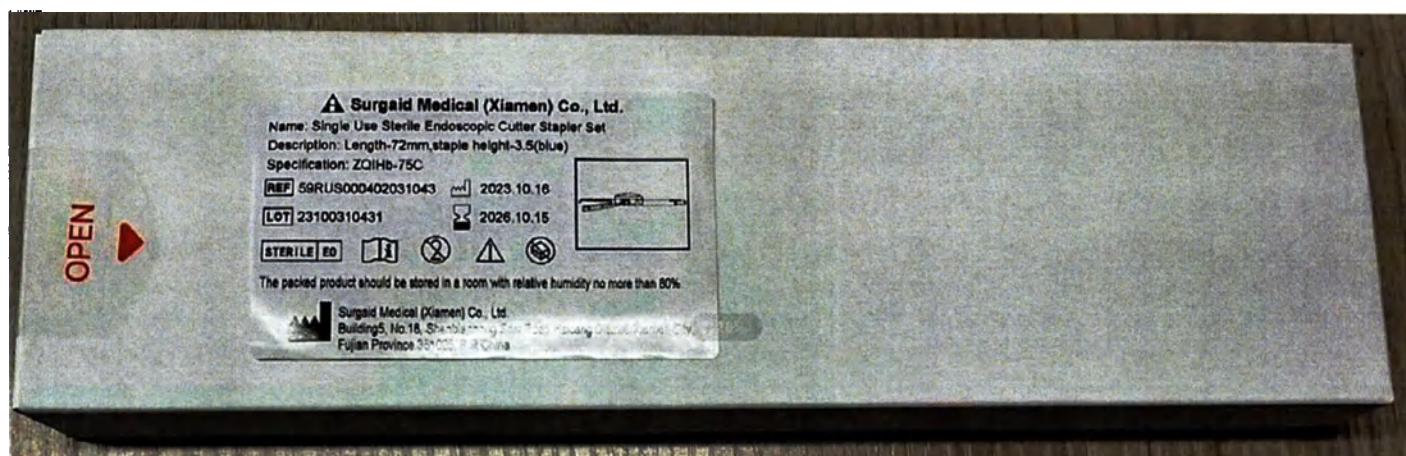


- Картридж для степлера ротационный, с загибом: ZQIHb-75A – не более 6 шт. (при необходимости);



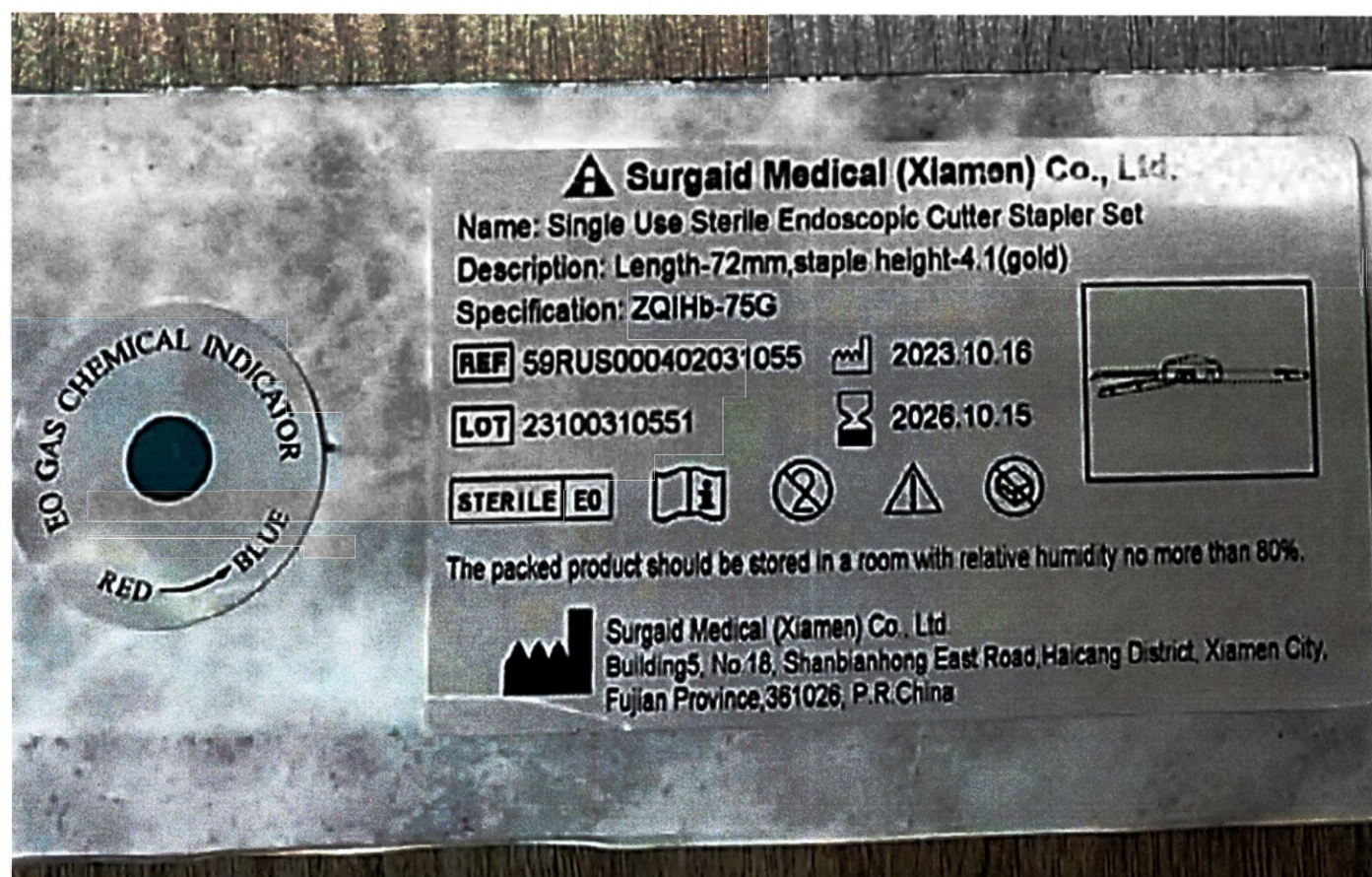
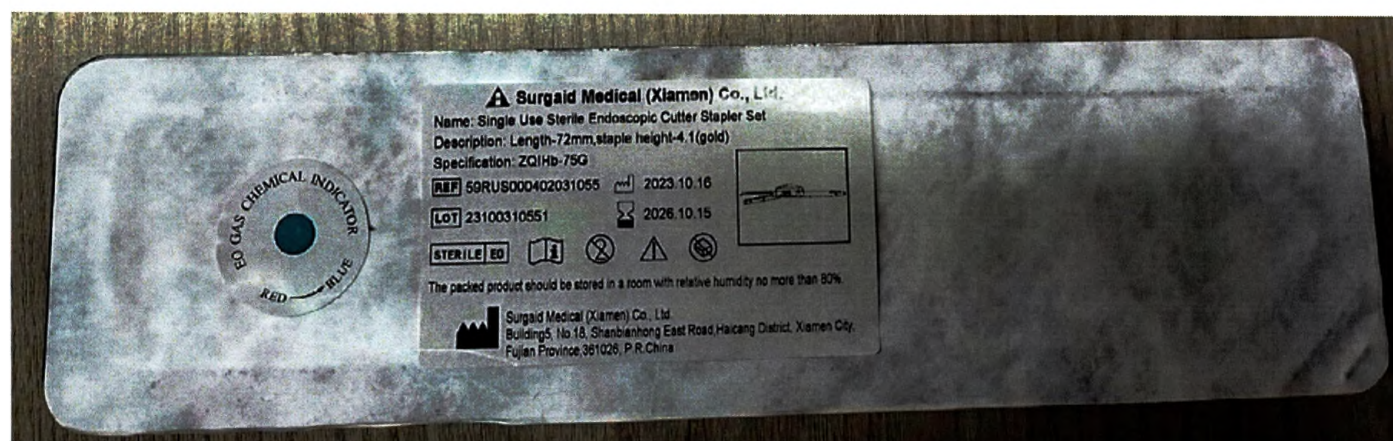
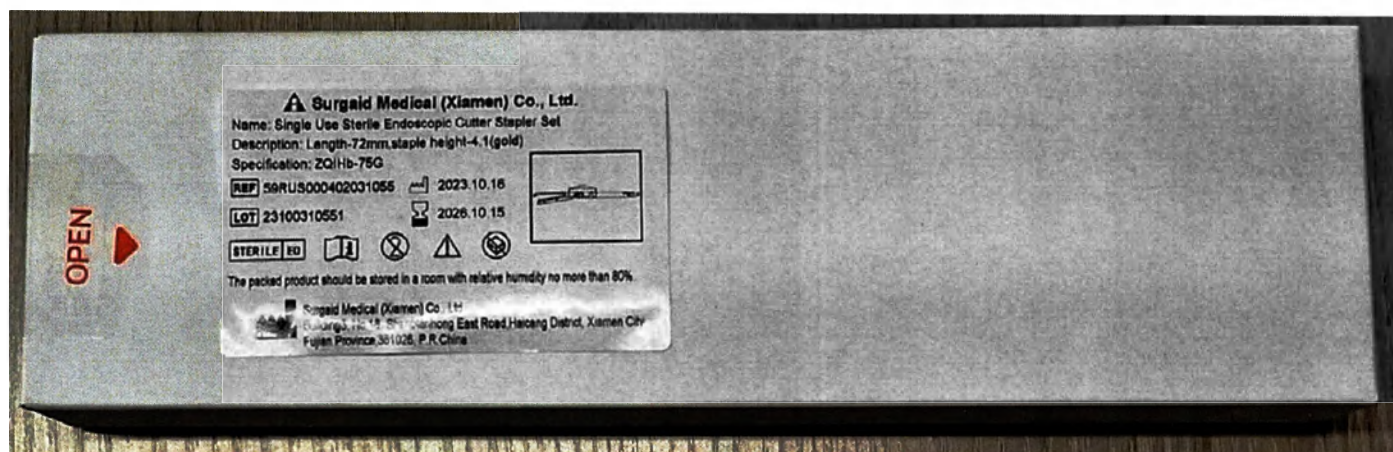


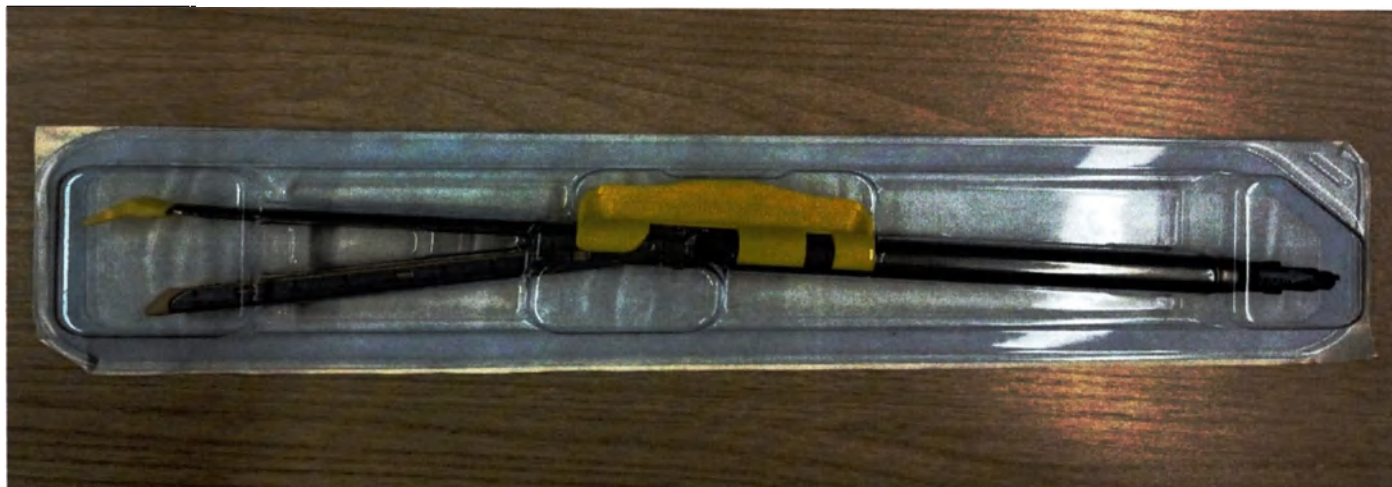
- Картридж для степлера ротационный, с загибом: ZQIHb-75C – не более 6 шт. (при необходимости);



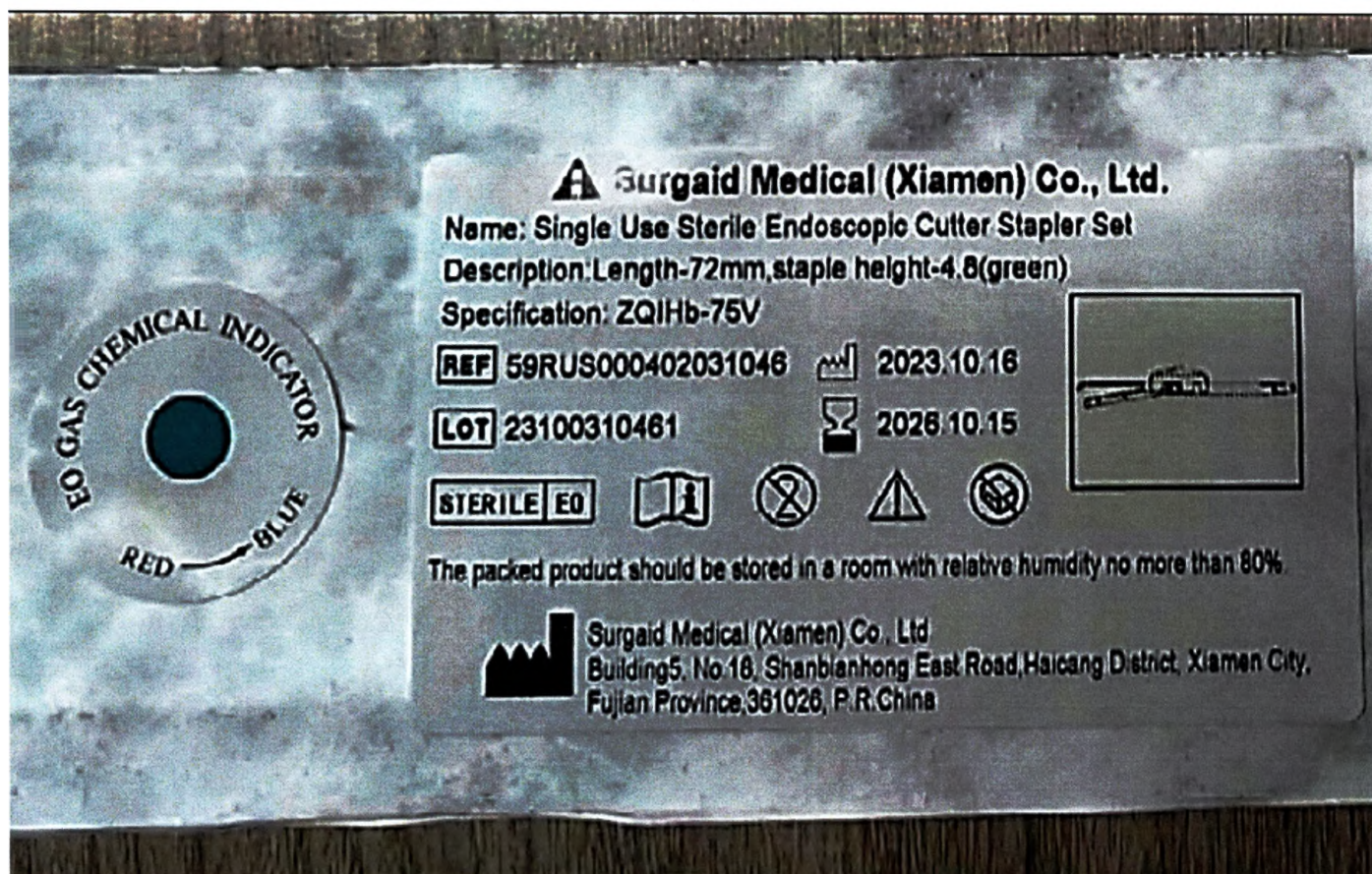
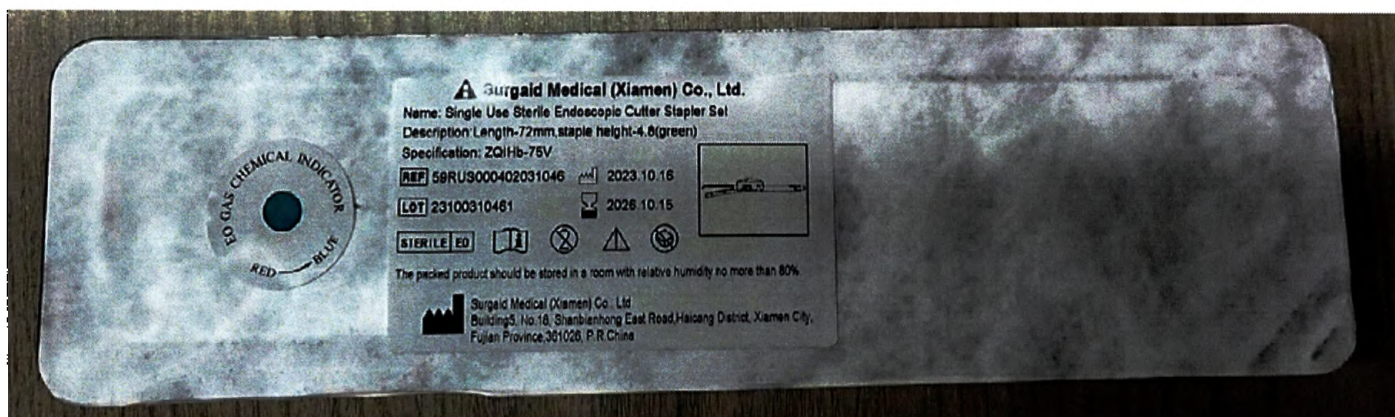
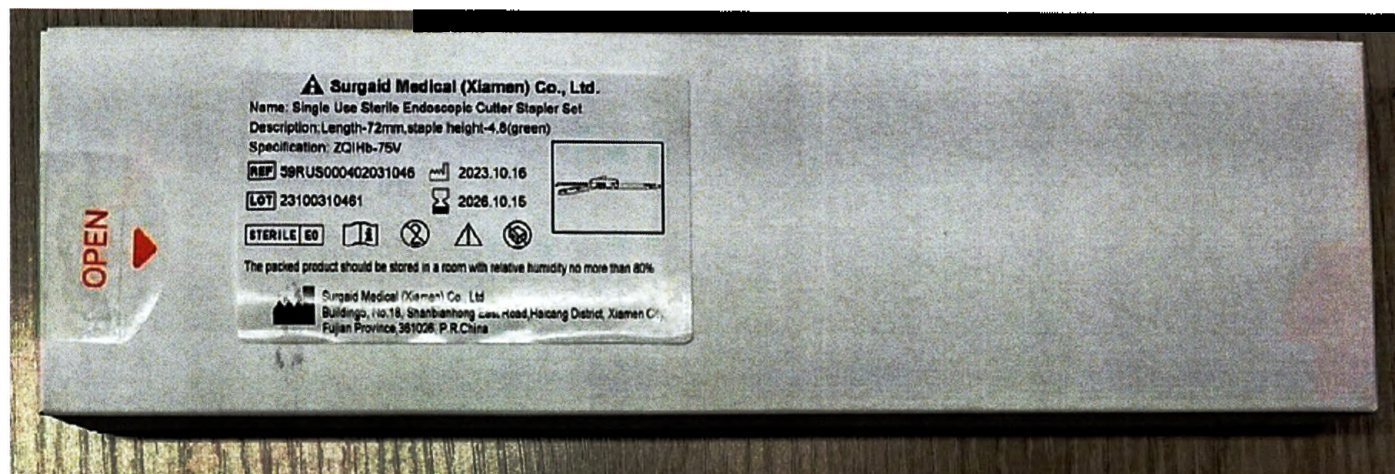


- Картридж для степлера ротационный, с загибом: ZQIHb-75G – не более 6 шт. (при необходимости);





- Картридж для степлера ротационный, с загибом: ZQIHb-75V – не более 6 шт. (при необходимости);





- 3) Инструкция по применению на Степлер хирургический одноразовый эндоскопический с одинарной рукояткой, Степлер хирургический одноразовый эндоскопический с двойной рукояткой – 1 шт.

Instruction for Use

I. Device Name:

Single Use Sterile Endoscopic Cutter Stapler Set

II. Product performance and major components

1. Performance:

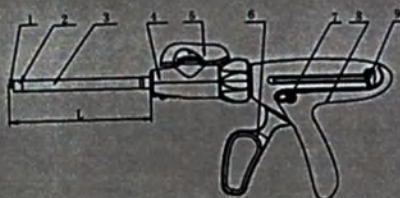
- Appearance:** The Endoscopic Cutter Stapler has smooth surface and well-defined contour without defects such as burrs, scratches or rust. Marks and indications on the outer surface are legible and aligned without malposition. The surface shall not contain any burr or flange.
- Flexibility:** Opening and closure of the stapler shall be flexible without jam. The reset spring shall be elastic enough to ensure complete reset of handle when the reset button is pressed.
- Assemblability:** Replacement of cartridge shall be convenient and positions fixed tightly; the staple shall not project out over the surface of reload when the cartridge is swung.
- Performance of resection and anastomosis:** The product shall perform well in anastomosis and resection for ≥ 5 times. The cartridge is replaceable and a B-shaped staple shall be formed after each anastomosis.
- The anastomotic area shall endure pressure of ≥ 3.6 KPa and no more than 10 drops of water are leaked within 15 seconds.**
- Surface roughness:** The outer surface roughness (Ra) of metal part of stapler shall not exceed $0.8 \mu\text{m}$.
- Corrosion resistance:** The anvil jaw shall have good corrosion resistance.
- The product shall be sterile. The residual ethylene oxide shall not exceed $10 \mu\text{g/g}$.**

2. Major components:

The Endoscopic Cutter Stapler (Model F) is mainly composed of an articulating joint, a shaft sleeve, an outer sleeve, a rotating handle, a swaying handle, a firing handle, a firing insurance, a fixed handle and a reset knob.

The Endoscopic Cutter Stapler (Model D) is mainly composed of reload unit, anvil jaw, cartridge jaw, cutter, outer sleeve, rotating handle, blade direction switch, blade direction indicator, fixed handle, reset button, locking handle and firing handle.

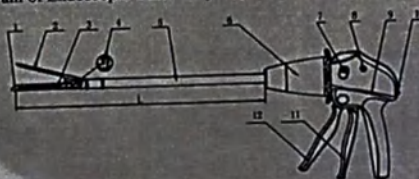
The cartridge is mainly composed of anvil jaw, reload, cutter, outer sleeve, and retaining cap. The structural diagrams of Endoscopic Cutter Stapler (Model F) are listed below:



1. Articulating joint; 2. Shaft sleeve; 3. Outer sleeve; 4. Rotating handle; 5. Swaying handle; 6. Firing handle; 7. Firing insurance; 8. Fixed handle 9. Reset knob

Figure 1. Structural diagram of Model F

The structural diagram of Endoscopic Cutter Stapler (Model with D) is listed below:

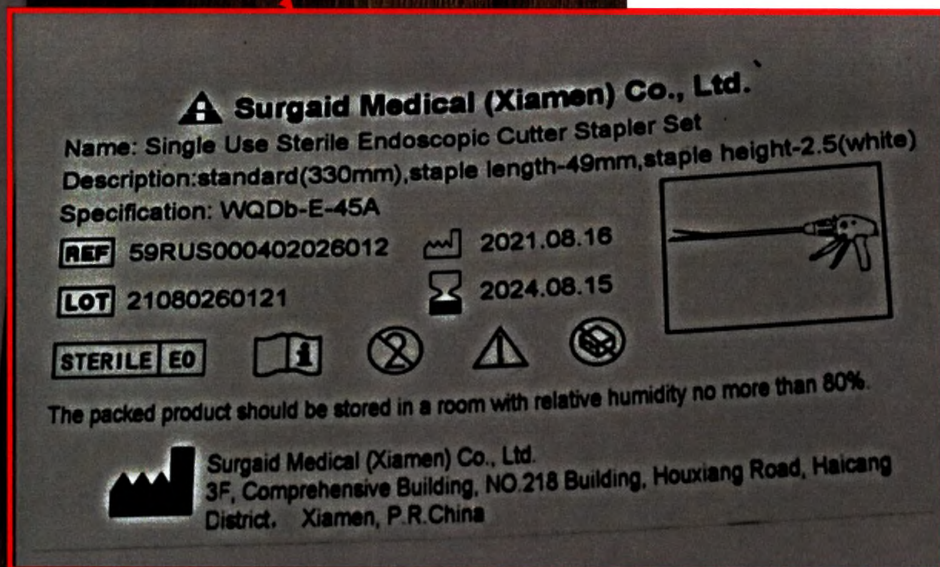
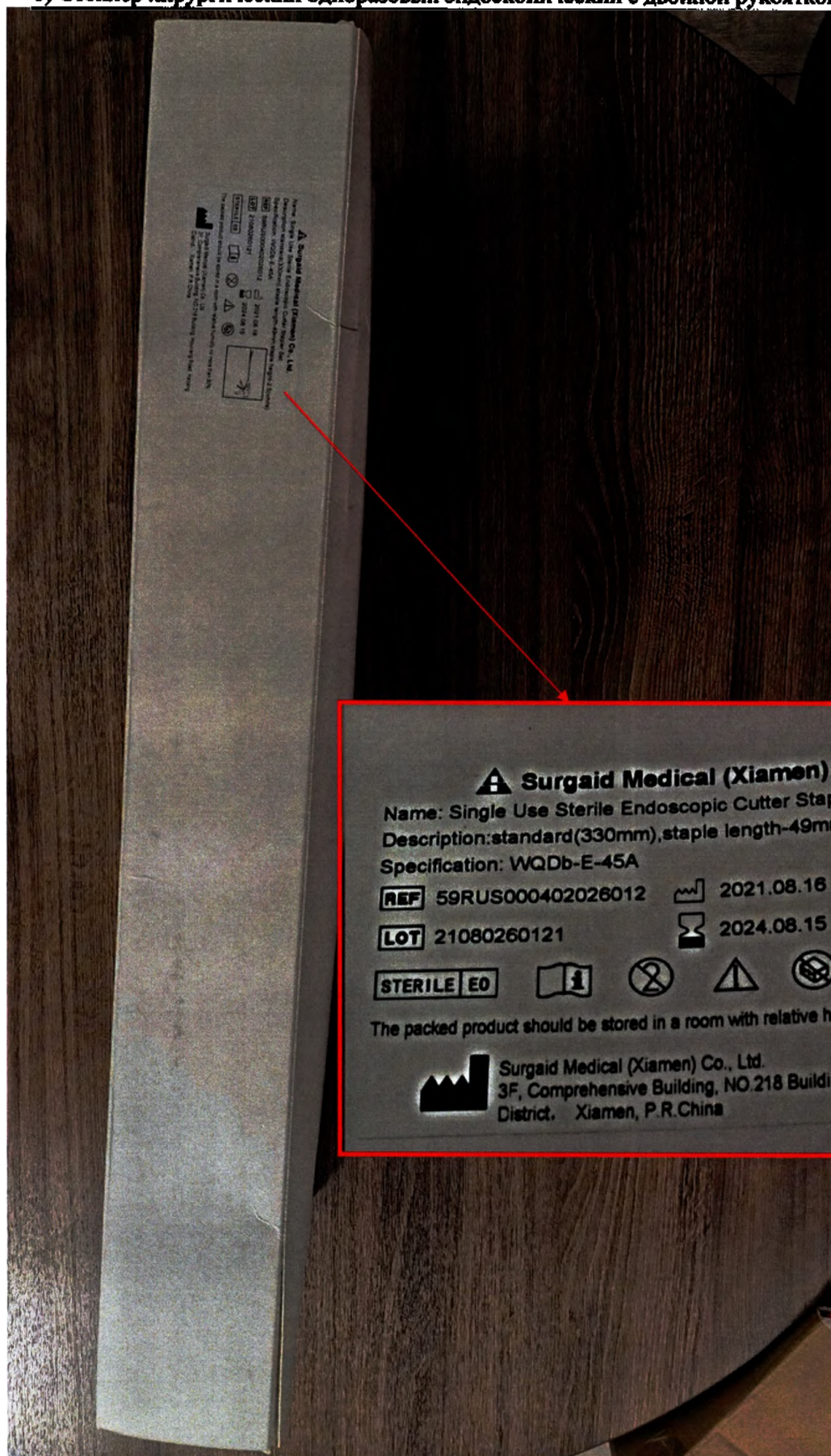


1. Reload 2. Anvil 3. Cartridge jaw 4. Cutter 5. Outer sleeve 6. Rotating handle 7. Blade direction switch 8. Blade direction indicator 9. Fixed handle 10. Reset button 11. Locking handle 12. Firing handle

Figure 2. Structural diagram of Model with D

Степлер хирургический одноразовый эндоскопический с двойной рукояткой: WQDb-E-45A, в составе:

1) Степлер хирургический одноразовый эндоскопический с двойной рукояткой: WQDb-E-45A – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Endoscopic Cutter Stapler Set
Description: standard(330mm),staple length-49mm,staple height-2.5(white)
Specification: WQDb-E-45A
REF: 59RUS000402026012 2021.08.16
LOT: 21080260121 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

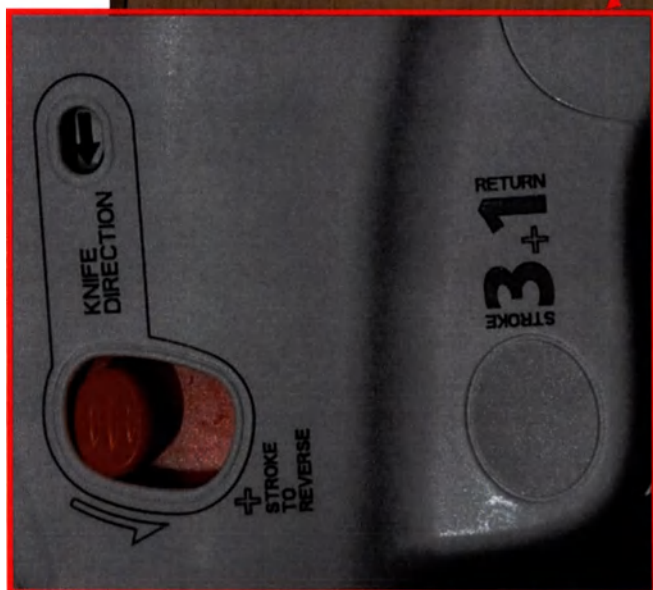
Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Endoscopic Cutter Stapler Set
Description: standard(330mm),staple length-49mm,staple height-2.5(white)
Specification: WQDb-E-45A

REF 59RUS000402026012	2021.08.16	
LOT 21080260121	2024.08.15	

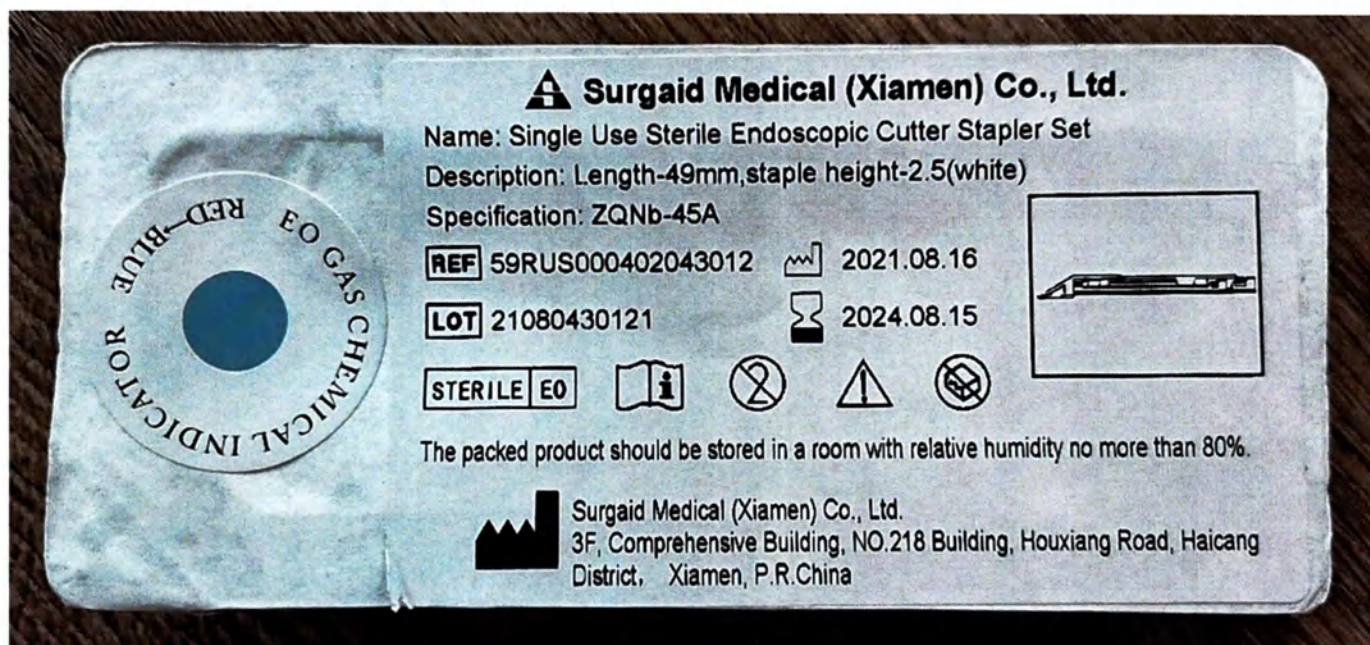
STERILE EO

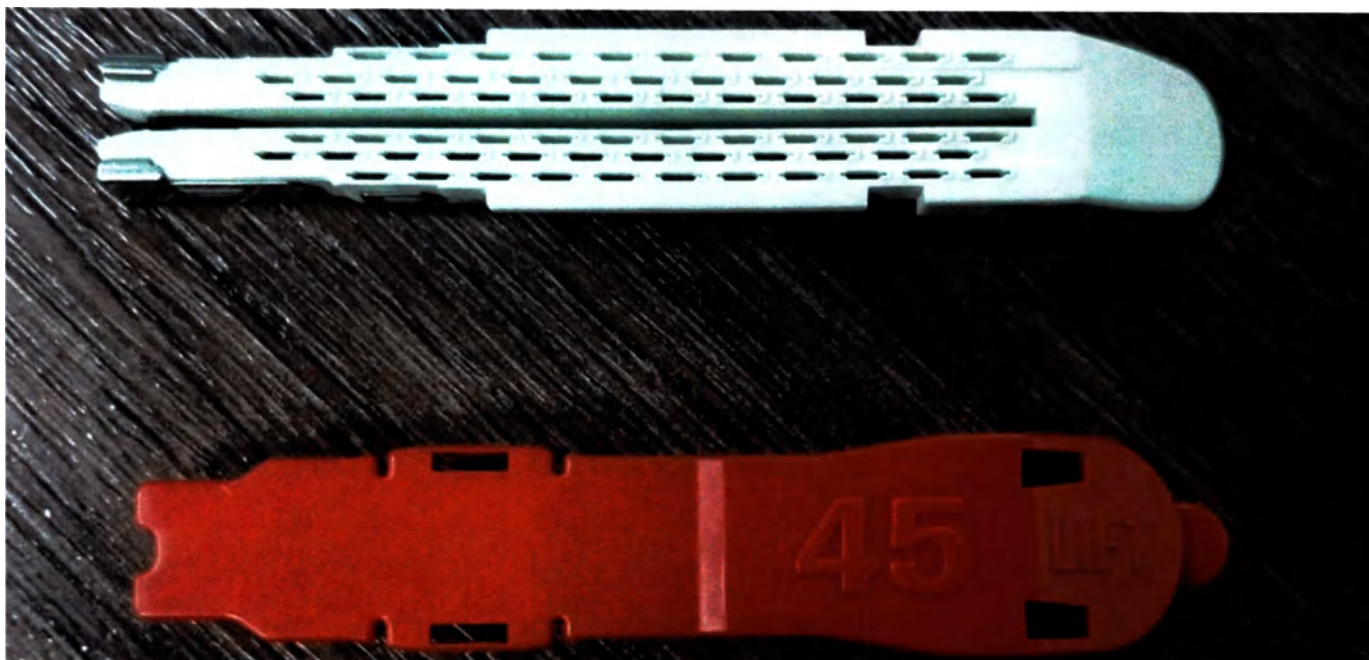
The packed product should be stored in a room with relative humidity no more than 80%.

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3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



2) Картридж для степлера: ZQNb-45A – не более 6 шт.;





- 3) Инструкция по применению на Степлер хирургический одноразовый эндоскопический с одинарной рукояткой, Степлер хирургический одноразовый эндоскопический с двойной рукояткой – 1 шт.

Instruction for Use

I. Device Name:

Single Use Sterile Endoscopic Cutter Stapler Set

II. Product performance and major components

1. Performance:

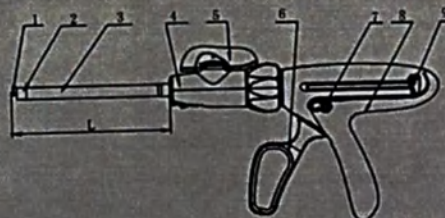
- Appearance:** The Endoscopic Cutter Stapler has smooth surface and well-defined contour without defects such as burrs, scratches or rust. Marks and indications on the outer surface are legible and aligned without malposition. The surface shall not contain any burr or flange.
- Flexibility:** Opening and closure of the stapler shall be flexible without jam. The reset spring shall be elastic enough to ensure complete reset of handle when the reset button is pressed.
- Assemblability:** Replacement of cartridge shall be convenient and positions fixed tightly; the staple shall not project out over the surface of reload when the cartridge is swung.
- Performance of resection and anastomosis:** The product shall perform well in anastomosis and resection for ≥ 5 times. The cartridge is replaceable and a B-shaped staple shall be formed after each anastomosis.
- The anastomotic area shall endure pressure of ≥ 3.6 KPa and no more than 10 drops of water are leaked within 15 seconds.**
- Surface roughness:** The outer surface roughness (Ra) of metal part of stapler shall not exceed $0.8 \mu\text{m}$.
- Corrosion resistance:** The anvil jaw shall have good corrosion resistance.
- The product shall be sterile. The residual ethylene oxide shall not exceed $10 \mu\text{g/g}$.**

2. Major components:

The Endoscopic Cutter Stapler (Model F) is mainly composed of an articulating joint, a shaft sleeve, an outer sleeve, a rotating handle, a swaying handle, a firing handle, a firing insurance, a fixed handle and a reset knob.

The Endoscopic Cutter Stapler (Model D) is mainly composed of reload unit, anvil jaw, cartridge jaw, cutter, outer sleeve, rotating handle, blade direction switch, blade direction indicator, fixed handle, reset button, locking handle and firing handle.

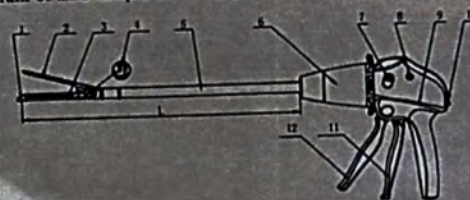
The cartridge is mainly composed of anvil jaw, reload, cutter, outer sleeve, and retaining cap. The structural diagrams of Endoscopic Cutter Stapler (Model F) are listed below:



1. Articulating joint; 2. Shaft sleeve; 3. Outer sleeve; 4. Rotating handle; 5. Swaying handle; 6. Firing handle; 7. Firing insurance; 8. Fixed handle 9. Reset knob

Figure 1. Structural diagram of Model F

The structural diagram of Endoscopic Cutter Stapler (Model with D) is listed below:

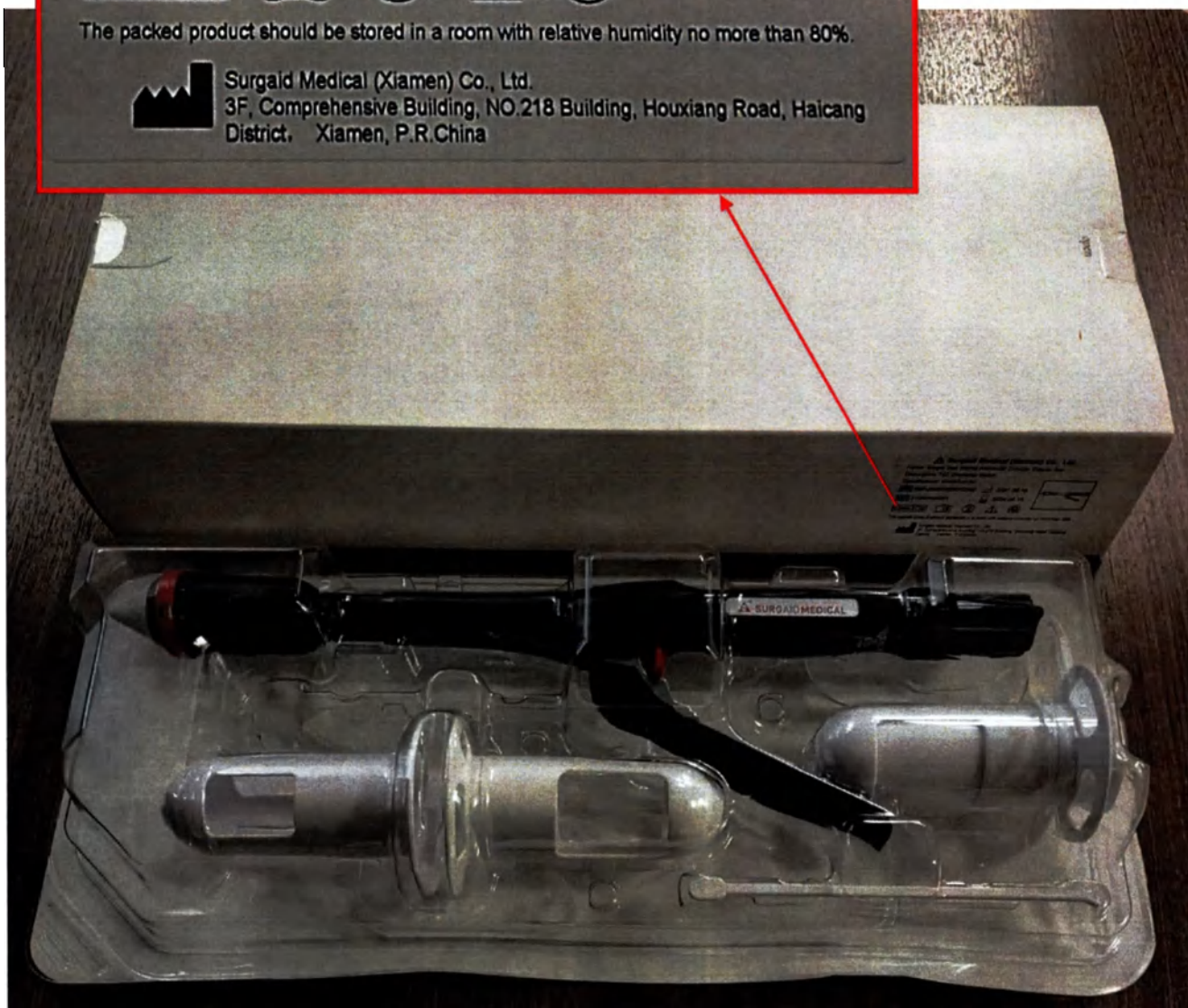
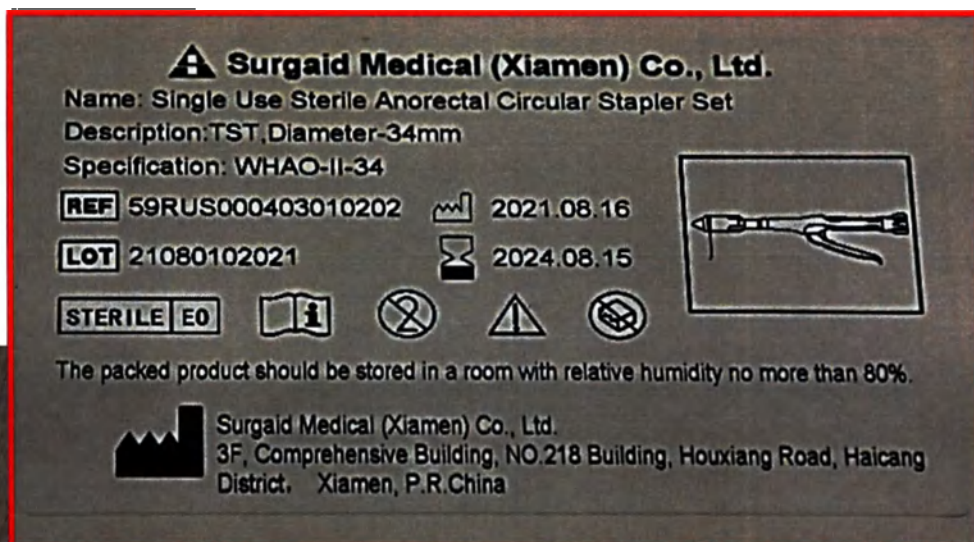


1. Reload 2. Anvil 3. Cartridge jaw 4. Cutter 5. Outer sleeve 6. Rotating handle 7. Blade direction switch 8. Blade direction indicator 9. Fixed handle 10. Reset button 11. Locking handle 12. Firing handle

Figure 2. Structural diagram of Model with D

Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, тип окна с непрозрачным картриджем: WHAO-II-34, в составе:

- 1) Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, тип окна с непрозрачным картриджем: WHAO-II-34 – 1 шт.;
- 2) Втулка опорная с одним отверстием – 1 шт.;
- 3) Втулка опорная с двумя отверстиями – 1 шт.;
- 4) Втулка опорная с тремя отверстиями – 1 шт.;
- 5) Сердечник для опорных втулок – 1 шт.;
- 6) Вилка переключающая – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Anorectal Circular Stapler Set
Description: TST, Diameter-34mm
Specification: WHAO-II-34

REF 59RUS000403010202 2021.08.16
LOT 21080102021 2024.08.15

STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%

Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China

Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Anorectal Circular Stapler Set
Description: TST, Diameter-34mm
Specification: WHAO-II-34

REF 59RUS000403010202 2021.08.16

LOT 21080102021 2024.08.15

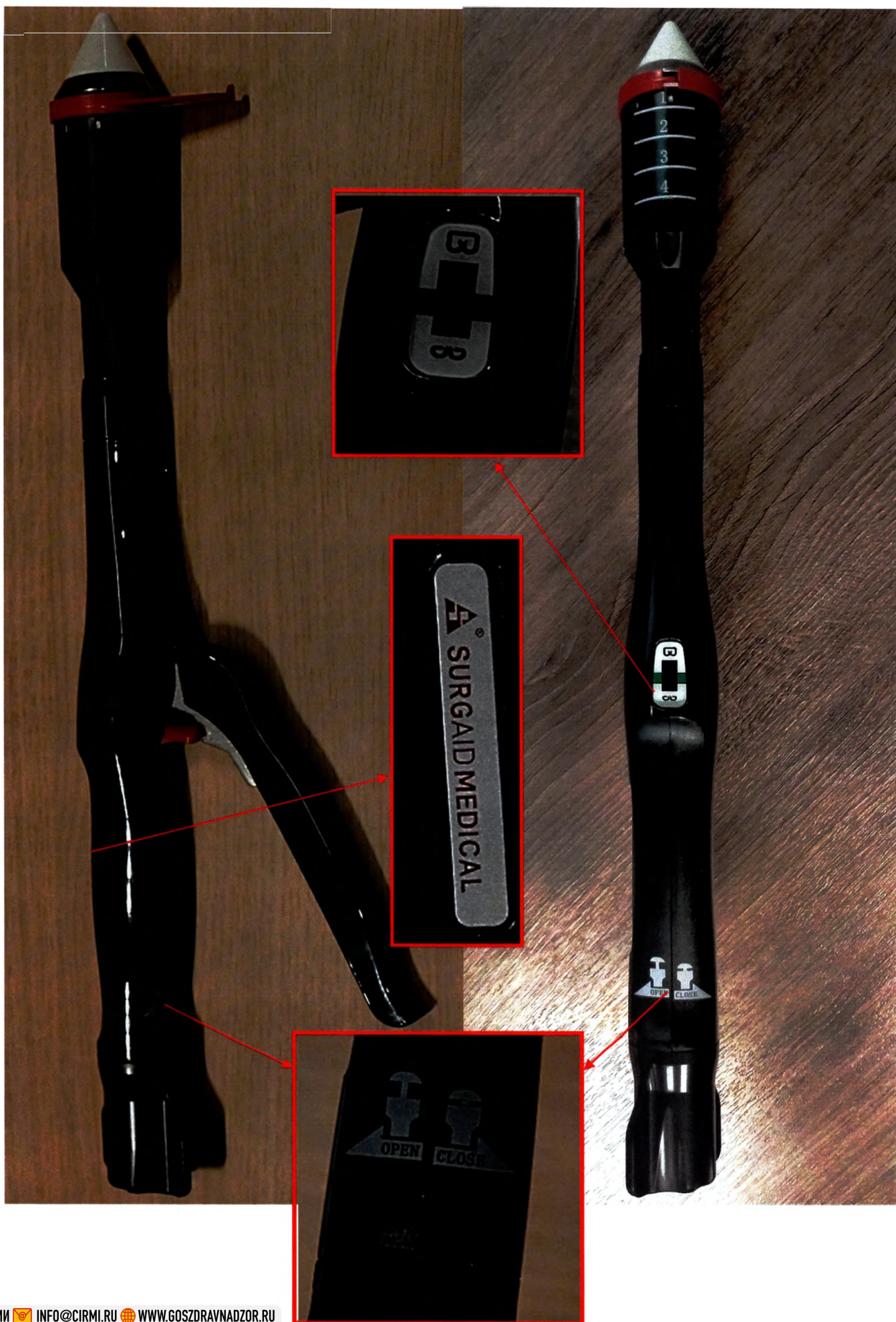
STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China



Instruction for Use

I. Device name

Single Use Sterile Anorectal Circular Stapler Set

II. Device performance

1. The surface of the stapler should be smooth, free from burrs and sharp edges, and be free of pores, cracks. The scale value or mark on the device should be clear. If the Anvil assembly of the stapler can be disassembled, it should be smoothly assembled and disassembled with the body. The head of the suture nail should be sharp, and the annular knife should not have the phenomenon of rolling edge or collapse. The safety button of anorectal stapler should be flexible and safe to use. The reset spring should be flexible enough to reset quickly when the handle is released. The two contact surfaces to be torn should be smooth and uniform without splitting or tearing. The ethylene oxide residue of the device shall not exceed 10 µg/g.
2. The anorectal stapler mainly consists of Anvil, nail cage, nail cage sleeve, fixed handle, safety button, movable handle, adjusting nut, cushion cutter ring, ring knife and staple. The accessory type I is composed of supporting sleeve, anal plug, peeping sleeve and hook rod, and the type II is composed of supporting sleeve, supporting sleeve core and dial fork. The product is sterilized by ethylene oxide and should be sterile.

III. Intended use

It is applicable for optional resection of mucous membrane on the dentate line.

IV. Contraindications

1. Severe mucosal edema.
2. Hemorrhoids are heavily fibrotic.
3. Hemorrhoid tissue repeated injection of sclerosing agent.
4. Pregnant women, refractory constipation, pelvic tumors, portal hypertension and Budd-Chiari syndrome.

V. Warnings and Precautions

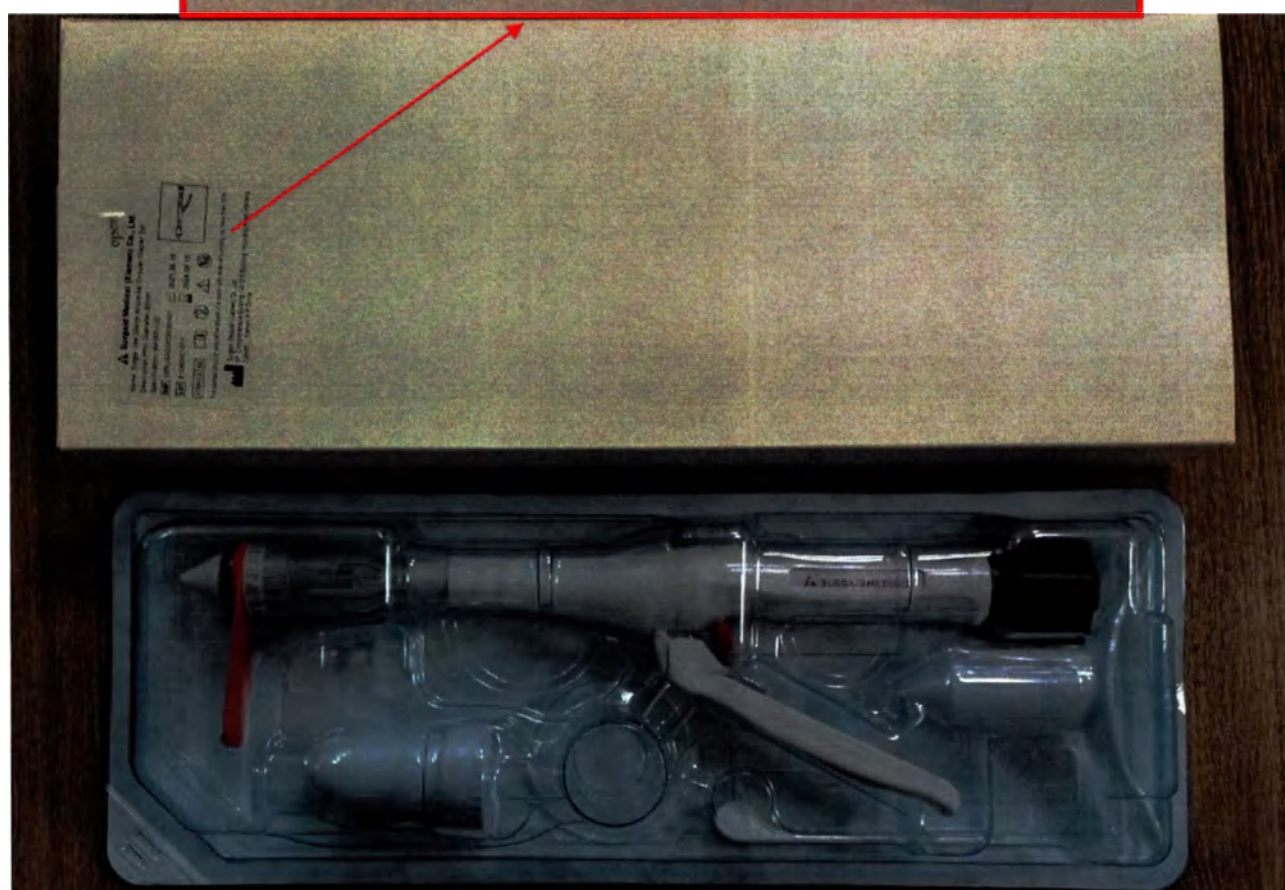
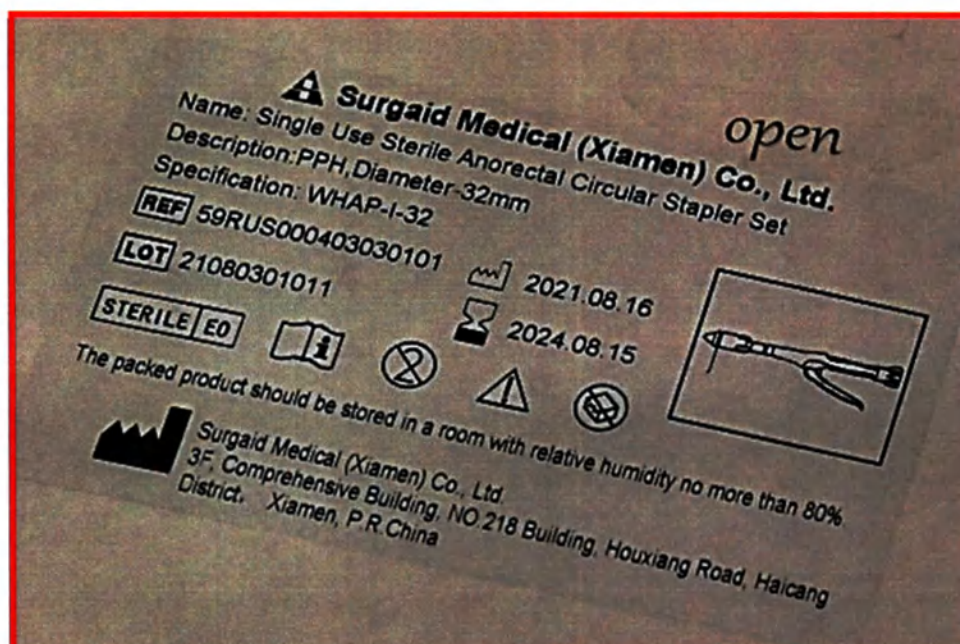
1. The device is prohibited to be use when its package opens, breaks or exceeds sterilization validity period.
2. Please read the instruction for use carefully before using the device, pay attention to the production date and expiration date of the device. The device can not be used when it exceeds its validity period.
3. The aseptic operation specification shall be strictly implemented when using the device.
4. This product is just for single use, which will be placed and handled as medical waste after used to avoid injury and environmental pollution.
5. The device is intended to be used by doctors who have been trained in stapler techniques or under the guidance of experienced physicians.
6. This manual can not be used as the basis for clinical surgical anastomosis technical guidance. For questions on clinical surgical anastomosis technical guidance, please refer to the professional literature or consult our company.
7. This procedure may cause anastomotic leakage, bleeding.
- Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
8. Disposal devices are medical waste and should be handled and disposed of according to local regulations.

VI. Instruction

1. The anal skin with less prolapse of the ankle and less anal valgus is fixed with four atraumatic forceps, so as to introduce the support sleeve and the anal plug into the anus, and fixed the dilator by suture.
2. The support sleeve and anal plug can support hemorrhoids prolapse or anal mucosa prolapse part reset, or can use anal plug to make prolapse part reset, and then introduce the support sleeve and anal plug to fix the support sleeve, and then pull out the anal plug, the prolapsed mucous membrane part falling into the support sleeve.
3. Through the peeping sleeve, the needle is inserted at 4 cm away from the dentate line, and the lower layer of rectal mucous membrane is uniformly sutured for 6-8 needles in a circle.
4. Remove the protective cover from the single use stapler assembly, rotate the adjusting nut counterclockwise to the maximum opening position (about 7.8 cm), insert the Anvil of the head of the stapler over the purse-string line, and tie the knot in the loop so that the tissue is evenly wrapped around the central rod.
5. Use the hook bar to pull out the sutures through the holes on both sides of the device, and tie the knot in the length that the finger can hook is suitable.
6. Maintain the position of the PPH head, make the PPH and the support sleeve in the same direction, rotate the adjusting nut to make the device close.

Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, открытого типа с прозрачным картриджем: WHAP-I-32, в составе:

- 1) Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, открытого типа с прозрачным картриджем: WHAP-I-32 – 1 шт.;
- 2) Втулка опорная – 1 шт.;
- 3) Пробка анальная – 1 шт.;
- 4) Втулка смотровая – 1 шт.;
- 5) Стержень с крючком – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Anorectal Circular Stapler Set

Description: PPH, Diameter-32mm

Specification: WHAP-I-32

REF 59RUS000403030101



2021.08.16

LOT 21080301011



2024.08.15



STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%.



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China

Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Anorectal Circular Stapler Set

Description: PPH, Diameter-32mm

Specification: WHAP-I-32

REF 59RUS000403030101

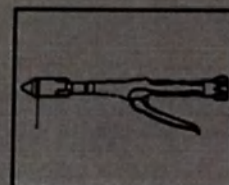


2021.08.16

LOT 21080301011



2024.08.15



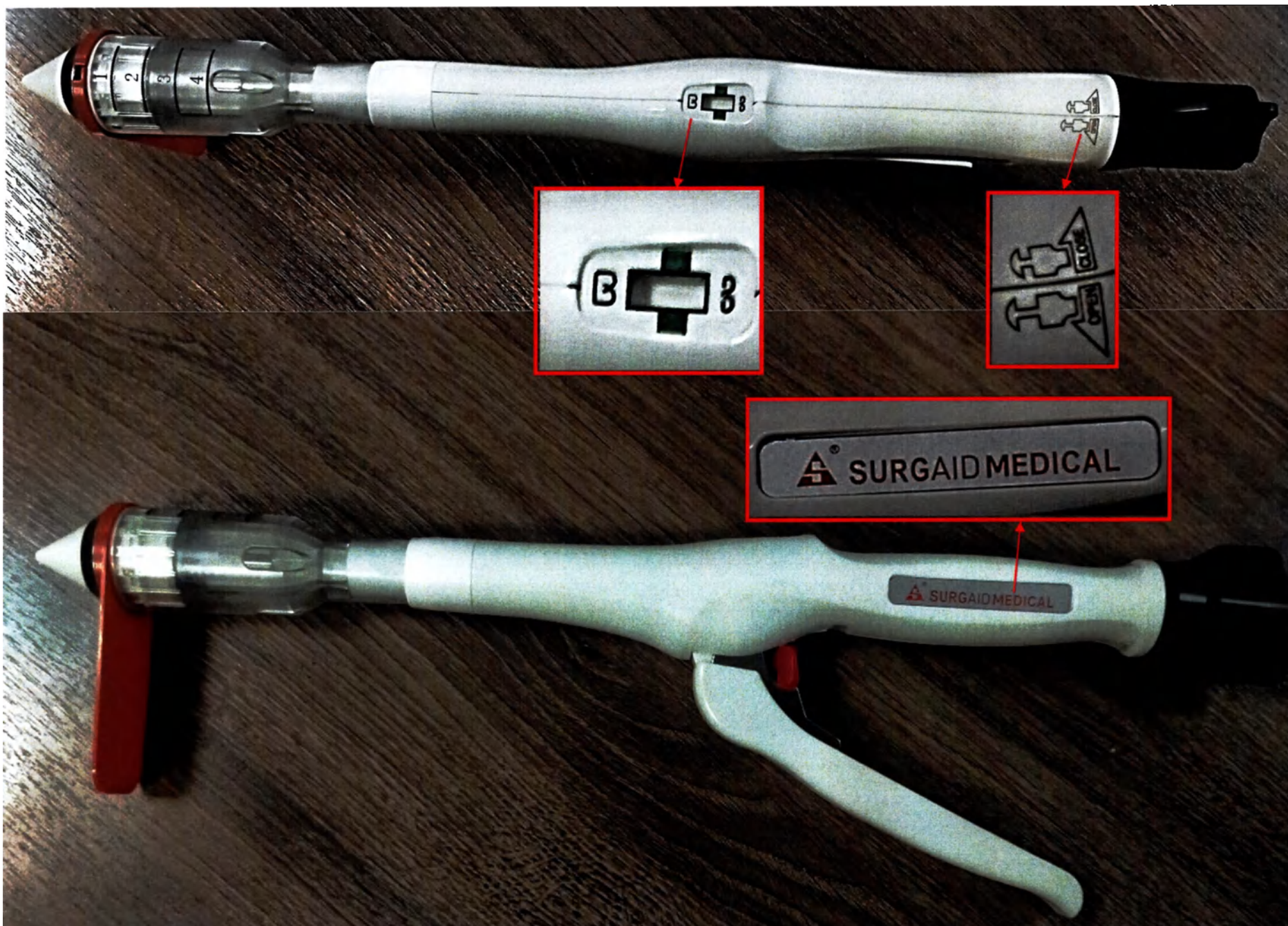
STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%.



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang
District, Xiamen, P.R.China



Instruction for Use

I. Device name

Single Use Sterile Anorectal Circular Stapler Set

II. Device performance

1. The surface of the stapler should be smooth, free from burrs and sharp edges, and be free of pores, cracks. The scale value or mark on the device should be clear. If the Anvil assembly of the stapler can be disassembled, it should be smoothly assembled and disassembled with the body. The head of the suture nail should be sharp, and the annular knife should not have the phenomenon of rolling edge or collapse. The safety button of anorectal stapler should be flexible and safe to use. The reset spring should be flexible enough to reset quickly when the handle is released. The two contact surfaces to be torn should be smooth and uniform without splitting or tearing. The ethylene oxide residue of the device shall not exceed 10 µg/g.
2. The anorectal stapler mainly consists of Anvil, nail cage, nail cage sleeve, fixed handle, safety button, movable handle, adjusting nut, cushion cutter ring, ring knife and staple. The accessory type I is composed of supporting sleeve, anal plug, peeping sleeve and hook rod, and the type II is composed of supporting sleeve, supporting sleeve core and dial fork. The product is sterilized by ethylene oxide and should be sterile.

III. Intended use

It is applicable for optional resection of mucous membrane on the dentate line.

IV. Contraindications

1. Severe mucosal edema.
2. Hemorrhoids are heavily fibrotic.
3. Hemorrhoid tissue repeated injection of sclerosing agent.
4. Pregnant women, refractory constipation, pelvic tumors, portal hypertension and Budd-Chiari syndrome.

V. Warnings and Precautions

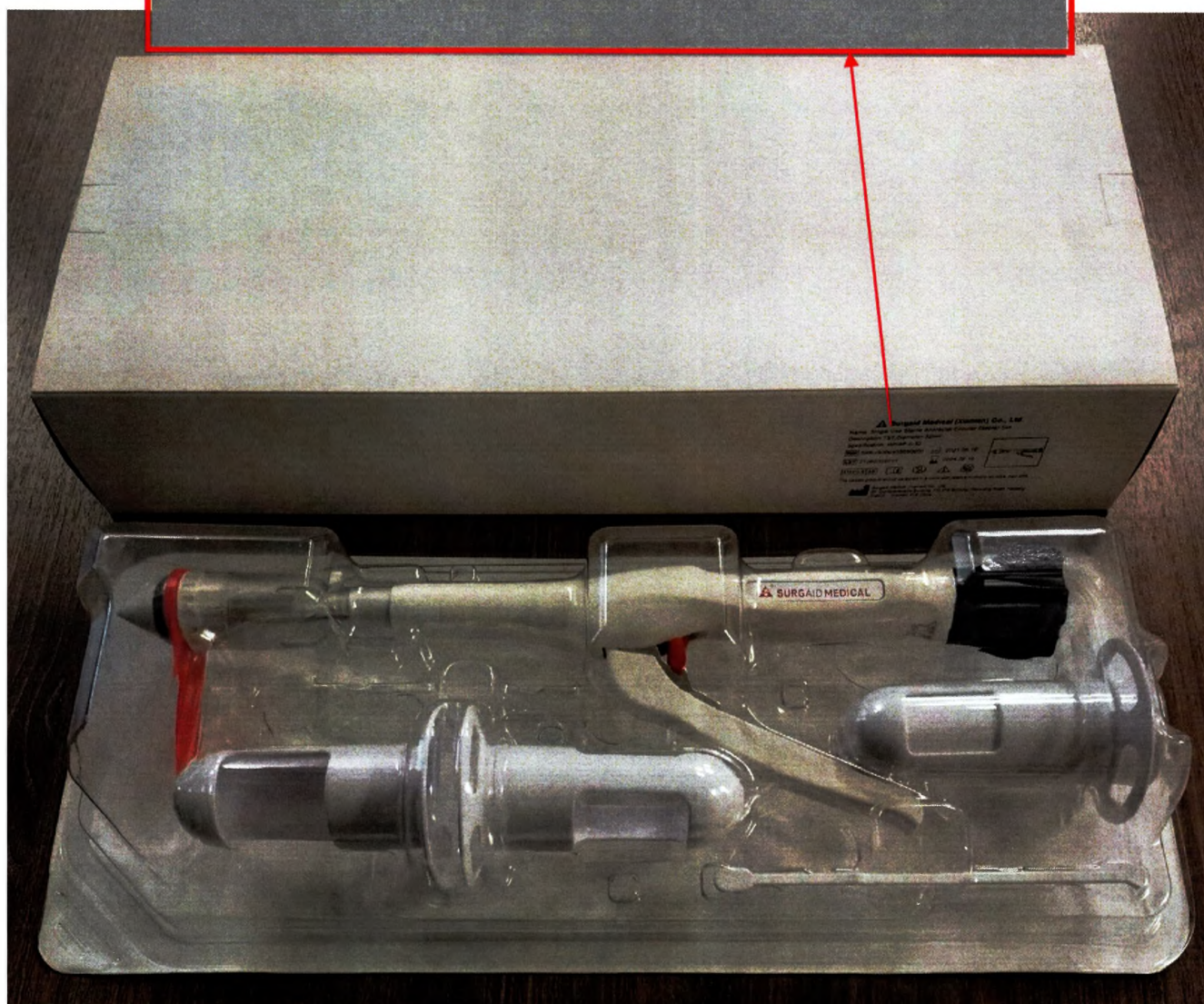
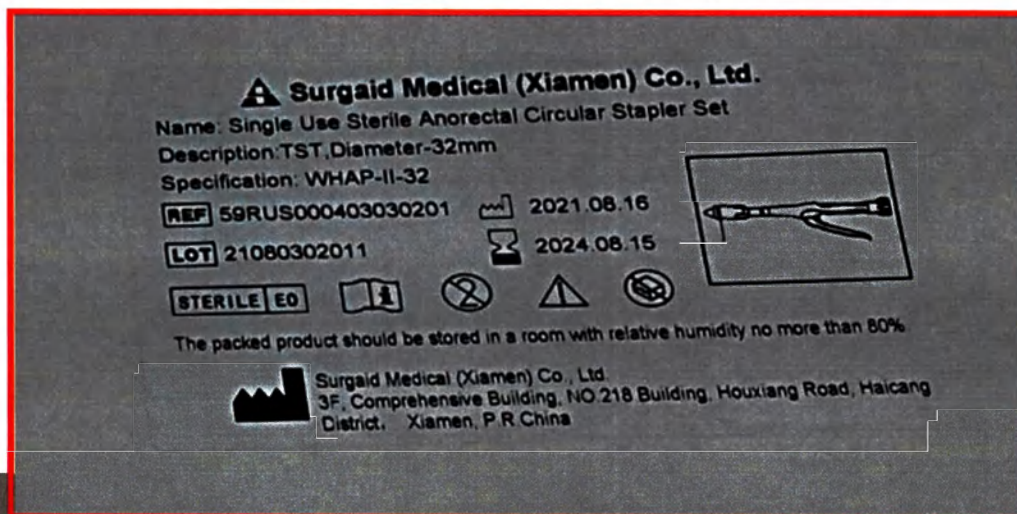
1. The device is prohibited to be used when its package opens, breaks or exceeds sterilization validity period.
2. Please read the instruction for use carefully before using the device, pay attention to the production date and expiration date of the device. The device can not be used when it exceeds its validity period.
3. The aseptic operation specification shall be strictly implemented when using the device.
4. This product is just for single use, which will be placed and handled as medical waste after used to avoid injury and environmental pollution.
5. The device is intended to be used by doctors who have been trained in stapler techniques or under the guidance of experienced physicians.
6. This manual can not be used as the basis for clinical surgical anastomosis technical guidance. For questions on clinical surgical anastomosis technical guidance, please refer to the professional literature or consult our company.
7. This procedure may cause anastomotic leakage, bleeding.
- Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
8. Disposal devices are medical waste and should be handled and disposed of according to local regulations.

VI. Instruction

1. The anal skin with less prolapse of the ankle and less anal valgus is fixed with four atraumatic forceps, so as to introduce the support sleeve and the anal plug into the anus, and fixed the dilator by suture.
2. The support sleeve and anal plug can support hemorrhoids prolapse or anal mucosa prolapse part reset, or can use anal plug to make prolapse part reset, and then introduce the support sleeve and anal plug to fix the support sleeve, and then pull out the anal plug, the prolapsed mucous membrane part falling into the support sleeve.
3. Through the peeping sleeve, the needle is inserted at 4 cm away from the dentate line, and the lower layer of rectal mucous membrane is uniformly sutured for 6-8 needles in a circle.
4. Remove the protective cover from the single use stapler assembly, rotate the adjusting nut counterclockwise to the maximum opening position (about 7.8 cm), insert the Anvil of the head of the stapler over the purse-string line, and tie the knot in the loop so that the tissue is evenly wrapped around the central rod.
5. Use the hook bar to pull out the sutures through the holes on both sides of the device, and tie the knot in the length that the finger can hook is suitable.
6. Maintain the position of the PPH head, make the PPH and the support sleeve in the same direction, rotate the adjusting nut to make the device close.

Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, тип окна с прозрачным картриджем: WHAP-II-32, в составе:

- 1) Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, тип окна с прозрачным картриджем: WHAP-II-32 – 1 шт.;
- 2) Втулка опорная с одним отверстием – 1 шт.;
- 3) Втулка опорная с двумя отверстиями – 1 шт.;
- 4) Втулка опорная с тремя отверстиями – 1 шт.;
- 5) Сердечник для опорных втулок – 1 шт.;
- 6) Вилка переключающая – 1 шт.;





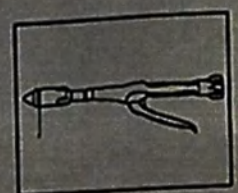
Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Anorectal Circular Stapler Set
Description: TST, Diameter-32mm
Specification: WHAP-II-32
REF: 59RUS000403030201 2021.08.16
LOT: 21080302011 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%.
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Anorectal Circular Stapler Set
Description: TST, Diameter-32mm
Specification: WHAP-II-32

REF: 59RUS000403030201 2021.08.16
LOT: 21080302011 2024.08.15

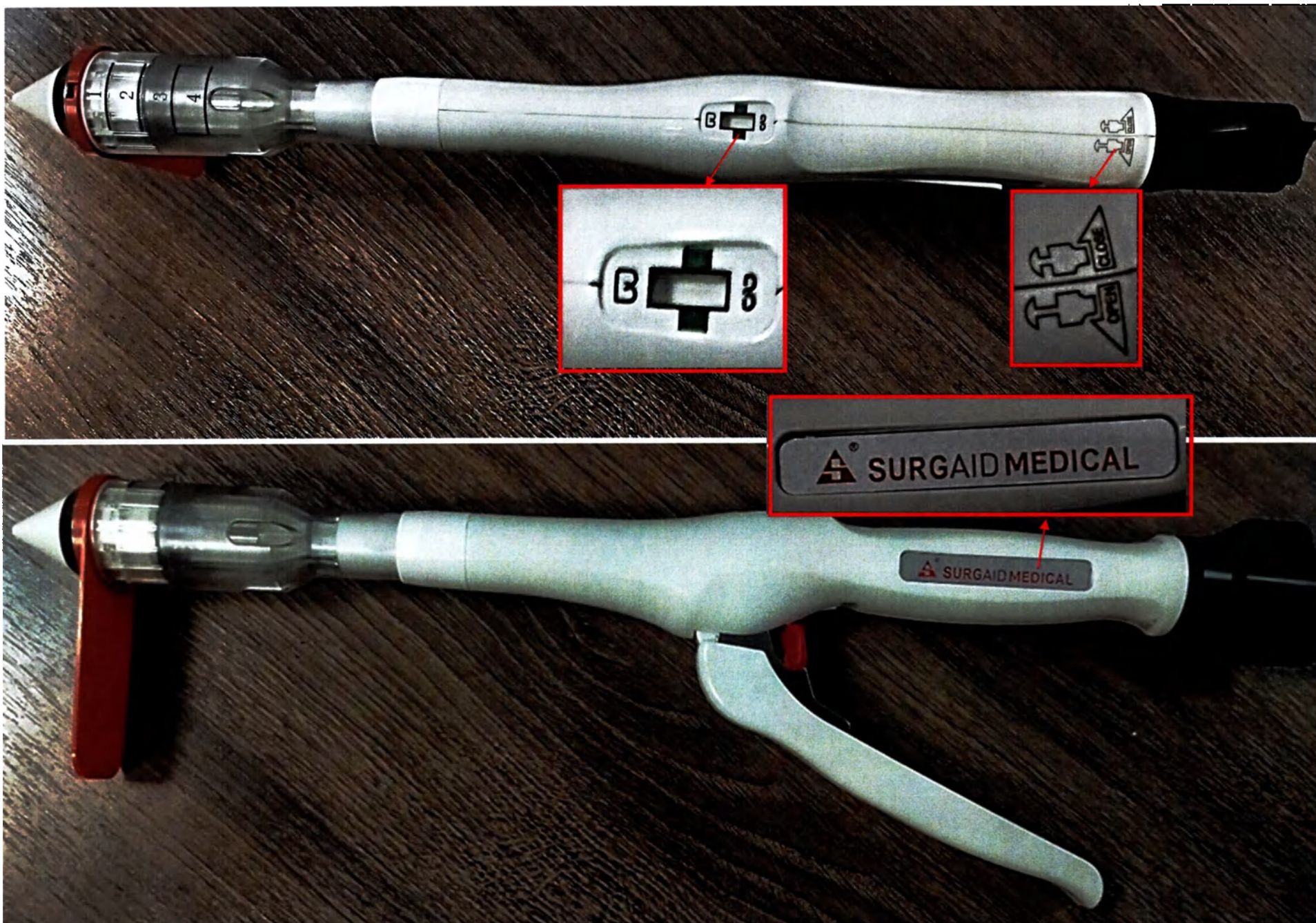
STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%.



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



Instruction for Use

I. Device name

Single Use Sterile Anorectal Circular Stapler Set

II. Device performance

1. The surface of the stapler should be smooth, free from burrs and sharp edges, and be free of pores, cracks. The scale value or mark on the device should be clear. If the Anvil assembly of the stapler can be disassembled, it should be smoothly assembled and disassembled with the body. The head of the suture nail should be sharp, and the annular knife should not have the phenomenon of rolling edge or collapse. The safety button of anorectal stapler should be flexible and safe to use. The reset spring should be flexible enough to reset quickly when the handle is released. The two contact surfaces to be torn should be smooth and uniform without splitting or tearing. The ethylene oxide residue of the device shall not exceed 10 µg/g.
2. The anorectal stapler mainly consists of Anvil, nail cage, nail cage sleeve, fixed handle, safety button, movable handle, adjusting nut, cushion cutter ring, ring knife and staple. The accessory type I is composed of supporting sleeve, anal plug, peeping sleeve and hook rod, and the type II is composed of supporting sleeve, supporting sleeve core and dial fork. The product is sterilized by ethylene oxide and should be sterile.

III. Intended use

It is applicable for optional resection of mucous membrane on the dentate line.

IV. Contraindications

1. Severe mucosal edema.
2. Hemorrhoids are heavily fibrotic.
3. Hemorrhoid tissue repeated injection of sclerosing agent.
4. Pregnant women, refractory constipation, pelvic tumors, portal hypertension and Budd-Chiari syndrome.

V. Warnings and Precautions

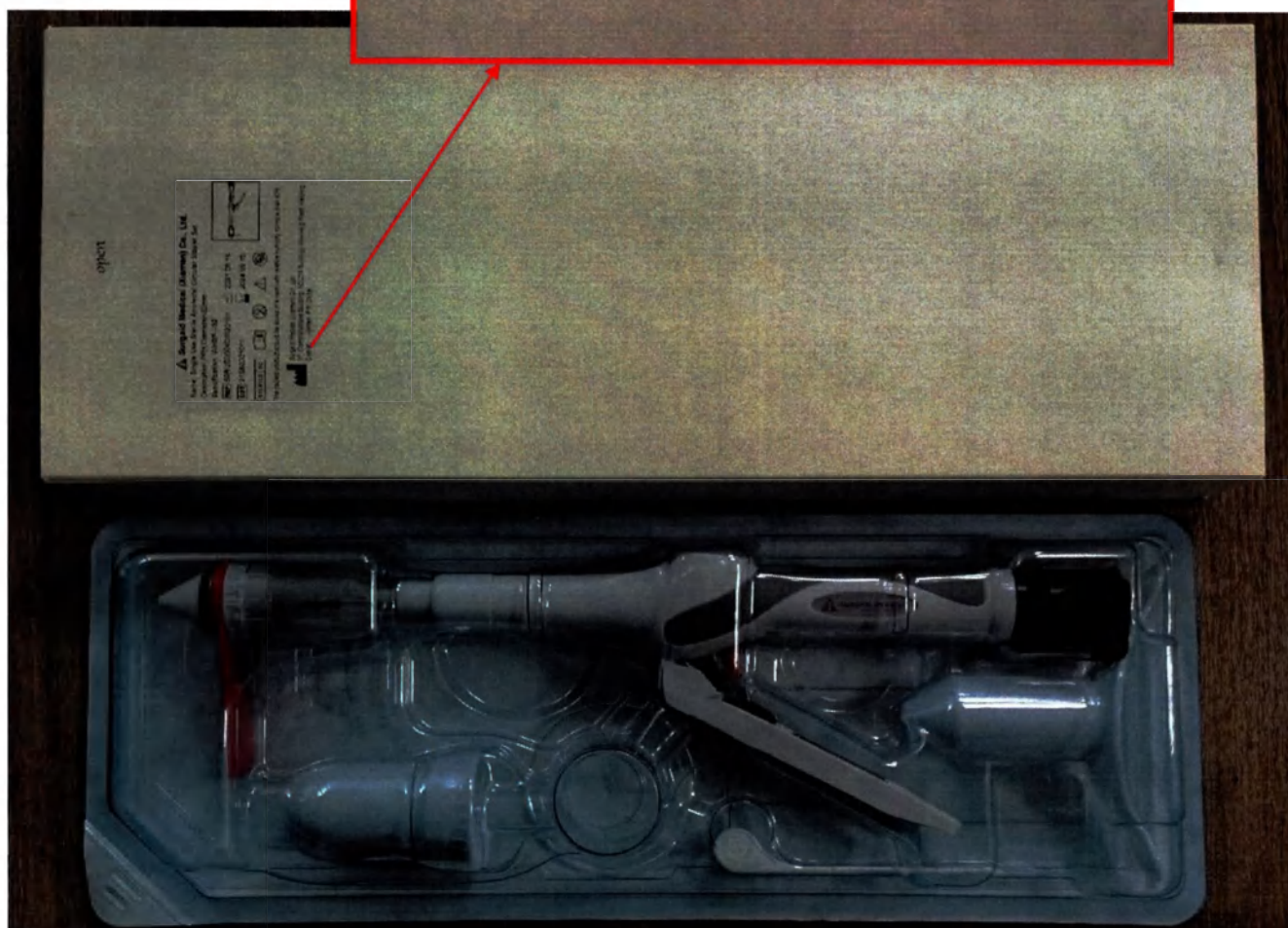
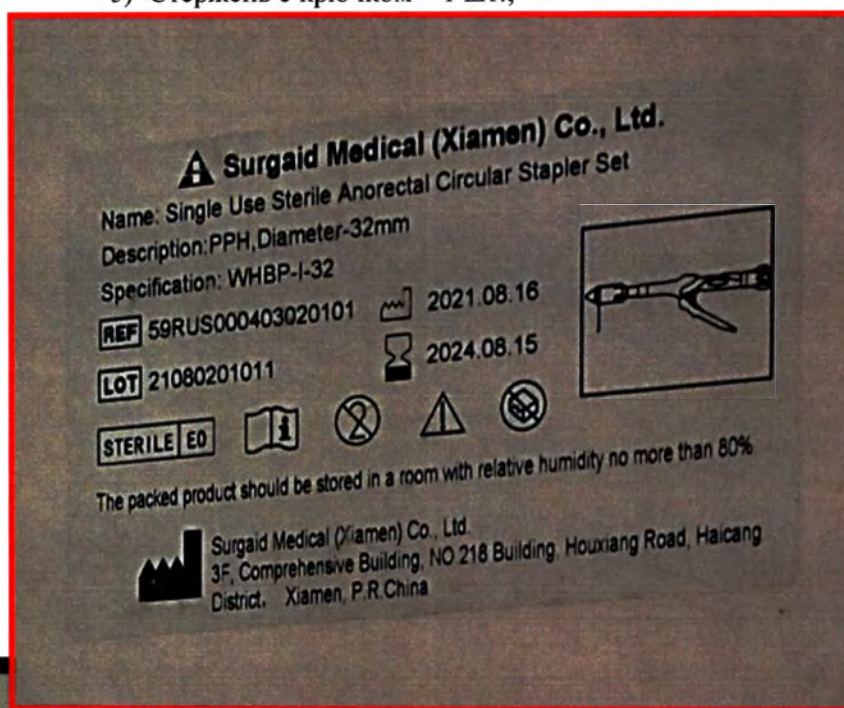
1. The device is prohibited to be use when its package opens, breaks or exceeds sterilization validity period.
2. Please read the instruction for use carefully before using the device, pay attention to the production date and expiration date of the device. The device can not be used when it exceeds its validity period.
3. The aseptic operation specification shall be strictly implemented when using the device.
4. This product is just for single use, which will be placed and handled as medical waste after used to avoid injury and environmental pollution.
5. The device is intended to be used by doctors who have been trained in stapler techniques or under the guidance of experienced physicians.
6. This manual can not be used as the basis for clinical surgical anastomosis technical guidance. For questions on clinical surgical anastomosis technical guidance, please refer to the professional literature or consult our company.
7. This procedure may cause anastomotic leakage, bleeding.
- Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
8. Disposal devices are medical waste and should be handled and disposed of according to local regulations.

VI. Instruction

1. The anal skin with less prolapse of the ankle and less anal valgus is fixed with four atraumatic forceps, so as to introduce the support sleeve and the anal plug into the anus, and fixed the dilator by suture.
2. The support sleeve and anal plug can support hemorrhoids prolapse or anal mucosa prolapse part reset, or can use anal plug to make prolapse part reset, and then introduce the support sleeve and anal plug to fix the support sleeve, and then pull out the anal plug, the prolapsed mucous membrane part falling into the support sleeve.
3. Through the peeping sleeve, the needle is inserted at 4 cm away from the dentate line, and the lower layer of rectal mucous membrane is uniformly sutured for 6-8 needles in a circle.
4. Remove the protective cover from the single use stapler assembly, rotate the adjusting nut counterclockwise to the maximum opening position (about 7.8 cm), insert the Anvil of the head of the stapler over the purse-string line, and tie the knot in the loop so that the tissue is evenly wrapped around the central rod.
5. Use the hook bar to pull out the sutures through the holes on both sides of the device, and tie the knot in the length that the finger can hook is suitable.
6. Maintain the position of the PPH head, make the PPH and the support sleeve in the same direction, rotate the adjusting nut to make the device close.

Степлер хирургический одноразовый аноректальный циркулярный с эргономичной рукояткой, открытого типа с прозрачным картриджем: WHBP-I-32, в составе:

- 1) Степлер хирургический одноразовый аноректальный циркулярный с эргономичной рукояткой, открытого типа с прозрачным картриджем: WHBP-I-32 – 1 шт.;
- 2) Втулка опорная – 1 шт.;
- 3) Пробка анальная – 1 шт.;
- 4) Втулка смотровая – 1 шт.;
- 5) Стержень с крючком – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Anorectal Circular Stapler Set
Description: PPH, Diameter-32mm
Specification: WHBP-I-32
REF 59RUS000403020101 2021.08.16
LOT 21080201011 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Anorectal Circular Stapler Set

Description: PPH, Diameter-32mm

Specification: WHBP-I-32

REF 59RUS000403020101



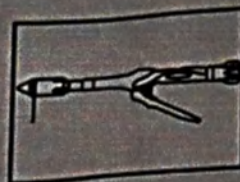
2021.08.16

LOT 21080201011



2024.08.15

STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%.



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



6) Инструкция по применению на Степлер хирургический одноразовый аноректальный циркулярный – 1 шт.

Instruction for Use

I. Device name

Single Use Sterile Anorectal Circular Stapler Set

II. Device performance

1. The surface of the stapler should be smooth, free from burrs and sharp edges, and be free of pores, cracks. The scale value or mark on the device should be clear. If the Anvil assembly of the stapler can be disassembled, it should be smoothly assembled and disassembled with the body. The head of the suture nail should be sharp, and the annular knife should not have the phenomenon of rolling edge or collapse. The safety button of anorectal stapler should be flexible and safe to use. The reset spring should be flexible enough to reset quickly when the handle is released. The two contact surfaces to be torn should be smooth and uniform without splitting or tearing. The ethylene oxide residue of the device shall not exceed 10 µg/g.
2. The anorectal stapler mainly consists of Anvil, nail cage, nail cage sleeve, fixed handle, safety button, movable handle, adjusting nut, cushion cutter ring, ring knife and staple. The accessory type I is composed of supporting sleeve, anal plug, peeping sleeve and hook rod, and the type II is composed of supporting sleeve, supporting sleeve core and dial fork. The product is sterilized by ethylene oxide and should be sterile.

III. Intended use

It is applicable for optional resection of mucous membrane on the dentate line.

IV. Contraindications

1. Severe mucosal edema.
2. Hemorrhoids are heavily fibrotic.
3. Hemorrhoid tissue repeated injection of sclerosing agent.
4. Pregnant women, refractory constipation, pelvic tumors, portal hypertension and Budd-Chiari syndrome.

V. Warnings and Precautions

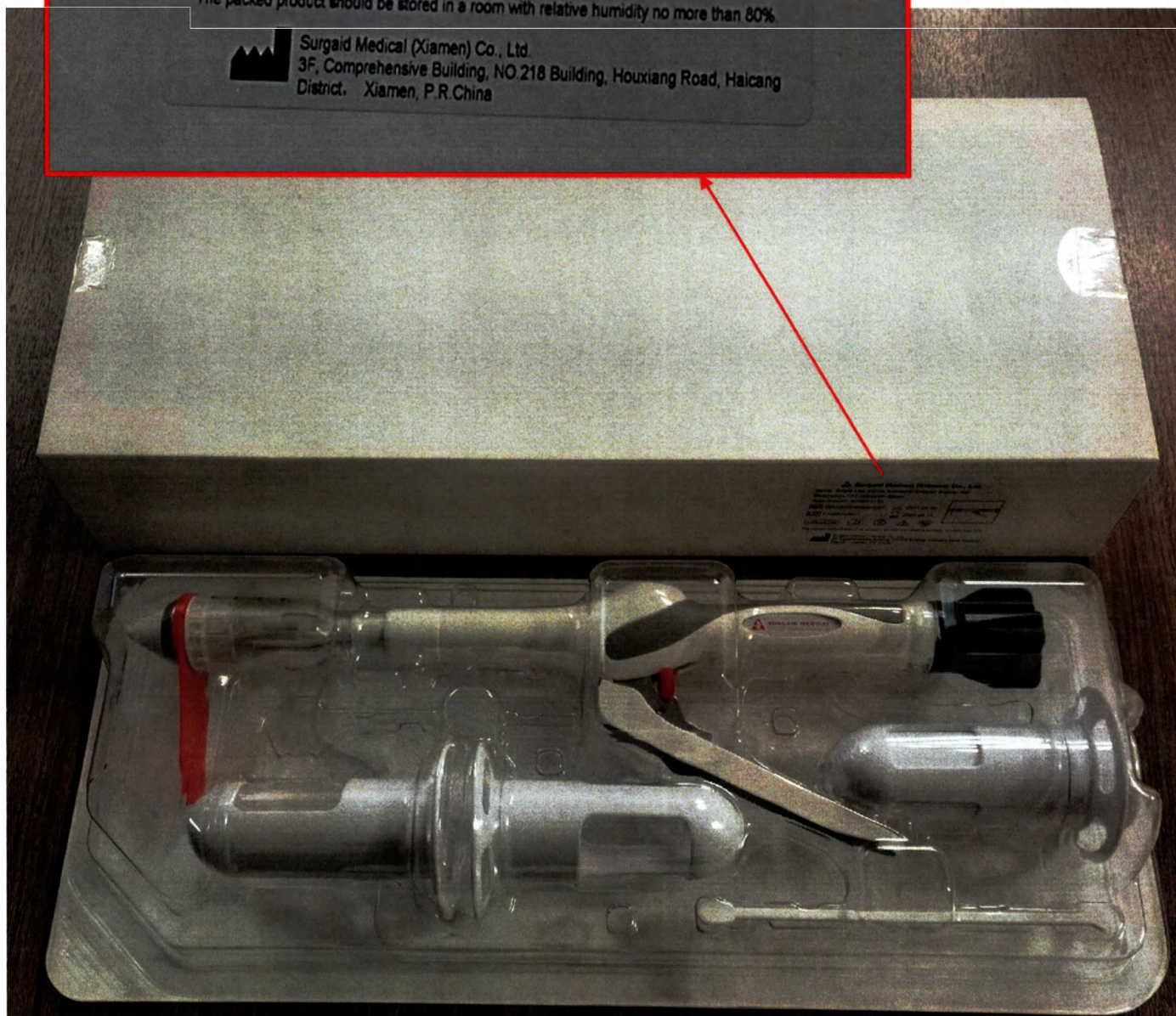
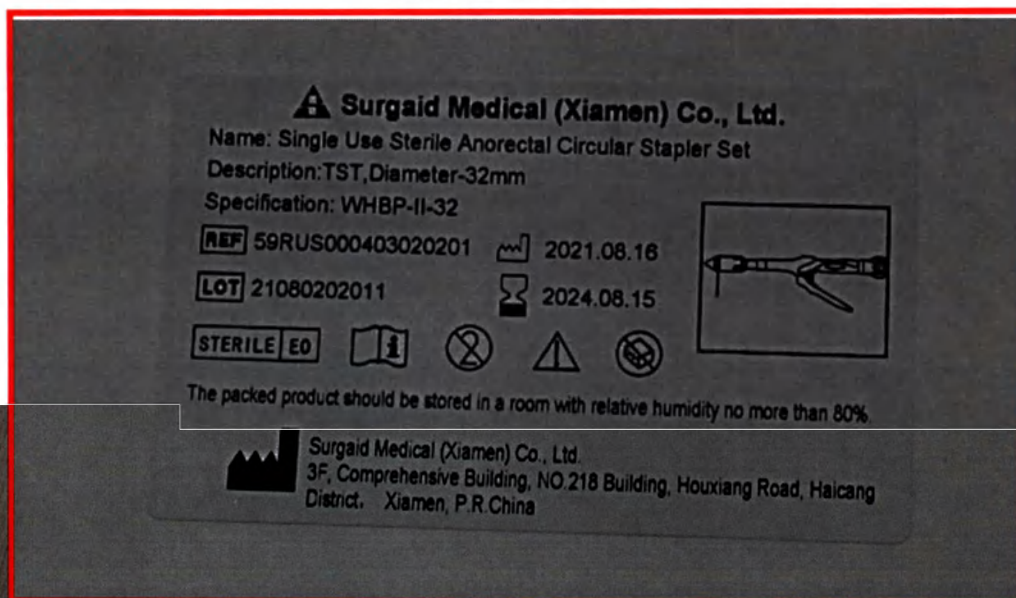
1. The device is prohibited to be used when its package opens, breaks or exceeds sterilization validity period.
2. Please read the instruction for use carefully before using the device, pay attention to the production date and expiration date of the device. The device can not be used when it exceeds its validity period.
3. The aseptic operation specification shall be strictly implemented when using the device.
4. This product is just for single use, which will be placed and handled as medical waste after used to avoid injury and environmental pollution.
5. The device is intended to be used by doctors who have been trained in stapler techniques or under the guidance of experienced physicians.
6. This manual can not be used as the basis for clinical surgical anastomosis technical guidance. For questions on clinical surgical anastomosis technical guidance, please refer to the professional literature or consult our company.
7. This procedure may cause anastomotic leakage, bleeding.
- Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
8. Disposal devices are medical waste and should be handled and disposed of according to local regulations.

VI. Instruction

1. The anal skin with less prolapse of the ankle and less anal valgus is fixed with four atraumatic forceps, so as to introduce the support sleeve and the anal plug into the anus, and fixed the dilator by suture.
2. The support sleeve and anal plug can support hemorrhoids prolapse or anal mucosa prolapse part reset, or can use anal plug to make prolapse part reset, and then introduce the support sleeve and anal plug to fix the support sleeve, and then pull out the anal plug, the prolapsed mucous membrane part falling into the support sleeve.
3. Through the peeping sleeve, the needle is inserted at 4 cm away from the dentate line, and the lower layer of rectal mucous membrane is uniformly sutured for 6-8 needles in a circle.
4. Remove the protective cover from the single use stapler assembly, rotate the adjusting nut counterclockwise to the maximum opening position (about 7.8 cm), insert the Anvil of the head of the stapler over the purse-string line, and tie the knot in the loop so that the tissue is evenly wrapped around the central rod.
5. Use the hook bar to pull out the sutures through the holes on both sides of the device, and tie the knot in the length that the finger can hook is suitable.
6. Maintain the position of the PPH head, make the PPH and the support sleeve in the same direction, rotate the adjusting nut to make the device close.

Степлер хирургический одноразовый аноректальный циркулярный с эргономичной рукояткой, тип окна с прозрачным картриджем: WHBP-II-32, в составе:

- 1) Степлер хирургический одноразовый аноректальный циркулярный с эргономичной рукояткой, тип окна с прозрачным картриджем: WHBP-II-32 – 1 шт.;
- 2) Втулка опорная с одним отверстием – 1 шт.;
- 3) Втулка опорная с двумя отверстиями – 1 шт.;
- 4) Втулка опорная с тремя отверстиями – 1 шт.;
- 5) Сердечник для опорных втулок – 1 шт.;
- 6) Вилка переключающая – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Anorectal Circular Stapler Set
Description: TST, Diameter-32mm
Specification: WHBP-II-32
REF 59RUS000403020201 2021.08.16
LOT 21080202011 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%.
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Anorectal Circular Stapler Set
Description: TST, Diameter-32mm
Specification: WHBP-II-32
REF 59RUS000403020201 2021.08.16
LOT 21080202011 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%.
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



Instruction for Use

I. Device name

Single Use Sterile Anorectal Circular Stapler Set

II. Device performance

1. The surface of the stapler should be smooth, free from burrs and sharp edges, and be free of pores, cracks. The scale value or mark on the device should be clear. If the Anvil assembly of the stapler can be disassembled, it should be smoothly assembled and disassembled with the body. The head of the suture nail should be sharp, and the annular knife should not have the phenomenon of rolling edge or collapse. The safety button of anorectal stapler should be flexible and safe to use. The reset spring should be flexible enough to reset quickly when the handle is released. The two contact surfaces to be torn should be smooth and uniform without splitting or tearing. The ethylene oxide residue of the device shall not exceed 10 µg/g.
2. The anorectal stapler mainly consists of Anvil, nail cage, nail cage sleeve, fixed handle, safety button, movable handle, adjusting nut, cushion cutter ring, ring knife and staple. The accessory type I is composed of supporting sleeve, anal plug, peeping sleeve and hook rod, and the type II is composed of supporting sleeve, supporting sleeve core and dial fork. The product is sterilized by ethylene oxide and should be sterile.

III. Intended use

It is applicable for optional resection of mucous membrane on the dentate line.

IV. Contraindications

1. Severe mucosal edema.
2. Hemorrhoids are heavily fibrotic.
3. Hemorrhoid tissue repeated injection of sclerosing agent.
4. Pregnant women, refractory constipation, pelvic tumors, portal hypertension and Budd-Chiari syndrome.

V. Warnings and Precautions

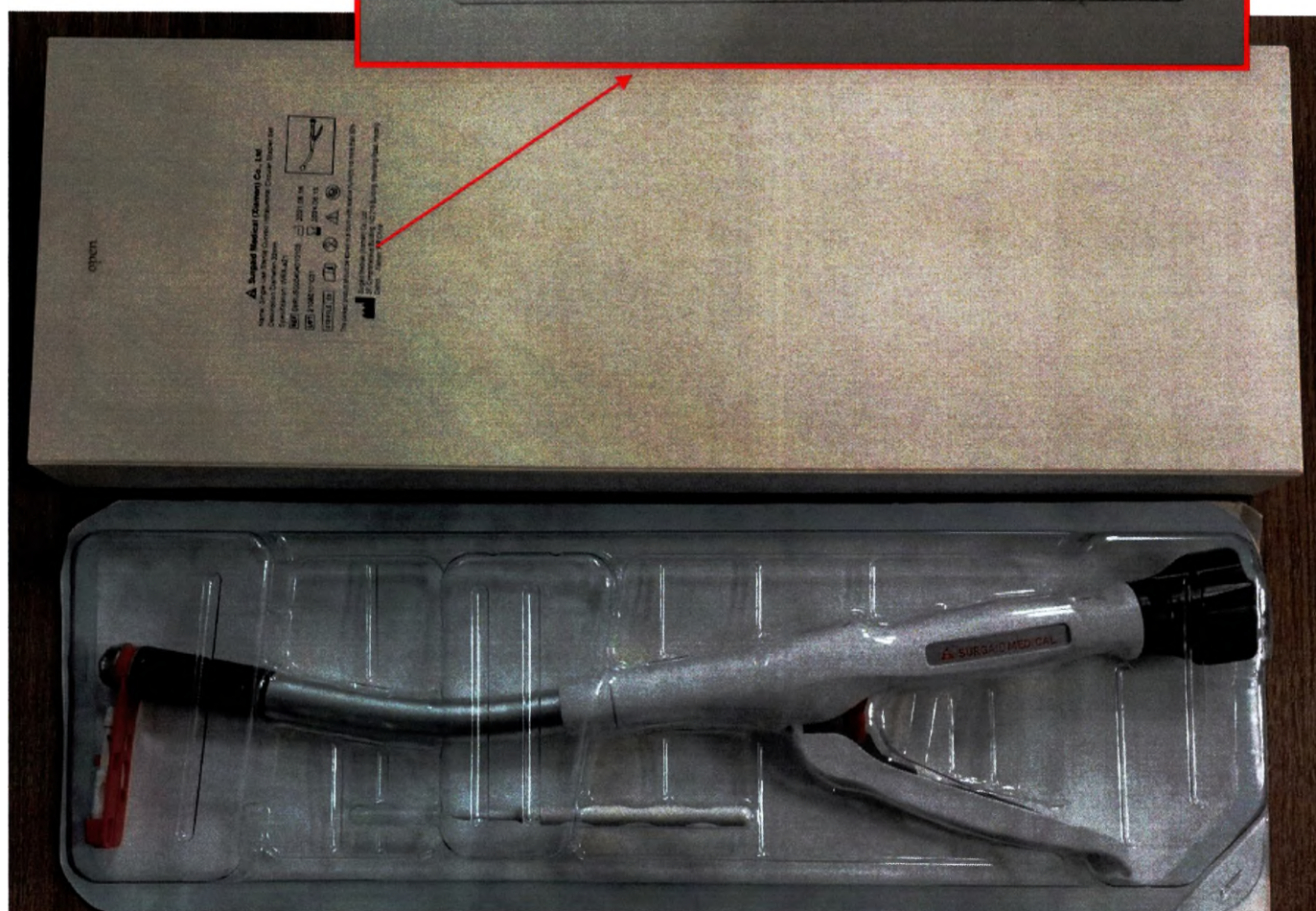
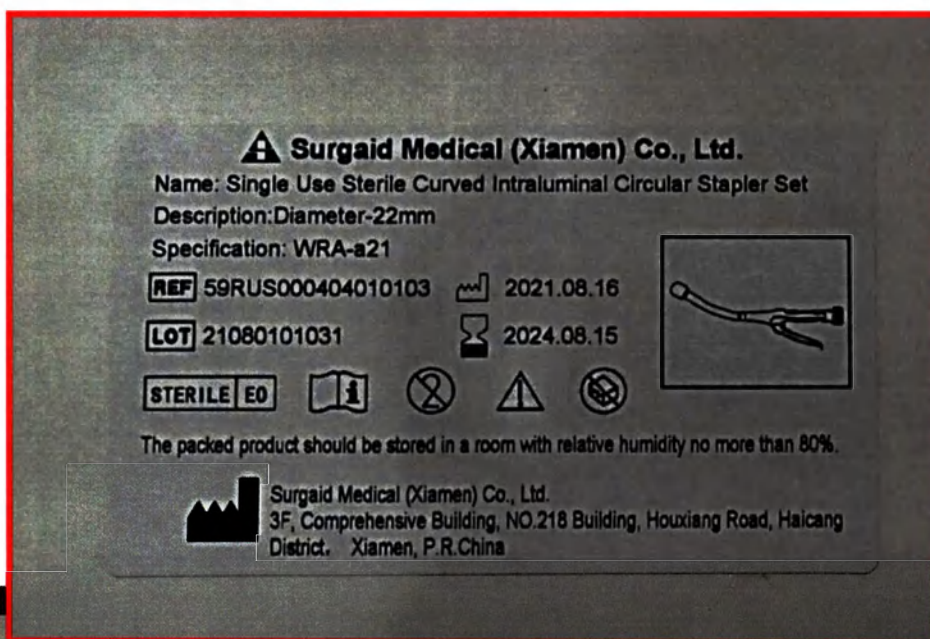
1. The device is prohibited to be use when its package opens, breaks or exceeds sterilization validity period.
2. Please read the instruction for use carefully before using the device, pay attention to the production date and expiration date of the device. The device can not be used when it exceeds its validity period.
3. The aseptic operation specification shall be strictly implemented when using the device.
4. This product is just for single use, which will be placed and handled as medical waste after used to avoid injury and environmental pollution.
5. The device is intended to be used by doctors who have been trained in stapler techniques or under the guidance of experienced physicians.
6. This manual can not be used as the basis for clinical surgical anastomosis technical guidance. For questions on clinical surgical anastomosis technical guidance, please refer to the professional literature or consult our company.
7. This procedure may cause anastomotic leakage, bleeding.
- Consult medical literature relative to techniques, complications, and hazards prior to performance of any procedure.
8. Disposal devices are medical waste and should be handled and disposed of according to local regulations.

VI. Instruction

1. The anal skin with less prolapse of the ankle and less anal valgus is fixed with four atraumatic forceps, so as to introduce the support sleeve and the anal plug into the anus, and fixed the dilator by suture.
2. The support sleeve and anal plug can support hemorrhoids prolapse or anal mucosa prolapse part reset, or can use anal plug to make prolapse part reset, and then introduce the support sleeve and anal plug to fix the support sleeve, and then pull out the anal plug, the prolapsed mucous membrane part falling into the support sleeve.
3. Through the peeping sleeve, the needle is inserted at 4 cm away from the dentate line, and the lower layer of rectal mucous membrane is uniformly sutured for 6-8 needles in a circle.
4. Remove the protective cover from the single use stapler assembly, rotate the adjusting nut counterclockwise to the maximum opening position (about 7.8 cm), insert the Anvil of the head of the stapler over the purse-string line, and tie the knot in the loop so that the tissue is evenly wrapped around the central rod.
5. Use the hook bar to pull out the sutures through the holes on both sides of the device, and tie the knot in the length that the finger can hook is suitable.
6. Maintain the position of the PPH head, make the PPH and the support sleeve in the same direction, rotate the adjusting nut to make the device close.

Степлер хирургический одноразовый внутрипросветный изогнутый циркулярный со стандартной рукояткой: WRA-a21, в составе:

- 1) Степлер хирургический одноразовый внутрипросветный изогнутый циркулярный со стандартной рукояткой: WRA-a21 – 1 шт.;
- 2) Накладка защитная – 1 шт.;
- 3) Направитель нитей – 1 шт.;
- 4) Головка копьевидная – 1 шт.;
- 5) Чехол пластиковый для закрытия острой части копия – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Curved Intraluminal Circular Stapler Set
Description: Diameter-22mm
Specification: WRA-a21
REF 59RUS000404010103 2021.08.16
LOT 21080101031 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%.
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China

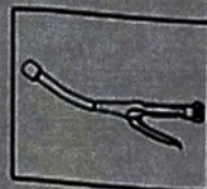
Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Curved Intraluminal Circular Stapler Set
Description: Diameter-22mm
Specification: WRA-a21

REF 59RUS000404010103 2021.08.16

LOT 21080101031 2024.08.15

STERILE EO



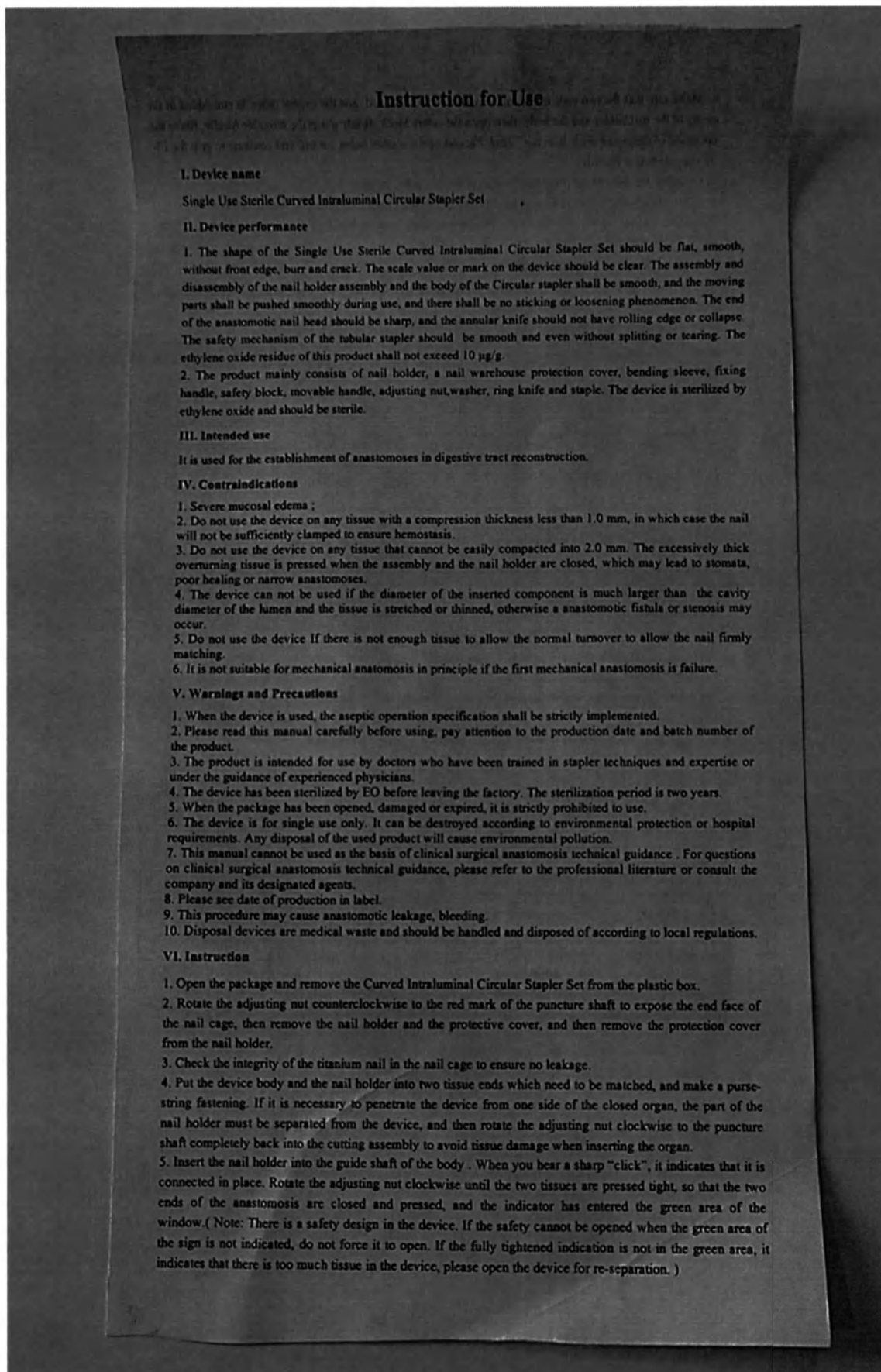
The packed product should be stored in a room with relative humidity no more than 80%.



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO.218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



6) Инструкция по применению на Степлер хирургический одноразовый внутрисветный изогнутый циркулярный – 1 шт.



Instruction for Use

I. Device name

Single Use Sterile Curved Intraluminal Circular Stapler Set

II. Device performance

1. The shape of the Single Use Sterile Curved Intraluminal Circular Stapler Set should be flat, smooth, without front edge, burr and crack. The scale value or mark on the device should be clear. The assembly and disassembly of the nail holder assembly and the body of the Circular stapler shall be smooth, and the moving parts shall be pushed smoothly during use, and there shall be no sticking or loosening phenomenon. The end of the anastomotic nail head should be sharp, and the annular knife should not have rolling edge or collapse. The safety mechanism of the tubular stapler should be smooth and even without splitting or tearing. The ethylene oxide residue of this product shall not exceed 10 µg/g.

2. The product mainly consists of nail holder, a nail warehouse protection cover, bending sleeve, fixing handle, safety block, movable handle, adjusting nut, washer, ring knife and staple. The device is sterilized by ethylene oxide and should be sterile.

III. Intended use

It is used for the establishment of anastomoses in digestive tract reconstruction.

IV. Contraindications

1. Severe mucosal edema;
2. Do not use the device on any tissue with a compression thickness less than 1.0 mm, in which case the nail will not be sufficiently clamped to ensure hemostasis.
3. Do not use the device on any tissue that cannot be easily compacted into 2.0 mm. The excessively thick overturning tissue is pressed when the assembly and the nail holder are closed, which may lead to stomata, poor healing or narrow anastomoses.
4. The device can not be used if the diameter of the inserted component is much larger than the cavity diameter of the lumen and the tissue is stretched or thinned, otherwise an anastomotic fistula or stenosis may occur.
5. Do not use the device if there is not enough tissue to allow the normal turnover to allow the nail firmly matching.
6. It is not suitable for mechanical anastomosis in principle if the first mechanical anastomosis is failure.

V. Warnings and Precautions

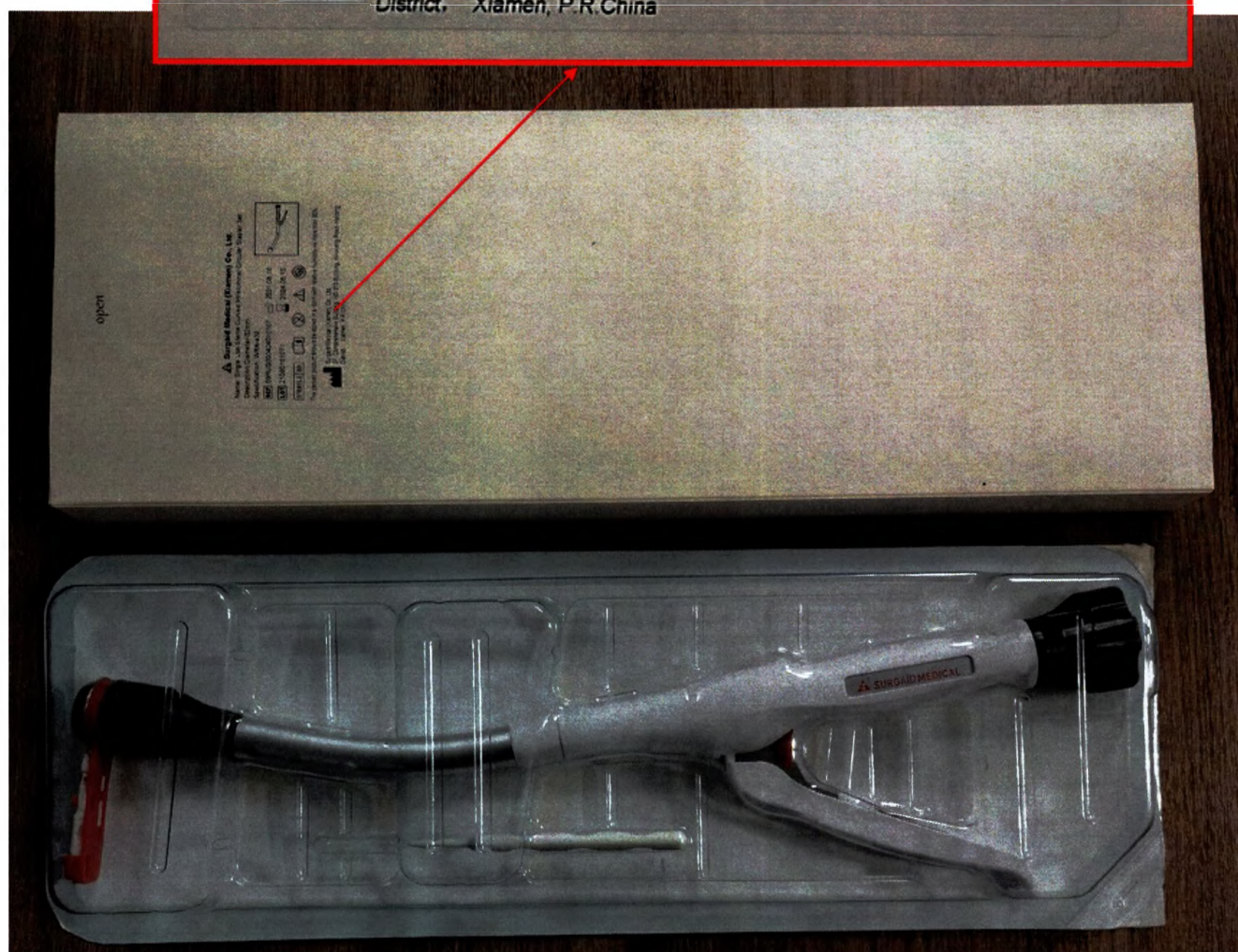
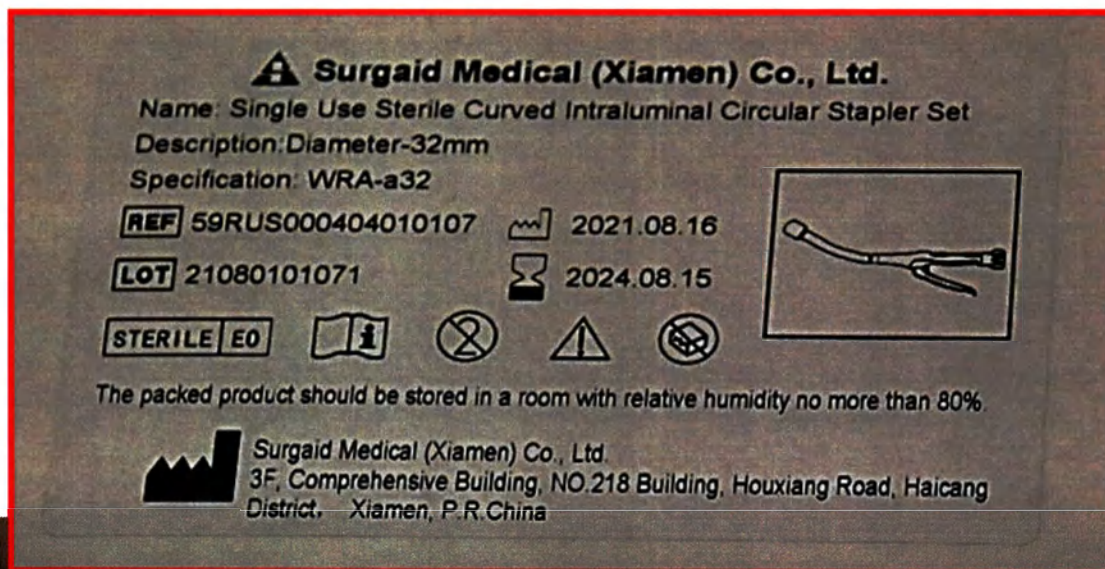
1. When the device is used, the aseptic operation specification shall be strictly implemented.
2. Please read this manual carefully before using, pay attention to the production date and batch number of the product.
3. The product is intended for use by doctors who have been trained in stapler techniques and expertise or under the guidance of experienced physicians.
4. The device has been sterilized by EO before leaving the factory. The sterilization period is two years.
5. When the package has been opened, damaged or expired, it is strictly prohibited to use.
6. The device is for single use only. It can be destroyed according to environmental protection or hospital requirements. Any disposal of the used product will cause environmental pollution.
7. This manual cannot be used as the basis of clinical surgical anastomosis technical guidance. For questions on clinical surgical anastomosis technical guidance, please refer to the professional literature or consult the company and its designated agents.
8. Please see date of production in label.
9. This procedure may cause anastomotic leakage, bleeding.
10. Disposal devices are medical waste and should be handled and disposed of according to local regulations.

VI. Instruction

1. Open the package and remove the Curved Intraluminal Circular Stapler Set from the plastic box.
2. Rotate the adjusting nut counterclockwise to the red mark of the puncture shaft to expose the end face of the nail cage, then remove the nail holder and the protective cover, and then remove the protection cover from the nail holder.
3. Check the integrity of the titanium nail in the nail cage to ensure no leakage.
4. Put the device body and the nail holder into two tissue ends which need to be matched, and make a purse-string fastening. If it is necessary to penetrate the device from one side of the closed organ, the part of the nail holder must be separated from the device, and then rotate the adjusting nut clockwise to the puncture shaft completely back into the cutting assembly to avoid tissue damage when inserting the organ.
5. Insert the nail holder into the guide shaft of the body. When you hear a sharp "click", it indicates that it is connected in place. Rotate the adjusting nut clockwise until the two tissues are pressed tight, so that the two ends of the anastomosis are closed and pressed, and the indicator has entered the green area of the window. (Note: There is a safety design in the device. If the safety cannot be opened when the green area of the sign is not indicated, do not force it to open. If the fully tightened indication is not in the green area, it indicates that there is too much tissue in the device, please open the device for re-separation.)

Степлер хирургический одноразовый внутрипросветный изогнутый циркулярный со стандартной рукояткой: WRA-a32, в составе:

- 1) Степлер хирургический одноразовый внутрипросветный изогнутый циркулярный со стандартной рукояткой: WRA-a32 – 1 шт.;
- 2) Накладка защитная – 1 шт.;
- 3) Направитель нитей – 1 шт.;
- 4) Головка копьевидная – 1 шт.;
- 5) Чехол пластиковый для закрытия острой части копия – 1 шт.;





Surgaid Medical (Xiamen) Co., Ltd.
Name: Single Use Sterile Curved Intraluminal Circular Stapler Set
Description: Diameter-32mm
Specification: WRA-a32
REF: 59RUS000404010107 2021.08.16
LOT: 21080101071 2024.08.15
STERILE EO
The packed product should be stored in a room with relative humidity no more than 80%
Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



Surgaid Medical (Xiamen) Co., Ltd.

Name: Single Use Sterile Curved Intraluminal Circular Stapler Set
Description: Diameter-32mm
Specification: WRA-a32

REF: 59RUS000404010107



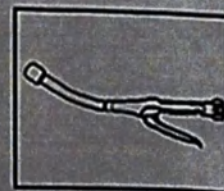
2021.08.16

LOT: 21080101071



2024.08.15

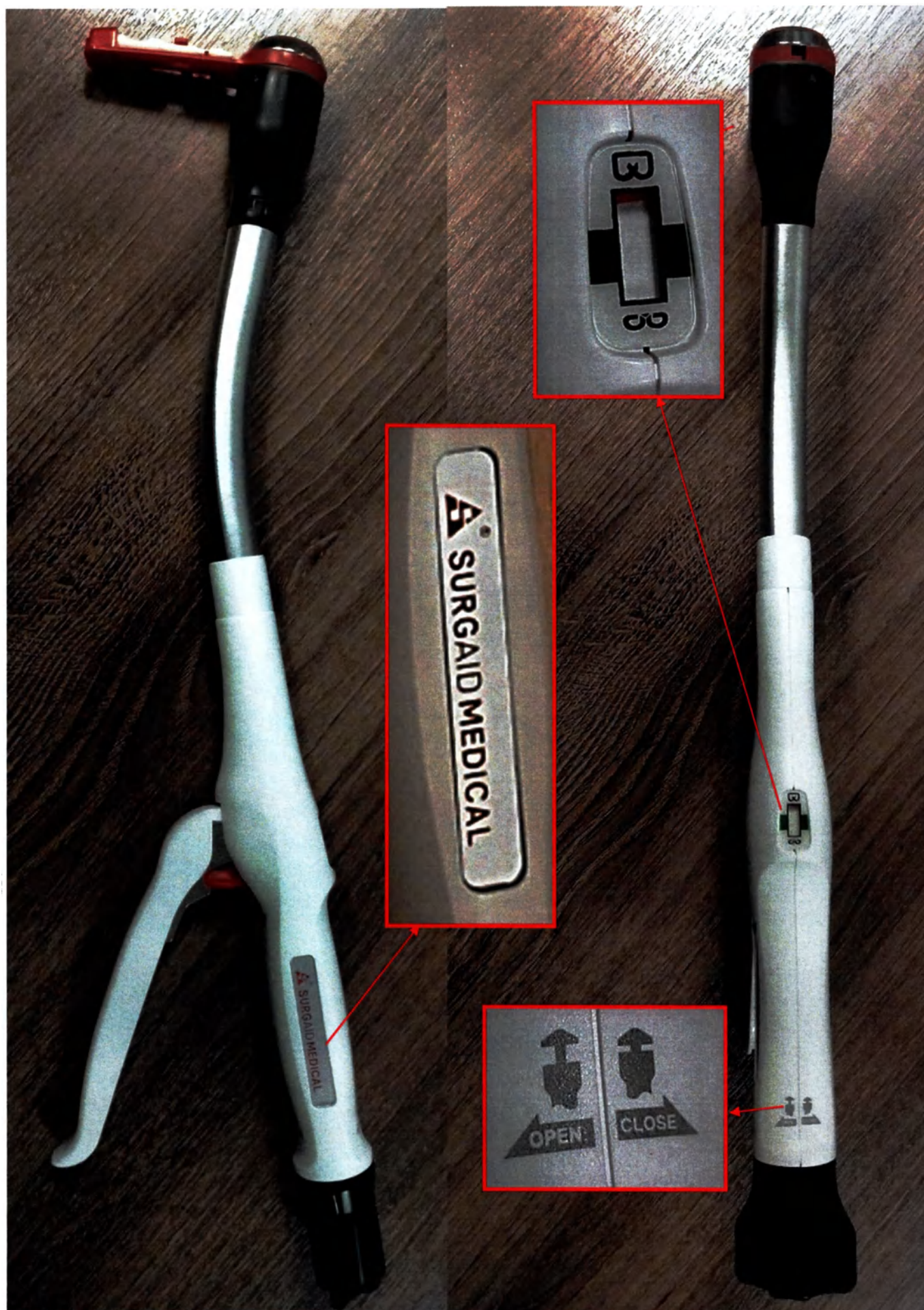
STERILE EO



The packed product should be stored in a room with relative humidity no more than 80%



Surgaid Medical (Xiamen) Co., Ltd.
3F, Comprehensive Building, NO 218 Building, Houxiang Road, Haicang District, Xiamen, P.R.China



6) Инструкция по применению на Степлер хирургический одноразовый внутрисветный изогнутый циркулярный – 1 шт.

Instruction for Use

I. Device name

Single Use Sterile Curved Intraluminal Circular Stapler Set

II. Device performance

1. The shape of the Single Use Sterile Curved Intraluminal Circular Stapler Set should be flat, smooth, without front edge, burr and crack. The scale value or mark on the device should be clear. The assembly and disassembly of the nail holder assembly and the body of the Circular stapler shall be smooth, and the moving parts shall be pushed smoothly during use, and there shall be no sticking or loosening phenomenon. The end of the anastomotic nail head should be sharp, and the annular knife should not have rolling edge or collapse. The safety mechanism of the tubular stapler should be smooth and even without splitting or tearing. The ethylene oxide residue of this product shall not exceed 10 µg/g.
2. The product mainly consists of nail holder, a nail warehouse protection cover, bending sleeve, fixing handle, safety block, movable handle, adjusting nut, washer, ring knife and staple. The device is sterilized by ethylene oxide and should be sterile.

III. Intended use

It is used for the establishment of anastomoses in digestive tract reconstruction.

IV. Contraindications

1. Severe mucosal edema ;
2. Do not use the device on any tissue with a compression thickness less than 1.0 mm, in which case the nail will not be sufficiently clamped to ensure hemostasis.
3. Do not use the device on any tissue that cannot be easily compacted into 2.0 mm. The excessively thick overturning tissue is pressed when the assembly and the nail holder are closed, which may lead to stomata, poor healing or narrow anastomoses.
4. The device can not be used if the diameter of the inserted component is much larger than the cavity diameter of the lumen and the tissue is stretched or thinned, otherwise an anastomotic fistula or stenosis may occur.
5. Do not use the device if there is not enough tissue to allow the normal turnover to allow the nail firmly matching.
6. It is not suitable for mechanical anastomosis in principle if the first mechanical anastomosis is failure.

V. Warnings and Precautions

1. When the device is used, the aseptic operation specification shall be strictly implemented.
2. Please read this manual carefully before using, pay attention to the production date and batch number of the product.
3. The product is intended for use by doctors who have been trained in stapler techniques and expertise or under the guidance of experienced physicians.
4. The device has been sterilized by EO before leaving the factory. The sterilization period is two years.
5. When the package has been opened, damaged or expired, it is strictly prohibited to use.
6. The device is for single use only. It can be destroyed according to environmental protection or hospital requirements. Any disposal of the used product will cause environmental pollution.
7. This manual cannot be used as the basis of clinical surgical anastomosis technical guidance. For questions on clinical surgical anastomosis technical guidance, please refer to the professional literature or consult the company and its designated agents.
8. Please see date of production in label.
9. This procedure may cause anastomotic leakage, bleeding.
10. Disposal devices are medical waste and should be handled and disposed of according to local regulations.

VI. Instruction

1. Open the package and remove the Curved Intraluminal Circular Stapler Set from the plastic box.
2. Rotate the adjusting nut counterclockwise to the red mark of the puncture shaft to expose the end face of the nail cage, then remove the nail holder and the protective cover, and then remove the protection cover from the nail holder.
3. Check the integrity of the titanium nail in the nail cage to ensure no leakage.
4. Put the device body and the nail holder into two tissue ends which need to be matched, and make a purse-string fastening. If it is necessary to penetrate the device from one side of the closed organ, the part of the nail holder must be separated from the device, and then rotate the adjusting nut clockwise to the puncture shaft completely back into the cutting assembly to avoid tissue damage when inserting the organ.
5. Insert the nail holder into the guide shaft of the body. When you hear a sharp "click", it indicates that it is connected in place. Rotate the adjusting nut clockwise until the two tissues are pressed tight, so that the two ends of the anastomosis are closed and pressed, and the indicator has entered the green area of the window. (Note: There is a safety design in the device. If the safety cannot be opened when the green area of the sign is not indicated, do not force it to open. If the fully tightened indication is not in the green area, it indicates that there is too much tissue in the device, please open the device for re-separation.)

Макет маркировки потребительской упаковки медицинского изделия

Для степлеров вариантов исполнения 1-5: на примере изделия
«Степлер хирургический одноразовый с резак линейный, резак в картридже: WKD-100G»

**Степлер хирургический одноразовый с резак линейный,
резак в картридже: WKD-100G**

Описание: длина анастомоза - 101 мм, высота скобы - 4,6 мм (зелёный)

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.

Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

Юридический адрес: 115054, г. Москва, ул. Дубининская, д. 57, стр. 2, пом/ком IV/9,10

Для степлеров вариантов исполнения 6-8: на примере изделия
«Степлер хирургический одноразовый эндоскопический с одинарной рукояткой: WQF-S»

**Степлер хирургический одноразовый эндоскопический
с одинарной рукояткой: WQF-S**

Описание: рабочая длина инструмента - короткая (60 мм)

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.

Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

Юридический адрес: 115054, г. Москва, ул. Дубининская, д. 57, стр. 2, пом/ком IV/9,10

Для степлеров вариантов исполнения 9-32: на примере изделия
«Степлер хирургический одноразовый эндоскопический с двойной рукояткой: WQDb-S-45A»

Степлер хирургический одноразовый эндоскопический с двойной рукояткой: WQDb-S-45A

Описание: рабочая длина инструмента - короткая (270 мм),
длина анастомоза - 49 мм, высота скобы - 2,5 мм (белый)

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.
Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

Юридический адрес: 115054, г. Москва, ул. Дубининская, д. 57, стр. 2, пом/ком IV/9,10

Для степлеров вариантов исполнения 33-41: на примере изделия
«Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, тип окна с
непрозрачным картриджем: WHAO-II-34»

Степлер хирургический одноразовый аноректальный циркулярный со стандартной рукояткой, тип окна с непрозрачным картриджем: WHAO-II-34

Описание: TST, внешний диаметр втулки картриджа - 34 мм

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.
Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

Юридический адрес: 115054, г. Москва, ул. Дубининская, д. 57, стр. 2, пом/ком IV/9,10

Для степлеров вариантов исполнения 42-51: на примере изделия
«Степлер хирургический одноразовый внутрипросветный изогнутый циркулярный со стандартной
рукояткой: WRA-a21»

Степлер хирургический одноразовый внутрипросветный изогнутый циркулярный со стандартной рукояткой: WRA-a21

Описание: внешний диаметр - 22 мм

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.
Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

Юридический адрес: 115054, г. Москва, ул. Дубининская, д. 57, стр. 2, пом/ком IV/9,10

Для картриджей в составе вариантов исполнения 1-5: на примере изделия
«Картридж ZKD-100G»

Картридж ZKD-100G

Описание: длина анастомоза - 101 мм, высота скобы - 4,6 мм (зелёный)

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.
Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

Юридический адрес: 115054, г. Москва, ул. Дубининская, д. 57, стр. 2, пом/ком IV/9,10

Для картриджей в составе вариантов исполнения 6-8: на примере изделия
«Картридж для степлера ротационный, прямой: ZQIUb-45A»

Картридж для степлера ротационный, прямой: ZQIUb-45A

Описание: длина анастомоза - 45 мм, высота скобы - 2,5 мм (белый)

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.

Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

Юридический адрес: 115054, г. Москва, ул. Дубининская, д. 57, стр. 2, пом/ком IV/9,10

Для картриджей в составе вариантов исполнения 9-32: на примере изделия
«Картридж для степлера ZQNb-45A»

Картридж для степлера: ZQNb-45A

Описание: длина анастомоза - 49 мм, высота скобы - 2,5 мм (белый)

REF XXXXXXXXXXXXX

 XXXXXXXXX

LOT XXXXXXXXXXXXX

 XXXXXXXXX

STERILE



РУ № _____ от _____



Surgaid Medical (Xiamen) Co., Ltd.

Building 5, No. 18, Shanbianhong East Road, Haicang District, Xiamen City, Fujian Province,
361026, P.R.China

Уполномоченный представитель: ООО «Здоровье»

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