

## Instruction for Use: Single Patient Use Skin Stapler

### 1. Use of product

Single Patient Use Skin Stapler is mainly used for surface of the skin incision sutured of surgery.

### 2. Explanation on the symbols on label



USE BY



BATCH CODE



DO NOT REUSE



DO NOT USE IF PACKAGE IS DAMAGED



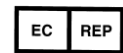
STERILIZED USING IRRADIATION



CAUTION



CONSULT INSTRUCTIONS FOR USE



AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY



DATE OF MANUFACTURE



MANUFACTURER

### 3. Product model, specifications and material

#### 3.1 Product model, specifications

unit (mm)

Spec.	size		Staple number	Spec.	size		Staple number
	L	H			L	H	
SSA15R	5.7±0.5	3.9±0.5	15±3	SSA35W	6.9±0.5	3.9±0.5	35±3
SSB15R				SSB35W			
SSA15W	6.9±0.5	3.9±0.5		SSA45R	5.7±0.5	3.9±0.5	45±3
SSB15W				SSB45R			
SSA25R	5.7±0.5	3.9±0.5	25±3	SSA45W	6.9±0.5	3.9±0.5	

SSB25R				SSB45W			55±3
SSA25W	6.9±0.5	3.9±0.5		SSA55R	5.7±0.5	3.9±0.5	
SSB25W				SSB55R			
SSA35R	5.7±0.5	3.9±0.5	35±3	SSA55W	6.9±0.5	3.9±0.5	
SSB35R				SSB55W			

### 3.2 Material

3.2.1 Staple press-board and staple slot board: 20Cr13, 12Cr18Ni9, 06Cr19Ni10.

3.2.2 Staple:SUS316.

### 4. Structure composing

Single Patient Use Skin Staplers is made up of frame and staples, the staple remover is the subassembly of skin stapler. The body frame is assembled by upper handle, neath handle, staple slot board, staple press board and fix frame.

### 5. Description of performance and operation

Using method of Skin Staplers:

- 1) When using the product during surgery, according to the suture's length to choose the product with suitable staples quantity ;
- 2) Using the teeth forceps to clamp the wound skin which has been done the debridement and sterilization, make the Skin Stapler is perpendicular to the wound;
- 3) suture the skin wound by clenching the handle, release the handle gently(Notice that don't pull the skin stapler at the moment);
- 4) Pull the stapler vertically, and then complete the suture operation of one staple.

Note:

There is matched skin stapler remover when removing; it's easy to remove the staples;

Choose the 2.7mm staple height when wound suturing distance is dense; choose the 3.2mm staple height when wound suturing distance is incompact.

Using method of Skin Stapler Remover:

- 1) Insert the left clamp body of the remover into the staple, make the staple slips to the slot of the left clamp body;
- 2) Clench the left and right clamp bodies of the remover, until the two bodies fold together, not to lift up the staple by the remover;
- 3) Move the remover after left and right clamp bodies are in right places, staples are complete out of shape and leave the skin.

### 6. Contraindications

6.1 Patients with sensitive or allergic reactions please do not use this device.

6.2 It is not suitable for the incision which needs to do tension suture use After the operation

6.3 If the distance of skin incision and the internal key tissue is not enough 5mm, prohibit using this equipment to suture the skin.

### 7. Warnings

- 7.1 The product has been sterilized by gamma ray (cobalt 60) at delivery. The product can not be used anymore when packing is damaged.
- 7.2 If the product is defective in visual check or is damaged in suspicion, the product shall not be used anymore. Please contact the representative of our company.
- 7.3 The product is only for one-time use and shall not be reused. Repeated processing or repeated sterilization may damage the product, and cause injury, infection or death of the patient. If the product is reused, the product may be polluted, or the patient is infected, or cross infection occurs.
- 7.4 The product is used only by the doctors who have professional knowledge on stapler.
- 7.5 Do not operate this product before completely reading this operation manual. Any incautious operation may cause operation unsuccessful.
- 7.6 After the product is used, it shall be destroyed.

## 8. Precautions

- 8.1 Please check carefully the product packing before using. Do not use it if the packing is broken.
- 8.2 Please check the mark on the sterilized packing box of the product. "Yellow" mark means that this product is not sterilized and can not be used directly. "Red" mark means that this product has been sterilized and can be used directly in clinic.
- 8.3 This product is only for one-time use and can not be sterilized again after using.
- 8.4 Please check the valid period of the product before using. The valid period of sterilization is five years. The product can not be used and sterilization after the valid period.
- 8.5 Sterilized product shall be stored in well-ventilated indoor without corrosive gases and with relative humidity not exceeding 80%. Prohibition of prolonged exposure to high temperature and avoid exposure to temperatures in excess of 54 °C environment.
- 8.6 Any stapler which has been dropped carelessly on ground or damaged actually or in suspicion shall not be used clinically.

## 9. Possible adverse reactions

- 9.1 Likely result in infection;
- 9.2 Likely result in tearing stoma;
- 9.3 Likely result in bleeding at stoma.

**10. Version: 2**     Date of Issue: 2018-12-19



This product is sterilized by gamma ray (cobalt 60) and can be used clinically.



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