

CE Technical File Disposable Skin Staplers	File No: HC/CE-04-2.1
	Rev. No: B/4

Instruction For Use

Document No.: HC/CE-04-2.1 (Rev. B/4)

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1. Product Introduction

1.1 Product name

Disposable Skin Staplers

1.2 Model

Model:

HC-PFB-15R, HC-PFB-15W, HC-PFB-25R, HC-PFB-25W, HC-PFB-35R, HC-PFB-35W, HC-PFB-45R, HC-PFB-45W, HC-PFB-55R, HC-PFB-55W

The differences of different models:

The Disposable Skin Staplers can be divided into five specifications 15, 25, 35, 45 and 55 according to the number of loaded staples; and two types according to the width of staples: regular type and wide type, which are represented by R and W respectively.

The differences are specified in the table below.

No.	Model	Model Description	No.	Model	Model Description
1	HC-PFB-15R	with 15 Regular staples	6	HC-PFB-35W	with 35 Wide staples
2	HC-PFB-15W	with 15 Wide staples	7	HC-PFB-45R	with 45 Regular staples
3	HC-PFB-25R	with 25 Regular staples	8	HC-PFB-45W	with 45 Wide staples
4	HC-PFB-25W	with 25 Wide staples	9	HC-PFB-55R	with 55 Regular staples
5	HC-PFB-35R	with 35 Regular staples	10	HC-PFB-55W	with 55 Wide staples

1.3 Principles of operation

Position the instrument over the everted skin edges, aligning the instrument arrow with the center of the incision. By squeezing the handle, the spring in the Staple cartridge pushes the staple which pre-installed in the Staple cartridge forward. Squeeze the handle fully and then release handle fully, make sure that the legs of the staple will enter the skin at equal distances on either side of the wound edge and extruded into rectangle shape by the staple forming device, bring the edges together adequately to complete the skin suture.

1.4 Instructions for Use

- 1) The skin edges were cleaned with povidine iodine and dried
- 2) Evert and approximate skin edges as desired. Several techniques are suggested:
 - a) With one tissue forceps, pull skin edges together until edges evert ,or
 - b) With two tissue forceps, pick up each wound edge individually and approximate the edges, or
 - c) Apply tension to either end of the incision, such that the tissue edges begin to approximate themselves. One forceps can be used to ensure that the edges are everted.
- 3) Position the instrument over the everted skin edges, aligning the instrument arrow with the center of the incision.
- 4) Squeeze the firing handle fully and then release firing handle fully, make sure that the legs of the staple will enter the skin at equal distances on either side of the wound edge and bring the edges together adequately. Than the stapler can be removed .
- 5) Move stapler to next desired position and repeat these steps to effectively suture the skin.

2. Intended Use

The Disposable Skin Staplers are used for suturing of skin in surgical procedures such as abdomen, head, chest, neck and limbs.

3. Indications

Applicable for suturing the superficial skin of abdomen, head, chest, neck and limbs of surgical incisions.

4. Contraindication

- 1) Stainless steel skin staples are not to be used on patients with nickel and/or metal (e.g. chromium, copper, cobalt, iron) hypersensitivity to prevent related adverse reactions.

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2) When it is not possible to maintain at least a 5 mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated.

3) Skin staplers should not be used for wounds that are:

- a) infected or heavily contaminated wounds;
- b) areas with very thin or delicate skin, such as around the eyes, lips;
- c) in areas where cosmetic outcomes are critical such as the face;
- d) burned skin;
- e) wounds with edges far apart;

5. Side-effects or complications

None known.

6. Target patient population

Patients with surgical incision of abdomen, head, chest, neck and limbs that require suturing.

7. Intended user and intended use environment

It can be used by the surgeons who are experienced in skin suture procedures in the professional medical environment.

8. Precautions and warnings

- 1) The stapler is a disposable product, and can be used after opening the sterile package. It is forbidden to use if the package is found damaged. When using the product, the sterile operation procedure shall be complied with.
- 2) Please check the indicator on the sterilization package box of the product; “red” indicates that the product is not sterilized with ethylene oxide, and cannot be used directly; “blue” indicates that the product has been sterilized with ethylene oxide, and can be directly used for clinical application;
- 3) The stapler is disposable and cannot be sterilized again after use;
- 4) Prior to use, please check whether the product is within the validity period; the sterilization validity period is three years, and it is forbidden to use if the product is beyond the validity period;
- 5) The product cannot be used clinically if any damage is occurred or suspected due to falling to the ground or improper handling.
- 6) The W-type skin stapler is suitable for suturing of surgical incisions in sites with thick fat (such as the abdomen). The R-type skin stapler is suitable for suturing of surgical incisions in sites with thin fats (such as scalp).
- 7) Before using the product, it is necessary to tightly suture each layer under the skin, stop wound bleeding and eliminate the dead space to avoid wound infection;
- 8) After the staples of the stapler are pressed into place, naturally loosen the firing handle. Be sure to exit backwards;
- 9) Be careful of the spacing of the staples. Generally, there is one staple between 5mm to 10mm.
- 10) If there are excessive skin tissue defects, skin tension bullae may occur due to overlarge tension, so use this product with caution.
- 11) Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination. Disposal of all medical device instruments and accessories should be performed according to local requirements and regulations.
- 12) Dispose of all opened instruments whether used or unused. This device is packaged and sterilized for single use only.
- 13) MRI Safety Information
Disposable Skin Staplers have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Disposable Skin Staplers in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
- 14) Staples shall be removed from the patient within 30 days.

9. The intended clinical benefits to patients

Patients have better wound healing when using Disposable Skin Staplers.

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10. Product packaging

Blister sealed packaging is adopted, and the packaging material is PET or PETG blister packaging box; Tyvek dialyzing paper is used for heat sealing with the blister packaging box on the surface, and then it is put into the packaging box in which there shall be a certificate of conformity. The packaging form is sealed packaging, and it shall be guaranteed that the product is sterile until opening.

11. Conditions and methods of storage and transportation

11.1 Storage: Store in a well-ventilated room where the relative humidity is not more than 80% and there is no corrosive gas.

11.2 Transportation: The product with intact package can be transported by normal tools; during transportation, handle with care and avoid direct sunlight, violent collision, rain and gravity extrusion.




















12. Shelf life

The shelf-life of the Disposable Skin Staplers is 3 years from the date of sterilization.

13. Incident Report

Notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

14. Symbol explanation

Symbol graphic	Title of symbol	Symbol graphic	Title of symbol
	Batch code		Do not use if package is damaged and consult instructions for use
	Manufacturer		Do not re-use
	Single sterile barrier system		Medical device
	Date of manufacture		Do not re-sterilize
	Catalogue number		Consult instructions for use or consult electronic instructions for use
	Use-by date		Sterilized using ethylene oxide
	Caution		Sterile
	Authorized representative in the European Community/European Union		Unique device identifier
	“CE” marking		Keep away from sunlight
	Keep dry		

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