Please Read the Instruction Carefully before Installing and Using This Product

Medical Device Registration Certificate No.: No. G2 102935 0002 Rev. 00

Medical Device Report No.: SH 19144701

Disposable Skin Stapler and Remover Instructions for Use

1. Product Name, Model and Specification

Product Name: Disposable Skin Stapler

Model and Specification:

Stapler(KHPF-10W、KHPF-10A、KHPF-10B、KHPF-15W、KHPF-15A、KHPF-15B、KHPF-25W、KHPF-25A、KHPF-25B、KHPF-35W、KHPF-35A、KHPF-35B、KHPF-45W、KHPF-45A、KHPF-45B)

Remover(KHPF-CW、KHPF-CB)

2. Product Performance

According to the appearance and the size of the suture staple before forming, the skin stapler can be divided into three types: W type, A type and B type. According to the number of suture staples, the skin stapler can be divided into five types: 10, 15, 25, 35 and 45.

The number of stitching staples loaded in the skin stapler should be consistent with the number marked, to avoid the phenomenon of missing staples loaded. When the skin stapler is in use, the moving components should move smoothly without clamping, sticking and loosening. The spring of the skin stapler should be elastic enough to quickly reset when the handle is released, and to make the suture staple square when the handle is clenched. The skin stapler should have good suture performance. The loaded suture staples should be able to pop out smoothly and strike normally, without getting stuck, multiple strikes and missing strikes. After hitting, the skin stapler should be able to penetrate the test material and form a rectangle, without distortion and deformation. The shaped stitching stapler should be able to withstand a tension of not less than 12N for 3 seconds without falling off. The parts of the nail remover should move smoothly without stalling. And should be able to ensure the smooth removal of stitching staples, and the test material surface should not be damaged.

3. Main Structural Composition

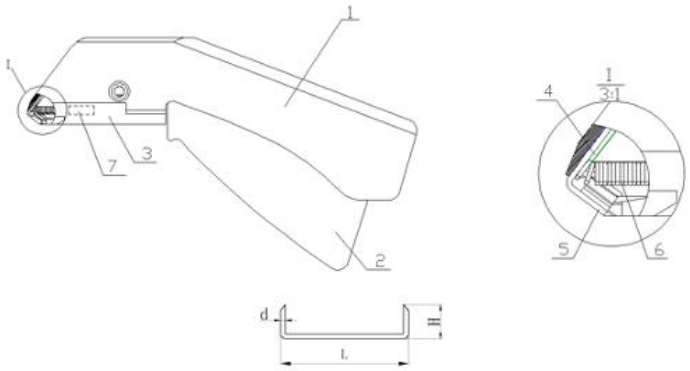
The disposable skin staple is composed of outer handle, inner handle, cartridge, push staple plate, cartridge plate, staple and push staple board. The staple removal device is an optional accessory, which is composed of pressure plate, support plate and handle.

Push staple plate, cartridge plate, pressure plate and support plate are made of standard GB/T 3280-2015 stainless steel cold-rolled steel plate (12Cr18Ni9) material, handle is made of standard GB/T12672-2009 acrylonitrile butadiene styrene (ABS) resin material, The cartridge and push staple plate are made of conforming HG/T 2503-1993 polycarbonate aryl ester (PC) material, and the staple is made of conforming GB4234-2003 stainless steel (00Cr18Ni14Mo3) material for surgical implants.

4. Scope of Application

It is used for suturing the superficial skin of wounds and surgical incisions

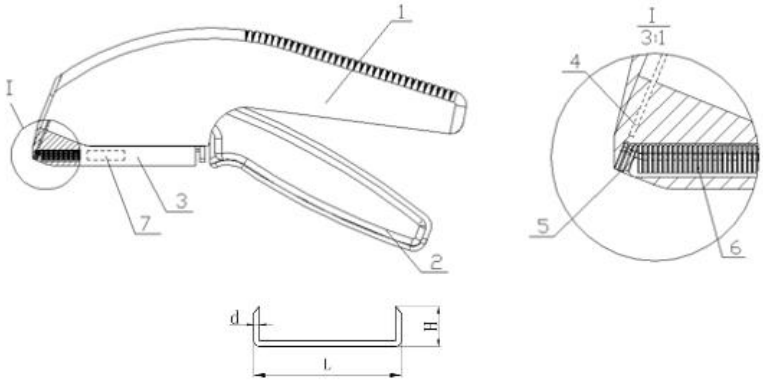
5. Product Structure



Staple before forming

1.Outer Handle, 2.Inner Handle, 3.Cartridge, 4.Push Staple Plate, 5.Cartridge Plate, 6.Staple, 7. Push Staple Board

Type W Disposable Skin Stapler Structure



Staple before forming

1.Outer Handle, 2.Inner Handle, 3.Cartridge, 4.Push Staple Plate, 5.Cartridge Plate, 6.Staple, 7. Push Staple Board

Type A, type B Disposable Skin Stapler Structure

6. Contraindications

1) If the distance between the skin incision and the internal important tissue is less than 5mm, the skin stapler is prohibited.

2) It cannot be used for surgical suture of internal tissues.

7. Installation

N/A

8. Instructions for Use

1)Use of Skin Stapler:

a) Hold the skin stapler, keep the suture staple perpendicular to the skin, and make the incision to be sutured in the middle of the suture staple and press it to the skin surface.

b) Hold the handle tightly until the skin is sutured with the suture staple (this process should be pressed to the end without stopping midway).

c) Loosen the handle, lift the tail end of the suture counter clockwise and exit the suture with the suture point as the center.

d) Repeat the above actions for subsequent suturing.

2) Use of Remover:

Please be sure to use the supporting staple remover to remove the stitching staples.

a) Hang the two parallel hooks of the staple remover between the suture staple and the tissue.

b) Holding the staple remover can lift the suture staple vertically from the suture tissue.

9. Product Maintenance

The packaged products should be stored in a well-ventilated room with a relative humidity of no more than 80%, no corrosive gas, ventilation and light protection.

10. Expiry Date

This product is sterilized by ethylene oxide, the sterilization period is three years, the expiration date is shown on the label.

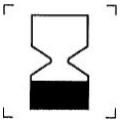
11. Accessories

None

12. Precautions and Warnings

1) When using this product, aseptic operation should be strictly carried out.
2) Please carefully check the package of this product before use. If the blister package is damaged, please stop using it.
3) This product is sterilized by ethylene oxide and used as a sterile product for clinical use.
4) This product is disposable and cannot be sterilized repeatedly.
5) Please check whether the product is within the validity period before use. The validity period of sterilization is 3 years.
6) It can only be used by doctors with surgical qualifications.
7) The incision of tension reduction suture should be made after operation, and the disposable skin suture device is not suitable for use.
8) This product is not suitable for suturing subcutaneous tissue. Suturing subcutaneous tissue Please use other suture materials for suturing.
9) Please read this manual carefully before use, pay attention to the production date and batch number of the product, and do not use it after the deadline.
10) This product is a disposable instrument, which must be destroyed after use, so that its parts no longer have the use function, and it has been sterilized and harmless.
11) Production date/expiration date: See the label for details.

12) Explanation of graphics, symbols and abbreviations used in packaging and labels.

						
Keep Dry	Fragile	Caution	Sterilized by Ethylene Oxide	Do not Re-use	Refer to instruction manual	Keep in Shade
						
Use-by Date	Reference No.	Date of Manufacture	Batch Code	Do not use if packaging is damaged	Sterile	No Secondary Sterilization

Manufacturer/Registrant/After-sales Service Unit:
Jiangsu Coopwin Med S&T Co.,Ltd.
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Building B3, Standard Workshop, Industrial Workshop, Hutang Science and Technology Industrial Park, No. 198, Xiahe Road, Hutang Town, Wujin District, Changzhou City
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Importer Information
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