Instructions for Use
Disposable Skin Stapler

CE 0197

【Version】 A/2

【Date of Issue】 2025-04-11

【Device Description】

The Disposable skin staplers consists of handle shell, firing handle and staple, not contain stapler remover. The material of handle shell and firing handle is ABS, the material of staple is 316L stainless steel. The product has two models AKYPF-35A and AKYPF-35B, the only difference is the size of staple. This product is EO sterilization, and the shelf life is 3 years. The removal time of the staple should be determined by the doctor based on the actual healing condition of the wound, and should not exceed 30 days at the longest.

【Intended Purpose】

The Disposable skin staplers are designed to apply the staples to approximate the free skin edges of an incision or wound.

【Intended user】

The device should be used by healthcare professionals having adequate training and familiarity with surgical techniques involving skin approximation.

【Indication】

The device is suitable for skin wound closure in a wide variety of surgical procedures.

【Intended Patient population】

This device is only suitable for adult patients.

【Clinical benefit】

Reduce time taken for skin wound closure.

【Specifications】

Model	Staple size (Unit: mm)								No. of Staples
	Diameter of staples	Limit deviation	Staple size before forming (L*H)	Limit deviation		Staple size after forming(L*H)	Limit deviation		
				L	H		L	H	
AKYPF-35A	0.6	±0.1	12.7*3.5	±0.2	±0.1	7.0*4.2	±0.2	±0.2	35
AKYPF-35B	0.5		10.8*2.8			6.0*3.8			

【Performance characteristics】

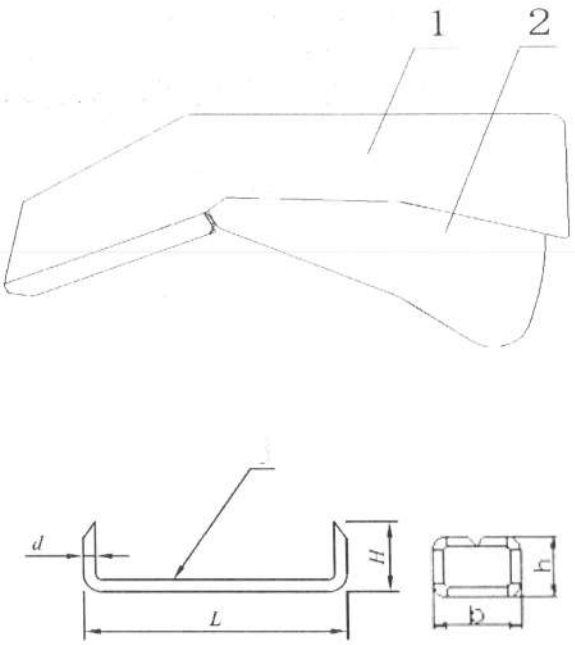
1) During use, all movable components of the skin stapler shall operate smoothly without jamming, staple sticking, or loosening. The springs of staplers shall have sufficient elasticity to allow rapid return to their original position when the handle is released. The staples inside the stapler shall be securely installed, and no staples shall fall out when the device is shaken.
2) The skin stapler shall possess good suturing performance. The loaded staples must be able to eject smoothly and fire normally without jamming, misfiring, or overfiring. After firing, the staples shall penetrate the test material completely and form a rectangular shape without any twisting or deformation.

【Contraindication】

1) When it is not possible to maintain at least 5mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated. Because such short intervals may lead to damage to blood vessels and nerves under the skin.
2) Do not use on patients too sensitive or allergic to this product.

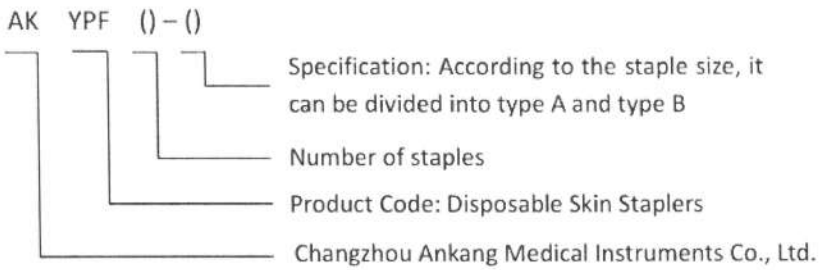
【Schematic View】

The illustration of structure and components is given in as follows:



1. Handle shell 2. Firing handle 3. Staple

According to the staple size of the Disposable Skin Staplers, it can be divided into type A and type B.



For example: AKYPF-35A means: Disposable Skin Stapler, type A, number of staples is 35, manufactured by Changzhou Ankang Medical Instruments Co., Ltd.

【Instruction for Use】

1. Pull skin edges together until edges evert with tissue forceps.

2. Position the device over the everted skin edges, aligning the device arrow with the center of the incision. Squeeze the trigger until the handle is closed.

3. Then release the trigger and remove the device from the fired staple.

【Precautions and Warning】

1. This device is packaged and sterilized for single use only, do not reuse, reprocess or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or

lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or re-sterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

2. This device is sterilized using ethylene oxide and is valid for three years. Do not use the product if the device is become invalid and the package is damaged or opened.

3. Do not examine patient with staples under MRI. Safety of staples under MRI has not been validated.

4. Once wound healing is completed, remove staples at the discretion of surgeons.

5. When using this product, follow the aseptic procedure strictly.

6. This manual cannot be used as a guide for surgical anastomosis. Regarding questions about surgical anastomosis technical guidance, please consult our company or the company's authorized agent, or refer to the related literature.

7. The users should read this instruction manual before use.

8.This product is strictly forbidden for re-sterilization. Repeated processing or repeated sterilization may damage the product, may cause the 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.

9. This product is only used in the same operation and for the same patient.

10. It is strictly prohibited in patients with contraindications.

11. Inform the manufacturer and the competent authority of the Member State in which the user and/or patient is established in case that any serious incident has occurred in relation to the device.

12. Please check the device before use.

13. If the device fails during use, do not continue to use it.

14. This product is for single use, please dispose it after use follow local regulation or the hospital's waste dispose policy.

【Potential Adverse Reaction】

Side effects may emerge after operation, possible causes include Operational factors of surgeon, selection of product indications, operation skills, surgical experience of a surgeon. Thus, selecting operation method according to clinical treatment plan based on patient's individual factors,

therapeutic tolerance and providing comprehensive training to improve users' operating skills to reduce side effects.

Side effects including: pain, bleeding, wound infection, wound breakdown, phlyctenae, edema, wound discharge, wound necrosis, wound fat liquefaction.

【Sterilization and Shelf life】

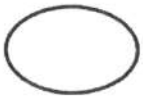
Ethylene oxide sterilization, 3 years

【Storage / Transportation conditions】

The product should be stored in a dry, well-ventilated environments away from direct sunlight, and without caustic gases.

Temperature	Relative humidity	Atmospheric pressure
-22℃～+55℃	10%～80%	700hPa～1060hPa

【Signs and Symbols Used on Labels】

CAK常安康®	Trademark of Manufacturer		Caution		Consult instructions for use
	Do not use if the package is damaged		Do not re-use		Do not re-sterilize
	Single sterile barrier system		Sterilized using ethylene oxide	CE 0197	CE marking of conformity, and Notified Body Code
	Batch code		Manufacture date		Use-by date
	Manufacturer		Authorized representative in		Unique Device Identifier

			the European Community		
REF	Catalogue number		Keep dry		Fragile, handle with care
	This way up	MD	Medical device	REF	Catalogue number
	Importer				

【Manufacturer】

Changzhou Ankang Medical Instruments Co., Ltd.

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