



Kaydee

西安凯德医疗器械有限责任公司  
Xi'an Kaydee Medical Appliances Co., Ltd

# Sterile Disposable Skin Stapler



STERILE EO



Patent No. ZL 2004 2 0085839.1  
ZL 2004 2 0085840.4  
ZL 2006 2 0079549.5

## Profile

Has been servicing the health care market for 15 years, without making any concession from the company principle of security, quality, reliability and customer satisfaction. Kaydee is a manufacturer of medical appliances, specializing in sterile disposable skin stapler and sterile disposable staple remover. Kaydee Co. who has been ISO13485:2003 certified by TUV SUD, the sterile



disposable skin stapler and the sterile disposable staple remover are CE & FDA certified.

Kaydee sterile disposable skin stapler and sterile disposable staple remover have been selling to many countries such as USA, Turkey, Korea, India, Hong Kong, Iran, Italy, France, Morocco, etc.; In China, they also have been widely used at over 1,000 hospitals in many large cities such as Beijing, Shanghai, Guangzhou, Xian etc.



100000 Grade Clean Room



Full Automatic Controlled  
ETO Sterilization Workshop

## Sterile Disposable Skin Stapler

### 1、 Benefits:

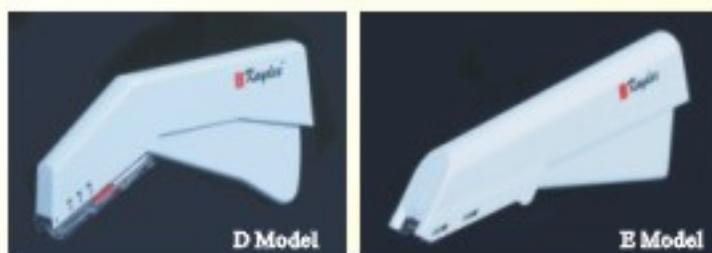
- The characteristics of the stapler's handle design for good texture and is suitable for various surgeon's hand.
- Angled head provides clear view to ensure precise staple placement and the staple could enter the tissue easily.
- The elaborate design of the staple release mechanism actuate the stapler with easy for using.
- Easy to use, reduce learning curve.
- Two model skin stapler, three staple sizes ( wide, regular and high ) and nine staple counts in stapler are true of all surgical field.

### 2、 Suggest Applications:

Operation Room    Labor and Delivery    Emergency Department  
Outpatient Surgery    Clinics and Physician's Office

### 3、 Technical Information:

- Two Model: D Model and E Model.  
D Model is suitable for big hands, male surgeons and nurses may be like it.  
E Model is suitable for small hands, female surgeons and nurses may be like it.

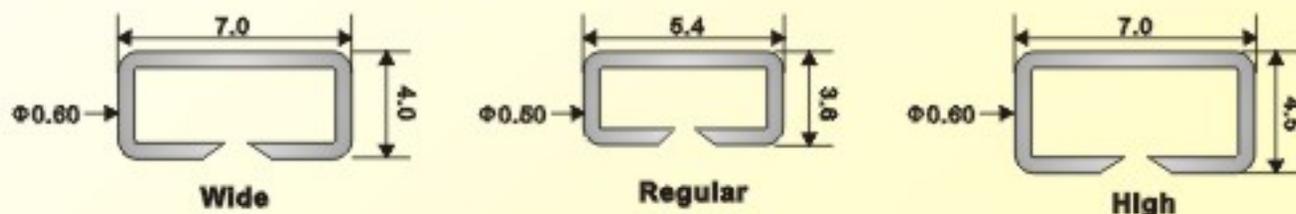


### • Three staple sizes:

Wide staple is applicable to the general part of body.

Regular staple is applicable to the thin part of body, for example: face or head.

High staple is applicable to the fat part of body, for example: fat person's stomach.



- Material of staple: 316L stainless steel imported from USA.
- Nine staple counts: 15/25/35/20/30/40/45/50/55.  
The different staple counts are applicable to the different incision.
- Sterile: with Ethylene Oxide, valid period is 3 years.
- Package: product packaged separately, packaged with DUPONT TYVEK paper.
- Packing: 80pcs/carton (10pcs/box 8boxes/carton).
- For single use.

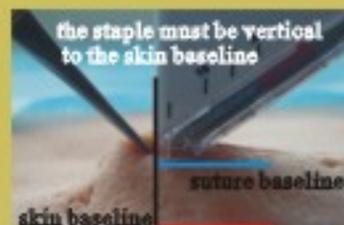
#### 4、Direction for use

- Evert and approximate skin edges.
- Position stapler over center of everted skin edges. Close by squeezing trigger fully until motion is halted.
- Release trigger fully to achieve staple release.



#### 5、Cautions:

- Put the mark to the middle line of the incision.
- The stapler's suture baseline parallel with skin baseline, the staple must be vertical to the skin baseline.



## Sterile Disposable Staple Remover

#### 1、Benefits

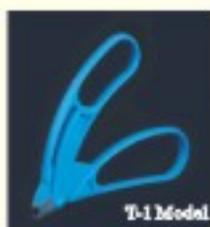
- The special design of the remover's jaw make the remover comfortable and easy for removing staple.
- The remover can remove all type staples.
- Three Model Staple Remover.

#### 2、Suggest Applications

- Removing surgical skin staples

#### 3、Technical Information

- **Three Models:** T-1 , T-2 and T-3 . T-1 and T-2 are single use. T-3 is made of stainless steel and reusable.



- **Sterile:** Product packaged sterile, sterile with Ethylene Oxide, valid is 3 years.
- **Package:** Product packaged separately, packaged with DUPONT TYVEK paper.
- **Packing:** 300pcs/carton (10pcs/box 30boxes/carton)

#### 4、Direction for use

- Press the hollow in lower jaw theremover beneath the staple spsn.
- Squeeze the handles of removerthumb to reform staple until handle is firmly touching.
- Always ensure staple is completely reformed before lifting remover fromskin. Never pull up before extractor is fully closed.





## Operation Case



Comparing skin stapler with traditional surgical sutures



Comparing the effect of wound closure between skin stapler and traditional surgical sutures



Comparing the effect between staples removed and not removed



Comparing the effect between staples removed and not removed



The operation case on shoulder



The operation case after staples removed

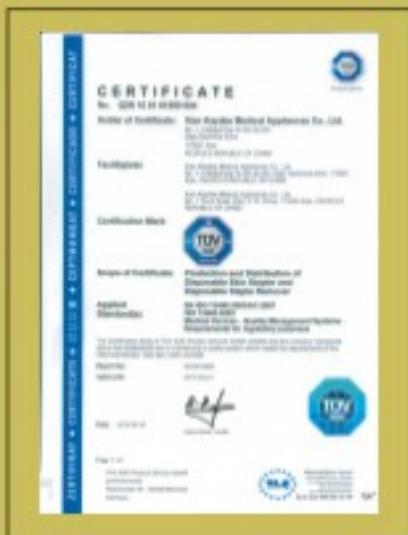


The operation case in one arm



The operation case in the head

## Certificate



ISO13485: 2003

New Search		Back To Search Results
Classification Name:	STAPLER, SURGICAL	
Product Code:	GAG	
Device Class:	1	
Regulation Number:	873.4900	
Medical Specialty:	General & Plastic Surgery	
Registered Establishment Name:	XIAN KAYDEE MEDICAL APPLIANCES CO., LTD.	
Registered Establishment Number:	3006859759	
Owner/Operator:	xian.kaydee.medical.appliances.co.,.ltd	
Owner/Operator Number:	10027460	
Establishment Operations:	Manufacture	

Registration Number:3006859759 in FDA U.S.A



Sterile Disposable Skin Stapler

Sterile Disposable Staple Remover



## Quality Assurance System

Product Realization Process	Control procedures	Process Control	Testing and inspection Control		Working Environmental Control	
			Process testing	Finished product inspection		
Design	Control procedures for design and development					
Process confirmation	Control procedures for process confirmation	Sterilization confirmation Packaging confirmation Cleaning Clean Room Overall confirmation Cleaning and disinfecting tooling / tools / utensils confirmation Cleaning sub-assemblies confirmation				
Purchase	Control procedures for the procurement	Procurement Sub-assemblies entering warehouse, storing, get from warehouse	Sub-assemblies testing			
Producing	Control procedures for test and detection devices	Manufacturing pure water	Pure water testing		※ Clean room management ※ Clean room cleaning and disinfection ※ Clean room's overall cleaning and disinfection ※ Clean room's tooling/tools/utensils cleaning and disinfection ※ Object surface and production staffs hands bacterial detection ※ Clean room's dust particle quantities detection ※ Clean room's bacteria quantities in air detection ※ Clean room's air changes rate detection	
		Cleaning sub-assemblies	Cleaning sub-assemblies testing			
		Loaded staple	Loaded staple testing			
		Installing the staple release mechanism	Installing the staple release mechanism testing			
	Control procedures for working environment	Assembling handle	Assembling handle testing			
		Welding cartridge	Welding cartridge testing			
	Control procedures for product classification	Make the staples in order	Make the staples in order testing	Product functions inspection		
				Product physical properties sample inspection		
	Control procedures for record	Packaging with DUPONT TYVEK paper Remain samples before sterilization	Packaging testing before sterilization Products' initial bacteria contamination testing			
Sterilization	Control procedures for track	ETO Sterilization	ETO Sterilization effect testing			
			Packaging testing after sterilization			
	Control procedures for traceability	Remain samples after sterilization		Bacterial endotoxin inspection Product PH inspection ETO residues inspection Sterility inspection		
Packing/Storage Sales	※ Control procedures for labeling and language	Packing	Packing testing			
	※ Control procedures for product protection	Storage				
	※ Control procedures for customer-related processes	Sales				



**西安凯楛医疗器械有限责任公司**

Xian Kaydee Medical Appliances Co., Ltd

8/F, Building 3, No.1 Torch Road, Xian 710043, Shaanxi, China

Tel: 0086-29-82683417 82682867

Fax: 0086-29-82681322

E-mail: [sales@kaydeemed.com](mailto:sales@kaydeemed.com)

Web: [www.kaydeemed.cn](http://www.kaydeemed.cn)

[www.surgical-staplers.com](http://www.surgical-staplers.com)

[www.kaydeemed.com](http://www.kaydeemed.com)