

Instructions for Surgical Incision Closure Set

[Product Name] Surgical Incision Closure Set

[Models and Size]

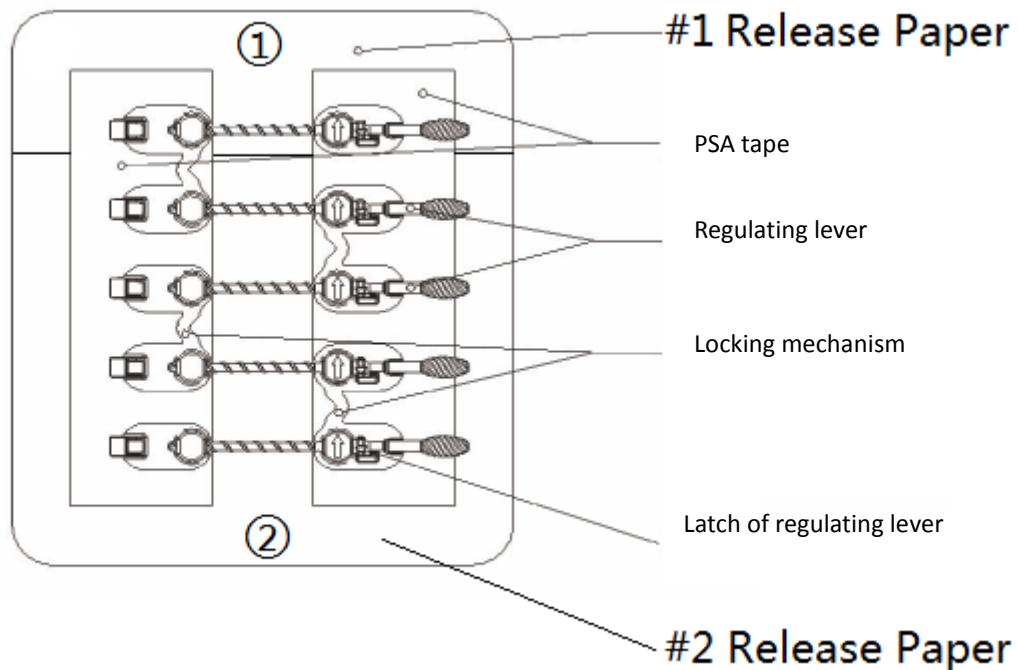
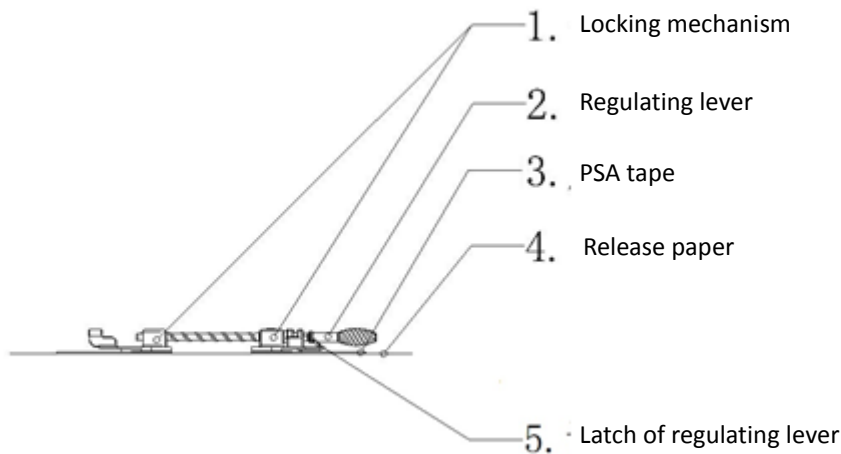
No.	Model	Size
1	5HWH-2A	2cm
2	5HWH-4A	4cm
3	5HWH-6A	6cm
		6cm (4cm*1, 2cm*1)
4	5HWH-8A	8cm
		8cm (4cm*2)
5	5HWH-10A	10cm
		10cm (2cm*3,4cm*1)
6	5HWH-12A	12cm
		12cm (6cm*2)
7	5HWH-14A	14cm
		14cm (4cm*1,10cm*1)
8	5HWH-16A	16cm
		16cm (8cm*2)
9	5HWH-18A	18cm
10	5HWH-20A	20cm
11	5HWH-22A	22cm
12	5HWH-24A	24cm

The size and combination mode can be customized according to customer requirements.

[Intended Use] This product is intended for occlusion of skin incision after surgical operation.

[Product Components] This product consists of medical PSA tape, regulating lever, lock mechanism, and release paper.

[Schematic Representation]



[Performance Specifications]

- The product is sterile after radiation sterilization
- The product is free from cytotoxicity
- The part in touch with human body produces no skin irritation
- The part in touch with human body has no delayed-type hypersensitivity (DTH)

[Directions for Use]

I. Preparation before using Surgical Incision Closure Set for incision closure

- 1 In case of stratified suture, subcutaneous suture is required to reduce the incision tension before applying the product.
- 2 Following standard practices, clean the adjacent area of the incision and ensure there are no tissue, tissue fluid, blood, lipid or other contaminant around the skin of incision, and wait that antimicrobial solution is completely dry for best adhesion.

II. Application of product

- 1 Select an appropriate Closure Set based on the length of incision.
- 2 Unpack the package and take out the Closure Set. If the Closure Set has a length larger than that of the incision, use the scissor to cut off excess length according to the size of incision before applying the product. This procedure must be performed aseptically.
- 3 Peel off the release paper ①.
- 4 Align the second regulating lever near release paper ① to one end of the incision. Place the Closure Set on skin, centered on the incision.
- 5 Press firmly where the exposed adhesive contacts skin by one hand. Lift the distal end of the Surgical Incision Closure Set and gently peel off the release paper ② by the other hand. Make sure that the incision is centered between the adhesive tapes while pressing the tapes down onto the skin slowly and firmly.
- 6 Screw the regulating levers from the middle or one end of the Closure Set while avoiding over tightness in the first round.
7. According to the distance of adjacent incision edge, screw the levers successively again so as to make the adjacent incision edges achieve complete merge with a little arching. When regulated too much, use a hemostat or a pair of forceps to remove the latch of regulating lever, and rotate the lever counterclockwise simultaneously.
- 8 Press the adhesive tape tightly, especially the area between the bolts to make it adhere to the skin as much as possible.
- 9 Put a secondary dressing on the Closure Set. The absorbent pad of dressing should be bigger than the Closure Set. Make sure that the adhesive of the dressing does not stick to the any part of Closure Set.

III. Post-operation monitoring and removal

- 1 Observe the post-operative healing of the incision from time to time. To keep incision clean and dry, debridement, drainage and treatment with medicine, and replace dressing could be done if necessary.
- 2 The Closure should be removed depending on the healing of the incision after 7-14 days. If necessary, replace the Closure Set with a new one after 14 days.
- 3 Removal of the Closure Set could be guided by the doctor. If remove by the patient himself, he/she can first peel one end of the adhesive tape off and remove the Closure Set off the incision slowly.

[Precautions and Warnings]

The Surgical Incision Closure Set is not recommended to use on the skin area such as sulcus auriculae posterior, armpit and groin, either on the incision with angle less than 90 degrees.

Minimize the incision tension to achieve its best effect on incision closing. If the distance between adjacent incision edges is too wide, squeeze the adjacent incision edges to be less than 1 cm by hand or auxiliary device before using this product.

This product is not designed for absorbing exudates or blood. It is the best to cover the wound surface with an exudate absorption dressing.

Before applying Surgical Incision Closure Set, it is necessary to clean the skin surface around the incision with antimicrobial solution and wait the wound surface to be completely dry for best adhesion.

Before applying medical adhesive tape, make sure the distance between adjacent incision edges is 10mm or less. Do not let the adhesive tape touch the incision for its strong adhesion. The distance between each pairs of regulating lever should be maintained consistent so that the tension between adjacent incision edges is uniform. Otherwise, a small percentage of individuals may experience allergic reaction and/or hypopigmentation or hyperpigmentation or tensile blisters following removal.

After applying medical adhesive tape, do not try any re-pasting action; otherwise the adhesion between skin and adhesive tape will be decrease. Please replace the Surgical Incision Closure Set if the adhesion is too weak.

If the secondary dressing covering on the Surgical Incision Closure Set is soaked by exudates, replace with a new one in case that the bonding strength of the device is reduced by soaked secondary dressing.

Surgical Incision Closure Set is for single use only. Do not reuse. Otherwise there will be risk of device failure or infection.

Don't use it in case its package has been damaged. Once used, it must be disposed of properly.

Do not use this product for patients who are serious allergic to the PSA..

Do not use the product on child or infant.

[Contraindication] This product is forbidden to use on incisions with damaged skin around, festered, apparently infected or difficult to heal and in some other similar situation.

[Storage] This product shall be stored indoors at 5~30 °C out of direct sunlight, and shall be free from corrosive gas and well ventilated.

[Shelf Life] 30 months

[Production date] See packing label

[Manufacturer] Zhejiang Haichuang Medical Device Co., Ltd.











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[Symbols]

Symbol	Meaning
	Sterilized using irradiation
	Do Not Re-use
	Consult instructions for Use
	Do Not Use if Package is Damaged
	Temperature limit
	Manufacturer
	Authorized representative in the European Community
	Use-by date
	Batch code
	Catalogue number