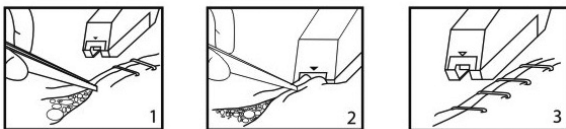


**CUCITRICE CUTANEA MONOUSO**  
**DISPOSABLE SKIN STAPLER**  
**AGRAFEUSE CUTANÉE JETABLE**  
**GRAPADORA DE PIEL DESECHABLE**  
**GRAMPEADOR DE PELE DESCARTÁVEL**  
**EINWEG-HAUTHEFTER**



**ENGLISH**

Our special designed and manufactured disposable skin stapler is the specific instrument for surgical skin suture. With novel structure and application security, our skin stapler has the advantages of quick speed of sewing up during the operation, little histological reaction, good wound matching and healing, small surgical scar, and no pain for removing, etc. Our disposable skin stapler enables you not to only work with higher efficiency, but also avoid cross-infection effectively.

**1. Main Structure**

- a. The product is composed of skin stapler and staple. Each skin stapler has some quantities of staples inside. (Please check the detail refer to the product label). The skin stapler is composed of the component of body, handle, cartridge, staple push device and staple turn back device.
- b. The raw material of the staple is the stainless steel for medical usage.

**2. Working Principle**

For the aim of skin suture, after the handle was pushed by outside force, the staples will be shaped after extrusion under the mechanical transmission of the each part.

**3. Capability Index**

- a. The suture force of the skin stapler should be no more than 55N
- b. The metal components of the skin stapler have the good function of anti-eroded.
- c. The skin stapler is sterilized with ethylene oxide. The leftover of the ethylene oxide should be less than 10 mg/kg before the products are released from factory.

**4. Application**

Disposable skin stapler is used to do the wound suture of skin during the surgical operation.

**5. How-to-use**

- a. Remove the Tyvek paper and take out the skin stapler from blister package.
- b. With a pair of tweezers lift the skin of both sides of the wound, bring them together and hold it.
- c. Make sure that the front end of the stapler is well over the wound and the staple is vertical to the longitudinal axis of the incision. Gently put the stapler onto the incision till the fore-arrow levels with the middle line of the incision. Do not press hard on the wound using the stapler as it would make the removal of the staples difficult and painful.
- d. Caution : Clasp the handle and do not loosen it until the staple is out, remove the stapler and get ready for the next step.  
See Images 1-2-3.

**6. Limit of use**

The use of this medical devices is exclusively for qualified medical personnel.

**7. Precautions of use**

- a. The skin stapler is sterilized with ethylene oxide.
- b. Sterile medical device, do not use in case of damaged single blister packaging or if the expiry date is over.
- c. Make sure the product can not be polluted when it was taken out of blister package.
- d. The product is limited to disposable use. Please destroy/dispose the finished product according to the related regulation.
- e. The skin stapler is only to be used for wound suture of at least 5 mm depth. If the depth of the wound suture is less than 5mm, the skin stapler is forbidden to be used for suture.

- f. If the hypodermic part under the incision is too thick, it is advised to first do an hypodermic suture and then a skin suture.
- g. The advised distance between each staple is of 5 to 10 mm. Please use the specific staple remover to remove the staples after 7-10 days. Or please refer to the doctor's prescribing.
- h. Please use the skin stapler within the period of validity.

**8. Contraindications**

If the wound depth is less than 5mm, the use of stapler for skin closure is contraindicated. The use of skin stapler is contraindicated in patients with known sensitivities or allergies to the metals contained in 317L stainless steel, i.e. chromium, nickel, iron, molybdenum, copper. Do not be used for internal tissue closure.

This product is not designed, sold, or intended for use except as indicated.

**9. Storage conditions**

The skin stapler must be stored in a cool dry place, with a humidity level  $\leq$  80% with no erosive gases. To be manipulated with care. Do not store other products on top of skin staplers' cartons.

**10. Period of Validity**








5 Years since sterile date. Please see expiry date of each product on the packaging.











**11. Service after Sold**

If you have any quality complains, please contact with suppliers or manufacturer.

**GIMA WARRANTY TERMS**

The Gima 12-month standard B2B warranty applies.

	<b>IT</b> Sterilizzato mediante ossido di etilene <b>GB</b> Sterilised using ethylene oxide <b>FR</b> Méthode de stérilisation utilisant de l'oxyde d'éthylène <b>ES</b> Esterilizado utilizando óxido de etileno <b>PT</b> Esterilizado com óxido de etileno <b>DE</b> Sterilisation mit Ethylenoxid	 <b>IT</b> Dispositivo monouso, non riutilizzare <b>GB</b> Disposable device, do not re-use <b>FR</b> Dispositif pour usage unique, ne pas réutiliser <b>ES</b> Dispositivo monouso, no reutilizable <b>PT</b> Dispositivo descartável, não reutilizar <b>DE</b> Für einmaligen Gebrauch, nicht wiederverwenden
	<b>IT</b> Leggere le istruzioni per l'uso <b>GB</b> Consult instructions for use <b>FR</b> Consulter les instructions d'utilisation <b>ES</b> Consultar las instrucciones de uso <b>PT</b> Consulte as instruções de uso <b>DE</b> Gebrauchsanweisung beachten	 <b>GB</b> Caution: read instructions (warnings) carefully <b>IT</b> Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso <b>FR</b> Attention: lisez attentivement les instructions (avertissements) <b>ES</b> Precaución: lea las instrucciones (advertencias) cuidadosamente <b>PT</b> Cuidado: leia as instruções (avisos) cuidadosamente <b>DE</b> Achtung: Anweisungen (Warnungen) sorgfältig lesen
	<b>IT</b> Questo lato su <b>GB</b> This side up <b>FR</b> Ce côté vers le haut <b>ES</b> Este lado hacia arriba <b>PT</b> Este lado para cima <b>DE</b> Diese Seite (nach) oben!	 <b>IT</b> Fragile, maneggiare con cura <b>GB</b> Fragile, handle with care <b>FR</b> Fragile, manipuler avec précautions <b>ES</b> Frágil, manejar con cuidado <b>PT</b> Frágil, manusear com cuidado <b>DE</b> Zerbrechlich, mit Sorgfalt behandeln
		

	<b>IT</b> Codice prodotto <b>GB</b> Product code <b>FR</b> Code produit <b>ES</b> Código producto <b>PT</b> Código produto <b>DE</b> Erzeugniscode	 <b>IT</b> Limite di umidità <b>GB</b> Humidity limit <b>FR</b> Limite d'humidité <b>ES</b> Limite de humedad <b>PT</b> Limite de humidade <b>DE</b> Feuchtigkeitsgrenzwert
	<b>IT</b> Numero di lotto <b>GB</b> Lot number <b>ES</b> Número de lote <b>FR</b> Numéro de lot <b>PT</b> Número de lote <b>DE</b> Chargennummer	 <b>IT</b> Fabricante <b>GB</b> Manufacturer <b>ES</b> Fabricante <b>FR</b> Fabricant <b>PT</b> Fabricante <b>DE</b> Hersteller
	<b>IT</b> Data di fabbricazione <b>GB</b> Date of Manufacturing <b>FR</b> Date de fabrication <b>ES</b> Fecha de fabricación <b>PT</b> Data de fabrico <b>DE</b> Herstellungsdatum	 <b>IT</b> Data di fabbricazione <b>GB</b> Date of manufacture <b>ES</b> Fecha de fabricación <b>FR</b> Date de fabrication <b>PT</b> Data de fabrico <b>DE</b> Herstellungsdatum
	<b>IT</b> Conservare in luogo fresco ed asciutto <b>GB</b> Keep in a cool, dry place <b>ES</b> Conservar en un lugar fresco y seco <b>FR</b> À conserver dans un endroit frais et sec <b>PT</b> Armazenar em local fresco e seco <b>DE</b> An einem kühlen und trockenen Ort lagern	 <b>IT</b> Conservare al riparo dalla luce solare <b>GB</b> Keep away from sunlight <b>FR</b> À conserver à l'abri de la lumière du soleil <b>ES</b> Conservar al amparo de la luz solar <b>PT</b> Guardar ao abrigo da luz solar <b>DE</b> Vor Sonneneinstrahlung geschützt lagern
	<b>IT</b> Rappresentante autorizzato nella Comunità europea <b>GB</b> Authorized representative in the European community <b>FR</b> Représentant autorisé dans la Communauté européenne <b>ES</b> Representante autorizado en la Comunidad Europea <b>PT</b> Representante autorizado na União Europeia <b>DE</b> Autorisierter Vertreter in der EG	 <b>IT</b> Dispositivo medico conforme alla Direttiva 93/42/CEE <b>GB</b> Medical Device complies with Directive 93/42/EEC <b>FR</b> Dispositif médical conforme à la directive 93/42 / CEE <b>ES</b> Dispositivo médico según a la Directiva 93/42 / CEE <b>PT</b> Dispositivo médico em conformidade com a Diretiva 93/42/CEE <b>DE</b> Medizinprodukt gemäß Richtlinie 93/42/CEE

**REF F-35W (25891)**

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 **STERILE EO**  
   



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