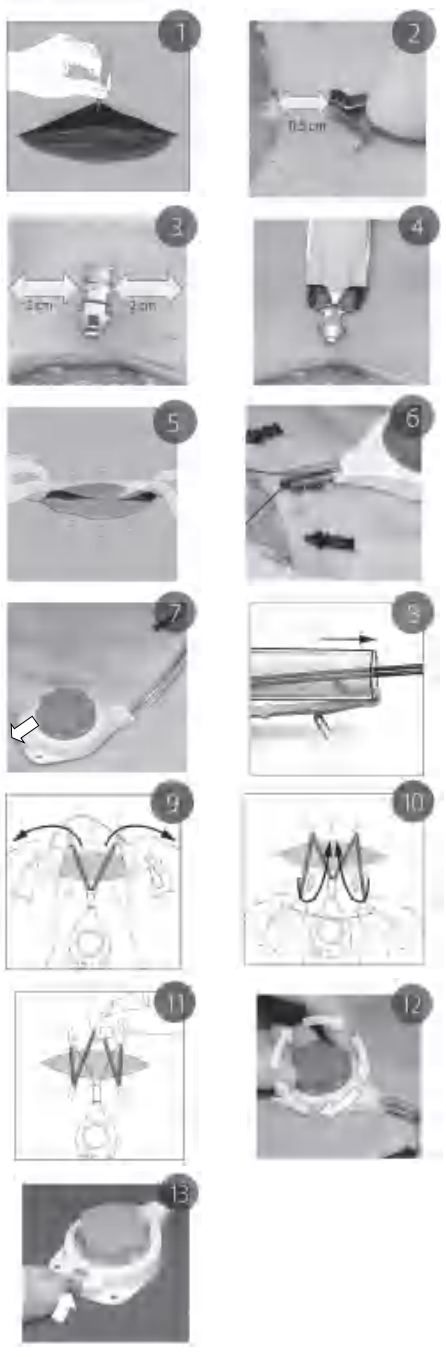


Application of the Tension Controlled Dermal Closure Device

Instructions Manual Tension Controlled Dermal Closure Device

[Product Name]
Tension Controlled Dermal Closure Device
[Models]

Product Name	REF/Models
Tension Controlled Dermal Closure Device	KC-66
	KC-96
	KC-66-II
	KC-96-II

[Main Components]
The tension controlled dermal closure device is is composed of tension controller and skin anchor.

Tension controller Skin anchor-M1 Skin anchor-M2

The tension controlled dermal closure device is a sterile continuous external tissue expander that facilitates rapid tissue movement to reduce or reap proximate wounds. KC-96 and KC-96-Ⅱ contains 30 cm more line than KC-66 and KC-66-Ⅱ and are intended for large wounds that are greater than 8 cm in width. After the initial application has been completed the tension controlled dermal closure device does not require any additional tightening. Depending on the location and size of the wound, one or more tension controlled dermal closure device may be left in place according to the wound healing time to provide the needed tissue expansion. Once the desired tissue expansion has occurred the device(s) can be removed.

[Main Performance]

- Breaking Strength: The average breaking strength of the suture should be≥34.5N.
- Corrosion Resistance: The corrosion resistance of the skin anchor should meet or exceed Grade A.
- Metal Ions: The total content of barium, chromium, copper, lead, and tin in the test solution should not exceed 1μg/mL, and the cadmium content should not exceed 0.1μg/mL.
- Reducing Substances: The difference in the volume of potassium permanganate solution [$c(KMnO_4)$ = 0.002mol /L] used should not exceed 2ml.
- Acidity/Alkalinity: The pH difference between the test solution and the blank control solution should not exceed 1.5.
- Sterility: The product must be sterile.

[Indications for use]
The tension controlled dermal closure device is indicated for use in assisting with the closure of moderate to large surgical or traumatic acute full thickness wounds of the skin by approximating and reducing the size of the wound.

[Intended Use]
The tension controlled dermal closure device is intended for the closure of wounds by approximating and reducing the size of the wound.

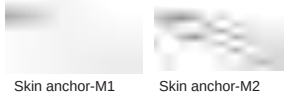
[Intended users]
The tension controlled dermal closure device is intended to be used by physicians but may be prepared by a nurse or a scrub technician.

[Intended Patient Population]
The tension controlled dermal closure device is intended for patients who need to undergo repair of moderate to large surgical or traumatic acute full thickness wounds.

[Package Contents]
Tension Controller
The tension controller is 44.5mm wide, 66.3mm long, 21mm high,

and is made of PC plastic.
The mono filament nylon line is 300mm in length for KC-66 and KC-66-Ⅱ and 450mm in length for KC-96 and KC-96-Ⅱ.The tension control knob is turned clockwise until a clicking sound is heard which indicates the appropriate force is being applied to the line. A lock button is located on the rear of the tension controller and is used to prevent unintended release of tension force. It must be in the “out” position to release or rotate the tension control knob (See the arrow positions in Figure 7).
The tension controller comes with a small section of bridge tubing (about 17mm in length). Fifteen centimeters of sterile tubing is included in the package so that the tension controller may be positioned remotely from the wound site. If necessary, the tubing should be cut to the desired length. After removing the preinstalled short tubing, the tension line is folded tight and then is threaded through the bridge tubing before application of the tension controlled dermal closure device.
If the tension controller n eeds to be placed away from the wound, or if the preinstalled tension bridge tubing (17mm) is accidentally worn, the appropriate length of tension bridge tubing can be replaced. When remote positioning is desired, the use of a large-size tension (KC-96 and KC-96-Ⅱ) controlled dermal closure device is recommended as this device provides extra tension line length.

Skin Anchor:
Each skin anchor is made of 022Cr17Ni12Mo2 surgical stainless steel with sharp flat barbs that penetrate the skin 4.5 mm. The package contains seven sterile skin anchors. One tension controlled dermal closure device with 6 skin anchors should be used for every 10 cm wound length. The skin anchor is held in place with two (or more) skin staples, and can also be fixed with sutures.



Skin anchor-M1 Skin anchor-M2

The tension controlled dermal closure device is intended to be used with six skin anchors and one tension controller for each 10 cm of length of wound. Use multiple devices for longer wounds.

[Contraindications]

- The tension controlled dermal closure device should not be used on ischemic, infected, or acute burned tissue.
- The tension controlled dermal closure device should not be used on fragile tissue at the edges of a wound.
- The tension controlled dermal closure device should not be used in patients allergic to stainless steel and polycarbonate materials.

[Prior to using]
Please read entire contents prior to using the Tension Controlled Dermal Closure Device.

[Potential Complications]

- Minor to moderate pain
- Infection
- Inflammation
- Tissue expansion may lead to increased levels of exudate.

[Cautions/Precautions]

- Open this package using appropriate sterile procedures.
- Skin anchors have sharp skin engagement barbs. Handle carefully and dispose of in a sharps container.
- Ensure wound bed has been thoroughly cleaned, debrided and is free of any foreign material prior to application.
- Thoroughly cleanse the area around the wound using an appropri ate anti-microbial agent.
- Utilize local, regional or general anesthesia at the health care provider’s discretion.
- Excise wound margins when indicated.
- The wound edges should be surgically undermined as needed to mobilize the dermis.
- Dispose of used device appropriately.
- Device should not be applied to wound for more than 14 days.
- Use caution when considering tension controlled dermal closure device where there is inadequate vascularity of the affected tissue.
- Irradiated skin may not respond to tissue expansion.
- Use caution when considering tension controlled dermal closure device in the presence of extensive scar tissue.
- If any serious incident occurs, please immediately contact the local distributor, notify the European Authorized Representative, report to the CA, and inform the NB and HRKC.

[Warnings]

- For single patient use only.
- Do not use if sterile packaging is open or compromised.
- Do not reprocess or resterilize. Attempts to resterilize and/or reuse this device may result in product failure and an increased risk of contamination.
- Skin anchors left in place for more than seven days increase the risk of scarring the skin.
- In case of mechanical failure such as rotation block or stuck of the knob of the skin fixation tension control suture device, the opera tion should be terminated immediately and a new instrument should be replaced to ensure the safety and effectiveness of wound closure.
- If mechanical failure such as rotation block or stuck of the knob of the tension controlled dermal closure device, the operation should be terminated immediately and a new instrument should be replaced to ensure the safety and effectiveness of wound closure.
- The tension controlled dermal closure device should only be used by trained and qualified personnel.
- Do not use the tension controlled dermal closure device during an MRI. The device is not compatible with an MRI environment.

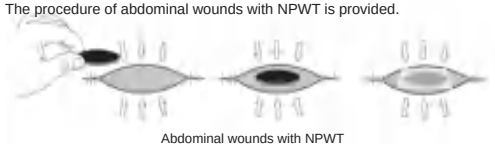
[Application]
Prior to Application:
Before application, ensure that the wound is thoroughly cleaned, debrided and that the wound edges are undermined (Fig 1).
It is necessary to create a tissue plane prior to applying the device. Undermine or elevate wound margins on a supra-fascial plane by approximately half the width of the wound when clinically indicated. Pre-marking the skin may be useful to ensure that the anchors are placed evenly along the opposing wound edges. More effective wound edge approximation can be achieved when each anchor has an opposing anchor on the opposite side of the wound. One tension controlled dermal closure device should be used for every 10 cm wound length.
Step 1 - Inserting the Skin Anchors:
Position the tips of the skin anchors approximately 0.5 to 1cm from the wound edge (Fig 2) and a maximum of 2cm apart (Fig 3) with the “anchor loop tab” facing the wound. (The anchors may be positioned up to 3cm from the wound margins and 3cm apart when clinically indicated for applications such as off-loading high-tension sutures or abdominal wounds.)
Press firmly so that the barbs fully penetrate the skin. Use stapler vertically to secure the skin anchors, hold the handle and completely tighten the extruder stitching, and secure the skin anchor in place with two skin staples (Fig 4). Staples should be placed in the gaps provided on the skin anchors. Repeat this step until the six skin. Skin anchors can be fixed by means of skin staples, sutures or combination.
Step 2 - Protect the Wound:
To help protect the wound bed from the tension controller line, it may be helpful to put petrolatum impregnated or similar non-adhering wound dressing on the wound bed and, if desired, under the wound margins before attaching the tension controller line to the tabs on the skin anchors (Fig 5).
If used for high tension offloading:
When using the tension controlled dermal closure device for high tension offloading, apply a petrolatum impregnated or similar
non-adhering wound dressing over the closed suture before lacing the tension line from the tension controller.
If Used with Negative Pressure Wound Therapy (NPWT):
However, the tension controlled dermal closure device works very well

alone and does NOT require the use of NPWT to be effective. If the surgeon determines the wound requires NPWT, following the NPWT tips in these instructions will help ensure a successful outcome.

Abdominal wounds with NPWT:

Cut the NPWT foam 50% smaller than the wound, insert within the wound, and place a layer of petrolatum impregnated or similar non-adhering wound dressing over the foam. This enables the tissue to easily glide over the foam after the tension line has been tightened. This is important to keep mobility of tissue under pressure of the NPWT.

The procedure of abdominal wounds with NPWT is provided.



Abdominal wounds with NPWT

Step 3- Positioning the Tension Controller:

Once all the required skin anchors have been secured in place it is recommended to position the tension controller at the center skin anchor. If the tension controller is to be seated close to the wound (Fig 6), leave the existing short bridge tubing in place. If the tension controller is to be placed remotely (Fig 7), remove the short section of bridge tubing from the tension line and cut a new section to fit from the enclosed 15 cm section of bridge tubing. Once the desired tube length has been determined, thread the line through the bridge tubing.

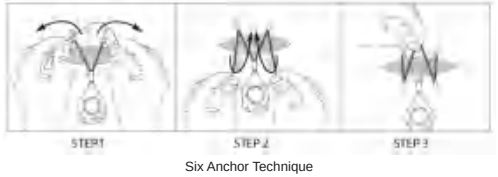
Step 4 -Attaching the Tension Line:

The tension controller is shipped with all available line extended. Caution: When all available line is extended do not turn the tension control knob counter-clockwise as this may damage the tension controller.

Seat the distal end of the bridge tubing on the “home anchor” by firmly pressing the lumen of the tubing into the top of the skin anchor tab (Fig 8).

Once this has been seated, using both hands, separate the two strands of the tension line and place over the respective off-set opposing skin anchors under the anchor tabs from the inside out (Fig 9). Next, guide the tension line around the tabs of the opposing two outer anchors from the outside in (Fig 10). Finally, guide the tension line over the final anchor tab opposite the “home anchor” (Fig 11) and gently pull on the tension controller to remove any slack in the line. See the Six Anchor Technique graphic and figures 9 through 11.

Caution: do not create any eyelets or loops around the skin anchors.



Six Anchor Technique

Step 5 - Winding the Tension Controller:

Once the tension line has been attached around the skin anchors, tension is applied by turning the tension control knob clockwise (Fig 12) until a clicking sound is heard. This indicates that the tension controller is fully tightened and that the internal clutch mechanism is preventing additional force from being applied. During application, if adjustment or tension release is needed, the line may be released by depressing the control knob and pulling line out.

When using the tension controlled dermal closure device for high tension offloading, the tension controller knob is turned clockwise only until sufficient offloading has been achieved, as determined by the clinician.

Once the full tension has been achieved, the tension controller should be locked to prevent accidental tension line release by pushing in the locking button on the rear of the device (Fig 13). The internal mechanism maintains a constant pulling force on the tension line. No additional tightening of the device is required.

Step 6 - Securing the Tension Controller:

Secure the tension controller to the skin by loosely suturing through the holes located on the rear of the device. You may also use tape to secure the tension controller; padding may be placed between the patient’ s skin and the tension controller device to protect the skin.

If Used with Negative Pressure Wound Therapy (NPWT):

Do not put the tension controller and tension bridge tube in direct contact with the skin to prevent the vacuum pressure from causing tissue damage under the controller and tubing.

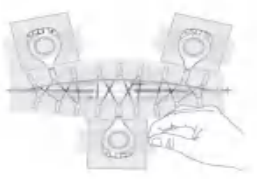
Caution: Do not place dry gauze under the tension controller when using NPWT. This will result in skin blistering under the tension controller.

Step 7 - Dressing the Wound:

Apply a suitable dressing to the wound as indicated. Please note that the pulling force on the skin may result in additional exudate. The tension controller may also be secured beneath the final gauze wrap. The tension controlled dermal closure device will immediately begin to mobilize the tissue and can be left in place until the desired tissue expansion has occurred. This can take anywhere from hours to days depending on wound location, size, and type of tissue. Evaluate tissue movement after 48 to 72 hours. If scarring from the anchors and skin staples is a concern, remove or reposition them prior to day seven. The maximum length of time tension controlled dermal closure device can be left on is fourteen (14) days.

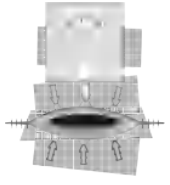
If Used with Negative Pressure Wound Therapy (NPWT):

Place a layer of petrolatum impregnated or similar non-adhering wound dressing over the tension line and all skin anchors; the anchors are sharp and can pierce the VAC drape. Also, place the dressing material over the controller to keep the NPWT drape from sticking to the controller.



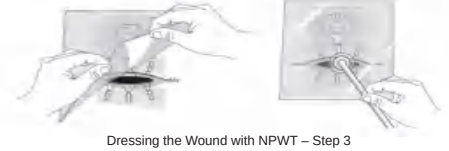
Dressing the Wound with NPWT – Step 1

For extremity wounds, cut NPWT foam 50% smaller than the wound and place the foam over the non-adhering wound dressing in the center of the wound.



Dressing the Wound with NPWT – Step 2

Place the NPWT drape over the wound (abdominal or extremity) and the entire tension controlled dermal closure device, including controller. Poke hole in NPWT drape to place suction over the foam.



Dressing the Wound with NPWT – Step 3

Step 8 - Removing the Tension Controlled Dermal Closure Device:

After the desired tissue expansion has occurred, remove the tension controlled dermal closure device. Remove the sutures and/or tape that is securing the tension controller. Release the line tension by any of the following methods:

- Cutting the tension line
- Pulling out the locking button, pressing down on the control knob and turning counter- clockwise. (Note: when under tension the tension control knob may automatically spin counter-clockwise when depressed)
- Removing the tension line from the skin anchors

Use a skin staple remover to remove the staples from the skin and dispose of them appropriately in a sharps container.

Remove each skin anchor and dispose of appropriately in a sharps container. The wound should then be sutured or stapled closed.

Dispose of the tension controller in accordance with applicable biohazard regulations.

Step 9: The wound should then be sutured or stapled closed.

[Compatibility]

The compatibility of the tension controlled dermal closure device with the disposable Skin Stapler and disposable staple remover.

NUM	Specification of the tension controller	Specification of skin anchor	skin staple	Size of the formed skin staple
1	KC-66	M1		L：6.8±0.3 mm H：4.2±0.1mm d：Φ 0.58±0.2mm
2	KC-96			
3	KC-66-II	M2		L：7.7±0.3 mm H：4.5±0.1mm d：Φ 0.61±0.2mm
4	KC-96-II			

Prior to surgery, it is essential to check that the staple size of the disposable skin stapler matches the model of the skin anchor. Following completion of surgical wound closure, it is recommended to use an appropriately sized disposable staple remover to remove the skin staples. Hua Rong Ke Chuang Biotechnology (Tianjin) Co., Ltd. shall assume no liability whatsoever for any and all adverse consequences arising from the use of staples with dimensions incompatible with the skin anchor.

(Recommendation: The Skin Fixation Tension Control Suture Device is recommended to be used exclusively with compatible disposable skin staplers manufactured by Changzhou Medical Bioengineering Co., Ltd.)

[Transportation] Avoid rain and rough handling during transportation.
[Storage] This product should be stored in the relative humidity is not more than 60%, the temperature is below 15℃~25℃, stored in a well-ventilated room without corrosive gas.
[Model/REF] See the individual product label.
[Date of Manufacture] See the individual product label.
[Batch Number] See the individual product label.
[Use-by Date] The product is valid for 5 years from the date of manufacture.
[Sterilization] Sterilization using Ethylene oxide.
[Manufacturer] Hua Rong Ke Chuang Biotechnology (Tianjin) Co., Ltd.
[Address] Building A, 1st Floor A Zone and 2nd Floor Building B, No. 69, Xin'An Road, Tianjin Economic-Technological Development Area West, Tianjin, 300462, China
[EU REP] NOVAMEDICAL GmbH
Elisabeth-Selbert-Str. 5 D-40764 Langenfeld Germany

REV.B Date: 2025-04-30

Symbol	Standard and Symbol Number	Symbol Title	Symbol Description
	EN ISO 15223-1 5.1.1	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1 5.1.2 AMENDMENT 1 2025-03	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union
	EN ISO 15223-1 5.1.4	Use-by date	Indicates the date after which the medical device is not to be used
	EN ISO 15223-1 5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	EN ISO 15223-1 5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	EN ISO 15223-1 5.1.11	Country of manufacture	To identify the country of manufacture of products
	EN ISO 15223-1 5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process
	EN ISO 15223-1 5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	EN ISO 15223-1 5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized
	EN ISO 15223-1 5.2.8	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	EN ISO 15223-1 5.2.12	Double sterile barrier system	Indicates two sterile barrier systems
	EN ISO 15223-1 5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	EN ISO 15223-1 5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
	EN ISO 15223-1 5.4.2	Do not re-use	Indicates a medical device that is intended for one single use only
	EN ISO 15223-1 5.4.3	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	EN ISO 15223-1 5.4.4	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	EN ISO 15223-1 5.7.7	Medical device	Indicates the item is a medical device
	EN ISO 15223-1 5.7.10	Unique device identifier	Indicates a carrier that contains unique device identifier information
	ASTM F2503-23	MR Unsafe	Indicates that the device is MR unsafe
		Notified Body code	