

# INSTRUCTIONS FOR USE

## SINGLE USE TRANSVERSE CUTTING LINEAR STAPLER

ENGLISH

### ⚠ BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION THOROUGHLY.

#### IMPORTANT!

This information is designed to assist in using this product. It is not a reference document for surgical stapling techniques.

#### INDICATIONS

The CHEX TRANSCUT TCLS Linear Staplers have applications in abdominal, gynaecological, paediatric and thoracic surgical procedures for the resection or transection of tissue.

#### CONTRAINDICATIONS

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

- The CHEX TRANSCUT TCLS Linear Staplers should not be used on tissues which, in the opinion of the surgeon, would not be able to tolerate conventional suture material or conventional closure techniques.
- The CHEX TRANSCUT TCLS Linear Stapler must not be used in instances where the retaining pin cannot be positioned securely in the retaining pin hole in the anvil jaw. Failure to secure the retaining pin may result in improperly formed staples and a compromised staple and cutting line, and may cause bleeding, leakage or disruption.
- Tissue thickness should be carefully evaluated before firing any stapler. Refer to "STAPLER PARAMETERS" and the "Tissue Compression Requirements" section. "Tissue Compression Requirements" refers to the compression requirement for each staple size. The TCLS should not be used on tissue that will not comfortably compress, or that compresses to less than the specified compression requirements. If these instructions are not followed, closure failure, tissue trauma, dehiscence, tissue tearing and displacement may occur, and /or haemostasis may not be obtained.
- The CHEX TRANSCUT TCLS Linear Staplers should not be used to staple liver, spleen, or similar tissue as compressing these tissues may be destructive.
- Do not use the instrument on ischemic or necrotic tissue.
- Do not use on the aorta.

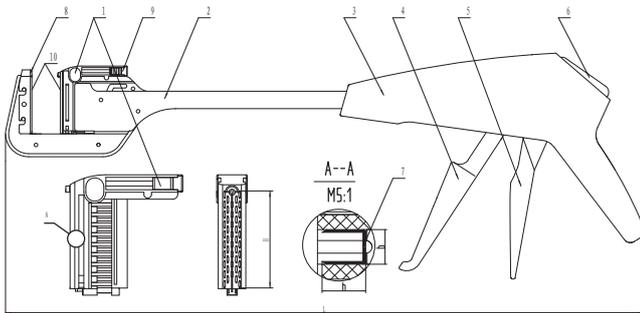
#### INSTRUMENT DESCRIPTION

The CHEX TRANSCUT TCLS Linear Stapler places two double staggered linear rows of titanium staples with a cutting blade in between and is available in 40mm staple line length. Two stapler sizes (3.8mm and 4.5mm) are available to accommodate various tissue thicknesses which are colour coded Blue for tissue compression of 1.5mm and Green for tissue compression of 2mm. Please refer to "STAPLER PARAMETER" for availability of staple sizes. Each CHEX TRANSCUT TCLS Linear Stapler is for single use only and cannot be reloaded or re-fired.

#### STAPLER PARAMETERS

Product Code				Staple rows	Staple Quantity	Stapling thickness (mm)	Staple Crown (mm)	Staple Leg Length (mm)	Stapling Line Length (mm)
Transverse cutting Linear stapler	Cartridge Reloads								
TCLS40G	Green	TCLSR40G	Green	4	38	2.0	3.0	4.5	39
TCLS40B	Blue	TCLSR40B	Blue	4	38	1.5	3.0	3.8	39
TCLS40W	White	TCLSR40W	White	4	38	1.0	3.0	2.5	39
TCLS60G	Green	TCLSR60G	Green	4	58	2.0	3.0	4.5	59
TCLS60B	Blue	TCLSR60B	Blue	4	58	1.5	3.0	3.8	59

#### SCHEMATIC VIEW



- CARTRIDGE
- SHAFT
- HANDLE
- FIRING TRIGGER
- CLOSING TRIGGER
- RELEASE BUTTON
- STAPLE
- ANVIL
- RETAINING PIN SLIDER
- JAWS

#### INSTRUMENT OPERATION

The CHEX TRANSCUT TCLS Linear Staplers are supplied sterile with the jaws in the open position and with either a blue or green staple cartridge in place.

- Remove the staple retaining cap from the instrument. Discard the staple retaining cap. Position tissue to be stapled within the jaws of the instrument. Note: Any tissue covering the hole in the anvil will be pierced by the Retaining Pin.
- Squeeze the Closing Trigger until a click is heard.
- The instrument is in an intermediate position, the pin is fully seated in the anvil capturing the tissue, and the jaws are partially open. Reposition

- tissue within the instrument if desired. Note: The Retaining Pin automatically seats into the anvil when operating the Closing Trigger.
- If desired, the Retaining Pin may be manually seated while the jaws remain fully open. Push the manual pin tab toward the Anvil after positioning the tissue to be stapled within the jaws of the instrument.
- Squeeze the Closing Trigger and the handle fully together until a second click is heard. The Closing Trigger is now latched to the handle and the jaws are clamped onto the tissue, which is ready to be stapled and cut. The Firing Trigger will simultaneously move down to the ready-to-fire position. **Note:** Continue to grasp and manipulate the instrument using the Closing Trigger until ready to fire the instrument. Do not grasp the Firing Trigger before the instrument is to be fired. **Note:** If the tissue needs to be repositioned within the instrument before stapling, open the jaws by pushing the Release Button and slowly releasing grasp of the Closing Trigger. The Closing Trigger will return to the fully open position and the jaws will release the tissue. Tissue can now be repositioned. Before firing, check to ensure the Retaining Pin is seated in the anvil. If the pin is not properly positioned, staples may not form properly, which may result in leakage or disruption of the staple and cutting line.
- Fire the instrument by pulling the Firing Trigger back completely against the Closing Trigger until a click is heard, signifying the staples are fully formed and the tissue has been completely cut. **Note:** The CHEX TCLS Linear Staplers are designed with a safety feature which prevents firing if an empty cartridge or pre-fired cartridge is in the instrument. If the Firing Trigger does not pull back completely against the Closing Trigger, the unit must be replaced with a fully loaded instrument
- Open the jaws by pushing the Release Button and releasing grasp of the Closing Trigger.
- The triggers and jaws will fully open, releasing the tissue. Remove the instrument. **Caution:** Examine the staple line for hemostasis/pneumostasis and proper staple formation. If hemostasis/pneumostasis is not present, appropriate techniques should be used to achieve hemostasis/pneumostasis.

#### NOTE

Tissue Compression Requirement refers to the compression requirement for each staple size. If tissue cannot be comfortably compressed to this requirement, or compressed to less than this requirement, the tissue may be too thick / thin for the staple size.

#### WARNINGS AND PRECAUTIONS

- Preoperative radiotherapy may result in changes to tissue. These changes may, for example, cause the tissue thickness to exceed the indicated range for the selected staple size. Careful consideration should be given to any pre-surgical treatment the patient may have undergone and in corresponding selection of staple size.
- Each component in the package must be used in the manner indicated.
- The CHEX TRANSCUT TCLS Linear Staplers are provided STERILE and are intended for single use during a single surgical procedure. DISCARD AFTER USE. DO NOT RESTERILISE.
- Do not modify this instrument in any way. Use of a modified device may result in improper instrument function. FRANKENMAN or its associated companies, makes no claim for or representation as to the performance characteristics of this product if any modifications have been made to the device or reloads in any way.

#### RECOMMENDED STORAGE CONDITIONS

STORE AT ROOM TEMPERATURE. AWAY FROM MOISTURE AND DIRECT HEAT.

DO NOT EXPOSE TO TEMPERATURES ABOVE 54 °C (130 DEGREES FAHRENHEIT).

THE CHEX TCLS TRANSVERSE CUTTING LINEAR STAPLER IS PROVIDED STERILIZED BY IRRADIATION. THE EXPIRY DATE AS INDICATED ON THE PACKAGING WILL BE THREE YEARS FROM IRRADIATION IF THE PACKAGING IS NOT BROKEN



STERILE R



Frankenman International Limited  
Suite B, 13F, Wing Tat Commercial Building  
121-125 Wing Lok Street, Sheung Wan, HongKong  
t: +852 3106 3035  
f: +852 3585 0519  
www.frankenman.hk



Shanghai International Trading Corp. GmbH(Hamburg)  
Eiffestrasse 80, 20537 Hamburg, Germany  
t: 0049-40-2513175  
f: 0049-40-255726

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SURGICAL STAPLERS