INFINITI MEDICAL
Advanced Technology for Vets and Pets

# INSTRUCTIONS FOR USE
# SINGLE USE RE-LOADABLE LINEAR STAPLER AND RELOADS

**CAUTION: U.S federal law restricts this device to sale by or on the order of a veterinarian.**
**CAUTION: This product is intended for veterinary use only. It is not for human use**

Target Species: Canine

**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE: FAILURE TO FOLLOW SPECIFIC INSTRUCTIONS WARNINGS AND PRECAUTIONS MAY RESULT IN PROCEDURE COMPLICATIONS. AN ASEPTIC TECHNIQUE IS REQUIRED.**

## INDICATIONS

The *CHEX LS Re-Loadable Linear Staplers* have applications in abdominal, pelvic and thoracic surgical procedures for the resection or transection of tissue. The CHEX LS30W Linear Stapler has application on internal tissue that can easily be compressed to 1 mm in thickness.

## CONTRAINDICATIONS

- This device is not designed, sold, or intended for use except as indicated
- The *CHEX LS Re-Loadable Linear Staplers and Reloads* 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 LS Re-Loadable Linear Stapler and Reloads* 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 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 LS 30, 45, 60 and 90 single use reloads 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 hemostasis may not be obtained.
- The *CHEX LS Re-Loadable 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 LS Re-Loadable Linear Stapler* places a double staggered row of titanium staples (three staggered rows of titanium staples for LS30W) and is available in 30mm, 45mm, 60mm and 90mm staple line lengths for use in various applications. Three staple sizes (2.5mm, 3.8mm and 4.5mm) are available to accommodate various tissue thicknesses. Please refer to “STAPLER PARAMETER” for availability of staple sizes and instrument / cartridge lengths. Each *CHEX LS Re-Loadable Linear Stapler* should only be reloaded up to 7 times for a total of 8 firings per instrument.



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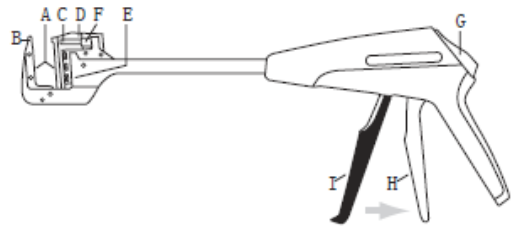
**STAPLER PARAMETERS**

| Product Code | | | | Stapling Thickness (mm) | Stapling Line Length (mm) | Staple Qty | Staple Crown (mm) | Staple Leg Length (mm) |
|---|---|---|---|---|---|---|---|---|
| Linear Stapler | | Cartridge Reloads | | | | | | |
| LS30W | White | LSR30W | White | 1.2 mm | 32 mm | 23 | 3.0 mm | 2.5 mm |
| LS30G | Green | LSR30G | Green | 2.0 mm | 32 mm | 13 | 3.5 mm | 4.5 mm |
| LS30B | Blue | LSR30B | Blue | 1.5 mm | 32 mm | 13 | 3.5 mm | 3.8 mm |
| LS45G | Green | LSR45G | Green | 2.0 mm | 46 mm | 19 | 3.5 mm | 4.5 mm |
| LS45B | Blue | LSR45B | Blue | 1.5 mm | 46 mm | 19 | 3.5 mm | 3.8 mm |
| LS60G | Green | LSR60G | Green | 2.0 mm | 60 mm | 25 | 3.5 mm | 4.5 mm |
| LS60B | Blue | LSR60B | Blue | 1.5 mm | 60 mm | 25 | 3.5 mm | 3.8 mm |
| LS90G | Green | LSR90G | Green | 2.0 mm | 90 mm | 37 | 3.5 mm | 4.5 mm |
| LS90B | Blue | LSR90B | Blue | 1.5 mm | 90 mm | 37 | 3.5 mm | 3.8 mm |

**SCHEMATIC VIEW**




**A)** JAWS
**B)** ANVIL
**C)** RETAINING PIN
**D)** SINGLE USE RELOADABLE CARTRIDGE
**E)** CARTRIDGE HOUSING
**F)** RETAINING PIN SLIDER
**G)** RELEASE BUTTON
**H)** CLOSING TRIGGER
**I)** FIRING TRIGGER

**INSTRUMENT OPERATION**

The *CHEX LS Re-Loadable Linear Staplers* are supplied sterile with the jaws in the open position and one single use reload in place. The CHEX LS Re-Loadable Linear Staplers should be used according to the general practice of use of staplers. (Consult veterinary surgical manuals and other such reference documents for detailed information.) The *CHEX LS Re-Loadable Linear Staplers* should only be used by veterinary surgeons having adequate training in stapling techniques and/or instructed by experienced persons. Check for the integrity of the package and make sure the instrument has no damage. Do not use the instrument if any damage or suspected damage is noticed in packaging materials. Using sterile technique, remove the instrument from the package. To avoid damage do not drop the instrument into the sterile field.



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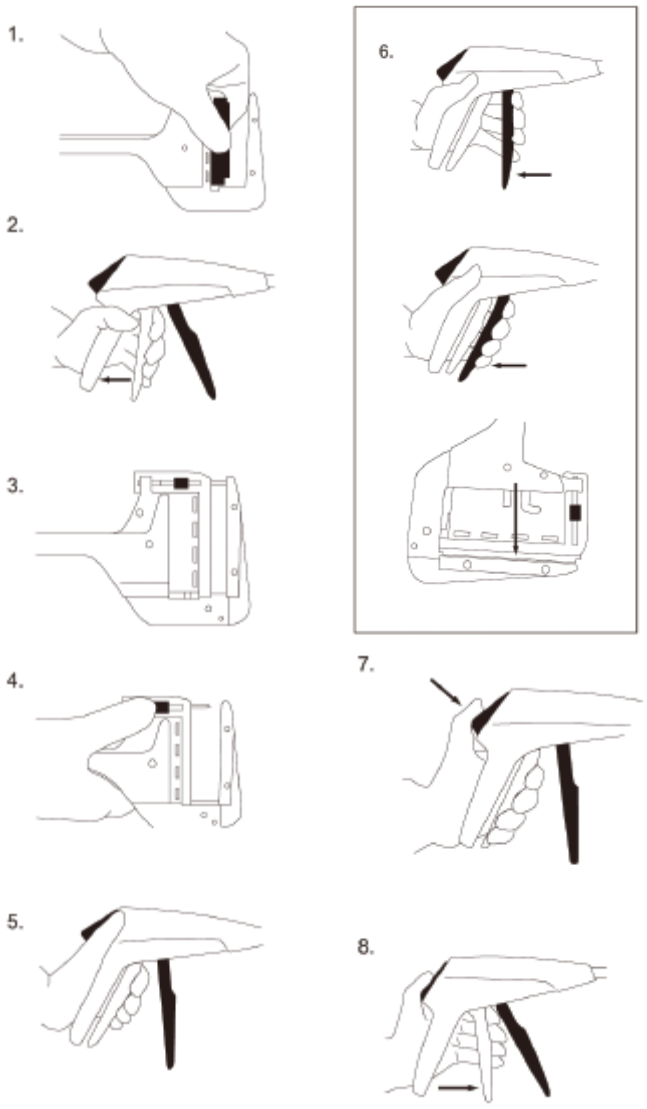
1. Remove the staple retaining cap from the instrument. Discard the staple retaining cap. Position tissue to be stapled within the jaws of the instrument. Note: Any tissue covering the hole in the anvil will be pierced by the Retaining Pin.
2. Squeeze the Closing Trigger until a click is heard.
3. The 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.
4. 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.
5. 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. 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 line.
6. 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.
   **Note:** The *CHEX LS Linear Staplers* are designed with a safety feature which prevents firing if a used Reload or no Reload is in the instrument. If the Firing Trigger does not pull back completely against the Closing Trigger, open the instrument as described in step 7. (Replace the Reload with a new Reload.) Prior to opening the instrument and releasing the tissue, the edge of the reload or the side of the anvil may be used as a guide to transect tissue or to excise excess tissue which is protruding through the jaws. This aids in cutting at a proper distance from the staple line. **Caution:** When using LS30W, open the instrument and examine the integrity of the staple line before cutting.
7. Open the jaws by pushing the Release Button and releasing grasp of the Closing Trigger.
8. The triggers and jaws will fully open, releasing the tissue. Remove



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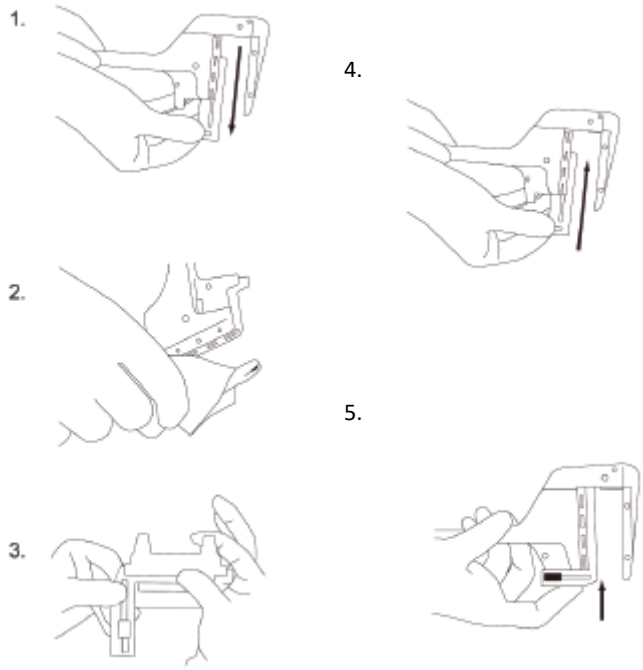
the instrument. **Caution:** Examine the staple line for hemostasis/pneumostasis and proper staple formation. If hemostasis/pneumostasis is not present, appropriate techniques should be used to achieve hemostasis/pneumostasis.

**Note:**

Examine the staple line for adequate hemostasis. Make additional sutures to stop bleeding when identified. The *CHEX LS linear Stapler* is designed for one patient. The device can be reloaded with reloading units during one surgical procedure.

**RELOADING THE LINEAR STAPLER**

1. Depress the Release Button to ensure the instrument is in the open position and the Retaining Pin is fully retracted into the reload.
2. Remove the used reload from the instrument. Grasp the top of the reload and lift upward, unsnapping the reload from the jaws. Properly discard the used reload.
3. Clean any formed but unused staples from the instrument by wiping the anvil and jaws or rinsing in sterile solution.
4. Examine the new reload for the presence of a staple retaining cap. Remove the staple retaining cap by sliding it off the reload. If the retaining cap is not in place, discard the reload.
5. Insert the new reload into the metal housing and snap into position. The tracks on each side of the reload should be used as guides to align the reload within the jaws of the instrument. When the reload is properly aligned, push the reload into the instrument until it is fully seated and a click is heard. Check that the reload is held firmly within the jaws.




**Caution:**

After reloading, observe the surface of the new reload. If colored drivers protrude out of the reload, replace with another reload. The Linear Stapler is now reloaded and ready for use.



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**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**

- This device should be used according to the general practice of use of linear staplers. (Consult veterinary surgical manuals and other such reference documents for detailed information.)
- Pet owners should be advised that anesthesia carries a risk of serious and irreversible injury including death.
- 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 LS Re-Loadable Linear Staplers* are provided STERILE and are intended for multiple use during a single surgical procedure.
  DISCARD AFTER USE. DO NOT RESTERILISE
- The Cartridge Reload is provided sterile and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILISE.
- Do not modify this instrument or cartridge reload. Use of a modified device may result in improper instrument function. Infiniti Medical® 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.
- Each Re-loadable cartridge will fit and operate in only the instrument(s) designed for use with the cartridge. Attempting to use a cartridge in any instrument other than that for which is has been designed will result in stapler malfunction.

**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 LS Linear Stapler and Reloads* are provided sterilized by irradiation. The expiry date as indicated on the packaging will be five years from irradiation if the packaging is not broken.



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**LIMITED WARRANTY**

Infiniti Medical warrants to Buyer that products supplied by Infiniti Medical that are sold to Buyer will be free from defects in material and workmanship for six (6) months after delivery to Buyer. Buyer must inspect and notify Infiniti Medical of any such defects within this six (6) month period. Further, notice of a defective product must be given to Infiniti Medical in writing within ten (10) days following the discovery of such defect prior to the expiration of the warranty period in order to recover under the warranty. All returns are subject to the prior authorization of INFINITI, in its discretion.
The warranty does not cover and Infiniti Medical will have no warranty obligation whatsoever with respect to any damage to a product caused by or associated with: (i) usage not in accordance with product instructions or usage for a purpose not indicated on the labeling; (ii) abuse, misuse, neglect, improper maintenance or storage, accident, vandalism, or the negligence of any party other than Infiniti Medical; (iii) external causes, including (but not limited to) natural disasters, acts of God, power failure, cosmetic damage or damage to product packaging; or (iv) use of unauthorized consumables and/or accessories with the product. Infiniti Medical's sole liability under this warranty will be, at Infiniti Medical's sole option, to a) replace; b) repair; or c) refund the purchase price of the defective product(s). This will be Buyer's exclusive remedy for a covered defect. Any oral or written statement concerning the products inconsistent with the limited warranty set forth herein will be of no force or effect.

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**RETURNS**

Buyer must notify Infiniti Medical within seven (7) calendar days of delivery regarding any products delivered to Buyer that were shipped in error, were damaged in shipping, or were in a shipping package that was damaged in shipping and such damage to the shipping package may have affected the quality of the products inside the shipping package.
Any products which Buyer wishes to return due to a) being shipped in error or damaged in shipping or b) a defect subject to the warranty provisions will be subject to receiving a Return Material Authorization (RMA) from Infiniti Medical. All returns are subject to the prior authorization of Infiniti Medical in its discretion. Only items appearing on an approved RMA are acceptable for return. Product returns will only be accepted from the original Buyer. Product returns will not be accepted from any third parties. Unauthorized returns will be destroyed and no credit issued. All authorized returned products must be shipped freight prepaid to the Infiniti Medical location indicated on the RMA, except Infiniti Medical will pay freight costs for product shipped-in-error or damaged in shipping.

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In no event shall Infiniti Medical be liable to Buyer for any unforeseen, indirect, incidental, special, punitive or consequential damages (including any loss of use, loss of revenue or damage for lost or anticipated profits), or otherwise arising out of or in connection with furnishing of products or service hereunder, or the performance, use of, or inability to use any products or service, or otherwise, whether based in contract, warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory. Infiniti Medical's total liability for any claim or action, whether based in contract, warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory shall not exceed the purchase price of the product or products out of which such claim or action arose, or Ten Thousand Dollars ($10,000.00), whichever is less.



P/N IFU0029 Rev B

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