INFINITI MEDICAL
Advanced Technology for Vets and Pets

INSTRUCTIONS FOR USE
CHEX LC SINGLE USE RELOADABLE LINEAR CUTTER 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.

DEVICE DESCRIPTION

The *CHEX LC Linear Cutter Stapler* is designed on the principles of surgical staplers. It delivers two double staggered rows of titanium staples and anastomoses the internal tissues and incisions during surgical procedures. The instrument may be reloaded during a single procedure. Do not reload the instrument more than seven times for a maximum of 8 firings per instrument. The use of the instrument with staple line buttressing materials, or across a previous staple line, may reduce the number of firings.

INSTRUCTIONS

The material contained in this document does not describe the procedure for using this product and is not intended as a reference document for that procedure.

The *CHEX LC Linear Cutter Stapler* 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 LC Linear Cutter Stapler* 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.

1. Using sterile technique, remove the instrument from the package. To avoid damage do not drop the instrument into the sterile field.
2. Open the handle (Alignment/Locking Lever) fully. Remove the red staple retaining cap.
3. Press the Anvil Fork on one side of the tissue to be transected or into the lumen to be anastomosed.
4. Fully open the Alignment/Locking Lever of the instrument. Place the Cartridge Fork on the other side of the tissue or into the other lumen.
5. Join the instrument halves together by aligning from the proximal end of the instrument.
6. Close the Alignment/Locking Lever completely and the instrument is locked.
7. Fire the instrument by - pushing the Firing Knob completely forward until the distal end of the Firing Knob reaches the end of its movement.
8. Completely return the Firing Knob to its original starting position.
9. Separate the instrument halves. Discard the fired reloading unit from the cartridge jaw and insert a new unit.

NOTE: Examine the staple line for adequate hemostasis. Make additional sutures to stop bleeding when identified.

The *CHEX LC linear Cutter Stapler* is designed for one patient. The device can be reloaded with reloading units during one surgical procedure.

CAUTION: If for any reason it is required to open the device midway through the complete firing throw, the cutting blade could be exposed in the cartridge if the slider is not fully returned. Exercise caution when handling the device in these cases to avoid injury.

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RELOADING INSTRUCTIONS

- To remove the fired CHEX LC cartridge, separate the instrument halves.
- Holding the Cartridge Half of the instrument, grasp the proximal end of the cartridge (cartridge tabs) and pull up and out to remove the cartridge from the Cartridge Forks. Properly discard the used Reload.
- Carefully clean and dry the instrument and interior of the cartridge fork whilst maintaining sterility.
- To place a new Reloadable cartridge in the instrument, hold the proximal end tabs, with the staple lines facing upwards, and position the distal end of the Reloadable cartridge against the leading edge of the cartridge fork tip at an angle of approximately 45°.
- With the leading edge engaged lower the proximal end down until it clips into place within the cartridge fork.
- Remove red staple protection cap.

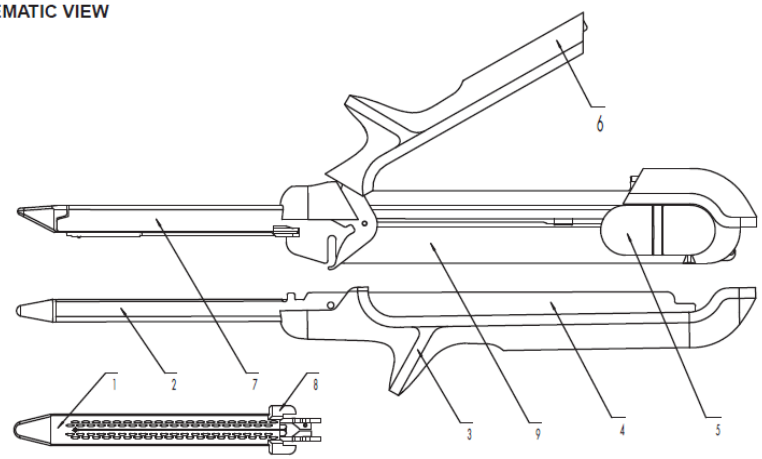
INDICATIONS

- The *CHEX LC Linear Cutter Stapler* is provided for single patient use.
- The *CHEX LC Linear Cutter Stapler* has application in abdominal, pelvic, and thoracic surgery for transection, resection and the creation of anastomoses.

CONTRAINDICATIONS

- The *CHEX LC Linear Cutter Stapler* should not be used on tissue such as liver or spleen where compressibility is such that the closure of the instrument would be destructive.
- Do not use the instruments with blue reload on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily to below 1.5 mm.
- Do not use the instruments with green reload on any tissue that requires excessive force to compress to 2.0 mm or on any tissue that compresses easily to below 2.0 mm.
- Do not use the instruments on ischemic or necrotic tissue.
- Do not use the instruments on the aorta.
- Do not use any Linear Cutter Stapler on major vessels without making provision for proximal and distal control.
- The *CHEX LC Linear Cutter Stapler* is not intended for use when surgical stapling is contraindicated.

SCHEMATIC VIEW



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STAPLER PARAMETERS

Product Code				Staple Crown (mm)	Staple Leg Length (mm)	Closed Staple size (mm)	Stapling Line Length (mm)	Staple Quantity
Linear Cutter Stapler		Cartridge Reloads						
LC60G	Green	LCR60G	Green	3.0	4.5	2.0	61	60
LC60B	Blue	LCR60B	Blue	3.0	3.8	1.5	61	60
LC80G	Green	LCR80G	Green	3.0	4.5	2.0	81	80
LC80B	Blue	LCR80B	Blue	3.0	3.8	1.5	81	80
LC100G	Green	LCR100G	Green	3.0	4.5	2.0	100	100
LC100B	Blue	LCR100B	Blue	3.0	3.8	1.5	100	100

PRECAUTIONS

- Consult veterinary literature relative to techniques, complications, and hazards prior to performance of any procedure.
- Pet owners should be advised that anesthesia carries a risk of serious and irreversible injury including death.
- Tissue thickness should be carefully evaluated before firing any stapler.
- When dividing major vascular structures, be sure to adhere to the basic surgical principle of proximal and distal control.
- Remove the staple retaining cap before firing the instrument.
- Before firing, ensure that the instrument Cartridge Fork and Anvil Fork are aligned and the tissue is properly positioned.
- Before closing the forks and removing the instrument, be sure that tissue is cleared from the forks.
- After removing the instrument, examine the staple line for hemostasis and proper staple closure. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Do not interchange instrument halves with other CHEX Linear Cutter devices.
- Crossing of staple lines may shorten the life of the instrument.
- When using a tissue or staple line buttressing material, the instructions of the manufacturer of the buttress material should be followed.
- Instruments or devices that come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused.
- This device is packaged sterile in a protective pouch and is for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing or re-sterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infection disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

PACKAGE AND STORAGE

- The *CHEX LC Linear Cutter Stapler* and Reloads are provided sterilized by irradiation. The expiry date as indicated on the package will be five years from sterilization provided the package is not damaged.
- This instrument should be stored at room temperature in dry, well ventilated environments away from direct sunlight.

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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.

LIMITATIONS OF LIABILITY

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.