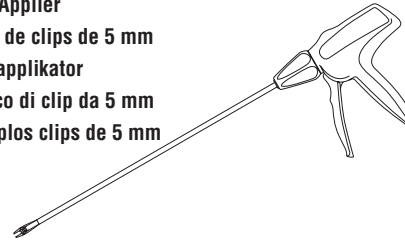


LIGAMAX⁵

5 mm Endoscopic Multiple Clip Applier
Multi-applicateur endoscopique de clips de 5 mm
5 mm Endoskopischer Multiclipapplikator
Applicatore multiplo endoscopico di clip da 5 mm
Aplicador endoscópico de múltiplos clips de 5 mm



Endoaplicador de clips múltiple de 5 mm
5 mm endoscopische multipiele-cliptang
5 mm endoskopisk multiclipstang
5 mm endoskooppinen klipsien kiinnitysinstrumentti
Ενδοσκοπική λαβίδα απολίνωσης πολλαπλών κλιπ 5 mm
5 mm endoskopisk multiclipsapplikator
Endoskopowa klipsownica o średnicy 5 mm do wielokrotnego zakładania klipsów
5 mm-es endoszkópos többszörös kapocsbehelyező
Endoskopický vícenásobný aplikátor sponek o průměru 5 mm
Endoskopický aplikátor viacerých svoriek o priemere 5 mm
5 毫米腔内连发施夹器

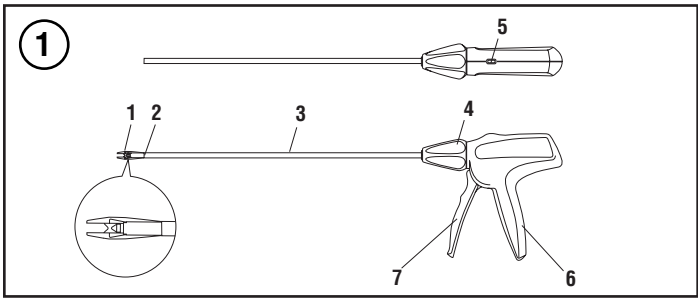
Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences, such as failure to ligate.

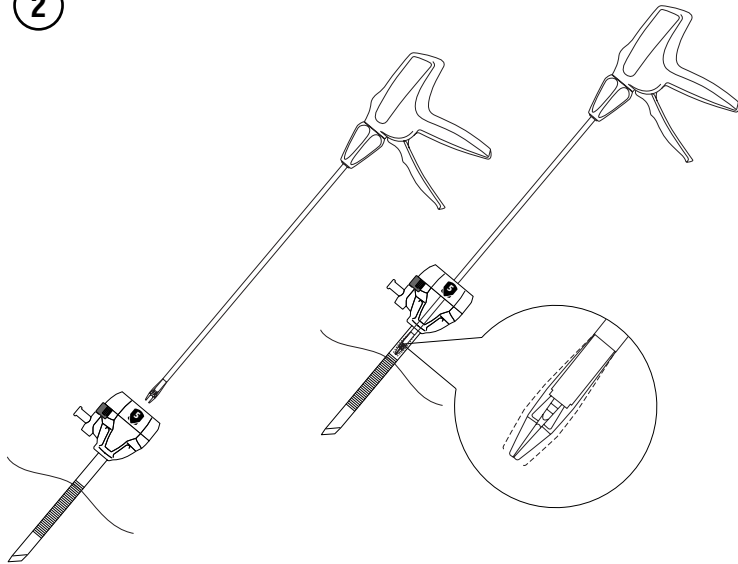
Important: This package insert is designed to provide instructions for use of the LIGAMAX⁵ – 5 mm Endoscopic Multiple Clip Applier. It is not a reference to ligation techniques.

 ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

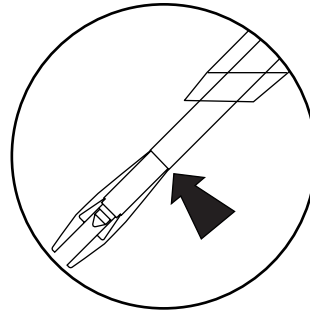
Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones,
Gebruiksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja,
Utasítások, Návod k použití, Návod, 使用说明



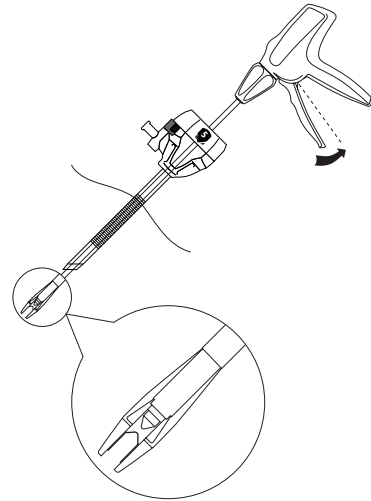
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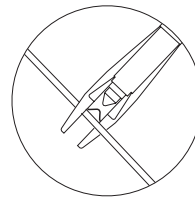
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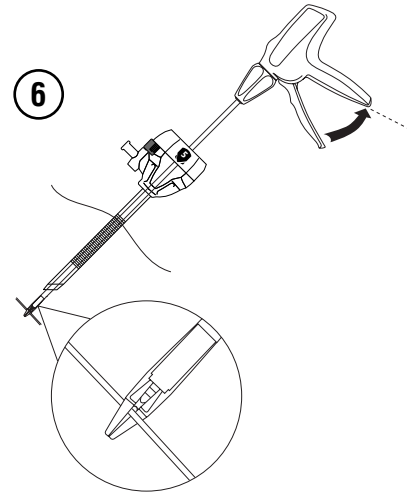
4



5



6



Indications

The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

Contraindications

- DO NOT use the instrument for contraceptive tubal occlusion.
- DO NOT use the instrument on tissue structures or vessels upon which metal ligating clips would not normally be used.

Device Description

The 5 mm Endoscopic Multiple Clip Applier is a sterile, single patient use instrument designed to provide a means of ligation through an appropriately-sized trocar. The instrument contains 15 titanium clips and the shaft can be rotated 360 degrees in either direction.

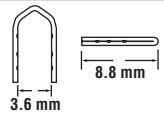
Product Code	Shaft Diameter	Clip Size/ No. of Clips	Clip Dimensions	Overall Shaft Length (approx.)
EL5ML	5.5 mm	Medium/Large 15		33 cm

Illustration and Nomenclature (Illustration 1)

- | | |
|------------------|---------------------|
| 1. Jaws | 5. Indicator Window |
| 2. Demarcation | 6. Handle |
| 3. Shaft | 7. Trigger |
| 4. Rotation Knob | |

Instructions For Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

- Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- Remove protective tip from the nose of the instrument.
- Insert the clip applier through an appropriately-sized trocar. The empty jaws will passively collapse as they pass through a 5 mm trocar and reopen when completely through the trocar. (Illustration 2)
Caution: Do not insert the clip applier through a trocar if a clip is present in the jaws. This may result in clip malformation, dislodged clips, or damage to the instrument. If a clip is present in the jaws, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws.
- Prior to loading a clip in the jaws, ensure that the demarcation between the jaws and the instrument shaft is past the end of the trocar cannula. (Illustration 3)
- Prior to positioning the jaws around the tubular structure or vessel, load a clip into the jaws by partially squeezing the trigger approximately one-third of the total firing stroke. (Illustration 4)
Caution: Inspect the jaw tips to ensure the clip is fully advanced in the jaws. (Illustration 4)
- Position the jaws with the clip completely around the tubular structure or vessel to be ligated. The structure to be ligated should be positioned abutting the apex of the clip. (Illustration 5)
Caution: Ensure that the clip is the correct size for the vessel or tubular structure being ligated. Note: The shaft can be rotated 360 degrees to facilitate visualization and accurate placement.
- Fully squeeze the trigger until it stops against the handle to completely form the clip on the targeted structure or vessel. (Illustration 6)
Caution: The trigger must be fully squeezed against the handle to ensure complete clip formation.

- After firing, fully release the trigger.
Note: A clip will not be loaded in the jaws until the trigger is squeezed again.
- Check to ensure that each clip has been securely placed around the tissue being ligated.
Note: If a clip is present in the jaws and the clip applier needs to be removed from the patient, fully squeeze and hold the trigger against the handle while removing the clip applier through the trocar with the jaws in the closed position. Once the clip applier is removed, fully release the trigger to release the clip from the jaws. The clip applier is then ready for the next clip application.
Note: If a clip is dislodged prematurely from the jaw tips or a clip fails to advance, remove the jaws from the targeted structure and fully squeeze and release the trigger to reset the device. Continue to use the instrument as noted in step 5.
- The 5 mm Endoscopic Multiple Clip Applier can be used to secure a catheter for cholangiography. During closure on the cystic duct and catheter, release the trigger after hearing the final audible click, prior to the trigger stopping against the handle.
- When the 13th clip is fired, an orange bar will begin to appear in the indicator window on top of the device handle. The clip applier is empty when the orange bar completely fills the indicator window.
Note: The instrument contains a last clip lockout feature designed to increase the force required to close the trigger, thereby reducing the possibility that the empty jaws will be closed on a structure or vessel. Do not attempt to fire through the lockout. If the trigger is forced closed once the last clip lockout has engaged, the jaws may remain closed. If the jaws do not open when the trigger is released, pull the trigger outward to re-open the jaws. Do not re-fire the instrument.
- To remove the instrument, ensure there is no clip remaining in the jaws, and withdraw the instrument from the trocar.




Warnings and Precautions



- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- Ensure that the clip is the correct size for the vessel or tubular structure being ligated.
- Do not insert the clip applier through a trocar if a clip is present in the jaws. This may result in clip malformation, dislodged clips, or damage to the instrument. If a clip is present, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws.
- Inspect the jaw tips to ensure the clip is fully advanced in the jaws.
- Ensure that each clip is securely and completely positioned around the tissue being ligated.
- Do not excessively twist or torque the instrument jaws when positioning or firing the instrument on a tubular structure or vessel. Excessive twisting or torquing may result in clip malformation.
- Do not excessively apply a side load to the jaws that would cause them to partially collapse and potentially result in a clip malformation. The device jaws should be fully open and parallel upon initiating the firing of the instrument.
- Do not push with excessive force on the proximal end of the instrument. Excessive force may result in clip malformation.
- The trigger must be fully squeezed against the handle to ensure complete clip formation.
- Ensure full release of the trigger after firing. A partial release of the trigger may disrupt clip feeding sequence and may result in clip malformation.
- Do not attempt to remove closed jaws from the structure or vessel. This could result in damage to the structure or vessel. Pull the trigger outward to re-open the jaws.
- Avoid firing the instrument over another clip or instrument. Firing the instrument in this manner may distort or yield the instrument jaws, which can cause the instrument to release the clip prematurely.
- Excessive tissue manipulation with clip in jaws may result in clip dislodgement.


- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- This device is packaged and sterilized for single use only. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or resterilization 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 infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

How Supplied

The LIGAMAX⁵ – 5 mm Endoscopic Multiple Clip Applier is supplied sterile for single patient use. Discard after use.

<p>STERILE </p>	<p>Sterilized by Irradiation. Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize. Stérilité par irradiation. Stérilité garantie si l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser. Strahlensterilisiert. Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist. Nicht reesterilisieren. Sterilizzato con radiazioni. Sterilità garantita, a meno che la confezione non venga aperta o danneggiata. Non risterilizzare. Esterilizado por irradiación. Esterilização garantida excepto se a embalagem estiver aberta ou danificada. Não reesterilizar. Estéril por radiación. Esterilización garantizada mientras el envase esté íntegro. No reesterilizar. Gesteriliseerd met straling. Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd. Niet opnieuw steriliseren. Steriliseret ved stråling. Garanteret sterilt, med mindre pakken er åbnet eller beskadiget. Må ikke gensteriliseres. Steriloitu säteilyttämällä. Tuote on steriili, kun pakkaus on avaaton ja ehjä. Ei saa steriloida uudestaan. Αποστειρωμένοι με ακτινοβολία. Η στεριότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε. Steriliserad med bestrålning. Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras. Urządzenie/sprzet sterylizowane promieniowaniem. Jalowość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone. Nie sterylizować ponownie. Besugárzással sterilizálva. A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás. Tilos újra sterilizálni! Sterilizace se provádí ozářením. Sterilnost je zaručena, pokud balení není otevřené nebo poškozené. Nástroj znovu nesterilizujte. Sterilizované ožarováním. Sterilita je zaručená, ak nie je otvorený alebo poškodený obal. Neresterilizujte. 辐射灭菌。 无菌保证。除非包装打开或损坏。勿再次灭菌。</p>
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REF
EL5ML

EC **REP** Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuetteleer Steindamm 71
22851 Norderstedt
GERMANY

Johnson & Johnson AG
CH-8957 Spreitenbach
SWITZERLAND


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