

LIGACLIP® EXTRA

Ligating Clips

Clips de Ligature

Ligaturclips

Clip di legatura

Clips de Laqueação

Clips de ligadura

Ligeerclips

Ligerende clips

Ligeerausklipsit

Κλιπ Απολίνωσης

Ligeringsclips

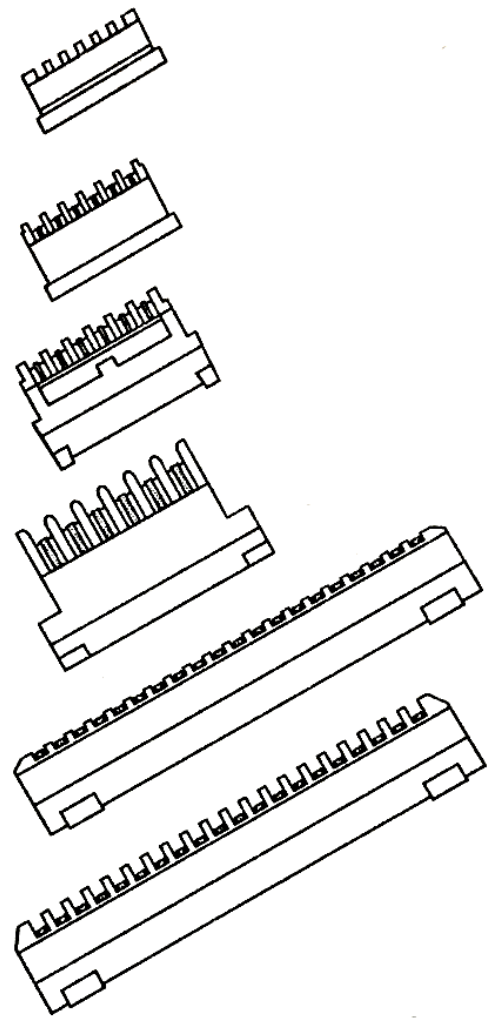
Klipsy do podwiązywania

Ligációs csipesz

Podvazovací svorky

Podvázovacie svorky

结扎夹



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 LIGACLIP® EXTRA Ligating Clips. It is not a reference to ligation techniques.

LIGACLIP is a trademark of Ethicon Endo-Surgery.



ETHICON ENDO-SURGERY, LLC

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



REF
LT100, LT200, LT300, LT400, LT102, LT202



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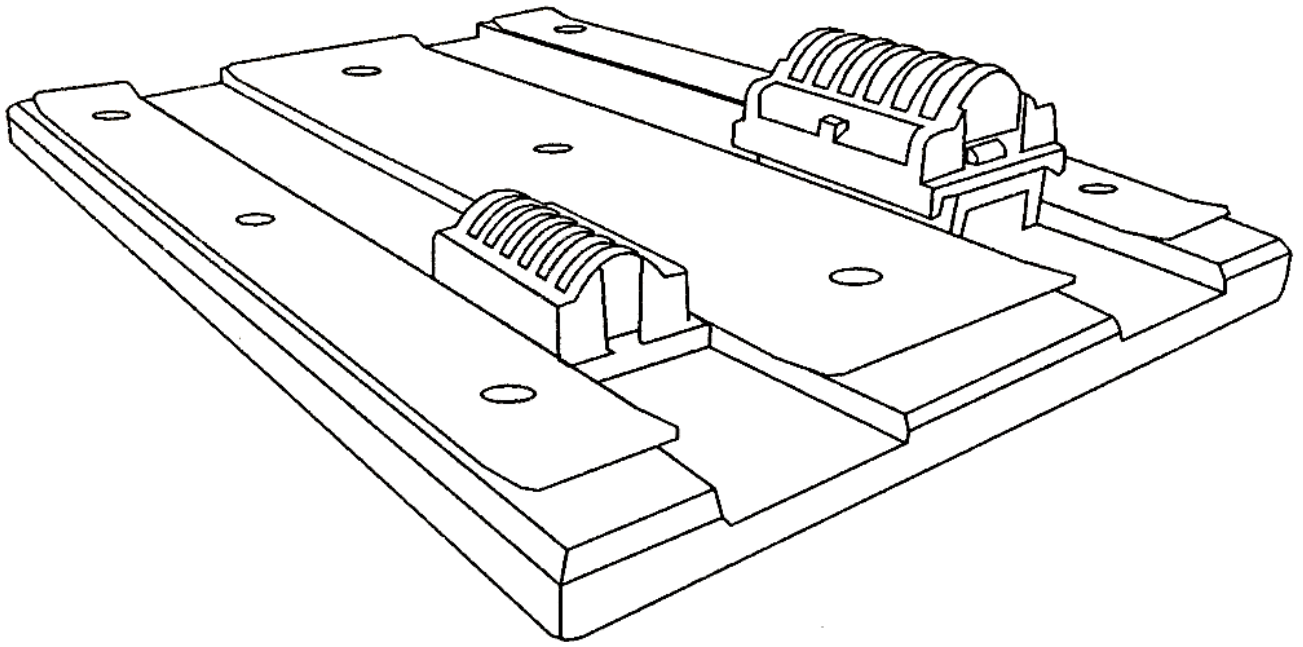
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475 Calle C
Guaynabo, PR 00969 USA



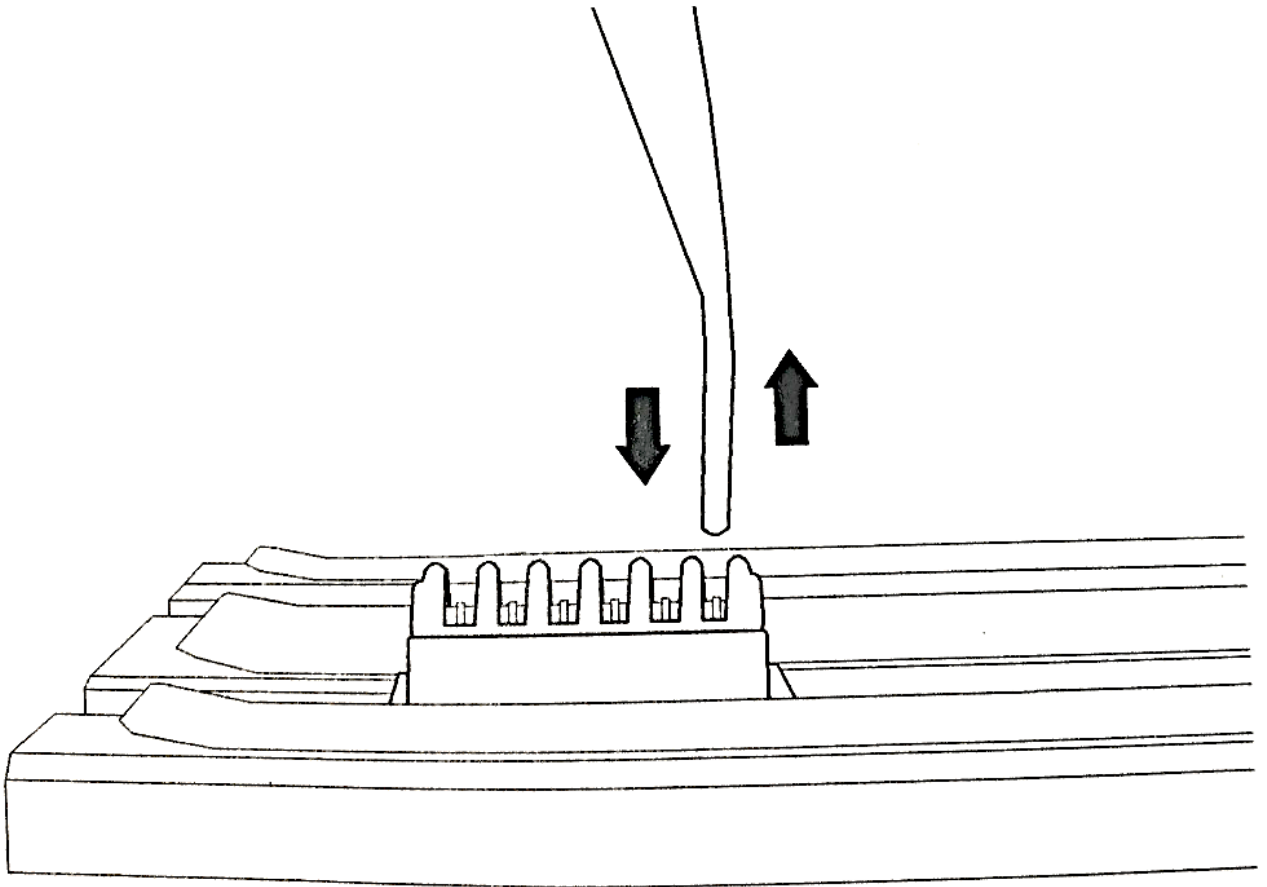
Rev. 2013-09

P40347P07

1



2



Indications

LIGACLIP EXTRA Ligating Clips have application for use on tubular structures or vessels wherever metal ligating clips are indicated. The tissue being ligated should be consistent with the size of the clip.

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

LIGACLIP EXTRA Ligating Clips are sterile, single patient use clips produced from titanium. The clips are designed for the ligation of tubular structures where a nonabsorbable ligating device is indicated.

The ligating clips are positioned around a tubular structure and closed by applying pressure to the handles of the applier.

MR Conditional

Non-clinical testing has demonstrated the implantable clips made of titanium in these devices are MR Conditional. A patient with the implanted clips can be scanned safely immediately after placement of the clips, under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Highest spatial magnetic gradient field of 6.5 Tesla/m
- Maximum MR System reported, whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 20 minutes of scanning (per pulse sequence).

MRI Related Heating

In non-clinical testing, a clip produced a temperature rise of less than 2°C using the following conditions:

- At 3-Tesla (Magnetom Trio Siemens Medical Solutions MR scanner, software version Numaris/4 syngo MRA30), a maximum MR system-reported whole body averaged SAR of 1.2 W/kg
- 20 minutes of continuous MR scanning (per pulse sequence) using transmit/receive RF body coil.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the clips. Therefore, optimization of MR imaging parameters to compensate for the presence of the clips may be necessary.

The worst case signal void size for a clip was:

Pulse Sequence	SE	SE	GRE	GRE
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal Void Size (mm ²)	199	336	378	348

Instructions for Use

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

- 1 Using sterile technique, remove the device from the package. To avoid damage, do not flip the device into the sterile field.
- 2 Select the appropriate size LIGACLIP EXTRA Ligating Clip cartridge and corresponding clip applier.
- 3 With the cartridge slots facing away from the base, insert the cartridge into one of the channel openings of the LC800 stainless steel cartridge base. Ensure that the cartridge is past the channel opening and securely held in place (Illustration 1).

- 4 Grasp the applier in the box lock area using pencil grip technique. If using an endoscopic applier, grasp the applier by the handle and trigger.
- 5 Insert the jaws of the instrument into the individual cartridge slot, making sure the tips of the applier are perpendicular to the surface of the cartridge (Illustration 2). Insert the applier until it stops. Do not force the applier. It should enter and withdraw from the cartridge smoothly.
- 6 Keeping the applier jaws perpendicular to the surface of the cartridge, retract the applier from the cartridge (Illustration 2). The clip will be securely held in the applier jaws. It is not necessary to maintain ring or trigger tension to hold the clip in the applier jaws.
- 7 Position the clip around the tubular structure to be ligated. Apply sufficient force to fully close the applier to assure that the clip is satisfactorily placed and secured.

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 procedures.
- A thorough understanding of the principles and techniques involved in laser, electro-surgical 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 electro-surgical instruments in liquid.
- Ensure that the clip is the correct size for the vessel or tubular structure being ligated.
- Upon each clip application, fully squeeze the handles of the instrument until they come to a stop. Failure to fully squeeze the handles can result in improper formation of clips, and therefore, unsatisfactory ligation of tissue.
- Ensure that each clip has been securely and completely positioned around the tissue being ligated.
- Do not close the jaws of the instrument over other surgical instruments.
- Appliers in disrepair should not be used. The use of such appliers could result in inadequate function of the clip.
- The condition of the LIGACLIP ligating applier, the closure force exerted by the surgeon, the thickness of the tissue to be ligated, and the nature of the clip itself are all critical to the performance of any ligating clip.
- As with any ligating method, inspect each ligation site following placement of the clip to insure that the clip has been satisfactorily placed.
- Dispose of all opened products whether used or unused.
- This device is packaged and sterilized for single use only. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness.

How Supplied

The LIGACLIP EXTRA Ligating Clips are supplied sterile for single patient use. Discard after use.



MR (Magnetic Resonance) Conditional
 Compatible dans certains environnements de résonance magnétique
 Bedingt MR-(Magnetresonanz)-sicher
 Condizionale rispetto alla risonanza magnetica
 Uso condicionado no ambiente de RM (Ressonância magnética)
 Condicionado para RMN (resonancia magnética nuclear)
 MR-conditioneel (MR = magnetische resonantie)
 MR-betinget (magnetisk resonans)
 MR (magneettiresonanssi) -ehdollinen
 Ασφαλές για MR (απεικόνιση μαγνητικού συντονισμού), υπό όρους
 MR (magnetisk resonans)-säker under vissa förutsättningar
 Warunkowo bezpieczny w obszarze oddziaływania rezonansu magnetycznego
 MR (mágneses rezonancia-) vizsgálatra feltételesen alkalmas
 Podmínůnú bezpečné pro MR (MR Conditional)
 Podmienečne vhodné pre použitie magnetickej rezonancie
 MR 磁共振条件

STERILE R

Sterilized by Irradiation.
Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize.
Stérilisé 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 irradiação.
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 avaamaton ja ehjä. Ei saa steriloida uudestaan.
Αποστειρωμένοι με ακτινοβολία.
Η στειρότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε.
Šteriliserad med bestråling.
Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras.
Urządzenie/sprzet sterylizowane promieniowaniem.
Jałowość 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。
如果产品包装未开封或者未被破损，保证无菌。不得再次灭菌。



See Instructions For Use
Voir notice d'utilisation
Bitte Gebrauchsanweisung beachten
Vedere le istruzioni per l'uso
Ver Instruções de Uso
Ver instrucciones de uso
Zie gebruiksaanwijzing
Se brugsvejledningen

Katso käyttöohjeet
Διαβάστε τις Οδηγίες Χρήσεως
Se bruksanvisning
Zobacz Instrukcja użytkowania
Lásd a használati útmutatót
Prostudujte návod k použití
Prečítajte si návod na použitie
参见使用说明

LOT

Lot
N° de lot
Ch.-B.
Lotto
N° do lote
N° de lote
Lotnr.
Parti





Erän koodi
Αρ. παρτίδας
Batchnummer
Numer partii produkcyjnej
Tétel
Šarže
Šarža
批号



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
Mise en garde : La loi fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription.
Achtung: Laut Gesetz darf dieses Instrument in den USA nur an einen Mediziner oder eine in seinem Auftrag handelnde Person verkauft werden.
Attenzione: la legge federale americana consente la vendita di questo dispositivo solo dietro richiesta medica.
Atenção: A lei federal (dos Estados Unidos) só permite a venda deste dispositivo a médicos ou sob receita destes.
Atención: la ley federal de EE.UU. impone que este producto sólo puede ser vendido por un médico o bajo prescripción médica.
Waarschuwing: De Federale wetgeving (in de VS) eist dat dit apparaat uitsluitend door of in opdracht van een arts wordt verkocht.
Forsigtig: I henhold til gældende lov må denne anordning kun sælges til eller bruges af en læge.
Varoitus: Yhdysvaltain lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.
Προσοχή: Το ομοσπονδιακό δίκαιο των ΗΠΑ περιορίζει την πώληση του εργαλείου αυτού μόνον από ιατρούς ή κατόπιν εντολής ιατρού.
Varning: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan.
Przestroga: Prawo federalne (USA) zezwala na sprzedaż tego urządzenia wyłącznie lekarzowi lub na jego zamówienie.
Figyelem! Az USA szövetségi törvényei értelmében az eszköz csak orvos megrendelésére értékesíthető.
Upozornění: Podle federálních zákonů USA je prodej tohoto zařízení omezen na prodej v lékárnách nebo na lékařský předpis.
Pozor: Podľa federálnych zákonov (v USA) sa toto zariadenie smie predávať iba lekárom alebo na lekársky predpis.
注意：联邦（美国）法律只允许医师销售或订购该器械。



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Representante autorizado nos EUA
Representante autorizado en EE.UU.
Bevoegd vertegenwoordiger in de VS
Bemyndiget repræsentant i USA
Valtuutettu edustaja Yhdysvalloissa
Εξουσιοδοτημένος αντιπρόσωπος στις ΗΠΑ
Auktoriserad representant i USA
Autoryzowany przedstawiciel w Stanach Zjednoczonych Ameryki
Meghatalmazott képviselő az Egyesült Államokban
Autorizovaný zástupce v USA
Autorizovaný zástupca v USA
美国授权代理人

	<p>Single Patient Use À utiliser sur un seul patient lors d'une seule intervention Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Usó en un solo paciente Voor gebruik bij één pati Til anvendelse på én patient</p>	<p>Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta 单个患者使用</p>
	<p>Use Until Date À utiliser avant Verw. bis Utilizzare entro Validade A utilizar antes de Gebruik vóór Holdbar til angivne dato</p>	<p>Käyttävä viimeistään Χρησιμοποιείτε μέχρι την Använd före Koniec okresu przydatności do użytku A feltüntetett dátumig használható fel Použit do data Použitelné do 有效期</p>
	<p>Manufacturer/Date of Manufacture Fabricant/Date de fabrication Hersteller/Herstellungsdatum Fabbricante/Data di fabbricazione Fabricante/Data de fabricaço Fabricante/Fecha de fabricaci3n Fabrikant/Productiedatum Producent/Fremstillingsdato Valmistaja/Valmistusäivä Κατασκευαστής/Ημερομηνία κατασκευής Tillverkare/Tillverkningsdatum Producent/Data produkcji Gyártó/Gyártás dátuma Výrobce/Datum výroby Výrobca/Dátum výroby 制造商/制造日期</p>	
		<p>Authorized Representative in the European Community Représentant autorisé dans la Communauté européenne Bevollmächtigter in der Europäischen Gemeinschaft Rappresentante autorizzato nella Comunità Europea Representante autorizado na Comunidade Europeia Representante autorizado en la Comunidad Europea Bevoegd vertegenwoordiger bij de Europese Gemeenschap Autoriseret repræsentant i det europæiske fællesskab Valtuutettu edustaja Euroopan yhteisön alueella Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα Auktoriserad representant i Europeiska gemenskapen Autoryzowany przedstawiciel w Unii Europejskiej Az Európai Közösség meghatalmazott képviselője Autorizovaný zástupce v Evropském společenství Autorizovaný zástupca EU 欧共同体内授权代理</p>