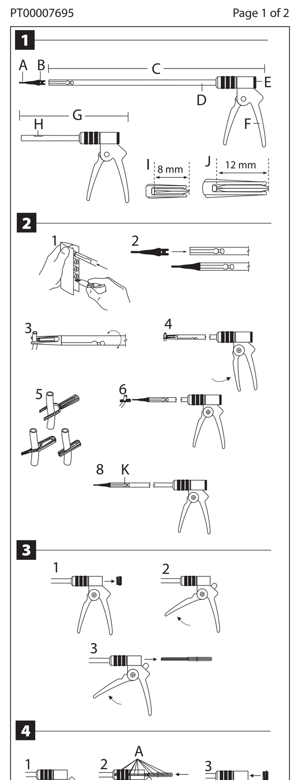
Box size: 8.88 x 4.44
Overall size: 18 x 28
Folds to: 3 x 7

COVIDIEN

Lapro-Clip™

Reusable Clip Applier and Absorbable Ligating Clip Cartridge

PT00007695 Page 1 of 2



EN

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques. It is not a reference guide to ligation techniques.

The single use components of this device were designed, tested and manufactured for single patient use only. Reuse or reprocessing of the single use components of this device may lead to their failure and subsequent patient injury. Reprocessing and/or resterilization of the single use components of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize the single use components of this device.

DESCRIPTION

The Lapro-Clip™ absorbable ligating clip cartridge is delivered by a single use cartridge and actuated by a reusable applier.

Lapro-Clip™ absorbable ligating clip cartridges are molded from two polymers: polyglycolic acid and polyglyconate. The outer body is polyglycolic acid and slides over a polyglyconate inner track. Lapro-Clip™ absorbable ligating clip cartridges are supplied sterile and undyed. Lapro-Clip™ absorbable ligating clip cartridges are available in two sizes: Medium/Large and Large. Clips are supplied one clip per single use cartridge with either one, two or six cartridges per sterile package. The absorption characteristics of polyglycolic acid and polyglyconate have been extensively studied and documented. The breakdown of these two polymers in the body occurs by hydrolysis.

The Lapro-Clip™ reusable clip applier is available in three sizes: The Lapro-Clip™ short reusable clip applier is 11 cm in length with a shaft diameter of 10 mm. The Lapro-Clip™ standard reusable clip applier is 26.5 cm in length with a shaft diameter of 10 mm. The Lapro-Clip™ long reusable clip applier is 33 cm in length with a shaft diameter of 10 mm. The standard and long Lapro-Clip™ reusable clip appliers are designed to be used through a 10 mm trocar cannula or larger with the use of a converter.

The clip applier has a limited life and may be used up to 350 procedures. A tracking card is provided in the package of the clip applier for the purpose of tracking the number of uses.

INDICATIONS

Lapro-Clip™ absorbable ligating clip cartridges are intended for use as absorbable ligatures. The Lapro-Clip™ absorbable ligating clip cartridges are radiotransparent and will not interfere with interpretations of post operative X-ray, CT or MRI scans. The Lapro-Clip™ absorbable ligating clip cartridge may be used for ligation of the cystic artery and cystic duct, and other general ligation.

CONTRAINDICATIONS

1. Lapro-Clip™ absorbable ligating clip cartridges should not be used where prolonged or permanent ligation of tissues or vessels is required.
2. This device is not intended for contraceptive tubal ligation, but may be used to achieve hemostasis following transection of the fallopian tube.

WARNINGS AND PRECAUTIONS

1. The Lapro-Clip™ reusable clip applier is supplied non-sterile and must be cleaned and sterilized prior to use.
2. The Lapro-Clip™ reusable clip applier(s) must be carefully inspected prior to and after each use, as any damage may affect the safe operation of the device. Failure to lubricate the device prior to sterilization may cause malfunctions such as jamming, difficult operation or unacceptable clip formation (if applicable). Devices with moving parts should be evaluated for proper function prior to application. If damage is suspected, contact your local representative for replacement or repair by the manufacturer.
3. Ensure that the tissue to be ligated is located completely within the closed clip.
4. Lapro-Clip™ absorbable ligating clip cartridges are a secure means of ligation. Prior to closure, all tissues within the clip should be inspected to ensure that the correct tissues will be ligated. It may be difficult to remove a fully closed clip. Improperly placed clips may be removed using Lapro-Clip™ ligating clip remover.
5. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. A thorough understanding of the technical principles, risks versus benefits, and the hazards involved in utilizing an endoscopic approach is necessary to avoid possible injury to the user and/or patient.
6. Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together in a procedure.
7. Covidien™ reusable devices must be carefully inspected prior to and after each use, as any damage may affect the safe operation of the device. Failure to lubricate the device prior to sterilization may cause malfunctions such as jamming, difficult operation, or unacceptable clip formation.
8. Devices with moving parts should be evaluated for proper function prior to application. If damage is suspected, contact your local representative for replacement or repair by the manufacturer.
9. Detergents and solutions for reusable devices should have a pH of 7.0 or greater.
10. Sterilization temperature should not exceed 275° F (135° C).

1 SCHEMATIC VIEW

A) CARTRIDGE
B) INTERLOCK GROOVE
C) SINGLE APPLIER LONG
D) ROTATING SHAFT
E) END CAP
F) HANDLE
G) SINGLE APPLIER SHORT
H) LATCH
I) MEDIUM/LARGE (8 mm) Lapro-Clip™ SINGLE ABSORBABLE LIGATING CLIP CARTRIDGE
J) LARGE (12 mm) Lapro-Clip™ SINGLE ABSORBABLE LIGATING CLIP CARTRIDGE

Reprocessing Instructions

Covidien™ reusable devices are supplied non-sterile. They must be cleaned and sterilized prior to use. Repeated processing at the listed parameters has minimal effect on Covidien™ reusable devices. Wear and damage due to use normally determine the end of instrument life.

CAUTION: Covidien™ reusable devices must be carefully inspected prior to and after each use, as any damage may affect the safe operation of the device. Failure to lubricate the device prior to sterilization may cause malfunctions such as jamming, difficult operation, or unacceptable clip formation.

Devices with moving parts should be evaluated for proper function prior to application. If damage is suspected, contact your local representative for replacement or repair by the manufacturer.

Point of Use:
Remove excess soil with disposable wipes.

Reprocessing Limitations:
The clip applier has a limited life and may be used up to 350 procedures. A tracking card is provided in the package of the clip applier for the purpose of tracking the number of uses. Repeated processing at the listed parameters has minimal effect on the stainless steel instruments. Wear and damage due to use normally determine the end of instrument life.

Containment and Transportation:
It is recommended that reusable instruments be reprocessed as soon as possible following use. They should be covered with a moist towel if reprocessing cannot be performed immediately.

Preparation for Cleaning:
Covidien™ reusable devices are supplied non-sterile. Prior to use, they must be cleaned and sterilized. After each use, they must be disassembled (if applicable) and any single use components discarded.

CAUTION: Enzymatic cleaners should have a pH between 7.5 and 9.5 and Alkaline Cleaners should have a pH between 12.7 and 14.0.

Sterilization temperature should not exceed 275°F (135°C).

Manual Cleaning:
Reusable instruments should be cleaned thoroughly immediately after each use to remove all traces of blood and debris. Pay particular attention to crevices and hard-to-reach areas while scrubbing instruments with a soft bristle brush in warm water (20–25° C) with a mild detergent/enzymatic cleaner. Manual brush time should be greater than five minutes and until visibly clean. Final rinse to be with purified water for at least 1 minute.

Lubrication:
Prior to sterilization, devices with moving parts must be lubricated with a water soluble lubricant solution to help ensure proper operation.

Automatic Cleaning:
Reusable instruments should be cleaned thoroughly immediately after each use to remove all traces of blood and debris. Pay particular attention to crevices and hard-to-reach areas while scrubbing instruments with a soft bristle brush in warm water (20–25° C) with a mild detergent/enzymatic cleaner. Covidien™ reusable devices may be placed in an automatic dishwasher at 194° F (90° C).

Treatment	Time (MM:SS) minimum	Temperature
Pre-Wash	00:45	Cold Tap Water
Enzyme Wash	04:00	Hot Tap Water
Rinse	00:15	Hot Tap Water
Wash	03:00	Hot Tap Water
Rinse	00:15	Hot Tap Water
Thermal Rinse	01:00	Hot Tap Water (heated to 180 °F or 82 °C)
Dry	05:00	High Setting (203 °F or 95 °C)

Disinfection:
See above (automatic cleaning)

Sterilization:
Covidien™ reusable devices are provided non-sterile and are designed for reuse. They may be sterilized in accordance with the following process parameters:
Steam Sterilization: 4 minutes 269.6°F (132°C) Prevacuum, wrapped; 3 minutes 273.2°F (134°C) Prevacuum, wrapped; 15 minutes 249.8°F (121°C) Gravity Cycle, wrapped

Maintenance:
Visually inspect the instruments for damage or wear and check for proper function prior to each use. Repeated autoclaving may tarnish or discolor instrument surfaces.

Packaging:
Items may be placed in a polyethylene pouch or standard hospital wrap.

Storage:
Store at room temperature.

Additional Information:
When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer manufacturer's stated maximum load is not exceeded.

2 INSTRUCTIONS FOR USE

1. Cartridge can be removed from package using applier or by hand prior to attachment to instrument.
2. Insert the cartridge into the distal end of the instrument until the latch closes and locks in place.
3. Place the jaws of the cartridge around the tissue to be ligated until they can be seen beyond the tissue. Rotation of the instrument shaft will facilitate placement of the clip cartridge. Ensure that the tissue to be ligated is located completely within the confines of the clip prior to closure.
4. The handle should be firmly squeezed until it will not move further without excessive force.

CAUTION: Failure to fully squeeze the handle may result in misformed clips which may result in incomplete closure and lack of hemostasis.

5. (Closure sequence of a clip.)
6. Clip will be released when handle is fully compressed.
7. The clip should be inspected to ensure closure and adequate ligation.
8. After firing clip, cartridge is removed by depressing the release button on shaft and pulling the cartridge forward, away from applier.
K) RELEASE BUTTON

3 DISASSEMBLY

1. Unscrew the end cap.
2. Push the handle forward.
3. Remove the inner shaft assembly.

4 ASSEMBLY

1. Push the handle forward.
2. Replace the inner shaft assembly taking care that all grooves are aligned between the handle, inner shaft, and rotating shaft.
A) TOP VIEW OF GROOVES
3. Pull the handle back and replace the end cap.

ADVERSE EVENT

Adverse events potentially associated with the use of this device include: variable rates of absorption over time; failure to provide adequate ligation; bleeding; tissue granulation; fibrosis and/or adhesion.

STORAGE

Lapro-Clip™ instruments must be completely dry before storing and must be handled with care to prevent damage. Instruments should be stored in areas which provide protection from extremes of temperature and humidity.

STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES.

FR
Applicateur d'attaches réutilisable et chargeur d'attaches résorbables pour ligature

DE
Wiederverwendbarer Hefter und resorbierbares Ligaturclip-Magazin

IT
Applicatore di clip riutilizzabile e cartuccia di clip di legatura assorbibile

ES
Aplicador de clips reutilizable y cartucho de clips absorbibles para ligadura

PT
Aplicador de clipe reutilizável e cartucho de clipe de ligadura absorvível

NL
Herbruikbare klemmenplaatser en resorbeerbare hechtingspatroon met clip

SV
Återanvändbar clipstång och resorberbart ligeringsclipsmagasin

DA
Genanvendelig clipsapplikator og absorberbart ligeringsclipsmagasin

FI
Kestokäyttöinen klipsinkäyttölaite ja resorboituva sidontaklipsien kasetti

EL
Επαναχρησιμοποιήσιμο όργανο εφαρμογής κλιπ και φύσιγγα απορροφήσιμου κλιπ απολίνωσης

PL
Aplikator zacisku wielokrotnego użytku i kaseta wchłanialnych zacisków podwiązujących

TR
Tekrar Kullanılabilir Klips Uygulayıcı ve Emilebilir Ligasyon Klipsi Kartuşu

RU
Многоразовый клипаппликатор и картридж с рассасывающимися клипсами для лигирования

CS
Opakovaně použitelný aplikátor svorek a zásobník absorbovatelných ligačních svorek

Do not use if package is opened or damaged. / Ne pas utiliser en cas d'endommagement ou d'ouverture de l'emballage. / Bei geöffneter oder beschädigter Verpackung nicht verwenden. / Non utilizzare se la confezione è aperta o danneggiata. / No usar el dispositivo si la envoltura está abierta o dañada. / Não utilizar se a embalagem estiver aberta ou danificada. / Niet gebruiken als de verpakking beschadigd of geopend is. / Får ej användas om förpackningen är öppnad eller skadad. / Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. / Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. / Μη χρησιμοποιείτε αν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά. / Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone. / Ambalaj açılmış ya da zarar görmüşse kullanmayın. / Не используйте изделие, если упаковка вскрыта или повреждена. / Pokud je balení otevřené nebo poškozené, produkt nepoužívejte.

STERILE EO

NON STERILE

Rx ONLY

Caution, consult accompanying documents

0123

© 2013 Covidien.

Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.

EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com

COVIDIEN, COVIDIEN with logo, and Covidien logo and Positive Results for Life are U.S. and internationally registered trademarks of Covidien AG. Other brands are trademarks of a Covidien company. ™* brands are trademarks of their respective owner.

2015 / 05 - 3

Регистрация МИ в Росздравнадзоре
www.nevacert.ru | info@nevacert.ru