WECK® Hem-o-lok®

en Take Apart Endoscopic Ligating Clip Appliers and Removers

bg Разглобяеми ендоскопични апликатори и отстранители на клипс за лигиране

cs Rozebratelné endoskopické aplikátory a odstraňovače ligačních svorek

da Adskillelige endoskopiske ligeringsclips applikatorer og clips fjernere

de Zerlegbare endoskopische Ligatur-clip-Anleg- und Entfernungsgeräte

el Αποσυναρμολογούμενα ενδοσκοπικά εφαρμοστήρια και εργαλεία αφαίρεσης κλιπ συρραφής

es Pinzas aplicadoras y extractores endoscópicos de grapas para ligadura desmontables

fi Purettu set endoskooppiset klipsiinsettimet ja poistimet

fr Applicateurs et extracteurs endoscopiques démontables de clips de ligature

hr Rastavljivi endoskopski uređaji za postavljanje i uklanjanje spona za hemostazu

hu Szétszerelhető endoszkópos érhéjtó klipsz adók és -eltávolítók

it Applicatori ed estrattori endoscopici smontabili di clip per legatura

lt Išardomi endoskopiniai ligavimo spaustukų užklijavo ir nuėmimo įtaisai

lv Izjaucami endoskopiskās noslēdzamo skavu aplikatori un noņēmēji

nl Demonteerbare endoscopische plastieslips-en verwijderhangers voor ligeerclips

no Endoskopisk ligeringsklips-applikator og -fjerner som kan tas fra hverandre

pl Endoskopowe aplikatory i ekstraktory do klipsów ligaturowych nadające się do rozmontowania

pt Aplicadores e removedores endoscópicos desmontáveis de clipes de ligaqueação

pt_br Aplicadores e removedores desmontáveis de clipes de ligadura endoscópica

ro Aplicatoare şi dispozitive de scoatere endoscopice demontabile pentru agrafe de ligătură

sk Odnímateľné aplikátory a extraktory endoskopických ligačných svoriek

sl Razstavljivi aplikatorji in odstranjevalniki endoskopskih sponk za podvezovanje

sv Isärtagbar endoskopisk applikator och borttagare för ligeringsklips

tr Sökülebilir Endoskopik Ligasyon Klips Uygulayıcıları ve Çıkartıcıları

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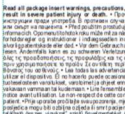

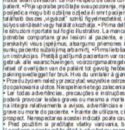

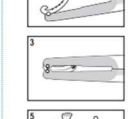

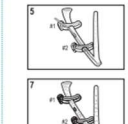

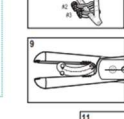

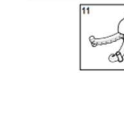

WECK® Hem-o-lok®

Ligating Clips and Appliers

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Patent: pat.teleflex.com

WECK® Hem-o-lok®

en

Take Apart Endoscopic Ligating Clip Appliers and Removers

Device Description

Weck® Hem-o-lok®, ligating Clips are single-use, non-absorbable, non-active implantable devices designed for use in general surgical procedures that require vessel or tissue ligation. The clips are manufactured from a medical grade polymer. The Hem-o-lok® clip is white in color. The clips are available in various sizes to accommodate different vessel diameters. Weck® Hem-o-lok® Endoscopic Ligating Clip Appliers are designed for use as delivery devices for Hem-o-lok® Ligating Clips. Take Apart Endoscopic clip appliers are reusable instruments that I manually load and deliver one clip at a time. Weck Hem-o-lok Take Apart Endoscopic Ligating Clip Removers are designed as removal devices for Hem-o-lok® Ligating Clips. The appliers and removers are not designed for compatibility with any other type of ligating clip.

For product sizing and compatibility, see Table 1.

Table 1: Product Sizing and Compatibility

Clip Size	Clip	Vessel/Tissue Size Ranges*	Color	Take Apart Endoscopic Appliers	Applier Cannula Size	Take Apart Endoscopic Removers	Remover Cannula Size
Medium	540251 540351	2mm – 11mm	Blue	540545T	5mm	540121	5mm
MedLarge	540252 540352	3mm – 13mm	Green	540561T 540562T	5mm 10mm	540121	5mm
Large	540260 540340	5mm – 13mm	Purple	540561T 540562T	5mm 10mm	540121 540123T	5mm 10mm
ExtraLarge	540250 540350	7mm – 18mm	Gold	540561T 540562T	5mm 10mm	540121 540123T	5mm 10mm

Indications

Hem-o-lok Ligating Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely compresses the vessel or tissue structure.

Hem-o-lok Take Apart Endoscopic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok Non-absorbable Polymer Ligating Clips through specific size tract laparoscopic cannulas.

Hem-o-lok Take Apart Endoscopic Ligating Clip Removers are designed for the removal of Hem-o-lok Non-absorbable Polymer Ligating Clips.

Contraindications

Hem-o-lok Ligating Clips are not intended for use as a fallopian contraceptive tubal occlusion device.

Hem-o-lok Ligating Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

Patient Target Group

The Hem-o-lok Ligation System is intended for use in patients requiring ligation of vessels or other structures.

Clinical Benefits

- Reduce post-op complications compared to alternative therapies
- Reduce mean operative time versus alternative therapies

Potential Side Effects

- Vessel damage
- Internal bleeding
- Surgical intervention
- Clip revision

Implantable Clip Material

Non-absorbable Acetal Homopolymer

WARNING

Hem-o-lok Ligating Clips

- Single use. Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.
- Hem-o-lok clips are intended for permanent ligation of vessels and/or tissue structures. Should clip removal be necessary, the Take Apart Endoscopic Remover may allow removal of the clip. Should breakage of the clip occur during the removal process the surgeon should determine the best course for the surgical site.

NOTE: Hem-o-lok ligating clips are supplied sterile. Hem-o-lok ligating clip cartridges contain barium and are radiopaque.

Hem-o-lok Take Apart Endoscopic Ligating Clip Appliers and Removers

- Misuse may injure patients or may result in damage, potentially resulting in user or patient injury.
- Instruments which are used chronically on patients with a prion-based disease (non-treatable spongiform encephalopathies, CJD, BSE, etc.) or on patients suspected of having one of these diseases are not safe to be reused and must be disposed of as per approved hospital procedures.
- Do not clean and/or sterilize instruments suspected of prion contamination prior to disposal. Prion contaminated instruments to the reprocessing facility may lead to contamination of other instruments under the reprocessing facility equipment.

CAUTION

Hem-o-lok Ligating Clips

- Improper use of the Hem-o-lok endoscopic donor nephrectomy Teleflex Medical recommends ligation of the renal artery with Hem-o-lok clips on the patient side with a minimum dual renal artery clip load on the applier and the distal clip.
- The clip must be latched to ensure proper ligation of the vessel or tissue. Visually confirm the ligation site after application to ensure proper closure of the clip. Security of the closure should be confirmed after ligation to avoid breakage from ligated blood vessels or hollow viscus.
- Application of a second clip on all other vessels other than the renal artery should be placed proximal to the first clip.
- The Hem-o-lok Polymer Ligating Clip is not designed for use as a bioabsorbable.
- Teleflex Medical recommends a Hem-o-lok endoscopic clip remover be manually available during endoscopic surgery involving the use of Hem-o-lok clips.
- Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper size clip. Ligating clip systems differ in closure characteristics according to clip design and other variables. It is the responsibility of the user to select structures for the application of clips and to ensure the proper clip size, after placement and after the use of any other surgical devices in the immediate area of the application.

Hem-o-lok Take Apart Endoscopic Ligating Clip Appliers and Removers

- This applier is NOT designed for use with an operative camera for the purposes of maintaining pneumoperitoneum.
- Proceed carefully when inserting the instrument through a cannula. DO NOT apply lateral pressure on the applier as damage to the working flying wire may occur.
- Do not use the applier if the jaws are bent, misaligned, cracked or worn parts.
- In order to avoid unnecessary jaw loss, ensure the clearing pad, up-fits tightly on the Luer-Lock flush port. A spare cap is provided for your convenience.
- Always confirm that the clip remains in the applier after insertion of the applier and clip through a cannula. Do not attempt to close the jaws on a vessel or anatomic structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or anatomic structure may result in patient injury.
- Ratchet mechanism should only be activated with jaws in open position. Failure to do this may result in damage to the applier and remover damage.
- Use of cleaning and sterilization methods other than those provided by Teleflex must be validated by the healthcare facility using applicable validated laboratory methods.
- It is the responsibility of the user to determine adequate opening of the ligating clip for safe removal of the clip from the vessel or anatomic structure.

NOTE: Once a clip has been removed from a vessel, do not attempt to reapply the used clip. A new clip must be used.

Clip Application Instructions for Use

Hem-o-lok ligating clips are generally suited to vessel and tissue structure sizes indicated in Table 1. Surgeon judgment should dictate clip selection for specific applications.

Loading clips and inserting the applier down the cannula

1. To load the applier, grasp the applier and carefully insert the jaws of the applier into the cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the applier over the clip until the jaws are audible double click. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily.
2. Confirm that the clip is properly loaded by viewing the clip is held securely in the applier jaws. The clip should be placed in the notches of the applier jaws (**Illustration 1**). It may be necessary to hold the cartridge to allow the clip to be removed.
3. Compress the applier handles and insert the applier jaws and shaft down the cannula. Maintain compression on the applier handles until the jaws clear the cannula.

Clips Positioning and Closure

4. Sufficiently visualize as the structure to be ligated to allow the locking mechanism of the clip to be clear of tissue. Do not close the clip or applier as a dissecting instrument.
5. During application, orient the single tooth of the clip as shown (**Illustration 1**). This allows the user to visually confirm that the clip is properly closed. Position the clip on the vessel or anatomic structure to be ligated in a manner that provides clear visualization of the locking mechanism (**Illustration 2**). NOTE: Avoid excess tissue in the locking mechanism of the clip. Apply sufficient force to the applier handles, so the jaws close and the clip locks shut (**Illustration 3**). Releasing pressure on the applier handles allows the applier to return to a fully open position.

NOTE: Leave a distal stump of at least approximately 3-5mm from the ligating clip if the vessel is divided (Illustration 4). I.e. DO NOT USE THE SIDE OF THE CLIP AS A CUTTING GUIDE.

INSTRUCTIONS FOR INTRAOPERATIVE CHOLANGIOGRAM UTILIZING HEM-O-LOK ML CLIPS AND TAUT LAPAROSCOPIC CHOLANGIOGRAM CATHETERS

The **Hem-o-lok ML** clip is a locking clip and is only recommended for use in intraoperative cholangiograms with Taut, Inc., NON-bulbous (non-shouldered) tipped catheters, Catalog #s 16305 and 16406.

NOTE: Only Medium-Large Hem-o-lok Ligating Clips should be used for intraoperative cholangiograms using Taut Laparoscopic Cholangiogram Catheters. Use of these catheters permit catheter remo val while maintaining a stable clip on the ML clip.

1. Ligate the cystic duct with **Hem-o-lok ML** clips (**2**) that are secured on the cystic duct to prevent egress of bile from the cystic duct remnant (**Illustration 5**).
2. A Taut Intraoperative Cholangiogram Catheter, Catalog #'s 16305 or #16406 is placed through a standard duodenotomy in the cystic duct and the cannulated duct is ligated around the catheter with a **Hem-o-lok ML** clip (**#2**) (**Illustration 5**).
3. Contrast is injected into the cystic duct and the Taut catheter is removed leaving the secure **Hem-o-lok ML** clip closest to the cystic duct (**Illustration 6**).
4. A third **Hem-o-lok ML** clip (**#3**) is secured in place on the cystic duct (**Illustration 7**).
5. The cystic duct is now divided during the securing of the third clip for secure ligation (**Illustration 8**). In the circumstance where a choledochgram is performed using any other type of 4.5 French Taut catheter, the ligation of the catheter is established by securing the catheter with a Hem-o-lok ML clip, the clip must be removed before attempting to remove the catheter. The clip may be removed with a compatible endoscopic remover.

Clip Remover Instructions for Use

1. Insert the Hem-o-lok Endoscopic Endoscopic clip remover down the cannula. The clip must be approached from the long side, not the locking mechanism side.
2. Approach the clip and using the turn knob, rotate the jaws of the remover so the jaws are directly over and aligned with the legs of the clip.
3. Advance the remover until the user visualizes the hinge of the clip resting at the back of the remover jaws as shown (**Illustration 9**). NOTE: The hinge of the clip MUST rest at the back of the remover jaws to ensure disengagement of the clip legs (**Illustration 10**).
4. Close the remover handles (**Illustration 11**) by applying slight pressure to the remover handles until a slight click is felt. This indicates the clip legs have disengaged. Opening the remover handles will allow the clip to open on the vessel. Visually confirm the clip has opened sufficiently and the tooth of the clip is clear of any tissue.
5. The remover may be used as a spacer after opening the clip (**Illustration 11**). Use the remover jaws to grasp the clip by the hinge. NOTE: The opened clip must be grasped by the hinge for withdrawal from the ligation site and up through the cannula. Hold the cannula and withdraw the clip up the cannula. Maintain ligating jaw force on the clip.

CARE, CLEANING AND STERILIZATION

- Manual applier and remover jaws are delicate and can easily become damaged as can some other applier/remover components.
- Inappropriate cleaning may result in improper load and/or closure of the jaws.
- Appropriate cleaning, lubrication and maintenance are important to ensure proper function.
- Please examine the applier/remover before each surgery for potential damage.
- Pay particular attention to the jaws. Damaged or misaligned applier jaws may not allow clips to close acceptably for occlusion of intended structure. Damaged remover jaws may not allow for clip removal.
- If repair is required, clean, sterilize and return to damaged instrument to Teleflex Medical.

NOTE: When lubricating the instrument, do not use mineral oil, petroleum or Silicone-based products.

NOTE: During cleaning of lumina, drill holes or blind holes. Special attention will be required.

Preparation at Point of Use

Directly after use, remove coarse contamination from the instruments and keep the instruments moist for transit to the reprocessing area. Prior to cleaning and sterilization clean as any fixing agents not water since this may lead to the fixation of residue and can have a negative influence on the cleaning process. Some Weck Hem-o-lok Take Apart Endoscopic Clip Appliers and Removers are provided with a cleaning port which permits access to the interior channels and cavities. Unclip the cleaning port, as necessary, but do not remove the cap/ latter completely from the instrument. Flush with warm distilled or filtered water for approximately two minutes or until the visible gross debris is removed from the device.

Transportation

During the transportation of the instrument to the processing site, store contaminated instrument securely in a closed container to avoid damage to the instrument and/or contamination of the environment.

Preparation for Reprocessing

Where applicable, the instrument must be disassembled and/or opened for cleaning.

Failure to clean the instrument could lead to inadequate sterilization.

Cleaning, Disinfection And Drying Instructions

Hem-o-lok Take Apart Endoscopic Ligating Clip Appliers and Removers should be cleaned independently according to the instructions listed below. The instruments are approved to be cleaned according to each of the following options:

Temperature Description	°Celsius	°Fahrenheit
Cold	< 22°C	< 72°F
Lukewarm	22-43 C per AAMI TIR 12:2010	72-110 F per AAMI TIR 12:2010
Hot	> 43°C	> 110°F

Automatic Processing Instructions for Use with Alkaline or Enzymatic Detergents	Manual Processing Instructions for Use with Enzymatic Detergents
Pre-Cleaning • Soak the instruments in lukewarm tap water for five (5) minutes (minimum). • Using soft bristle brushes (Spectrum M16 or similar), brush the submerged instruments under lukewarm tap water for a minimum of thirty (30) seconds or until all visible residue is removed. • Rinse instrument and flush lumens with a syringe with lukewarm tap water for one (1) minute (minimum).	
Enzymatic or Alkaline Automatic Cleaning • Place the opened instrument in a wire basket on the slide-in tray and start the cleaning process. • Pre-rinse for two (2) minutes with cold tap water. • Empty. • Wash for five (5) minutes in hot tap water with a 0.8% enzymatic cleaner or a 0.5% alkaline cleaner. See note below. • Empty. • Neutralize with cold tap water for three (3) minutes. • Empty. • Rinse for fifteen (15) minutes in cold, filtered tap water. • Empty. • Perform automated dry cycle for fifteen (15) minutes according to washer parameters. Note: The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use provided by the detergent manufacturer. Detergents must be approved for use with metal reusable general surgical instruments. Examples of detergents used during validations: Enzymatic detergent: Cidezyme/Enzol. Alkaline detergent: Neodisher Mediclean.	**Enzymatic Manual Cleaning** • Place the instrument in a lukewarm ultrasonic water bath with 0.8% enzymatic cleaner. • Sonicate for fifteen (15) minutes (minimum). • Remove instruments from ultrasonic bath. • Using a soft bristle brush (Spectrum M16 or similar for exterior cleaning), brush the instrument under running lukewarm tap water for one (1) minute (minimum) or until all visible residue is removed. • Rinse instruments and flush lumens with running lukewarm tap water for one (1) minute (minimum). Note: The preparation of concentration, temperature and application time of the cleaning agent must be according to the instructions for use provided by the detergent manufacturer. Detergents must be approved for use with metal reusable general surgical instruments. Examples of detergents used during validations: Enzymatic detergent: Cidezyme/Enzol.

Thermal Disinfection

The final rinse cycle for one (1) minute at a temperature of 90°C with purified water.

Visual Inspection

Visually inspect the instrument in a well-lit area to ensure all surfaces are clean. If it is determined that the instrument is not clean, repeat the cleaning steps.

Drying

Wipe dry with a clean, lint-free cloth (Kimwipe or equivalent). Filtered, compressed air may be used.

Lubrication

Lubricate parts using a non-silicone, water-based surgical grade lubricant as per manufacturer's instructions.

NOTE: It is the responsibility of the healthcare facility to ensure adequate cleaning of the brushes between each use. Reassemble the appliers, complete functional check and sterilize assembled.

Functional Check

- It is mandatory to inspect the instrument prior to use as it may be damaged during transit to the customer, at the customer's site during receiving, during use in a previous procedure or during the cleaning or sterilization process.
- All moving parts must be inspected for wear and confirmed to be functional.
- Confirm smooth operation during open ing and closing of instrument handle and that tips align properly.
- As screws may become loose during normal operation of an instrument, inspect before and after use in order to ensure proper function.
- Inspect instruments for readability of device markings, as applicable, rust, pitting, cracking or burns, staining or discoloration and worn or broken parts.
- Repair or replace any instrument found not to be acceptable.

Maintenance, Handling and Operation of Surgical Instruments

- The assembly and disassembly of the instrument must only be performed by personnel trained to the institution's training requirements.
- The instrument must be cleaned, lubricated, functionally checked and sterilized prior to each use.

Packaging

- After cleaning and inspection as outlined above, place the instrument in a sterilization container or packaging which will protect the instrument from the environment as well as permit sterilization.
- After sterilization the instrument should remain in the sterilization container or packaging for protection from the environment and to maintain sterility.

Sterilization

To avoid electrochemical reactions, separate instruments fabricated from different materials.

The instruments are approved to be sterilized according to the following parameters:

Sterilization Method	Instrument Configuration	Temperature	Exposure Time (minimum)	Drying Time (minimum)
Prevac	Wrapped	270 F (132 C)	4 min	30 min
Prevac	Wrapped	275 F (135 C)	3 min	30 min
Gravity	Wrapped	275 F (135 C)	10 min	30 min

NOTE: The following methods of sterilization are NOT recommended as they could damage the instrument: flash sterilization, ethylene oxide sterilization, dry heat sterilization, liquid chemical sterilants, chemical sterilant gases.

Storage

Instrument must be stored in a dry, clean, chemical-free and dust-free environment. Instrument must remain in wrapper (or within the sterilization container to maintain sterility.

Environmental Conditions

MR Safe

MR Weck Hem-o-lok clips are constructed of a non-absorbable polymer material and are considered MR Safe according to the current criteria and labeling terminology (MR safe is an item that poses no known hazards in all MR environments. Using the terminology, "MR Safe" items are non-conducting, nonmetallic and nonmagnetic[1].

PRODUCT INFORMATION DISCLOSURE

Teleflex excludes all warranties, except Teleflex is applicable Standard Warranty whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Teleflex shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product except for the intended use specified. Teleflex does not authorize nor authorizes any person to assume for them any other or additional liability or responsibility in connection with these products.

LIGATING CLIP APPLIER WARRANTY

Weck take-apart manual load endoscopic appliers are covered by a three-year warranty on defects in materials and workmanship and a three-year repair service on to alignment and refurbishment as long as the applier is used as intended for application of Weck clips and has not been repaired by unauthorized personnel.

LIFE EXPECTANCY

- The instruments should be inspected for readability of device markings, as applicable, signs of rust, cracking, pitting, breaking, staining and/or discoloration, burrs, sharp edges or protrusion as well as any other signs of defects.
- Instruments found with any signs of the aforementioned defects are not safe for use with patients and should be immediately discarded.

Disposal

This device should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

LIGATING SYSTEM COMPATIBILITY

- There are a number of ligating clips on the market today in addition to Hem-o-lok ligating clips from Teleflex Medical.
- Your Weck Hem-o-lok appliers and removers have been designed for use exclusively with Hem-o-lok Ligating Clips.
- Applier color coding matches the color of the ligating clip cartridge with which it is to be used.
- Teleflex Medical does not assume responsibility for unsatisfactory results caused by the use of any equipment or clips not specifically certified by Teleflex Medical as an integral part of this specific system.
- For additional information, contact your Teleflex Sales Representative or Teleflex Customer Service.

[1] Gil and Shellock, Journal of Cardiovascular Magnetic Resonance, 2012, 14:3.

After launch of European Database on Medical Devices EUDAMED, the summary of safety and clinical performance (SSCP) will be made available to the public at https://ec.europa.eu/tools/eudamed. For a patient serious incident in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices), if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

An electronic version of the IFU can be found at www.teleflex.com/IFU.