# WECK® Hem-o-lok®

en **Take Apart Endoscopic Ligating Clip Appliers and Removers**
bg **Разглобяеми ендоскопски лигиращи клипс-апликатори и екстрактори**
cs **Rozebratelné endoskopické aplikátory a odstraňovače ligačních svorek**
da **Adskillelige endoskopiske ligeringsclipsapplikatorer og clipsfjernere**
de **Zerlegbare endoskopische Ligaturclip-Anlege- und Entfernungszangen**
el **Αποσυναρμολογούμενοι ενδοσκοπικοί εφαρμοστές και εργαλεία αφαίρεσης κλιπ απολίνωσης**
es **Pinzas aplicadoras y extractores endoscópicos de grapas para ligadura desmontables**
fi **Purettavat endoskooppiset klipsinasettimet ja poistimet**
fr **Applicateurs et extracteurs endoscopiques démontables de clips de ligature**
hr **Razdvojivi endoskopski uređaji za postavljanje i uklanjanje poveznih stezaljki**
hu **Szétszerelhető endoszkópos érlekötő kliprakók és -eltávolítók**
it **Applicatori ed estrattori endoscopici smontabili di clip per legatura**
lt **Išardomi endoskopiniai ligavimo spaustukų uždėjimo ir nuėmimo įtaisai**
lv **Izjaucami endoskopisko nosiešanas skavu aplikatori un noņēmēji**
nl **Demontabele endoscopische plaatsings- en verwijdertangen voor ligeerclips**
no **Endoskopisk ligeringsklipsapplikator og -fjerner som kan tas fra hverandre**
pl **Endoskopowe aplikatory i ekstraktory do klipsów ligacyjnych nadające się do rozmontowania**
pt **Aplicadores e removedores endoscópicos desmontáveis de clipes de laqueação**
pt_br **Aplicadores e removedores desmontáveis de clipes de ligadura endoscópica**
ro **Aplicatoare și dispozitive de scoatere endoscopice demontabile pentru agrafe de ligatură**
sk **Odnímateľné aplikátory a extraktory endoskopických ligačných svoriek**
sl **Razstavljivi aplikatorji in odstranjevalniki endoskopskih sponk za podvezovanje**
sv **Isärtagbar endoskopisk applikator och borttagare för ligeringsclips**
tr **Sökülebilir Endoskopik Ligasyon Klips Uygulayıcıları ve Çıkartıcıları**


WECK® Hem-o-lok®

Ligating Clips and Appliers

Teleflex MEDICAL

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L02424 R02 (2021-01)


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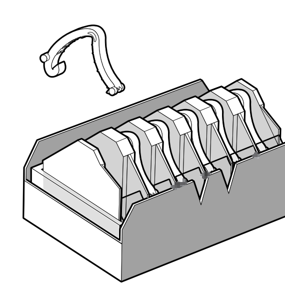

en **Ligating Clips**
bg **Лигиращи клипси**
cs **Ligační svorky**
da **Ligeringsclips**
de **Ligaturclips**
el **Κλιπ απολίνωσης**
es **Grapas para ligadura**
fi **Ligaatioklipsit**
fr **Clips de ligature**
hr **Povezne stezaljke**
hu **Érlekötő klipek**
it **Clip di legatura**
lt **Ligavimo spaustukai**
lv **Nosiešanas skavas**
nl **Ligeerclips**
no **Ligeringsklips**
pl **Klipsy ligacyjne**
pt **Clipes de laqueação**
pt_br **Clipes de ligadura**
ro **Agrafe de ligatură**
sk **Ligačné svorky**
sl **Sponke za podvezovanje**
sv **Ligeringsclips**
tr **Ligasyon Klipsleri**

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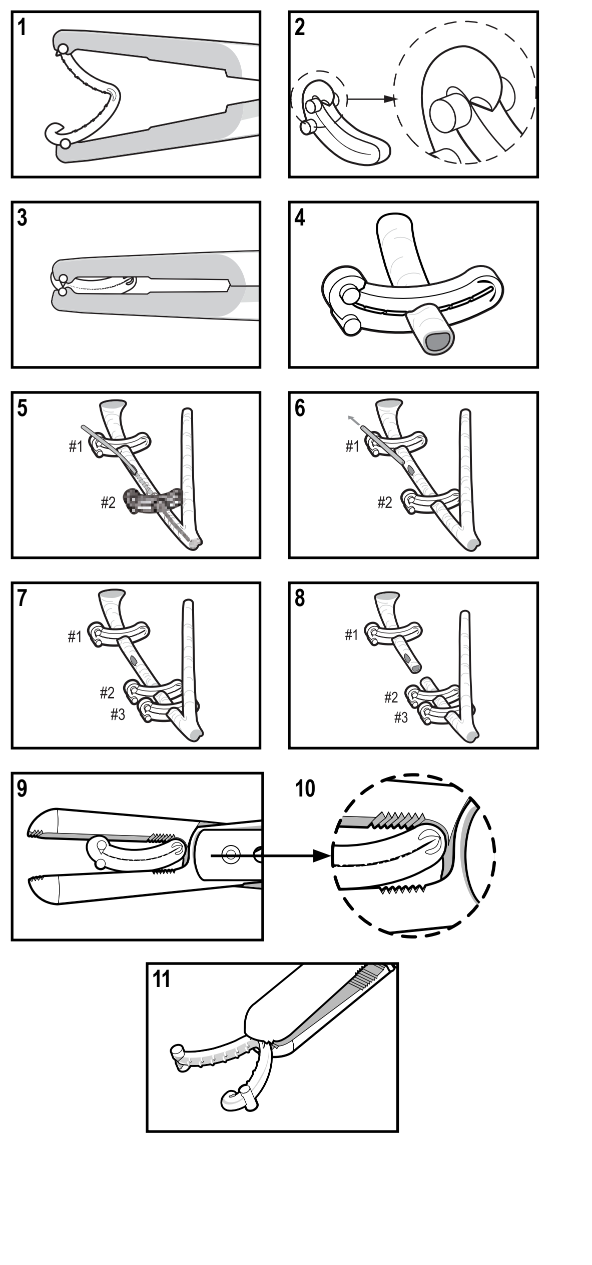



# WECK® Hem-o-lok® en

## 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 non-absorbable polymer material. Clip cartridge adhesive backing allows convenient placement of the cartridge to any sterile area. Weck Hem-o-lok Take Apart 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 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 Range | Color | Take Apart Endoscopic Appliers | Applier Cannula Size | Take Apart Endoscopic Removers | Remover Cannula Size |
|---|---|---|---|---|---|---|---|
| Medium | 544220 | 2mm – 7mm | Blue | 544945T | 5mm | 544121T | 5mm |
| Med-Large | 544230<br>544233 | 3mm – 10mm | Green | 544965T<br>544965T20 | 5mm<br>10mm | 544121T | 5mm |
| Large | 544240<br>544243 | 5mm – 13mm | Purple | 544995T<br>544995T20 | 10mm<br>12mm | 544121T<br>544130T<br>544130T20 | 5mm<br>10mm<br>15mm |
| Extra-Large | 544250<br>544253 | 7mm – 16mm | Gold | 544990T<br>544990T20 | 10mm<br>15mm | 544121T<br>544130T<br>544130T20 | 5mm<br>10mm<br>15mm |

### Indications
Hem-o-lok Ligation 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 encompasses 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 sized trocar 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/tissue trauma
- Internal bleeding
- Surgical intervention
- Clip erosion

### Implantable Clip Material
Non-absorbable Acetal Homopolymer

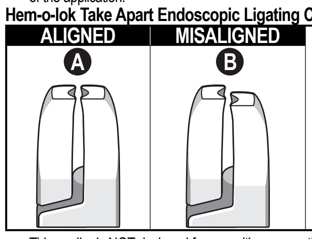
### WARNING
#### Hem-o-lok Ligating Clips
- Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss 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 remove the broken clip from 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 and improper handling may result in damage, potentially resulting in user or patient injury.
- Instruments which are used consciously on patients with a prion-based disease (transmissible spongiform encephalopathy disease, 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, as introducing these instruments to the reprocessing facility may lead to contamination of other instruments and/or the reprocessing facility equipment.

### CAUTION
#### Hem-o-lok Ligating Clips
- In procedures other than laparoscopic donor nephrectomy, Teleflex Medical recommends ligation of the renal artery with more than one clip on the patient side with a minimum distal renal artery cuff of 2-3mm beyond the distal clip.
- The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure of the clip. Security of the closure should be confirmed after ligation to avoid leakage from ligated blood vessels or hollow viscus.
- Application of a second clip on all other vessels (other than the renal artery) should be dictated by the surgeon's judgment.
- The Hem-o-lok Polymer Ligating Clip is not designed for use as a tissue marker.
- Teleflex Medical recommends a Hem-o-lok endoscopic clip remover be readily 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 confirm clip security after placement and after the use of other surgical devices in the immediate area of the application.

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




- Always check the alignment of the applier and remover jaws before use.
- When closed, jaw tips should be directly aligned and not offset.
- Alignment of the jaw is critical for safe application of the clip. If this is not done, patient injury may occur.
- Alignment of the remover jaw is critical for safe removal of the clip. If this is not done, the ligating clip legs may not disengage.
- Proper maintenance, care and cleaning are necessary to ensure proper functionality.

- This applier is NOT designed for use with an operative cannula 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 tip may occur.
- Before use, examine the instrument for bent, broken, cracked or worn parts.
- In order to avoid unnecessary gas loss, ensure the cleaning port cap 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.
- Rotation knob 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 appropriate 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 should 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 there is an 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. Remove the applier from the cartridge ensuring the clip is held securely in the applier jaws. The clip bosses should seat 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.

#### Clip positioning and closure
4. Sufficiently skeletonize the structure to be ligated to allow the locking mechanism of the clip to be clear of tissue. Do not use 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 encapsulation of the structure being ligated. Position the clip around the tissue 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 cuff of tissue approximately 2-3mm 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 18305 and 18400.
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 removal without having to remove a locked Hem-o-lok ML clip.
1. An optional **Hem-o-lok ML** clip **(#1)** may be secured on the cystic duct to prevent egress of bile from the gallbladder ductotomy **(illustration 5)**.
2. A Taut Intraoperative Cholangiogram Catheter, Catalog #18305 or #18400 is placed through a standard ductotomy in the cystic duct and the cannulated duct is ligated around the catheter with a **Hem-o-lok ML** clip **(#2) (illustration 5)**.
3. After completion of the cholangiogram, the Taut catheter is removed leaving the secure **Hem-o-lok ML** clip closed on 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 using the security of the third clip for secure ligation **(illustration 8)**. In the circumstance where a cholangiogram is performed using any other type of 4.5 French Taut catheter, and the stabilization 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 Take Apart endoscopic clip remover down the cannula. The clip must be approached from the hinge 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. Once the clip is properly positioned in the jaws as shown, apply steady 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 grasper 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, maintaining grasping 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.
- Mishandling of appliers may result in improper load and/or closure of the jaws.
- Appropriate care, 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 damaged instrument to Teleflex Medical.

**NOTE: When lubricating the instrument, do not use mineral oil, petroleum or silicon-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 processing site. Prior to cleaning and sterilization do not use any fixing agents or hot 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. Uncap the cleaning port, as necessary, but do not remove the cap tether 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**
Thermal 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 joints 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 opening 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 burrs, 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 wrapped or within the sterilization container to maintain sterility.

### Environmental Conditions
MR
**MR Safe**
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 MRI environments. Using the terminology, "MR Safe" items are non-conducting, nonmetallic and nonmagnetic)[1].

### PRODUCT INFORMATION DISCLOSURE
Teleflex excludes all warranties, except Teleflex's 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 assume 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 tip 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 identified by Teleflex Medical as an integral part of this specific system.
- For additional information, contact your Teleflex Sales Representative or Teleflex Customer Service.

[1]*Gill 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/user/third party 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 authorized 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.**

# WECK® Hem-o-lok® bg

## Разглобяеми ендоскопски лигиращи клипс-апликатори и екстрактори

### Описание на изделието
Лигиращите клипси Weck® Hem-o-lok® са неабсорбируеми, неактивни изделия за еднократна употреба, предвидени за използване при общи хирургически процедури, които изискват лигиране на кръвоносни съдове или тъкани. Клипсите са произведени от неабсорбируем полимерен материал. Лепящата подложка на гърба на касетата позволява удобно разполагане на касетата в стерилното поле. Разглобяемите ендоскопски клипс-апликатори Weck Hem-o-lok са проектирани за употреба като устройства за поставяне на лигиращи клипси Hem-o-lok. Разглобяемите ендоскопски клипс-апликатори са инструменти за многократна употреба, които се зареждат ръчно и подават по един клипс. Разглобяемите ендоскопски лигиращи клипс-екстрактори Weck Hem-o-lok са проектирани като устройства за отстраняване на лигиращи клипси Hem-o-lok. За апликаторите и екстракторите не е предвидено да бъдат съвместими с какъвто и да е друг тип лигиращи клипси.
За размери и съвместимост на продукта вижте **Таблица 1**.

**Таблица 1: Размери и съвместимост на продукта**

| Размер на клипса | Клипс | Диапазон на размерите на кръвоносния съд/тъканта | Цвят | Разглобяеми ендоскопски апликатори | Размер на канюлата на апликатора | Разглобяеми ендоскопски екстрактори | Размер на канюлата на екстрактора |
|---|---|---|---|---|---|---|---|
| Среден | 544220 | 2 mm – 7 mm | Син | 544945T | 5 mm | 544121T | 5 mm |
| Средноголям | 544230<br>544233 | 3 mm – 10 mm | Зелен | 544965T<br>544965T20 | 5 mm<br>10 mm | 544121T | 5 mm |
| Голям | 544240<br>544243 | 5 mm – 13 mm | Виолетов | 544995T<br>544995T20 | 10 mm<br>12 mm | 544121T<br>544130T<br>544130T20 | 5 mm<br>10 mm<br>15 mm |
| Много голям | 544250<br>544253 | 7 mm – 16 mm | Златист | 544990T<br>544990T20 | 10 mm<br>15 mm | 544121T<br>544130T<br>544130T20 | 5 mm<br>10 mm<br>15 mm |

### Показания
Лигиращите клипси Hem-o-lok са предназначени за употреба при процедури, в които се налага лигиране на кръвоносни съдове или тъканни структури. Хирурзите трябва да използват клипси с подходящ размер за размера на кръвоносния съд или тъканната структура, които се лигират, така че клипсът изцяло да обхваща кръвоносния съд или тъканната структура.
Разглобяемите ендоскопски лигиращи клипс-апликатори Hem-o-lok са предназначени за употреба като устройства за поставяне на неабсорбируеми полимерни лигиращи клипси Hem-o-lok през специално оразмерени канюли на троакари.
Разглобяемите ендоскопски лигиращи клипс-екстрактори Hem-o-lok са предназначени за премахване на неабсорбируеми полимерни лигиращи клипси Hem-o-lok.

### Противопоказания
Лигиращите клипси Hem-o-lok не са предназначени за употреба като оклузивно изделие на маточните тръби като средство за контрацепция.
Лигиращите клипси Hem-o-lok са противопоказни за употреба при лигиране на бъбречната артерия по време на лапароскопски донорски нефректомии.

### Целева група пациенти
Системата за лигиране Hem-o-lok е предназначена за употреба при пациенти, при които се изисква лигиране на кръвоносни съдове или други структури.

### Клинични ползи
- Намаляване на постоперативните усложнения в сравнение с алтернативните терапии
- Намаляване на общото оперативно време в сравнение с алтернативните терапии

### Потенциални странични ефекти
- Травма на съд/тъкан
- Вътрешно кървене
- Хирургична интервенция
- Ерозия на клипса

### Материал на имплантируем клипс
Неабсорбируем ацетал хомополимер

### ПРЕДУПРЕЖДЕНИЕ
#### Лигиращи клипси Hem-o-lok
- Еднократна употреба: Да не се използва, обработва или стерилизира повторно. Повторното използване на устройството е предпоставка за риск от сериозно нараняване и/или инфектиране, което може да доведе до смърт. Повторната обработка на медицински устройства, предназначени единствено за еднократна употреба, може да доведе до частична или пълна загуба на ефективност.
- Клипсите Hem-o-lok са предназначени за перманентно лигиране на кръвоносни съдове и/или тъканни структури. Ако е необходимо отстраняване на клипс, разглобяемият ендоскопски екстрактор може да се използва за тази цел. Ако клипсът се счупи по време на процеса на отстраняване, хирургът трябва да отстрани счупения клипс от мястото на хирургичната операция.

**ЗАБЕЛЕЖКА: Лигиращите клипси Hem-o-lok се доставят стерилни. Касетите с лигиращи клипси Hem-o-lok съдържат барий и са рентгеноконтрастни.**

#### Разглобяеми ендоскопски лигиращи клипс-апликатори и екстрактори Hem-o-lok
- Неправилно използване и неправилно боравене с инструментите може да доведе до потенциални увреждания на потребителя или до нараняване на пациента.
- Инструменти, които се използват съзнателно при пациент с прионово заболяване (трансмисивна спонгиформна енцефалопатия, болест на Кройцфелд-Якоб – CJD, спонгиформна енцефалопатия по говедата – BSE (СЕГ) и т.н.) или при пациенти, суспектни за някое от тези заболявания, не са безопасни за повторно използване и трябва да бъдат изхвърлени съгласно одобрените болнични процедури.
- Не почиствайте и/или не стерилизирайте инструменти, суспектни за контаминация с приони,