WECK®

en Ligating Clips, Appliers and Removers
bg Лигиращи клипси, апликатори и екстрактори
cs Ligační svorky, aplikátory a odstraňovače
da Ligeringsclipsapplikatorer og clipsfjernere
de Ligaturclips, Anlegezangen und Entfernungszangen
el Κλιπ στειλώματος, εφαρμογείς και εργαλεία αφαίρεσης
es Grapas para ligadura, pinzas aplicadoras y extractores
fi Ligaatioklipsit, asettimet ja poistimet
fr Clips de ligature, applicateurs et extracteurs
hr Povezne steznjke, uređaji za postavljanje i uklanjanje
hu Érelektő klipek, kliprakók és -eltávolítók
it Clip per legatura, applicatori ed estrattori
lt Ligavimo spaustukai, uždějimo ir nuėmimo įtaisai
lv Ligācijas skavas, aplikatori un ieņēmēji
nl Ligeerclips, ligeercliptang en ligeerclipverwijdertang
no Ligeringsklips, applikatorer og fjernere
pl Klipsy ligaturujące, aplikatory i ekstraktory
pt Clipes de laqueação, aplicadores e removedores
pt_br Clipes de ligadura, aplicadores e removedores
ro Agrafe de ligatură, aplicatoare şi dispozitive de scoatere
sk Aplikátory a extraktory ligačných svoriek
sl Sponke za podvezovanje, aplikatorji in odstranjevalniki
sv Ligeringsclips, applikatorer och borttagare
tr Ligasyon Klipsleri, Uygulayıcılar ve Çıkartıcılar

MD Rx ONLY

EU Authorized Representative and Importer:
CE 1639
EC REP
Teleflex Medical (UK Business and Technology Park Ballybrit Galway, Co. Westmeath Ireland

Clean and sterilize before use. • Почистване и стерилизиране преди употреба. • Před použitím vyčistěte a sterilizujte. • Rengør og sterilisere inden anvendelse. • Vor der Verwendung reinigen und sterilisieren. • Καθαρίζετε και αποστειρώνετε πριν από τη χρήση. • Limpiar y esterilizar antes de su uso. • Puhdistettava ja steriloitava ennen käyttöä. • Nettoyer et stériliser avant utilisation. • Očistite i sterilizirajte prije uporabe. • Használat előtt tisztítani és sterilizálni kell. • Pulire e sterilizzare prima dell'uso. • Prieš naudojant, išvalykit ir sterilizuokit. • Pirms lietošanas notīriet un sterilizējiet. • Voor gebruik reinigen en steriliseren. • Rengjør og steriliser før bruk. • Przed użyciem poddać czyszczeniu i sterylizacji. • Limpe e esterilize antes de utilizar. • Limpie e esterilice antes de usar. • Är se curăța și sterilizați înainte de utilizare. • Pred použitím sa musia vyčistiť a sterilizovať. • Pred uporabo očistite in sterilizirajte. • Rengör och sterilisera före användning. •Kullanmadan önce temizleyin ve sterilize edin.

MD Rx ONLY STERILE EO

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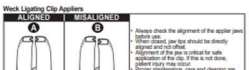
CE 1639
EC REP
Teleflex Medical (UK Business and Technology Park Ballybrit Galway, Co. Westmeath Ireland

en Metal Ligation Clips
bg Метални лигиращи клипси
cs Kovové ligační svorky
da Ligeringsclips af metal
de Metall-Ligaturclips
el Μεταλλικά κλιπ στειλώματος
es Grapas metálicas para ligadura
fi Metalliset ligaatioklipsit
fr Clips de ligature métalliques
hr Metalne povezne stezaljke
hu Fém érelektő klipek
it Clip per legatura metalliche
lt Metaliniai ligavimo spaustukai
lv Metāla ligāzijas klipši
nl Metalen ligeerclips
no Ligeringsklips i metall
pl Metalowe klipsy ligaturujące
pt Clipes de laqueação metálicos
pt_br Clipes metálicos de ligadura
ro Agrafe de ligatură metalice
sk Kovové ligačné svorky
sl Kovinske sponke za podvezovanje
sv Ligeringsclips i metall
tr Metal Ligasyon Klipsleri

Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death. • Прочетете всички предупреждения, предпазни мерки и инструкции преди употреба. В противен случай може да бъдат причинени сериозни нараняващи ене смърт на пациента. • Před použitím si prostudujte veškerá varování, bezpečnostní upozornění a pokyny v příbalových informacích. Opomenutí tohoto kroku může mít za následek těžké poranění či smrt pacienta. • Læs alle advarsler, forholdsregler og instruktioner i indlægsseddlen inden brug. Forsømmelse af dette punkt kan resultere i alvorlig patientskade eller død. • Vor dem Gebrauch alle Warnungen, Vorsichtsmaßnahmen und Anweisungen lesen. Andernfalls kann es zu schweren Verletzungen oder zum Tod des Patienten kommen. • Πριν από τη χρήση, διαβάστε όλες τις προειδοποιήσεις, τις προφυλάξεις και τις οδηγίες που περιλαμβάνονται στο έντθετο συσκευασίας. Σε αντίθετη περίπτωση, μπορεί να προκληθεί σοβαρός τραυματισμός ή θάνατος του ασθενούς. • Lea todas las advertencias, precauciones e instrucciones del prospecto antes de utilizar el dispositivo. El no hacerlo puede ocasionar lesiones graves o la muerte del paciente. • Lue kaikki luotesalosteen varoitukset, varotoimet ja ohjeet ennen käyttöä. Jos näin ei tehdä, se saattaa johtaa potilaan vakavaan vammaan tai kuolemaan. • Lire l'ensemble des avertissements, mises en garde et instructions de la notice avant utilisation. Le non-respect de cette consigne peut provoquer des lésions graves ou le décès du patient. • Prije uporabe pročitajte sva upozorenja, mjere opreza i upute umetnute u pakiranje. Ako to ne učinite, posljedice mogu biti ozbiljna ozljeda ili smrt pacijenta. • Használat előtt olvassa el a használati utasításban található összes „figyeljat" szintű figyelmeztetést, óvintézkedést és utasítást. Ennek elmulasztása a beteg súlyos sérülését vagy halálát okozhatja. • Prima dell'uso, leggere interamente le avvertenze, le precauzioni e le istruzioni riportate sul foglio illustrativo. La mancata osservanza di tali avvertenze, precauzioni e istruzioni potrebbe comportare lesioni gravi o mortali al paziente. • Prieš naudojant, būtina perskaityti visus spėjimus, atsargumo priemones ir nurodymus, feralaikant šių perspėjimų, galima sukelti sunkų paciento sužalojimą arba mirtį. • Pirms lietošanas izlasiet visus brīdinājumus, piesardzības pasākumus un instrukcijas lietošanas instrukcijā. Pretējā gadījumā pacientu var gūt smagas traumas vai var iestāties nāve. • Lees vóór gebruik alle waarschuwingen, voorzorgsmaatregelen en instructies in de bijsluiter. Dit nalaten kan ernstig letsel of overlijden van de patiënt tot gevolg hebben. • Les alle advarsler, forholdsregler og instruksjoner i pakningsvedlegget før bruk. Hvis du unnlater å gjøre dette, kan resultatet bli alvorlig pasientskade eller død. • Przed użyciem należy przeczytać wszystkie ostrzeżenia, przestrogi i instrukcje zamieszczone w ulotce pakowej. Do opisywania użycia. Niespełnienie tego zalecenia może spowodować ciężkie obrażenia lub zgon pacjenta. • Ler todas as advertências, precauções e instruções do folheto informativo antes da utilização. Não fazê-lo poderá provocar lesões graves ou mesmo a morte do doente. • Antes de usar, leia todas as advertências, precauções e instruções do folheto informativo Não fazê-lo pode resultar em lesão grave ou morte do paciente. • Înainte de utilizare, citiți toate avertismentele, atenționările și instrucțiunile din prospect. Nerespectarea acestei indicații poate cauza vătămarea gravă a pacientului sau decesul acestuia. • Pred použitím si prečítajte všetky varovania, upozornenia a pokyny v príbalovom letáku. Ich nedodržanie môže viesť k ťažkým zraneniam alebo smrti pacienta. • Pred uporabo pomotrite vsa priložena obvestila, previdnostne ukrepe in navodila. Če tega ne storite, lahko pride do resnih poškodb ali smrti bolnika. • Läs alla varningar, försiktighetsåtgärder och anvisningar i förpackningsinlagan före användning. Underlåtenhet att läsa den kan resultera i allvarlig patientskada eller dödsfall. • Kullanmadan önce tüm prospektüsteki uyarıları, önlemleri ve talimatını okuyun. Aksi halde hastanın ciddi şekilde zarar görmesine veya ölümüne neden olunabilir.

Weck Ligating Clip Appliers



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

- Do not attempt to close the jaws on a vessel or anatomic structure without a clip properly loaded into the jaws. Doing so may result in damage to the vessel or tissue, and/or patient injury.
- Before use, examine the instrument for bent, broken, cracked or worn parts.
- Use of cleaning and sterilization methods other than those provided by Teleflex must be validated by the healthcare facility using appropriate validated laboratory methods.

Weck Ligating Clip Removers

1. When removing a clip, the alignment of the clip in the jaws of the remover is necessary in order to avoid trauma to the vessel or tissue. If this is not done, the ligating clip may not open and injury to the vessel or patient injury may occur. 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 anatomical 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 Applier Instructions for Use

1. Load the applier ring-handles so they are fully open and the jaws will not compress as the applier is inserted into the cartridge.
2. Align applier jaws vertically and laterally over a clip in the cartridge and push the applier firmly onto the clip without compressing the handles. Minimal force is required.
3. Verify that the clip is fully seated.
4. Verify that the clip is fully inserted into the applier jaws and the clip legs do not protrude beyond the end of the jaws. The clip should be seated firmly.
5. Handle the applier carefully. The jaws should not close prematurely.
6. At the surgical site, the surgeon should close the applier ring-handles with a smooth, firm, continuous motion until the clip is fully closed. Releasing the pressure on the ring-handles will cause the applier jaws to spring open.
7. Remove the applier from the surgical site.

Clip Removal Instructions for Use

Weck Metal Clip Removing Forceps may be used to remove all Weck metal ligating clips during open procedures. To remove a ligating clip, grasp the clip with the forceps, applying pressure to the side of the clip at the closed end (**Illustration 1**). The clip will spread open (**Illustration 2**). Adequacy of the opening for clip removal is a surgeon judgment (**Illustration 3**).

CARE, CLEANING AND STERILIZATION

Weck Ligating Clip Appliers and Removers 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 ligating clips.
- Appropriate care, cleaning, lubrication and maintenance are important to ensure proper function.
- Please examine the applier before each surgery for potential damage.
- Do not attempt to close the jaws of the applier or remover if a clip is not in the jaws as doing so may allow clips to close accidentally for occlusion of intended structure. Damaged remover jaws may not allow for clip removal.

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

Preparation at Point of Use

Directly after use, remove coarse contamination from the instruments and keep the instrument moist for transit to the processing site. Prior to cleaning and sterilization do not use any fixing agents or hot water (> 40 °C/104 °F) since this may lead to the fixation of residue and can have a negative influence on the cleaning process.

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

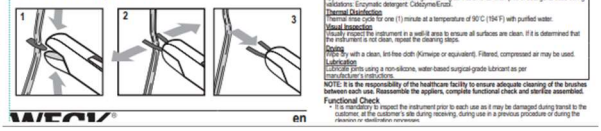
- Where applicable, the instrument must be disassembled and/or opened for cleaning.
- Open the handled instruments so that ratchets are not engaged and access to the interlocking box is maximized.
- Failure to clean the instrument could lead to inadequate sterilization.

CLEANING, DISINFECTION AND DRYING INSTRUCTIONS

Weck 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	< 21°C	< 71°F
Lukewarm	24.5(+/-2)°C AND 76.1(+/-2)°C	76.1(+/-2)°F AND 76.1(+/-2)°F
Hot	> 43°C	> 110°F

CLIP REMOVAL INSTRUCTIONS FOR USE • ИНСТРУКЦИИ ЗА УПОТРЕБА ПРИ ПРЕМАХВАНЕ НА КЛИПСИ • POKYNY K ODSTRANĚNÍ SVOREK • VEJLEDNING TIL FJERNELSE AF CLIPS • VORGEHENSWEISE ZUM ENTFERNEN VON CLIPS • ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ ΓΙΑ ΤΗΝ ΑΦΑΙΡΕΣΗ ΤΟΥ ΚΛΙΠ • INSTRUCCIONES PARA LA EXTRACCIÓN DE LAS GRAPAS • KÄYTTÖOHJEET KLIPSIN POISTOA VAATEN • MODE D'EMPLOI POUR LE RETRAIT DU CLIP • UPUTE ZA UPORABU UREĐAJA ZA UKLANJANJE STEZALJKI • KLIPELTÁVOLÍTÁSRA VONATKOZÓ HASZNÁLATI UTASÍTÁS • ISTRUZIONI PER L'USO • ŠALINIMO INSTRUKCIJA • NUĖMIMO ĮTAISO NAUDOJIMO INSTRUKCIJOS • SKAVU IZŅEMŠANAS INSTRUKCIJAS • AANWIJZINGEN VOOR HET VERWIJDEREN VAN CLIPS • BRUKSANVISNING FOR FJERNING AV KLIPS • INSTRUKCJA UŻYCIA EKSTRAKTORA KLIPSÓW • INSTRUÇÕES DE UTILIZAÇÃO PARA REMOÇÃO DE CLIPES • INSTRUCȚIUNI DE UTILIZARE PRIVIND SCOATEREA AGRAFELOR • NÁVOD NA ODSTRÁNENIE SVORIEK • NAVODILA ZA ODSTRANJEVANJE SPONKE • ANVISNINGAR FÖR AVLÄGSNANDE AV CLIPS • KLİPS ÇIKARMA TALİMATLARI



Automatic Processing Instructions for Use with Alkaline or 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 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. See note below.
- 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.

Thermal Disinfection

Thermal rinse cycle for one (1) minute at a temperature of 90°C (194°F) 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.

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 with lukewarm tap water for one (1) minute (minimum).

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 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 (194°F) 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 each 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 processes.
- 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 with any instrument, inspect for damage 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.
- Replace 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.
- If repair is required, return clean and sterile instruments to Teleflex.

Packaging

- After cleaning and inspection, 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)
Pre-Vac	Wrapped	270°F (132°C)	4 min	30 min
Pre-Vac	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 Conditional

The Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips were determined to be MR Conditional.

Non-clinical testing demonstrated that the Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips are MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less.
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less.

MRI-Related Heating

In non-clinical testing, the Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips produced the following temperature rise during MRI performed for 15-min of scanning (i.e. per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of the Weck® Hemoclip Traditional, Hemoclip Plus and Horizon Clips.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	57mm²	364mm²	1,109mm²	873mm²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

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

All Weck ring-handled reusable open-surgical appliers purchased by customers are covered by a warranty. Weck will repair or replace, free of charge, any reusable open-surgical ring-handled manual load ligation applier. This free repair is provided as long as the appliers are used as intended for application of Weck clips and have not been repaired by unauthorized personnel.

LIFE EXPECTANCY

Immediately following each complete sterilization cycle the instrument should be inspected prior to use. 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 defect. 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 genuine Horizon, Hemoclip Plus and Hemoclip Traditional ligating clips from Weck. Your Weck Applier has been designed and calibrated for use with specific Horizon, Hemoclip Plus or Hemoclip Traditional ligating clips as indicated. Applier color coding matches the color of the ligating clip cartridge for which it is to be used. Weck does not assume responsibility for unsatisfactory results caused by the use of any equipment or clips not specifically identified by Weck as an integral part of that specific system.

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.
For additional information, contact your Teleflex Sales Representative or Teleflex Customer Service.
An electronic version of the IFU can be found at www.teleflex.com/IFU

WECK®

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Ligating Clips, Appliers and Removers

Device Description

Weck® Metal 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 available in three product lines: Hemoclip Traditional, Hemoclip Plus and Horizon Clips. Each product line possesses a unique design necessary for compatibility with its respective metal ligating clip. The clip applier and remover designs are unique to each product line. The differences in clip size allow the end user to ligate a wide range of vessels and tissue structures. Where applicable, clip cartridge adhesive backing allows convenient placement of the cartridge to any sterile area.

Weck Ligating Clip appliers are designed for use as delivery devices for Weck Metal Ligating Clips. Manual open clip appliers are reusable instruments that manually load and deliver one clip at a time. Differences in tip set, groove slot design and overall jaw configuration differentiate the Hemoclip Traditional, Hemoclip Plus and Horizon appliers. The differences in jaw design not only provide the unique characteristics for clip compatibility but also offer the end-user with a different feel when loading/applying a ligating clip. Each product line is specifically designed for compatibility solely with their respective metal ligating clips. The appliers are not designed for compatibility with any other type of ligating clip.

Teleflex Medical's Weck Metal Clip Removing Forceps are used as a removal device for all Weck Metal Ligating Clips that have been applied in an open surgical setting.

For product sizing and compatibility, see **Table 1** at the end of this instruction.

Indications

Weck ligating clips are intended for use in procedures involving vessels or anatomic structures for which the surgeon determines ligating clips are the best choice. Surgeons should select the size, type and material of the clip based upon their experience, judgment and needs.

Weck Ligating Clip appliers are indicated for use as delivery devices for Weck metal ligating clips.

Weck Metal Clip Removing Forceps are designed to allow the removal of all Weck metal ligating clips during open procedures.

Contraindications

Weck ligating clips are not intended for use as a contraceptive tubal occlusion device.

Weck ligating clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

Patient Target Group

The Weck Ligation System is intended for use in patients requiring ligation of vessels or other structures.

Clinical Benefits

Ligation of nerves, veins, arteries and vessels relating to tissues including but not limited to lungs, appendix, spleen, liver, gallbladder, and central and peripheral vasculature.

Potential Side Effects

- Vessel Trauma
- Internal Bleeding
- Surgical intervention

Implantable Clip Material

Medical Grade titanium, tantalum or stainless-steel alloys.

WARNING

Weck 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 may result in degraded performance or a loss of functionality.
- Weck metal clips are intended for permanent ligation of vessels and/or tissue structures. Should clip removal be necessary, the 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.

Weck 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

Weck 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 3-mm beyond the distal clip. Application of a second clip on all other vessels (other than the renal artery) should be dictated by the surgeon's judgment. Security of the clips should be confirmed after ligation.
- Weck Ligating Clips are not indicated for use in the ligation of the cystic duct. Alternative clips are available during surgery including use of Weck metal ligating 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 secure grip of the clips after placement and after the use of other surgical devices in the immediate area of the application.
- The Weck Ligating Clip is not designed for use as a tissue marker.

NOTE: Weck ligating clips are supplied sterile. DO NOT re-sterilize ligating clip cartridges. Horizon ligating clip cartridges contain barium and are radiopaque.

- It is mandatory to inspect the instrument prior to each 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 processes.
- 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 with any instrument, inspect for damage 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.
- Replace 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.
- If repair is required, return clean and sterile instruments to Teleflex.

Packaging

- After cleaning and inspection, 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)
Pre-Vac	Wrapped	270°F (132°C)	4 min	30 min
Pre-Vac	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 Conditional

The Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips were determined to be MR Conditional.

Non-clinical testing demonstrated that the Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips are MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less.
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less.

MRI-Related Heating

In non-clinical testing, the Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips produced the following temperature rise during MRI performed for 15-min of scanning (i.e. per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Weck Hemoclip Traditional, Hemoclip Plus and Horizon Clips. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10-mm relative to the size and shape of the Weck® Hemoclip Traditional, Hemoclip Plus and Horizon Clips.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	57mm²	364mm²	1,109mm²	873mm²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

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

All Weck ring-handled reusable open-surgical appliers purchased by customers are covered by a warranty. Weck will repair or replace, free of charge, any reusable open-surgical ring-handled manual load ligation applier. This free repair is provided as long as the appliers are used as intended for application of Weck clips and have not been repaired by unauthorized personnel.

LIFE EXPECTANCY

Immediately following each complete sterilization cycle the instrument should be inspected prior to use. 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 defect. 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 genuine Horizon, Hemoclip Plus and Hemoclip Traditional ligating clips from Weck. Your Weck Applier has been designed and calibrated for use with specific Horizon, Hemoclip Plus or Hemoclip Traditional ligating clips as indicated. Applier color coding matches the color of the ligating clip cartridge for which it is to be used. Weck does not assume responsibility for unsatisfactory results caused by the use of any equipment or clips not specifically identified by Weck as an integral part of that specific system.

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.
For additional information, contact your Teleflex Sales Representative or Teleflex Customer Service.
An electronic version of the IFU can be found at www.teleflex.com/IFU