Click'aV® Ligating Clips Removers
Instruction for use

Ref. no.:
For open surgery: **0301-R804MMLL, 0301-R804XL**
For endosurgery non detachable:
5 mm: **0301-R804MLLE, 0301-R804MLLEB**
10 mm: **0301-R804LXLE, 0301-R804LXLEB**
For endosurgery detachable:
Inserts:
5 mm: **0301-R804MLLEI, 0301-R804MLLEIB**
10 mm: **0301-R804LXLEI, 0301-R804LXLEIB**
Handle with shaft:
5 mm: **0301-R804MLLEHS, 0301-R804MLLEHSB**
10 mm: **0301-R804LXLEHS, , 0301-R804LXLEHSB**

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Important:

The instructions provided herein are not intended to serve as a comprehensive manual for surgical techniques related to the use of the Click'aV® Ligating Clips Removers. Acquiring proficiency in surgical techniques necessitates direct engagement with our company or an authorized distributor to access detailed technical instructions, consult professional medical literature, and complete requisite training under the mentorship of a surgeon skilled in minimally invasive procedures. Prior to utilization of the device, we strongly advise a thorough review of all information contained in this manual. Failure to adhere to these guidelines may result in severe surgical outcomes, including patient injury, contamination, infection, cross-infection, or death.

Indications:

Grena Click'aV® Ligating Clip Removers are designed to safely open and remove Grena Click'aV® and Click'aV Plus™ polymer ligating clips from tissue when removal is necessary.
Due to the secure locking mechanism of Click'aV® Ligating Clips, they are highly resistant to opening with standard surgical instruments. Therefore, it is strongly recommended that a remover be readily available during any procedure involving the use of Click'aV® or Click'aV Plus™ Ligating Clips.
Patient target group - adult and adolescent patients of all genders.
Intended users: product is intended to be used exclusively by qualified medical professionals.

Contraindications:

No known contraindications for the device.

Description of the device:

Click'aV® Ligating Clip Removers are reusable surgical instruments available in versions for both open and endoscopic surgery, including a 45 cm bariatric model (designated by letter "B" in the reference number). Each clip size must be removed using a corresponding and compatible clip remover. Non-detachable endoscopic removers feature a built-in flushing channel and do not require disassembly for cleaning. The detachable version requires disassembly for cleaning by unscrewing the insert from the shaft in a counterclockwise direction. The flushing channel in the detachable version facilitates debris removal from the shaft after the insert is removed. MLL inserts are compatible with 5 mm handles, while LXL inserts fit 10 mm handles. The remover's shaft can be rotated 360° relative to the handle.

Instructions for use:

1. Check the compatibility of all devices prior to use.
2. Confirm the compatibility of all devices prior to use.
3. Select the appropriate type and size of the remover compatible with the clip to be opened. If using an endoscopic detachable remover, choose an insert and handle corresponding to the clip size. Insert it into the handle shaft and screw it in clockwise until resistance is felt.
4. Grip the open surgery remover by the handles just like standard instrument of this type and position the jaws near the clip to be opened. For endoscopic removers, compress the handles while inserting the remover jaws and shaft through the cannula. Maintain compression until the jaws have fully cleared the cannula. This step is essential, as the inner diameter of most cannulas is smaller than the external width of the opened remover jaws. Compression on the remover handles may also be required when withdrawing the instrument from the cannula
5. Approach the clip from the hinge side, not the locking mechanism side.
6. Position the remover over the clip on the tissue and rotate it so that the jaws are aligned directly with the clip's legs
7. Advance the remover until the hinge of the clip is clearly visualized resting at the back of the remover jaws. Ensuring the hinge is properly positioned at the back of the jaws is essential for the successful disengagement of the clip legs.
8. Gently close remover over the clip, ensuring that no tissue is caught between the clip and instrument jaws. Each clip leg should be in contact with its corresponding jaw. Apply appropriate force to fully close the instrument until a slight click is felt, indicating that the clip legs have successfully disengaged.
9. Open the remover handles to release the clip. Visually confirm that the clip has opened sufficiently and that its tooth is clear of any tissue.
10. The remover may be used as a grasper to extract the opened clip. Grasp the clip and withdraw it from surgical site while maintaining a secure grip. For endoscopic procedures, the opened clip must be grasped by the hinge to ensure proper withdrawal through the cannula.

Compatibility:

Click'aV® and Click'aV Plus™ clips size	Compatible Click'aV® endo surgery clip removers	Compatible Click'aV® open surgery clip removers
M	0301-R804MLLE, 0301-R804MLLEB, 0301-R804MLLEI, 0301-R804MLLEIB, 0301-R804MLLEHS, 0301-R804MLLEHSB	0301-R804MMLL
ML	0301-R804MLLE, 0301-R804MLLEB, 0301-R804MLLEI, 0301-R804MLLEIB, 0301-R804MLLEHS, 0301-R804MLLEHSB	
L	0301-R804MLLE, 0301-R804MLLEB, 0301-R804MLLEI, 0301-R804MLLEIB, 0301-R804MLLEHS, 0301-R804MLLEHSB **0301-R804LXLE, 0301-R804LXLEB, 0301-R804LXLEI, 0301-R804LXLEIB, 0301-R804LXLEHS, 0301-R804LXLEHSB – mostly recommended**	
XL	0301-R804LXLE, 0301-R804LXLEB, 0301-R804LXLEI, 0301-R804LXLEIB, 0301-R804LXLEHS, 0301-R804LXLEHSB	0301-R804XL

All removers are also compatible with polymer clips from other manufacturers that have the same type and size of locking mechanism, provided clip size matches the remover size. For optimal performance, it is highly recommended to use Grena removers specifically designed for Click'aV® and Click'aV Plus™ ligating clips.

Warnings and precautions measures:

1. Carefully inspect instrument for any signs of damage after and before each use. Do not use damaged removers, as this may result in inability to open the clip or tissue injury. When closed, jaws should be directly aligned and not offset. Always check the alignment of the remover jaws before use. Misalignment of the jaws may cause clip breaking during closure, leaving broken pieces of the clip in the body cavity and potentially leading to patient injury.
2. Any surgical and minimally invasive procedures should be performed only by persons having adequate training and familiarity with the techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure.
3. Surgical instruments may vary from manufacturer to manufacturer. When surgical instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure. Failure to do so can result in an extended procedure time, inability to perform surgery, or necessity to convert to an open surgery.
4. Click'aV® removers are compatible with Click'aV® and Click'aV Plus™ clips only and are not compatible with LigaV® or Vclip® clips. Always ensure that correct Grena's remover type was selected prior to initiation of the procedure. Failure to do so can result in inability to perform surgery.
5. Do not use the remover as a dissecting or general grasping instrument, except for the extraction of an opened clip, as it is not designed for these procedures and will be ineffective.
6. Do not squeeze the remover over other surgical instruments as it can damage both remover and other instrument.
7. After removing a clip, it is essential to inspect the ligation site to ensure that no clinically significant tissue injury has occurred. If any injury is detected, an appropriate repair technique should be applied.
8. Always inspect the site for hemostasis before procedure is finished. Bleeding must be controlled by appropriate surgical methods.
9. An opened clip must be discarded and must not be reapplied, even if no visible damage is present.
10. If it is necessary to dispose of the product, it must be done in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
11. Exercise caution when there is a potential for exposure to blood or bodily fluids. Adhere to hospital protocols regarding the use of protective wear and equipment.

Ligating Clips Removers warranty

All Grena's Click'aV® Ligating Clips Removers are covered by one year warranty. Grena will repair free of charge any remover, provided it is used for normal surgical purposes with Grena ligating clips for which it was designed, and has not been repaired by unauthorized personnel. If a remover malfunction occurs which is caused by the use of a non Grena clips, the warranty does not apply.

Reprocessing instructions:

The following sections outline the steps required for the reprocessing of Grena Click'aV® and Click'aV Plus™ Ligating Clips Removers.
This includes pre-treatment at the point of use, manual cleaning and disinfection, machine processing as well as steam sterilization in the fractionated vacuum process.

WARNINGS	**ATTENTION:** Flushing channel is long and narrow. It requires special attention during cleaning to remove all the soil from it. Do not use solidifying detergents. **ATTENTION:** The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual. Furthermore, the hospital hygiene regulations must be observed as well as the recommendation of the relevant professional associations. **ATTENTION:** Used devices must be thoroughly processed according to these instructions prior to use. **ATTENTION:** **Universal Precautions should be observed** by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges. **ATTENTION:** During all reprocessing steps **Personal Protective Equipment (PPE) should be worn** when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gowns, masks, goggles or face shields, gloves and shoe covers. Observe the usual regulations for handling contaminated objects and the following precautionary measures: - Use protective gloves when touching. - Isolate the contaminated material using suitable packaging and labeling. **ATTENTION:** **Do not place heavy instruments on top of delicate devices. Metal brushes or scouring pads must not be used** during manual cleaning procedures. These materials will damage the surface and finish of the instruments. Soft bristled, nylon brushes and pipe cleaners should be used. **ATTENTION:** **Do not allow contaminated devices to dry prior to reprocessing.** All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices. Used devices **must be** transported to the central supply in closed or covered containers to prevent unnecessary contamination risk. **ATTENTION:** After the treatment is over, all parts that come into contact with the patient must be cleaned and disinfected. **ATTENTION:** Only use cleaning agents / disinfectants approved for the reprocessing of medical devices. Observe the manufacturer's instructions for the cleaning / disinfecting agents. If unsuitable cleaning or disinfecting solutions are used, or if unsuitable cleaning or disinfection procedures are applied, this can have negative consequences for the devices: - Damage or corrosion - Discoloration of the product - Corrosion of metal parts - Reduced service life - Expiration of the guarantee **ATTENTION:** Grena Ltd. recommends using only EN ISO 15883-1 and -2 compliant washer-disinfectors for automated cleaning / disinfection. It is recommended that mechanical reprocessing should, if possible, be given preference over manual reprocessing methods.
Limitations on reprocessing	Instruments are delivered non-sterile and must be cleaned and sterilized before each use. For endoscopic devices **the initial cleaning** should be performed using an ultrasonic cleaner to remove the preservative from the device. The recommended parameters are 3 min, 40°C, 35 kHz. Extensive use or repeated reprocessing can have significant impact on the instruments. Product lifetime is determined by prints of wear and damages due to usage. Do not use damaged or corroded instruments. **Use of hard water should be avoided**. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate limescale deposits on the devices. One or more of the following processes may be used to purify water; ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.
INSTRUCTIONS	
Point of use:	A pre-cleaning of the devices should be carried out immediately after treatment, taking personal protection into account. The aim is to prevent organic material and chemical residues from drying on in the lumen or on the outer parts of the instruments and to prevent contamination of the surrounding area. 1. Remove excess soil, body fluids and tissue with disposable cloth/paper wipe. 2. Submerge instrument in the water (temperature below 40ºC) immediately after use. 3. Do not use solidifying detergents or water with temperature exceeding 40ºC because they can lead to sticking of the soil and influence further steps of reprocessing.
Containment and transportation:	It is recommended that devices are reprocessed as soon as it is reasonably practical following use. To avoid any damage devices should be safely stored and transported to the place of further reprocessing in the closed container (e.g. tub with lid) to avoid contamination of the surrounding area Maximum time between pre-cleaning the instrument and further steps of cleaning must not exceed 1 hour. Transport instruments to the processing room and pace it in the basin with cleaning solution.
Preparation for cleaning:	Disassembly is required for detachable endoscopic removerss only. They can be recognized by HS as a part of reference number printed on the handle. To disassemble, grasp distal part of the shaft with two fingers and rotate rotating knob counterclockwise to unscrew insert. Remove insert from the shaft. To assemble follow reverse sequence. Do not attempt to hold remover by the jaws for disassembly / assembly procedure, but rather directly behind them on the hinge, otherwise proper jaws alignment may be affected. Proper alignment of the jaws is essential for the clip applicators to function properly. All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of the recommended temperatures is important for optimal performance of cleaning agents. **NOTE: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).**
Cleaning/ Disinfection: Manual	Equipment: pH neutral or alkaline proteolytic enzymatic detergent, Steris 1B33B3 soft bristle brush or similar, cleaning pressure pistol or high volume syringe, ultrasonic water bath. **Validated pre-cleaning procedure:** 1. Soak the device in a washing/disinfecting solution for 5 minutes. (4% Sekusept Activ, 30-35°C was used for validation) 2. Using soft bristle brush and keeping the device inside the soaking solution apply washing/disinfecting solution to all surfaces ensuring that jaws are cleaned in both opened and closed positions. Make sure that all visible contamination has been removed. Flush the inside of the shaft with the solution. 3. Rinse instrument with tap water (<40 °C), while actuating device until there is no sign of blood or soil on the device or in the rinse stream, but at least for 3 minutes. 4. Use a high-volume syringe (or cleaning pressure pistol) to aggressively flush the inside of the shaft with tap water (<40 °C) through the flushing port at the proximal end of the shaft until no visible soil leaves the shaft, but at least for 1 minute. **Validated manual cleaning procedure:** 1. Place device in ultrasonic water bath filled with a washing/disinfecting solution and sonicate for 3 min, 40±1°C, 35 kHz (2% Sekusept Activ was used for validation). 2. Remove instrument from ultrasonic water bath. 3. Using soft bristle brush scrub the instrument under running tap water below 40°C for minimum of 1 minute or until all visible residue is removed. 4. Use cleaning pressure pistol or high volume syringe to aggressively flush inside of the shaft with tap water (below 40°C) until no visible soil leaves the shaft, but for minimum of 1 minute. 5. Rinse device under clean running water, including flushing channel, while actuating device. UF, RO or DI water should be used for this step. 6. Remove excess moisture from the device with a clean, absorbent and non-shedding wipe. 7. Dry the device with compressed medical air including flushing channel. **NOTE:** One should remember that any cleaning and disinfection process should be validated. Check visually for cleanliness to ensure that all debris have been removed. If not visually clean, repeat the reprocessing steps until the device is visually clean. **NOTE:** It is recommended that used cleaning brushes must be cleaned after each use (if possible in an ultrasonic water bath) and then disinfected. After cleaning, disinfection and sterilization they must be stored dry and protected from contamination.
Cleaning/ Disinfection: Automated	Equipment - Washer / disinfector, pH neutral or alkaline proteolytic enzymatic detergent, Steris 1B33B3 soft bristle brush or similar, cleaning pressure pistol or high volume syringe, ultrasonic water bath. Endoscopic instruments have channels, crevices and fine joints. Dried soiling is very difficult to remove from such areas by automated cleaning. In order to achieve effective cleaning, it is necessary to remove massive impurities before automated reprocessing, therefore Grena Ltd. recommends manual pre-cleaning. In particular, make sure to pre-clean the shaft before cleaning in the washer /disinfector. **Validated pre-cleaning procedure:** 1. Soak the device in a washing/disinfecting solution for 5 minutes. (4% Sekusept Activ, 30-35°C was used for validation) 2. Using soft bristle brush and keeping the device inside the soaking solution apply washing/disinfecting solution to all surfaces ensuring that jaws are cleaned in both opened and closed positions. Make sure that all visible contamination has been removed. Flush the inside of the shaft with the solution. 3. Rinse instrument with tap water (<40 °C), while actuating device until there is no sign of blood or soil on the device or in the rinse stream, but at least for 3 minutes. 4. Use a high-volume syringe (or cleaning pressure pistol) to aggressively flush the inside of the shaft with tap water (<40 °C) through the flushing port at the proximal end of the shaft until no visible soil leaves the shaft, but at least for 1 minute. **Validated automatic cleaning procedure:** Grena Ltd. recommends the use of an EN ISO 15883-1 and -2 compliant cleaning / disinfection device in combination with a suitable load carrier. Follow the instructions for use of the manufacturer of the washer / disinfector. Load instruments into the washer / disinfector according to the manufacturer instructions. Connect flushing channels (if equipped) of the instruments to the washer / disinfector so that it is rinsed through. The following process parameters are suitable for reprocessing the instruments:

	1. Cold pre-wash, water <40°C, 1 min. 2. Washing, hot water, 10 minutes, detergent concentration and temperature as per manufacturer's recommendation (process validated with 0,7% Thermosept® RKF, 55 °C). 3. Neutralization, neutralizing agent concentration and time as per manufacturer's recommendation (process validated with 0,15% Thermosept® NKZ, >30°C, 2 min). 4. Rinse, cold water below 40°C, 1 min. 5. Thermal disinfection >2,5 min, > 93°C with UF, RO or DI water, concentration of additive as per manufacturer's recommendation (process validated without any additive). 6. Drying 110°C, 6 min. **NOTE:** One should remember that any cleaning and disinfection process should be validated. **NOTE:** The validated parameters correspond to a process with an A0 value of > 3000s. Grena Ltd. Recommends to use only processes with an A0 value of > 3000s. **NOTE:** Never leave the instruments wet after reprocessing. This can lead to corrosion and germ growth. If the devices are not completely dry after the machine processing has been completed, dry the removers manually (see drying section) and store accordingly.
Drying:	Dry any remaining moisture with a clean, absorbent, non-shedding cloth. Use compressed medical air or a high volume syringe to blow flushing channel and jaws hinge until no more moisture escapes.
Maintenance:	Hinges and other moving parts should be lubricated with a water soluble product intended for surgical instruments that must be sterilized. Manufacturer's expiration dates should be adhered to for both stock and use-dilution concentrations of the cleaning / disinfecting agents.
Inspection and function testing:	Inspect the device for functionality – in case of any technical impairment instrument must be rejected. Check the action of moving parts (e.g. jaws, hinges, connectors, etc.) to ensure smooth operation throughout the intended range of motion. Check jaws for excessive play. Visually inspect for damage and wear. Pay attention to proper jaws alignment. Check the shaft for distortion. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning / disinfection process. Discard damaged instruments.
Packaging:	Singly: A standard commercially available, medical grade steam sterilization pouches or wrap may be used. Ensure that the pack is large enough to contain the device without stressing the seals. Do not use packaging that is too large to prevent the instruments from sliding around in the packaging. In sets: Instruments may be loaded into general-purpose sterilization trays. Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap. Ensure that jaws are protected. The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs for the safety of the personnel handling instrument sets; instrument cases exceeding 11.4kg/25lbs should be split into separate trays for sterilization. All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact. The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case. Silicone mats may be used to keep devices in place. Devices for validation of sterilization process were packed in pouches compliant with EN ISO 11607-1.
Sterilization:	Equipment: Grena Ltd. recommends the use of a sterilizer in accordance with EN ISO 17665 or EN 285. The sterilization must be carried out in packaging suitable for the sterilization process. The packaging should comply with EN ISO 11607 (e.g. paper / laminate film). Moist heat/steam sterilization is the preferred and recommended method for Grena devices. The hospital is responsible for in-house procedures for the inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital. Sterilizer Manufacturer's Instructions for operations and load configuration should be followed explicitly. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded. Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces. **CAUTION:** Plasma gas sterilization should not be used. **ATTENTION:** Never sterilize uncleaned instruments! The success of a sterilization depends on the previous cleaning status! Minimum validated steam sterilization parameters required to achieve a 10^{-6} sterility assurance level (SAL) are as follows:

Cycle type	Temperature [°C]	Exposure time [min]	Pressure [bar]	Drying time [min]
Fractional prevacuum 10 kPa	134	3	>3	15

	NOTE: One should remember that any sterilization process should be validated prior to use. The validation of the suitability of the above parameters for the fractional vacuum process was carried out by Grena in accordance with the requirements of EN ISO 17665-1. The user is responsible for validating the correct functioning of the sterilizer.
Storage:	Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, insects, vermin, and temperature/humidity extremes.
Additional information:	The instructions provided above have been recommended by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences. Users must then establish an appropriate cleaning protocol for the reusable medical devices used at their sites, using the recommendations of the device manufacturer and cleaner manufacturer. Because of the many variables involved in sterilization / decontamination, each Medical Facility should calibrate and verify the sterilization / decontamination process (e.g., temperatures, times) used with their equipment. It is the responsibility of the Medical Facility to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result.
A notice to the user and/or patient:	If any serious incident has occurred in relation to the device it should be reported to the manufacturer and the competent authority of the Member State.
Manufacturer contact:	See the headline of instructions for use.


Caution, consult accompanying documents


Keep dry

Consult electronic instructions for use


Manufacturer

Authorized representative in the European Community

Catalogue number

Batch code


Quantity in package

Medical Device

The hard copies of instructions for use delivered with Grena products are always in english language.

Please scan the below QR code with the appropriate application.
You can enter the website directly by typing in www.grena.co.uk/IFU in your browser.

Make sure that paper version of IFU in your possession is in the latest revision prior to use of the device.
Always use the IFU in the latest revision.