LigaV® Ligating Clips Appliers
Instructions for use

Ref. no.:
For open surgery:
0301-02S15, 0301-02S185, 0301-02S19, 0301-02S20, 0301-02S28, 0301-02M15, 0301-02M185, 0301-02M19, 0301-02M20, 0301-02M28, 0301-02ML20, 0301-02ML275A45, 0301-02ML28, 0301-02L20, 0301-02L28

For endosurgery:
0301-02ME, 0301-02MLE, 0301-02LE, 0301-02MEB, 0301-02MLEB, 0301-02LEB, 0301-02MLEA25

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Important:
This instruction for use cannot be used as a manual for surgical techniques used during the work with Ligating Clips. To learn adequate knowledge about surgical technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of surgeon experienced in techniques of microinvasive surgery. Before use we recommend reading precisely all information included in this manual. Not being obedient to this information may lead to serious surgical consequences such as patient injury, contamination, infection, cross-infection inability of ligation or death.

Indications:
Grena LigaV® Ligating Clips Appliers are indicated for use as delivery devices for Grena LigaV® titanium ligating clips during laparoscopic and thoracoscopic procedures as well as in open surgery. Conformity of the size of the occluded tissue and the clips is required.
Patient target group - adult and young patients, males and females.
Intended users: product is intended to be used exclusively by qualified medical staff.

Contraindications:
DO NOT use for tubal ligation as contraceptive method due to lack of sufficient data on efficacy and safety in these applications.
DO NOT use on structures where use of metal clips is not appropriate.
DO NOT use in case of just suspicion of allergy to titanium.

Description of the device:
LigaV® Ligating Clips Appliers are reusable surgical instruments. They are available as open surgery and endooscopic surgery versions. Each size of a clip needs to be applied with corresponding and compatible clip applier. Endo appliers are equipped with flushing channel which helps to wash out debris from the shaft. Sizes M, ML and L of endoscopic appliers can pass 10 mm trocar cannula. The applier's shaft can be rotated 360° relative to the handle.

Instructions for use:
1. Choose the appropriate size of the clip and the compatible applier.
2. Check the compatibility of all devices prior to use.
3. Following aseptic rules remove clips cartridge from the single packing. To prevent any damage of the device place it on a sterile surface.
4. Grip the open surgery applier around the bolt (alike pencil is griped). For endo appliers grip applier around the shaft. Holding the applier by the handle while loading the clip is a mistake that can cause the jaws to close to some extent, causing the clip to fall out of the applier.
5. Align applier jaws vertically and laterally over a clip in the cartridge and advance product jaws into the slot of the clip cartridge making sure they are perpendicular to the surface of the cartridge. Advance the jaws till they are stopped. Do not use force to push the applier. The applier should move inside and outside of the slot easily.
6. Remove the applier from the cartridge. The clip should fit securely in the jaws.
7. Verify that the clip is fully inserted into the applier jaws and the clip legs do not protrude beyond the end of the jaws. If the clip does not fit properly to the jaws or if the legs protrude beyond the jaws, this indicates an incorrect loading procedure or damage to the applier what may result in the inability to securely close the clip, scissoring or falling out of the applier.
8. Handle the applier carefully. The jaws should not close prematurely. Even a slight closing of the jaws prematurely will cause the clip to fall out of the applier.
9. Place the clip around the structure intended for ligation or marking. Use appropriate force to close the clip completely making sure it is placed properly. Closure should be made with a smooth, firm continuous motion until clip is fully closed. Releasing the pressure on the handles will cause the applier jaws to spring open. Releasing the pressure on the applier's handle before the clip is fully closed will cause the clip to remain partially opened, which may result in bleeding or slipping the clip off the vessel.
10. Remove the applier from the surgical site.

Compatibility:

LigaV® clip size	Compatible LigaV® clip appliers	Ligated structure size in mm
S	0301-02S15, 0301-02S185, 0301-02S19, 0301-02S20, 0301-02S28	0,3 to 1,5
M	0301-02M15, 0301-02M185, 0301-02M19, 0301-02M20, 0301-02M28, 0301-02ME, 0301-02MEB	1,0 to 2,5
ML	0301-02ML20, 0301-02ML28, 0301-02ML275A45, 0301-02MLE, 0301-02MLEB, 0301-02MLEA25	2,5 to 4,0
L	0301-02L20, 0301-02L28, 0301-02LE, 0301-02LEB	3,5 to 7,5

Warnings and precautions measures:
1. Carefully inspect instrument for any signs of damage after and before each use. Do not use damaged appliers. Using of damaged applier may result in dislocation of a clip. Always check the alignment of the applier jaws before use to prevent clip deformation and scissoring which could lead to vessel injury with vessel cutting included.
2. Any surgical and minimally invasive procedures should be performed only by persons having adequate training and familiarity with those 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 this can result in inability to perform surgery.
4. LigaV® appliers are compatible with LigaV® clips only and are not compatible with Vclip® or Click'aV® clips. Always ensure that correct Grena's applier type was chosen prior to initiation of the procedure. Failure to do this can result in inability to perform surgery.
5. Surgeon is fully responsible to choose proper size of the clip and corresponding applier and must determine how many clips is necessary to achieve satisfactory hemostasis and closure security.
6. Do not use the clip loaded into the jaws or applier alone as a dissecting instrument as clip may drop off and applier's tips may cause tissue injury.
7. If endoscopic procedure is performed always confirm that the clip remains in the applier after insertion of the applier and clip trough a cannula.
8. Do not attempt to close the jaws on any tissue structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or anatomic structure may result in patient injury.
9. Do not squeeze the applier over other surgical instruments, staples, clips, gallstones or other hard structures as it may led to bleeding and/or cause the clip to be ineffective.
10. After each clip is placed it is required to close the applier fully. A not full squeeze may result in dislocation of the clip and therefore improper ligation.
11. Make sure every clip was placed and closed well on ligated structure. This should be repeated after the use of other surgical devices in the immediate area of the application so as not to miss accidental displacement of the clip.
12. When working with the LigaV® applier, carefully follow the instructions for use of LigaV® ligating clips
13. 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.

Ligating Clips Appliers warranty
All Grena's LigaV® Ligating Clips Appliers are covered by one year warranty. Grena will repair free of charge any applier, 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 an applier malfunction occurs which is caused by the use of a non-Grena clips, the warranty does not apply.

Reprocessing instructions:
The following sections describe the preparation after use for Grena LigaV® Ligating Clips Appliers.
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 needs special attention during cleaning to remove all the soil from it. Do not use solidifying detergents as they can clog flushing channel lumen. **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. To avoid injury 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 dosed 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 first wash** 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 place it in the basin with cleaning solution.
Preparation for cleaning:	The device should NOT be disassembled for cleaning or sterilization. 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, soft brush, cleaning pressure pistol or high volume syringe, ultrasonic washer. 1. Soak instrument in washing/disinfecting solution and follow disinfectant manufacturer instructions. (4% Secusept Plus, 15 min, 30-35 °C was used for validation). 2. Using brush and keeping 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 inside of the shaft with the solution, if instrument is equipped with flushing channel. 3. Rinse with tap water (below 40°C), while actuating device until there is no sign of blood or soil on the device or in the rinse stream, but for 3 minutes at least. 4. If instrument is equipped with a flushing channel, use cleaning pressure pistol or high volume syringe to aggressively flush inside of the shaft with tap water (below 40°C). This should be done through flushing port at proximal side of the shaft until no visible soil leaves the shaft. 5. If the instrument is equipped with a flushing channel, dry it with compressed medical air. 6. Place device in ultrasonic washer filled with a washing / disinfecting solution for 3 min, 40°C, 35 kHz. The process was validated with 2% Sekusept Aktiv. 7. Rinse under clean running water, including flushing channel (if equipped), while actuating device. UF, RO or DI water should be used for this step. 8. Remove excess moisture from the device with a clean, absorbent and non-shedding wipe. Dry the device with compressed medical air including flushing channel (if equipped). **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 cleaner) and then disinfected. After cleaning and disinfection, they must be stored dry and protected from contamination.
Cleaning/ Disinfection: Automated	Equipment - Washer / disinfector, pH neutral or alkaline proteolytic enzymatic detergent, soft brush, ultrasonic washer. 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 precleaning procedure:** 1. Remove excess soil using soft brush. 2. Immerse instrument in a washing/disinfecting solution 15 min, 30ºC - 35ºC (4% Secusept Plus was used for validation). Take care to fill flushing channel with the solution. 3. Place device in ultrasonic cleaner filled with a washing/disinfecting solution 3 min, 40ºC, 35 kHz (4% Sekusept Plus was used for validation). **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, 40 °C, 2 min). 4. Rinse, cold water below 40 °C, 2 min. 5. Thermal disinfection 90°C, 8 min, concentration of additive as per manufacturer's recommendation (process validated without any additive). 6. Drying 110°C, 6min. **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 appliers manually (see drying point) 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.
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 11.4 kg/25 lbs for the safety of the personnel handling instrument sets; instrument cases exceeding 11.4 kg/25 lbs 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 in which the user and/or patient is established.
Manufacturer contact:	See the headline of instructions for use.


Caution


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.
If you require a hard copy of IFU in other language, you can contact Grena Ltd.
*at **ifu@grena.co.uk** or **+ 44 115 9704 800.***

Please scan the below QR code with the appropriate application.
It will connect you with Grena Ltd. website where you can choose eIFU in your preferable language.

*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.