Reusable (Limited Use) Endoscopic Instruments
Instructions for use

Ref. no.: 0207-LS01XF, 0207-LS02XF, 0207-LS03XF, 0207-LS03XFB, 0207-LD01XF, 0207-LD01RF, 0207-LD01RFB, 0207-LG01RF, 0207-LG02RF, 0207-LG03RF, 0207-LG04RF, 0207-LG05RF, 0207-LG04RFB, 0207-LG05RFB

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Attention:
Read and understand all information contained in these instructions. Failure to do so properly may lead to serious surgical consequences. This instruction cannot be used as a manual for surgical techniques used in minimal invasive surgery. 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 endoscopic surgery.
Instrument is delivered sterile for the first use and is intended for limited number of resterilization and reuse cycles up to maximum 9 times what gives maximum 10 uses possible in total.

Indications:
Reusable endoscopic instruments are indicated for cutting, grasping, dissecting and coagulation of tissue in laparoscopic and thoracoscopic surgical procedures.
Patient target group - adult and young patients, males and females.
Intended users: product is intended to be used exclusively by qualified medical staff.

Contraindications:
The use of reusable endoscopic instruments is contraindicated whenever endoscopic surgical techniques are contraindicated for any reason.

Prior to the first use:
Carefully inspect the shipping carton, its contents and individual pouch for any sign of damage. If damage is visible, do not use the instrument.

Illustration of the instrument (pic. I):

A.Jaws	C. Rotating knob	E. Back handle	G. Ratchet trigger
B.Shaft	D. HF connector	F. Front handle	H. Flushing port

Instructions for use:
1. Open the package by using standard aseptic technique.
2. Ensure that the product functions and is intact.
3. Remove protecting caps from jaws and electrocautery connector as well as paper protector.
4. If ratcheted instrument is used, open jaws and push trigger down in order to engage the ratchet mechanism (pic. IV).
5. Close the handles to the desired grasping position. The instrument is locked on the tissue (pic. IV).
6. To release jaws, push the trigger up (pic. V).
7. In order to use ratcheted instrument as a non-ratcheted one leave trigger in the up position. The instrument will open and close freely (pic. III).
8. Non ratcheted instrument opens and closes freely without any action.
9. Use rotating knob to turn instrument jaws in any direction (pic. II)

Electrocautery:
First, connect the electrosurgical cord (not furnished with the instrument) to the instrument by placing 4mm female end of the cord on the 4mm male adapter pin. Plug the other end of the cord into the monopolar receptacle of the HF generator. If instrument and/or return electrode is not properly connected to the generator electrosurgery will not be possible to perform. Recommended maximal output power of the generator to be used with the device is 350W for cut and 120W for coagulation with blend cut power between above values. Rated accessory voltage of the device – 1 500V

Electrocautery precautions:
1. A complete understanding of the principle of monopolar electrocautery surgical procedures is necessary to avoid accidental shocks, burns, or potential gas embolism to the patient.
2. Be sure that the entire area of the return electrode has been properly attached to the patient's body and is as close to the operating field as possible. Incomplete body-electrode contact may lead to burns and/or inability to perform elctrosurgery.
3. The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.) as it may lead to burn injury of the patient. The use of antistatic sheeting is recommended for this purpose.
4. To protect patient from burns skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
5. The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away. Combustible gases can ignite during electrosurgery, seriously injuring the patient and the surgeon.
6. Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF surgical instrument is used. Residual flammable agents can ignite during HF surgery, leading to severe thermal injuries of the patient and the surgeon.
7. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal of the HF surgical instrument leading to thermal injuries of the patient and the surgeon.
8. For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.
9. If any physiological monitoring equipment is used simultaneously with HF generator on the same patient, any monitoring electrodes (including monitoring device) should be placed as far as possible from HF generator. Needle monitoring electrodes are not recommended as they may cause patient burns. The use of monitoring systems incorporating high frequency current limiting devices is recommended.
10. The cables to the electrosurgical instruments (including HF generator) should be positioned in such a way that contact with the patient or other leads is avoided to prevent short-circuit or patient burns in case of insulation damage.
11. Temporarily unused electrosurgical instruments (including HF generator) should be stored in a location that is isolated from the patient.
12. For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area, the use of bipolar or pure heat techniques may be desirable in order to avoid unwanted coagulation.
13. Do not activate the generator until instruments' jaws are in contact with tissue or are in a position to deliver high frequency energy to the tissue. Premature activation can lead to coagulation at unintended sites.
14. Keep the output power as low as possible to achieve the desired effect. Surgeon is fully responsible for the correct coagulation time and power. Prolonged coagulation time and/or excessive power may lead to tissue charring and widening of the area of lateral lesions.
15. Avoid HF output settings of the generator where maximum output voltage may exceed rated accessory voltage. Exceeding the rated voltage may damage the insulation and result in thermal injury of the patient and the operator.
16. Apparent low output or failure of the HF surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.
17. When using electrosurgery, verify that jaws of the instrument are not in contact with a conductive irrigation fluid. HF current flowing through conductive fluid may lead to burns in multiple areas inside the patient body.
18. Electrosurgical generators used with these devices may cause unintended destruction of tissue and are dangerous if operated improperly. Read carefully instruction for use of the generator prior to procedure.
19. Sufficient care and distance must be maintained during use to prevent arcing to other instruments leading to unintended coagulation of the sites remaining in direct contact with these instruments.

Additional warnings and precautions:
1. Minimally invasive surgery should be performed only by physicians who are thoroughly trained in minimally invasive techniques.
2. To avoid injury to internal organs, a pneumoperitoneum must be maintained during the use of reusable endoscopic instrumentation.
3. Verify that the devices are compatible with other products that will be used in surgery prior to the procedure. Incompatibility may lead to an extended procedure time, inability to perform surgery or necessity to covert to an open surgery.
4. Use immediately after opening original single package. Keeping the instruments post package opening leads to their contamination and creates a risk of an infection to the patient.
5. Modification of the device may lead to serious consequences with death of patient included.
6. If the jaws are closed on a thin tissue, pressure exerted by the tissue may not be sufficient to open the jaws after the ratchet trigger is released. If it occurs slightly squeeze the thumb handle which will release the trigger and jaws would open.
7. Take care to discard the product and packing after the 10th use in accordance with hospital waste disposal practices and local regulations including, without limitation, those pertaining to human health and safety and the environment.

Warranty:
Warranty is limited to the first use only. Instrument should be checked carefully prior to the first use and in case of any technical failure send back to the manufacturer. Claims after the first use will not be considered.

Reprocessing instructions:
The following sections describe the preparation after use for the Grena Reusable (Limited Use) Endoscopic Instruments.
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:** Flashing channel is long and narrow. It needs 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 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:	Instrument is delivered sterile, ready for use and guaranteed to be fully operational during the first use. Extensive use or repeated reprocessing can have effect on these instruments. Manufacturer's warranty does not cover any failures or actions after the first use. Product lifetime is determined by prints of wear and damages due to usage. Anyway, even when product is visually in good condition do not reprocess it more than 9 times what allows using it maximum 10 times. 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 proteolytic enzymatic detergent, soft brush, cleaning pressure pistol or high volume syringe. 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. Dry the device with compressed medical air, including flushing channel. 6. Rinse under clean running water, including flushing channel, while actuating device. UF, RO or DI water should be used for this step. 7. Remove excess moisture from the device with a clean, absorbent and non-shedding wipe. 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 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 proteolitic enzymatic detergent. 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. 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 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, 8 minutes, detergent concentration and temperature as per manufacturer's recommendation (process validated with 0,85% Thermosept RKF, 55°C). 3. Neutralization, neutralizing agent concentration and time as per manufacturer's recommendation (process validated with 0,20% Thermosept NKZ, 36°C, 1 min). 4. Rinse, cold water below 40°C, 1 min. 5. Thermal disinfection recommends to use only processes with an A0 value of > 3000 s, 93°C, 3 min (the validated parameters correspond to process with an A0 value of 3050 s, 93°C, 3 min). 6. Drying 110°C, 5 min. **NOTE:** One should remember that any cleaning and disinfection process should be validated. **ATTENTION:** 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 instruments 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 inside of the shaft 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. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. 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, knobs 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 cutting edges of the scissors to be free of nicks. 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 form 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	3,11	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.


Keep dry

Consult electronic instructions for use


Manufacturer


Date of manufacture


Caution

Sterilized using ethylene oxide


Do not use if package is damaged and consult instructions for use


Use-by date

Authorized Representative in the European Community

Catalogue number

Batch code


Quantity in package

Medical device


Single sterile barrier system

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.