Disposable Endoscopic Instruments
Instructions for use

Ref. no.: 0208-DS01XX, 0208-DS02XX, 0208-DS03XX, 0208-DD01XX, 0208-DD01RX, 0208-DG01RX, 0208-DG02RX, 0208-DG03RX, 0208-DG04RX, 0208-DG05RX, 0208-DG02RXB, 0208-DG04RXB, 0208-DG05RXB

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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 and is intended for single use.

Indications:

Disposable endoscopic instruments are indicated for cutting, grasping, dissecting and coagulation of tissue in laparoscopic and thoracoscopic surgical procedures. They are intended for single patient and procedure use.

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 disposable endoscopic instruments is contraindicated whenever endoscopic surgical techniques are contraindicated for any reason.

Prior to the 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
B. Shaft
C. Rotating knob
D. HF connector
E. Thumb handle
F. Front handle
G. Ratchet trigger

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 HF connector as well as paper protectors.
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 the trigger in the up position. The instrument will open and close freely (pic. III).
8. Non ratcheted instrument opens and closes freely without any additional action.
9. Use rotating knob to turn instrument jaws in any direction (pic. II)

Electrosurgery:

First, connect the electrosurgical cord (not furnished with the instrument) to the instrument by placing 4mm female end of the cord on the 4 mm male HF connector. 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

Electrosurgery precautions:

1. A complete understanding of the principle of monopolar electrosurgical 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 electrosurgery.
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 disposable 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. Dispose of all opened instruments whether used or unused to prevent accidental use of a contaminated device.
5. Use immediately after opening. Keeping the instruments post package opening leads to their contamination and creates a risk of an infection to the patient.
6. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
7. 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.
8. Take care to discard the product and packing after use, as well as unused but opened devices in accordance with hospital waste disposal practices and local regulations including, without limitation, those pertaining to human health and safety and the environment.
9. 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.

Keep dry	Consult electronic instructions for use	Manufacturer	Date of manufacture
Caution	Do not resterilize	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
Sterilized using ethylene oxide	Do not re-use	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.