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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Important:
The instructions provided herein are not intended to serve as a comprehensive manual for surgical techniques related to the use of the Disposable Endoscopic Instruments. 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.
Instrument is delivered sterile and is intended for single use. The device can be introduced through 5mm trocar cannula.

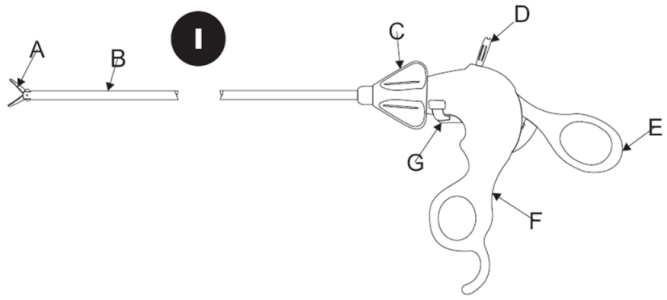
Indications:
Disposable Endoscopic Instruments are indicated for cutting, grasping, dissecting and coagulation of tissue in laparoscopic and thoracoscopic surgical procedures. They are intended for single patient and procedure use.
Patient target group - adult and young patients, males and females.
Intended users: product is intended to be used exclusively by qualified medical professionals.

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

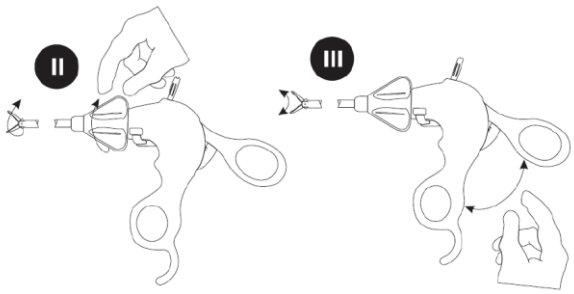
Prior to use:
Carefully inspect the shipping carton, its contents and individual pouch for any sign of damage. If damage is visible, do not use the instrument.

Illustration of the instrument (pic. I):

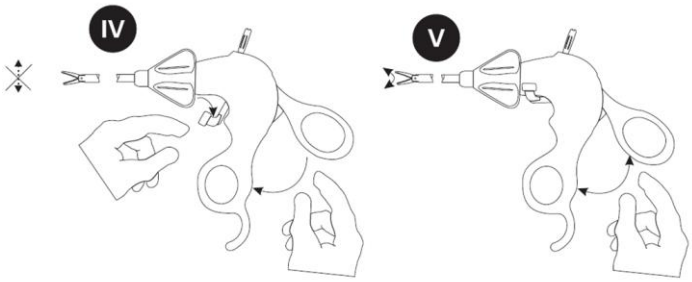
A. Jaws
B. Shaft
C. Rotation knob
D. HF connector
E. Back handle
F. Front handle
G. Ratchet trigger



Instructions for use:
1. Open the package using standard aseptic technique.
2. Remove the protecting caps from jaws and HF connector as well as any paper protectors.
3. Verify that the instrument is intact and functions correctly.
4. Rotate rotation knob 360° in both directions to confirm smooth, unrestricted movement (pic. II).
5. Close and open the handles to ensure proper jaws movement (pic. III).



6. For ratcheted instruments:
   • Open the jaws and press the trigger downward to engage the ratchet mechanism (pic. IV).
   • Confirm that, once engaged, the mechanism allows the jaws to close but prevents reopening (pic. IV).
   • To release the jaws, press the trigger upward (pic. V).
7. If coagulation is required, connect a monopolar HF cable with the standard 4 mm connector.
8. Insert the instrument into the cannula with the jaws in the closed position.
9. Perform grasping, dissection, cutting, or coagulation as appropriate for the instrument type and surgical requirements. Engage or disengage the ratchet mechanism as needed.
10. Withdraw the instrument out of the cannula with the jaws closed.
11. Non-ratcheted instruments open and close freely without requiring additional action.



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. 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.
2. To avoid injury to internal organs, a pneumoperitoneum must be maintained during the use of disposable endoscopic instruments.
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. Dispose of all opened instruments whether used or unused to prevent accidental use of a contaminated device.
5. Use the device immediately upon opening. Storing the device after the package has been opened may result in contamination, increasing the risk of patient infection.
6. If the jaws of the instrument are not closed when inserting or removing it from the plastic cannula, it may lead to scraping of the material from the inner surface of the cannula and the detached plastic particles may fall into the body cavities.
7. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
8. 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 back handle which will release the trigger and jaws would open.
9. 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.
10. 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.
11. In the case of Disposable Endoscopic Scissors, do not cut hard structures such as clips, staples etc. as this will lead to accelerated blunting of blades.
12. Always inspect the site for hemostasis before procedure is finished.
13. Grena does not promote or recommend any specific surgical practices. Surgical technique, types and sizes of tissues and vessels appropriate for cutting, grasping, dissecting and coagulation with Disposable Endoscopic Instruments are the responsibility of the surgeon.
14. 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.


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 Union

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.