Reusable OMNIFinger™ Articulating Endoscopic Scissors
Instructions for use

Ref. no.: 0207-RS02OMNXF, 0207-RS02OMNXFB, 0207-RS01OMNXF, 0207-RS01OMNXFB

Grena Ltd, 1000 Great West Road, Brentford, Middlesex TW8 9HH, United Kingdom	**Contact information:** Phone/Fax: + 44 115 9704 800	EU REP **MDML INTL LTD.** Unit 7, Argus House Greenmount Office Park, Harold's Cross Road Dublin 6W DUBLIN Ireland D6W PP38	CE 0197	**ENG** IFU-OMNRS-ENG_08

Important:
The instructions provided herein are not intended to serve as a comprehensive manual for surgical techniques related to the use of the Reusable OMNIFinger™ Articulating Endoscopic Scissors. 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:
Reusable OMNIFinger™ Articulating Endoscopic Scissors are indicated for cutting 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 professionals.

Contraindications:
The use of Reusable OMNIFinger™ Articulating Endoscopic Scissors is contraindicated whenever endoscopic surgical techniques are contraindicated for any reason.

Description of the device:
OMNIFinger™ Articulating Endoscopic Scissors are reusable surgical instruments. They are available as endoscopic surgery version only. Reusable OMNIFinger™ Articulating Endoscopic Scissors are non-detachable and thus are equipped with flushing channel and do not need to be disassembled for cleaning. Flushing channel allows to wash out debris from the shaft. Bariatric version is indicated by "B" index in the reference number. There are two types of blades available - curved (RS01) and straight (RS02). Scissors are compatible with 5 mm trocar cannulas.

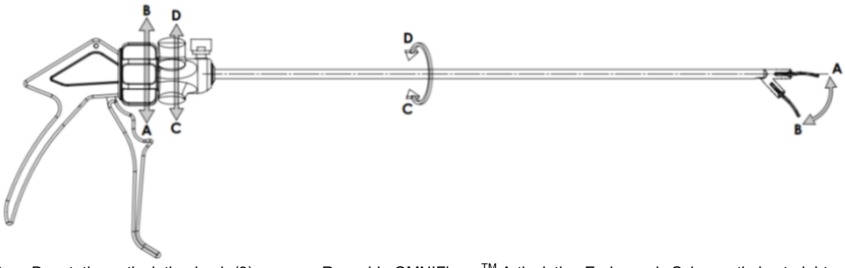
Ilustration of Reusable OMNIFinger™ Articulating Endoscopic Scissors (pic. I)

1. Trigger
2. Handle
3. Articulation knob
4. Rotation knob
5. Flushing port
6. Shaft
7. Blades

I

Instructions for use:
1. Check the Reusable OMNIFinger™ Articulating Endoscopic Scissors for proper action prior to use. To do it, rotate rotation knob (4) 360° in both directions (pic. II, C and D) to ensure that shaft (6) rotates without excessive resistance. Rotate articulation knob clockwise and counterclockwise to ensure Reusable OMNIFinger™ Articulating Endoscopic Scissors tip articulates (pic II, A and B). Do not use the product if any of the above tests fails.

II



2. By rotating articulation knob (3), arrange Reusable OMNIFinger™ Articulating Endoscopic Scissors tip in straight position like on the picture I.
3. Compress the Reusable OMNIFinger™ Articulating Endoscopic Scissors handles and insert the instrument blades (7) and shaft (6) down the cannula.
   Warning: Never attempt to insert scissors through the trocar unless the tip is in the straight position and the jaws are closed, as this may result in permanent damage to the instrument that is not covered by the warranty.
4. Use rotation knob (4) to turn instrument jaws (7) in any direction (pic. II)
5. If necessary, use articulation knob (3) to adjust Reusable OMNIFinger™ Articulating Endoscopic Scissors tip to desired angle for easy access to the structure being cut.
6. Position blades (7) on the structure intended to be cut. Compress the OMNIFinger™ Articulating Endoscopic Scissors handles (1) to cut the tissue.
7. By rotating articulation knob (3) arrange instrument tip in a straight position like on the picture I.
8. Remove the Reusable OMNIFinger™ Articulating Endoscopic Scissors from the surgical site with blades in closed position.
   Warning: Never attempt to withdraw scissors through the trocar unless the tip is in the straight position, as this may result in permanent damage to the instrument that is not covered by the warranty.

Warnings and precautions measures:
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. 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.
3. To avoid injury to internal organs, a pneumoperitoneum must be maintained during the use of reusable endoscopic instruments.
4. **Never attempt to adjust the angle of the device tip by applying direct force to it. Ensure that no bending or straightening forces are applied to the tip during storage, transportation, or reprocessing, as this may cause permanent damage to the device, which is not covered under warranty. The articulation knob is the only safe and acceptable method for adjusting the tip angle.**
5. Do not use damaged instrument. Using of damaged Reusable OMNIFinger™ Articulating Endoscopic Scissors may result in improper tissue cutting. Always check the alignment of the instrument blades before use. If this is not done, patient injury may occur.
6. The scissors should not have direct or indirect (e.g. through flushing fluid) contact with electrosurgical instruments when the electrosurgical instrument is activated. Such contact can lead to unintended patient burns.
7. 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.
8. Do not cut hard structures such as clips, staples etc. as this will lead to accelerated blunting of blades, not covered by the warranty.
9. Always inspect the site for hemostasis before procedure is finished.
10. Grena does not promote or recommend any specific surgical practices. Surgical technique, types and sizes of tissues and vessels appropriate for cutting with OMNIFinger™ Articulating Endoscopic Scissors are the responsibility of the surgeon.
11. 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.
12. 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.

Reusable OMNIFinger™ Articulating Endoscopic Scissors warranty

Reusable OMNIFinger™ Articulating Endoscopic Scissors are covered by one year warranty. Grena will repair free of charge any Reusable OMNIFinger™ Articulating Endoscopic Scissors, provided it is used for normal surgical purposes and has not been repaired by unauthorized personnel. The warranty does not cover the gradual loss of sharpness of the cutting edges resulting from normal use.

Reprocessing instructions:

The following sections outline the steps required for the reprocessing of Grena's Reusable OMNIFinger™ Articulating Endoscopic Scissors.
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 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 to prevent cross-contamination. 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. **The initial cleaning** should be performed using an ultrasonic cleaner to remove any 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:	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, 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 instruments wet after reprocessing. This can lead to corrosion and microbial growth. If the devices are not completely dry after machine processing has been completed, dry the instrument manually (see drying section) and store as directed.
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, 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 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 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	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 Union

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.