Reusable Trocar
Instructions for use

Ref. no.: 0250-SI05, 0250-SI10, 0250-SI12, 0250-VS05, 0250-VS1012, 0250-VSLC, 0250-ROP05100, 0250-ROP10100, 0250-ROP12100, 0250-ROS05100, 0250-ROS10100, 0250-ROS12100, 0250-ROB05100, 0250-ROB10100, 0250-ROB12100, 0250-RTCVS05100, 0250-RTCVS10100, 0250-RTCVS12100

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Important:
This instruction cannot be used as a manual for surgical techniques used during the work with Trocar. 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 or death.

Indications:
Reusable Trocar is used in gynecologic and abdominal endoscopic procedures for establishment of a port of entry for instrumentation.

Description:
Reusable Trocar Cannula is available in 5, 10 and 12 mm diameter and standard length of 100 mm. Obturator may be equipped with pyramidal, pencil point sharp or pencil point blunt tip. Cannulas and obturators are sold separately. Obturator of a given size is compatible with cannula of the same size regardless of obturator's tip. Silicone valve, instrument seal and luer-lock cap for insufflation port are delivered with the cannula but, as they have limited lifetime, can be also purchased separately. Silicone valve 0250-VS05 is compatible with 5 mm cannula only while 0250-VS1012 is compatible with 10 and 12 mm cannulas. Instrument seals 0250-SI05, 0250-SI10, 0250-SI12 are dedicated to 5, 10 and 12 mm cannulas respectively.

Contraindications:
1. Do not use in the area of local inflammation.
2. Do not use if endoscopic techniques are contraindicated.

Instructions for use:
1. Take cannula of required size and compatible obturator. Check if silicone valve, instrument seal and luer-lock cap for insufflation port are in place.
2. Create pneumoperitoneum in the abdomen prior to insertion of the Trocar.
3. Prepare the abdominal cavity for Trocar insertion by making an adequate incision to accommodate cannula circumference. One of the ways to ensure that an adequate incision is made is to press the unarmed Trocar cannula against the body wall, making oval impression, and then incise the major axis of the impression.
   Warning: when inserting a sharp edged obturator, take care not to damage cannula seal with obturator blade.
4. Insert the obturator into the Trocar cannula and close insufflation port with an integral cap.
5. Position the Trocar at the appropriate angle to the abdomen wall.
6. Squeeze down on the top of the obturator placing it close to cannula top.
7. While maintaining compression of both parts of the Trocar, introduce the Trocar through the skin incision. Apply continuous downward pressure during entry of the trocar.
8. When the instrument is in the desired position within the abdominal cavity, remove the obturator from the Trocar cannula, leaving cannula in place.
9. Connect an insufflation tube to an insufflation port, if required.
10. To desufflate, disconnect insufflation tube.
11. After surgery is completed, pull the cannula out of the body wall and use appropriate surgical technique to treat the wound.

Additional warnings and precautions:
1. Minimally invasive procedures should be performed only by physicians having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
2. Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive 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 loss of pneumoperitoneum or inability to perform surgery.
3. Direct contact of sharp instrument components with the silicone seals of the trocar should be avoided, as this may damage seals and pneumoperitoneum would be lost.
4. A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding of co-used devices is not compromised.
5. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, thereby impeding the advancement of the device and increasing the risk of injury to internal structures.
6. Adhesions, anatomical anomalies, or other obstructions may obstruct advancement of the device exposing internal structures to injury.
7. The incorrect trocar insertion may result in aortic puncture. Anatomy changes relative to patient's position should be always taken into consideration.
8. After removing the Trocar from the abdominal cavity, always inspect the site for hemostasis. Bleeding can be controlled by electrocautery or surgical sutures.
9. Do not use damaged trocars. Using of damaged trocars may result in instrument jam in the trocar cannula or patient injury.
10. Cannulas and obturators should always be stored separately. If obturator is left inside the cannula for a longer time silicone valve may be deformed and tightness would not be ensured.
11. Always inspect silicone seals and luer-lock cap for insufflation port for signs of wear or damage. In case of any damage replace them with a set of new ones.
12. Product is intended to be used exclusively by qualified medical staff.
13. The product requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.

Warranty
All Grena's Reusable Trocars are covered by one year warranty. Grena will repair free of charge any Trocar, provided it is used for standard surgical purposes for with it was designed, and has not been repaired by unauthorized personnel. If Trocar malfunction occurs which is caused by the use in contrary to the intended use, the warranty does not apply.

Reprocessing instructions:
The following sections describe the preparation after use for the articles Grena's Reusable Trocar.
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:** Trocar cannula 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:	Instruments are delivered non-sterile and must be cleaned and sterilized before each use. **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 pace it in the basin with cleaning solution.
Preparation for cleaning:	Luer-lock cap for insufflation port, instrument seal and silicone valve must be removed for cleaning and should be cleaned separately. 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. 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 including inner surfaces of cannula and insufflation port. Make sure that all visible contamination has been removed. 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 the hospital's internal procedures require the use of an ultrasonic cleaner, the recommended parameters for are 3 min, 40 °C, 35 kHz with a cleaner / disinfectant added. The process was validated with 2% Sekusept Aktiv. This process can be used in addition to the manual cleaning process or as a pre-treatment for the automated reprocessing process. 5. Dry the device with compressed air. 6. Rinse under clean running water. 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. **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. Trocars have insufflation port and inner surface of cannula. 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 inner surface of cannula 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. The following process parameters are suitable for reprocessing the instruments: 1. Cold pre-wash, water <40°C, 2min. 2. Washing, hot water, 10 minutes, detergent concentration and temperature as per manufacturer's recommendation (process validated with 8% Thermosept Xtra, 55°C). 3. Neutralization, neutralizing agent concentration and time as per manufacturer's recommendation (process validated with 2% Thermosept NKZ, 42°C, 1 min). 4. Rinse, cold water below 40°C, 1 min. 5. Thermal disinfection 93°C, 5 min, concentration of additive as per manufacturer's recommendation (process validated with 0,2% Thermosept BSK). 6. Drying 120°C, 30min. **NOTE:** One should remember that any cleaning and disinfection process should be validated. **NOTE:** The validated parameters correspond to process with an A0 value of > 3000s. Grena Ltd. Recommends to use only processes with an A0 value of > 3000s. **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 sterile air to blow inner of the cannula and insufflation port.
Maintenance:	No special recommendations
Inspection and function testing:	Inspect for any abnormalities – in case of any technical impairment instrument must be rejected. Check cannula for any dents and distortion. Visually inspect for damage and wear. Pay attention to surfaces which come in contact with seals and silicone luer-lock cap for insufflation port. Check silicone seals and luer-lock cap for insufflation port for tears or deformations. Reject silicone parts with any signs of damage. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning / disinfection process. Discard damaged trocars.
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 trocar without stressing the seals. Do not use packaging that is too large, to prevent the instruments form sliding around in the packaging. In sets: Trocars 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 sharp tips are protected. The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs for the safety of the personnel handling instrument sets; instrument cases exceeding 11.4kg/25lbs 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 trocars 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.

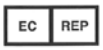
A notice to the user and/or patient:	If any serious incident has occurred in relation to the device it should be reported to the manufacturer and the competent authority of the Member State.
Manufacturer contact:	See the headline of instructions for use.


Caution, consult accompanying documents


Keep dry


Consult instructions for use


Manufacturer



Authorized representative in the European Community

Catalogue number

Batch code


Quantity in package