## Ref. No.: 0208-VN12, 0208-VN15

GRENA®	Contact information: Phone/ Fax: + 44 115 9704 800	EC REP	C € 0197	ENG IFU-VN-ENG-07
Middlesex TW8 9HH, United Kingdom		Co. Cork, P85 K230, Republic of Ireland		

Important: This instruction cannot be used as a manual for surgical techniques used during the work with Veress Needle. To learn adequate knowledge about surgical technique it is necessary to contact our company or 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: Veress Needle is a disposable device used in gynecologic and abdominal endoscopic procedures for establishment of pneumoperitoneum. Description: Veress Needle has a spring-loaded, blunt stylet mechanism. It is used to establish pneumoperitoneum prior to abdominal endoscopy. Stainless steel needle is attached at its proximal end to a plastic handle. The handle is ergonomically shaped for comfortable gripping action, as well as stopcock and luer lock for inflating the abdominal cavity. Inside the needle cannula and extending beyond the tip is spring-loaded, blunt stylet. The stylet retracts as the needle is pushed through the abdominal wall and automatically advances forward once the peritoneum has been penetrated. Observation of the lens provides clear information if needle tip is actually blunt or sharp edge is exposed. Device is available in 2 lengths: 120 mm (VN12) and 150 mm (VN15). Outside diameter is 14G. **Tool illustration:** A. Needle cannula B. Handle C. Blunt tip indicator (green) E. Lens G. Two-way stopcock F. Spring D. Sharp tip indicator (red) H. Blunt stylet Contraindications: Do not use in the area of local inflammation 2 Do not use if endoscopic techniques are contraindicated. Instructions for use: Open the package using aseptic technique and inspect the instrument handle to ensure that color of the lens (E) changes from green to red when blunt stylet (H) is pushed back. This action indicates the retraction of the blunt stylet (H) and exposure of the sharp needle for penetration. Once the blunt stylet (H) is free of pressure from the tissue, the lens (E) color should change back to green indicating that sharp needle tip 1 is protected by protruding blunt stylet (H). Close, open and close again 2-way stopcock (G) to ensure it works properly and to ensure it will remain closed during insertion. Stopcock (G) is closed when its' arms are in transverse position to the longitudinal 2. axis of the needle. Make small incision to insert Veress Needle 3. Grasp Veress Needle handle between the thumb and forefinger and advance it through the incision. Pay attention to the color of the lens (E) which at the beginning of insertion changes from green to red, than returns back to green. Slight "click" is audible. Color reversion from red to green indicates that peritoneal cavity was penetrated and blunt stylet (H) is exposed to protect internal organs. 4 Ensure Veress Needle is actually in the peritoneal cavity. Connect an insufflation tube to luer lock connector of the Veress Needle, open 2-way stopcock and inflate the peritoneal cavity. 5 6 Following insufflation, remove the Veress Needle from the abdomen and proceed with the endoscopic procedure. Additional warnings and precautions: Minimally invasive procedures should be performed only by persons 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. 3. 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 is not compromised. Do not attempt to insert the Veress Needle if there is no color change in the lens from green to red when blunt stylet is pushed back, as this indicates the needle point will not be exposed for insertion. 4. 5. Do not attempt to insert the Veress Needle if there is no color charge back in the lens from red to green, as this indicates the blunt stylet will not protect intraabdominal organs from injury due to the needle point which will remain exposed after insertion. While checking blunt stylet mobility never press the stylet with a finger to avoid injury by the needle sharp point. 6. The stopcock should be closed during insertion to prevent the abdominal pressure from equilibrating with the ambient pressure, when penetration of the peritoneum occurs. 8 After removing the Veress Needle from the abdominal cavity, always inspect the site for hemostasis. Dispose of all opened instruments whether used or unused. 9. 10 Use immediately after opening. 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.

- 11
- This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included. 12
- Product is intended to be used exclusively by qualified medical staff.
- 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. 14.

