Veress Needle
Instructions for use

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

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-VN-ENG_10

Important:
The instructions provided herein are not intended to serve as a comprehensive manual for surgical techniques related to the use of the Veress Needle. 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 Veress Needle, 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:
The needle is a single-use device employed in gynecological and abdominal endoscopic procedures to establish pneumoperitoneum.
Patient target group - adult and young patients, males and females.
Intended users: product is intended to be used exclusively by qualified medical staff.

Description:
The Veress Needle features a spring-loaded, blunt stylet mechanism, designed for establishing pneumoperitoneum prior to abdominal endoscopy. The needle, made of stainless steel, is affixed at its proximal end to an ergonomically shaped plastic handle, ensuring comfortable operation. The handle includes a stopcock and luer lock for inflating the abdominal cavity. Within the needle cannula, the blunt stylet extends beyond the tip; it retracts as the needle penetrates the abdominal wall and automatically advances once the peritoneum is breached. An observation lens on the device allows for clear verification of the needle tip's condition, indicating whether it is blunt or if a sharp edge is exposed. The device is available in two lengths: 120 mm (VN12) and 150 mm (VN15), with an outside diameter of 14G.

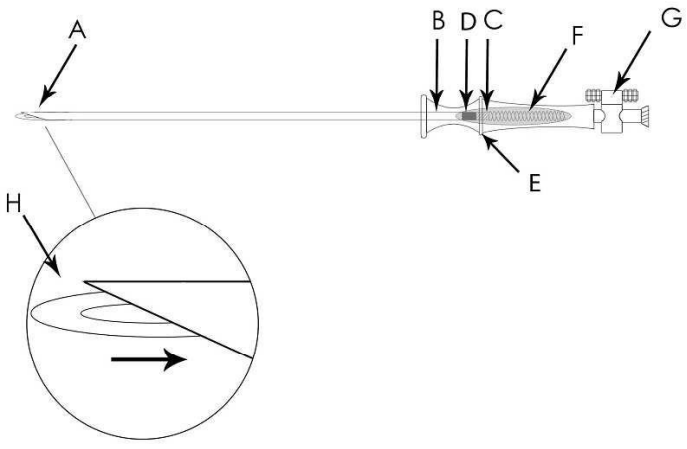
Tool illustration:

A. Needle cannula	C. Blunt tip indicator (green)	E. Lens	G. Two-way stopcock
B. Handle	D. Sharp tip indicator (red)	F. Spring	H. Blunt stylet

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

Instructions for use:
1. Utilize aseptic technique to open the package and carefully inspect the instrument handle. Verify that the color of the lens (E) transitions from green to red when the blunt stylet (H) is retracted. This color change indicates that the blunt stylet (H) has retracted, exposing the sharp needle for penetration. When the blunt stylet (H) is no longer under tissue pressure, the lens (E) should revert to green, signifying that the sharp needle tip is shielded by the protruding blunt stylet (H).
2. Manipulate the 2-way stopcock (G) by closing, opening, and then closing it again to verify its functionality and to ensure it remains securely closed during insertion. The stopcock (G) is considered closed when its arms are positioned transversely to the longitudinal axis of the needle.
3. Create a small incision to facilitate the insertion of the Veress Needle.
4. Hold the Veress Needle handle between the thumb and forefinger and gently advance it through the incision. Monitor the color of the lens (E), which initially changes from green to red and then back to green. A slight "click" may be heard. The transition of the color from red to green signifies penetration into the peritoneal cavity and the exposure of the blunt stylet (H) to protect internal organs.
5. Confirm that the Veress Needle is properly positioned within the peritoneal cavity.
6. Attach an insufflation tube to the luer lock connector of the Veress Needle. Open the 2-way stopcock and proceed to inflate the peritoneal cavity.
7. After completing insufflation, close the 2-way stopcock, disconnect the insufflation tube, carefully withdraw the Veress Needle from the abdomen and proceed with the endoscopic procedure.

Additional warnings and precautions:
1. Minimally invasive procedures should only be performed by individuals with appropriate training and familiarity with such techniques. Prior to undertaking any minimally invasive procedure, it is essential to consult relevant medical literature regarding techniques, potential complications, and risks.
2. Minimally invasive instruments may differ across manufacturers. Ensure compatibility of instruments and accessories from different manufacturers before commencing a procedure. Incompatibility may lead to an extended procedure time, inability to perform surgery or necessity to convert to an open surgery.
3. During functional testing of the device, if the lens does not transition from green to red when the blunt stylet is pushed back, the Veress Needle must not be used. This absence of color change signifies that the needle point will not be exposed during penetration of the body wall, rendering the device unsuitable for its intended surgical application. Using a needle with such a defect may require greater force to penetrate the body wall and as a result, lead to injury to internal organs.
4. During functional testing of the device, should the lens fail to revert from red to green upon releasing pressure on the blunt stylet, the Veress Needle must not be used. This lack of color change indicates an inability to safeguard intra-abdominal organs by concealing the needle point after insertion. Using a needle with such a defect may lead to injury to internal organs.
5. To avoid injury from the sharp needle point, never test the mobility of the blunt stylet by pressing it with a finger.
6. Keep the stopcock closed during insertion to prevent the equilibration of abdominal pressure with ambient pressure upon penetration of the peritoneum.
7. After removal of the Veress Needle from the abdominal cavity, always inspect the insertion site for hemostasis to prevent hemorrhage.
8. Dispose of all opened devices, regardless of whether they have been used, to prevent accidental reuse of a potentially contaminated device. The device's sterility and full functionality can only be ensured if used immediately after opening the packaging.
9. 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.
10. 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.
11. 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.
12. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
13. 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	eIFU indicator www.grena.co.uk/IFU	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
EU REP	Authorized representative in the European Union	REF	Catalogue number	LOT	Batch code		Quantity in package
STERILE EO	Sterilized using ethylene oxide		Do not re-use		Single sterile barrier system	MD	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.