HERO™ Click'aV® Ligating Clip Appliers
Instructions for use

Ref. no.:

0301-04MEN, 0301-04MEA20N, 0301-04MEA45N, 0301-04MEBN, 0301-04MEA20BN, 0301-04MEA45BN, 0301-04MLEN, 0301-04MLEA20N, 0301-04MLEA45N, 0301-04MLEBN, 0301-04MLEA20BN, 0301-04MLEA45BN, 0301-04LEN, 0301-04LEA20N, 0301-04LEA45N, 0301-04LEBN, 0301-04LEA20BN, 0301-04LEA45BN, 0301-04XLEN, 0301-04XLEA20N, 0301-04XLEA45N, 0301-04XLEBN, 0301-04XLEA20BN, 0301-04XLEA45BN, 0301-04XXLEN, 0301-04XXLEBN.

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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 HERO™ Click'aV® Ligating Clip Appliers. 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:
Grena HERO™ Click'aV® Ligating Clip Appliers are indicated for use as delivery devices for Grena Click'aV® and Click'aV Plus™ polymer ligating clips during laparoscopic and thoracoscopic surgical procedures. It is crucial to ensure the proper compatibility between the size of the occluded tissue and the selected clips to achieve optimal performance and safety.
Patient target group - adult and young patients, males and females.
Intended users: product is intended to be used exclusively by qualified medical professionals.

Contraindications:
DO NOT use for tubal ligation as contraceptive method due to lack of sufficient data on efficacy and safety in these conditions.
DO NOT use for renal artery ligation during laparoscopic live donor nephrectomy.
DO NOT use to apply clips as a tissue marker.

Description of the device:
HERO™ Click'aV® Ligating Clip Appliers are reusable surgical instruments. The appliers feature a non-detachable design and an integrated flushing channel to facilitate the removal of debris from the shaft, ensuring optimal hygiene and performance. Each size of a clip must be applied using a corresponding and compatible clip applier.
Appliers for M and ML sizes are compatible with 5 mm trocar cannulas (or 10 mm for angled 20° and 45°), while appliers for L, XL, and XXL sizes generally require 10 mm trocar cannulas (or 12 mm for angled 20°). However, **L and XL appliers with a 45° angled jaws are designed specifically for VATS (Video-Assisted Thoracoscopic Surgery) procedures and are not compatible with trocar cannulas.** The appliers are equipped with the innovative **HERO™ (High Energy Override)** mechanism, which limits the compression exerted by the jaws to a predetermined level. This feature ensures the prevention of excessive tissue compression, enhances patient safety, and extends the durability of the instrument by protecting its internal mechanisms and jaws. The applier's shaft can be rotated **360°** relative to the handle. Bariatric versions are designated by the letter **"B"** in the reference number.

Instructions for use:
1. Choose the appropriate size of the clip and the compatible applier.
2. Confirm the compatibility of all devices prior to use.
3. Adhering to aseptic procedures, remove the clips cartridge from its sterile packing. To prevent any damage of the device place it on a sterile surface.
4. Grip the applier around the shaft. Such a grip ensures that the jaws of the device remain fully open, which is essential for proper clip loading.
5. Align applier jaws vertically and laterally over a clip in the cartridge and advance product jaws into the slot of the clip cartridge ensuring they are perpendicular to the surface of the cartridge. Incorrect position of the jaws during loading may lead to incorrect seating of the clip in the jaws, which may result in the inability to securely close the clip, its cracking, deformation or falling out of the applier. Advance the jaws gently till there is an audible click. Do not use force to push the applier. The applier should move inside and outside of the slot easily. Using excessive force to push the applier may break the clip.
6. Remove the applier from the cartridge. It may be necessary to hold the cartridge to allow the clip to be removed. Verify that the clip is securely affixed in the jaws. The clip bosses should seat in the notches of the applier's jaws. Incorrect seating of the clip in the jaws, may result in the inability to securely close the clip, its cracking, deformation or falling out of the applier.
7. Sufficiently skeletonize the structure to be ligated to allow locking mechanism of the clip to be clear of the tissue to avoid penetration of the latch through the tissue. Penetration of the tissue by the latch affects closure security, may deform or even break the clip.
8. Squeeze the applier handles gently (without locking the clip) and insert the applier jaws and shaft down the cannula. Maintain compression on the applier handles until the jaws clear the cannula, as most cannulas have an inner diameter smaller than the opened jaws of the applier. Squeezing of the applier's handles may be also necessary when withdrawing the applier from the cannula. If the handles are not sufficiently squeezed, the jaws of the applier can scrape the material from the inside of the cannula and detached plastic particles can fall into the body cavities.
9. During application, rotate endoapplier's shaft so that the single big tooth of the clip's latch is oriented downward and visible from the top and side at a time. This allows the user to visually confirm encapsulation of the structure being ligated and the latch of the clip being free of the tissue.
   Position the clip around the structure intended for ligation in a manner that provides clear visualization of the locking mechanism. Apply appropriate force to close the clip completely until it locks shut, making sure it is placed properly.
   Releasing the pressure on the handles will cause the applier jaws to spring open.
   Note: When during squeezing the trigger perceptible resistance occurs means the HERO™ mechanism is activated. If clip is still not closed properly, squeeze trigger to override resistance to exert higher force on the jaws and to close the clip. HERO™ mechanism will NOT allow to exceed maximum safe force exerted on the tissue and applier's construction.
10. Remove the applier from the surgical site.

Compatibility:

Click'aV® and Click'aV Plus™ clips size	Ligated structure size in [mm]	Compatible HERO™ Click'aV® Ligating Clip Appliers	Compatible trocar cannula diameter in [mm]
M	2 to 7	0301-04MEN, 0301-04MEBN	5
		0301-04MEA20N, 0301-04MEA45N, 0301-04MEA20BN, 0301-04MEA45BN	10
ML	3 to 10	0301-04MLEN, 0301-04MLEBN	5
		0301-04MLEA20N, 0301-04MLEA45N, 0301-04MLEA20BN, 0301-04MLEA45BN	10
L	5 to 13	0301-04LEN, 0301-04LEBN	10
		0301-04LEA20N, 0301-04LEA20BN	12
		0301-04LEA45N, 0301-04LEA45BN	Not applicable
XL	7 to 16	0301-04XLEN, 0301-04XLEBN	10
		0301-04XLEA20N, 0301-04XLEA20BN	12
		0301-04XLEA45N, 0301-04XLEA45BN	Not applicable
XXL	10 to 22	0301-04XXLEN, 0301-04XXLEBN	10

Warnings and precautions measures:
1. Carefully inspect instrument for any signs of damage after and before each use. Do not use damaged appliers, as this may result in improper clip placement. When closed, jaw tips should be directly aligned and not offset. Always check the alignment of the applier jaws before use. Misalignment of the jaws may cause severe clip deformation during closure, preventing proper latching and potentially leading to patient injury.
2. 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.
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. HERO™ Click'aV® appliers are compatible with Click'aV® and Click'aV Plus™ clips only and are not compatible with LigaV® or Vclip® clips. Always ensure that correct Grena applier type was selected prior to initiation of the procedure. Failure to do so can result in inability to perform surgery.
5. Surgeon is fully responsible for selecting proper surgical technique, type and size of the tissue and vessels appropriate for ligation, size of the clip and corresponding applier, as well as determining the number of clips needed to achieve satisfactory haemostasis and closure security.
6. Do not use the clip loaded into the jaws or applier alone as a dissecting instrument, as clip may drop off and applier's tips may cause tissue injury.
7. Always confirm that the clip remains securely in the applier jaws after passing the applier and clip trough the cannula.
8. Do not attempt to close the jaws on any tissue structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or anatomic structure may result in patient injury.

9. Do not squeeze the applier over other surgical instruments, staples, clips, gallstones or other hard structures as it may cause the clip to break.
10. After each clip is placed it is required to close the applier fully. A partial squeeze may result in clip dislocation leading to improper ligation.
11. The clip must be securely latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure each clip was placed and closed well on ligated structure. This should be repeated after the use of other surgical devices in the immediate area of the application so as not to miss accidental displacement of the clip.
12. Click'aV® and Click'aV Plus™ ligating clips can be opened with specially designed clip remover. It is highly recommended that remover be readily available during surgery involving the use of Click'aV® and Click'aV Plus™ ligating clips. Once opened, the clip must be discarded and should not be reapplied again even if no visible damage is present. Clip opened with the remover may develop microcracks and such clip could break or slip off the vessel leading to haemorrhage.
13. When working with the HERO™ Click'aV® applier, carefully follow the instructions for use of Click'aV® and Click'aV Plus™ ligating clips.
14. 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.
15. 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.

Ligating Clips Appliers warranty:
All Grena HERO™ Click'aV® Ligating Clip Appliers are covered by one year warranty. Grena will repair free of charge any applier, provided it is used for normal surgical purposes with Grena ligating clips for which it was designed, and has not been repaired by unauthorized personnel. If an applier malfunction occurs which is caused by the use of a non-Grena clips, the warranty does not apply.

Reprocessing instructions:
The following sections outline the steps required for the reprocessing of Grena HERO™ Click'aV® Ligating Clip Appliers.
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 place them 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 appliers 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.
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, 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 from 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 11.4kg/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: Fractional prevacuum 10 kPa; Temperature [°C]: 134; Exposure time [min]: 3; Pressure [bar]: >3; Drying time [min]: 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. 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 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.

Please scan the below QR code with the appropriate application.
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.