Disposable Jumbo Pack
Instructions for use

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Important:
This instruction cannot be used as a manual for surgical techniques used during the work with Disposable Jumbo Pack. 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:
Disposable Jumbo Pack is a set of devices used in gynecological and abdominal endoscopic procedures to perform majority of standard surgical steps like:
1. establishment of pneumoperitoneum – Veress Needle,
2. establishment of a port of entry for instrumentation – Trocars,
3. marking and/or ligating of any linear tissue structures or vessels during an operation for hemostasis or marking purposes where use of non-absorbable clips is required – Ligating Clips,
4. safe and convenient collection and extraction of tissue specimens such as the appendix, gallbladder, ovaries, fibroid tumors, spleen, ectopic pregnancy, lymph nodes, bowel specimens, other tissues and calculi – Retrieval Bag.

Description:
Jumbo is sterile disposable set containing following devices:
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. Outer diameter is 14G. Needle length 120 mm.
Trocars – there are two 5 mm cannulas with single pencil point sharp obturator, two 10 mm cannulas with single obturator (pencil point blunt or pencil point sharp, or pyramidal). Cannulas length 100 mm. Fixing silicone ring and adhesive tape allows to fix cannula to the body surface. Included one-way stopcock can be connected to any cannula if necessary.
Ligating clips – there are two types of ML clips in the package: Vclip (triangular crossection) and LigaV (rectangular crossection) to be able to use with the most popular appliers on the market. Clips are made of medical grade titanium. They are placed around the tissue and closed with the grip of a compatible clip applier.
Retrieval Bag – consists of an introducer sheath with preloaded tissue bag and a pusher. This device is designed for use through a standard 10 mm trocar cannula. Bag volume 400 ml.

Illustration of the device:
Veress Needle
A. Needle cannula B. Handle C. Blunt tip indicator (green) D. Sharp tip indicator (red)
E. Lens F. Spring G. 2-way stopcock (luer-lock female) H. Blunt stylet

Trocar
A. Obturator B. Cannula C. Cap D. Insufflation port E. Seal F. Silicone ring

Contraindications:
1. Do not use device in the area of local inflammation.
2. Do not use device if endoscopic techniques are contraindicated.
3. Do not use clips for tubal ligation as contraceptive method.
4. Do not use clips on structures where use of metal clips is not appropriate.
5. Do not use clips in case of just suspicion of allergy to titanium.
6. Removal of tissues containing sharp-edged structures which may damage the retrieval bag is a relative contraindication to use retrieval bag.
7. Retrieval bag should not be used with any tissue that will not fit within the confines of the specimen pouch to allow complete closure.

Instructions for use (Veress Needle):
1. 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 is protected by protruding blunt stylet (H).
2. 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 axis of the needle.
3. Make small incision in the umbilicus to insert Veress Needle.
4. 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.
5. Ensure Veress Needle is actually in the peritoneal cavity.
6. Connect an insufflation tube to luer lock connector of the Veress Needle, open 2-way stopcock and inflate the peritoneal cavity.
7. Following insufflation, remove the Veress Needle from the abdomen and proceed with the endoscopic procedure.

Instructions for use (Trocar):
1. Create pneumoperitoneum in the abdomen prior to insertion of the Trocar.
2. 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.
3. Insert the obturator into the Trocar cannula (pic. 2) and close insufflation port with an integral cap (pic. 2) or fix one-way stopcock supplied with the device. If stopcock is used close it before trocar insertion.
   Warning: when inserting a sharp edged obturator, take care not to damage cannula seal with obturator blade.
4. Move silicone sling along the cannula to the position reflecting intended depth of Trocar insertion.
5. Position the Trocar at the appropriate angle to the abdomen wall (pic. 3).
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 (pic. 3). 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 (pic. 4).
9. To fix cannula to the body surface remove main part of adhesive tape cover from fixing tape (pic. 5). Two rectangular tape covers at the edge of the tape should be used as holders to avoid sticking the tape to gloves. After main part of adhesive tape cover is removed, position tape above silicone ring and stick it to the skin and ring. Remove two rectangular adhesive tape covers and stick both tips of adhesive tape to the skin (pic. 6)
   Warning: do not touch bottom of adhesive tape after cover is removed.
   As an option, sutures can be applied to fix silicone ring to the body surface.
10. Connect an insufflation tube to an insufflation port or one-way stopcock, if required. If stopcock is used open it to commence insufflation.
11. To desufflate, disconnect insufflation tube. If one-way stopcock is used open it after insufflation tube is removed or disconnect stopcock from cannula.

Instructions for use (Ligating Clips):
1. Take the compatible type of ML applier – Vclip or LigaV depending which of the two types of clips will be used.
2. Check the compatibility of all devices prior to use.
3. Remove clips cartridge from packing. To prevent any damage of the device place it on a sterile surface.
4. Grip the applier around the bolt (alike pencil is griped). For endo appliers grip applier around the shaft.
5. Align applier jaws vertically and laterally over a clip in the cartridge and advance product jaws into the slot of the clip cartridge making sure they are perpendicular to the surface of the cartridge. Advance the jaws till they are stopped. Do not use force to push the applier. The applier should move inside and outside of the slot easily.

6. Remove the applier from the cartridge. The clip is affixed in the jaws. It is not required to take any actions to keep the clip in place.
7. Verify that the clip is fully inserted into the applier jaws and the clip legs do not protrude beyond the end of the jaws.
8. Handle the applier carefully. The jaws should not close prematurely.
9. Place the clip around the structure intended for ligation or marking. Use appropriate force to close the clip completely making sure it is placed properly. Closure should be made with a smooth, firm continuous motion until clip is fully closed. Releasing the pressure on the handles will cause the applier jaws to spring open.
10. Remove the applier from the surgical site.

Instructions for use (Retrieval Bag):

1. Check if bag is completely packed inside introducer tube.
2. Follow standard laparoscopic procedures up to the point of tissue collection.
3. Insert the introducer sheath into the trocar, retrieval bag first (pic. 1).
   CAUTION: DO NOT push on the pushing cannula while inserting the introducer sheath into the trocar.
4. Deliver the retrieval bag into the body cavity by pushing on the pushing cannula until the retrieval bag is fully exposed (pic. 2).
5. Remove the pushing cannula and the introducer sheath (pic. 3).
6. Once released from the introducer sheath, retrieval bag will open to receive tissue. If it does not fully open atraumatic graspers should be used to facilitate opening.
7. Place the desired tissue inside the retrieval bag (pic. 4).
   NOTE: large tissue specimens may need to be cut into smaller pieces for removal.
8. To remove, use grasper to grasp the closure loop located at the end of closure wire (pic. 5). Retract the closure loop through the trocar to securely close the retrieval bag, sealing the tissue inside. Continue to retract the closure loop until the retrieval bag is at the base of the trocar (pic. 5).
   NOTE: grasping the wire instead of closure loop can cause inability to close the bag and wire shield can flake into body cavity.
9. With the retrieval bag at the base of the trocar, withdraw the trocar sheath together with retrieval bag until the closed mouth of the retrieval bag is at the trocar incision site (pic. 6). Continue to move the retrieval bag through the trocar incision site by hand under direct vision.
   NOTE: if the contents of the retrieval bag are too large to pass through the trocar incision, the incision may need to be enlarged to facilitate removal of the retrieval bag.
10. The contents of the retrieval bag may then be aspirated or removed with forceps (pic. 7).

MRI safety information for ligating clips:

MR Conditional

The implantable clips made of titanium in the Disposable Jumbo Pack are MR Conditional. A patient with the implanted clips can be scanned safely immediately after placement of the clips, under the following conditions:

- Static magnetic field of 3,0 Tesla or less
- Highest spatial magnetic gradient field of 6.5 Tesla/m
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.7 W/kg for 20 minutes of scanning (per pulse sequence).

MRI Related Heating

A clip can produce a temperature rise of less than 0.6°C using the following conditions:

- At 3-Tesla, a maximum MR system reported whole body averaged SAR of 1.7 W/kg
- 20 minutes of continuous MR scanning (per pulse sequence) using transmit/receive RF body coil.

Artifact Information

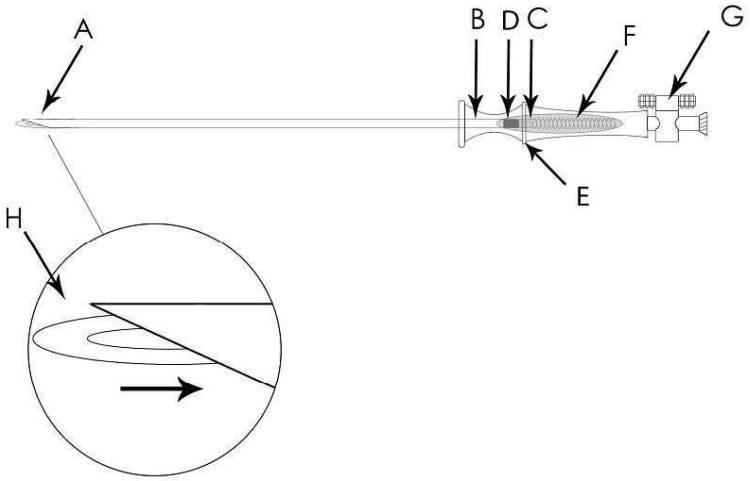
MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the clips. Therefore, optimization of MR imaging parameters to compensate for the presence of the clips may be necessary.
The worst case signal void size for a clip can be:

Pulse Sequence	SE	SE	GRE	GRE
Plane orientation	Parallel	Perpendicular	Parallel	Perpendicular
Signal void size (mm^2)	199	336	378	348

Additional warnings and precautions:

1. 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. Failure to do this can result in loss of pneumoperitoneum or inability to perform surgery.
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.
4. 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.
5. Do not attempt to insert the Veress Needle if there is no color change 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.
6. While checking Veress needle blunt stylet mobility never press the stylet with a finger to avoid injury by the needle sharp point.
7. The stopcock of Veress needle 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.
9. Do not attempt to insert the Veress Needle if the safety indicator in the handle does not slide back toward the stopcock, as this indicates the needle point will not be exposed for insertion.
10. Do not attempt to insert the Veress Needle if the safety indicator in the handle does not returns to its original position in the distal portion of the handle, as this indicates the blunt stylet will not protect intraabdominal organs from injury due to the needle point which will remain exposed after insertion.
11. While checking Veress Needle blunt stylet mobility never press the stylet with a finger to avoid injury by the needle sharp point.
12. The stopcock should be closed during insertion of Veress Needle to prevent the abdominal pressure from equilibrating with the ambient pressure, when penetration of the peritoneum occurs.
13. After removing the Trocar or Veress Needle from the abdominal cavity, always inspect the site for hemostasis. Bleeding can be controlled by electrocautery or surgical sutures.
14. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, thereby impeding the advancement of the shield and increasing the risk of injury to internal structures.
15. Adhesions, anatomical anomalies, or other obstructions may lead to injury of internal structures. Always inspect each insertion site for potential injuries.
16. The incorrect trocar insertion may result in aortic puncture. Anatomy changes relative to patient's position should be always taken into consideration.
17. 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.
18. Vclip® ligating clips are compatible with Vclip® ligating clip appliers only. LigaV® clips are compatible with LigaV® clip appliers only. Always ensure that correct Grena's applier type was chosen prior to initiation of the procedure. Failure to do this can result in inability to perform surgery.
19. Surgeon is fully responsible to choose proper size and type of the clip applier and must determine how many clips are necessary to achieve satisfactory hemostasis.
20. Make sure clip's size is appropriate for the structure to be ligated.
21. After each clip is placed it is required to close the applier fully. A not full squeeze may result in dislocation of the clip and therefore improper ligation.
22. Make sure 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.
23. Do not use damaged appliers. Using of damaged applier may result in dislocation of a clip. Always check the alignment of the applier jaws before use. If this is not done, patient injury may occur.
24. Make sure clip's size is appropriate for the structure to be ligated.
25. After each clip is placed it is required to close the applier fully. A not full squeeze may result in dislocation of the clip and therefore improper ligation.
26. Make sure every 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.
27. Do not squeeze the applier over other surgical instruments.
28. Do not use damaged appliers. Using of damaged applier may result in dislocation of a clip. Always check the alignment of the applier jaws before use. If this is not done, patient injury may occur.
29. The following factors have serious influence on the closure of a clip: condition of an applier, force used by surgeon to close the clip, size of ligated structure and features of the clip itself.
30. As for all other ligation technique it is required to check the place of ligation after applying a clip making sure it was located appropriately.
31. Always inspect each ligated site for hemostasis before procedure is finished. Bleeding can be controlled by additional clips placement, electrocautery or surgical sutures.
32. Retrieval Bag is not intended for use with any tissue that will not fit within the confines of the specimen bag and allow complete closure of the bag.
33. Once Retrieval bag is cinched, the specimen bag cannot be readily reopened in situ.
34. Do not attempt to remove the Retrieval Bag with specimen through the trocar as this may lead to bag rupture and spillage of contents.

35. Do not use morcellators with Retrieval Bag.
36. Care should be taken to avoid contact of the Retrieval Bag with sharp instruments, cutting devices, electrocautery and laser or other instruments.
37. Excessive forces should be avoided during Retrieval Bag extraction.
38. If the Retrieval Bag with specimen cannot be removed through the access site, carefully enlarge the access site to facilitate easy bag removal. Do not force the bag through the access site as this may lead to bag rupture and spillage of its contents.
39. If procedure described in clause 9 of instructions for use for Retrieval Bag is not strictly followed and user attempts to withdraw the bag through the incision site by pulling the wire using excessive force, wire can break and user or/and patient injury by the sharp wire tip is possible.
40. Dispose of all opened instruments whether used or unused.
41. Use immediately after opening.
42. The instrument 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.
43. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
44. Product is intended to be used exclusively by qualified medical staff.
45. 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.
46. 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.



Keep dry

eIFU indicator
www.grena.co.uk/IFU
Consult electronic instructions for use

Manufacturer

Date of manufacture

Caution, consult accompanying document

Do not resterilize

Do not use if package is damaged and consult instructions for use

Use-by date

EC REP
Authorized Representative in the European Community

REF
Catalogue number

LOT
Batch code

Quantity in package

STERILE EO
Sterilized using ethylene oxide

Do not re-use

MR
MR safe
(refers to ligating clips only)

Date of manufacture

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.
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