Retrieval Bag
Instructions for use

Ref. No.: 0208-RBM200, 0208-RBM400, 0208-RBM800, 0208-RBM1200, 0208-RBM1500.

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Important:

These Instructions For Use cannot be used as a surgical manual describing the use of retrieval bags. As needed, please contact our company or your authorized distributor. You should acquaint yourself with appropriate technical instructions, review the professional medical literature, and obtain formal graduate training under the supervision of a surgeon experienced in minimally invasive surgical techniques. We recommend thoroughly reviewing all information in this IFU; inattention to the instructions provided below may have serious clinical consequences such as patient injury, contamination, crossinfection, or death.

Indications:

Retrieval Bag is a disposable device used as a receptacle for the safe and convenient collection and extraction of tissue specimens such as the appendix, gallbladder, ovaries, fibroid tumors, spleen, ectopic pregnancy, lymph nodes, lung and bowel specimens, other tissues and calculi during laparo- and thoracoscopic surgical procedures.

Patient target group - adult and young patients, males and females.

Intended users: product is intended to be used exclusively by qualified medical staff.

Function:

Semitransparent bag opens after deployment inside body cavity. Thin but strong membrane prevents fluid leakage and malignant cells contamination during the manipulation in the course of procedure.

Description:

Retrieval Bag is a sterile, disposable device that consists of an introducer sheath with a preloaded tissue bag and a pushing cannula. This device is designed for use through a standard 10 or 12 mm trocar (not supplied). Available bag volumes are 200, 400, 800, 1200 and 1500 ml.

Contraindications:

1. Removal of tissues containing sharp-edged structures which may damage the retrieval bag is a relative contraindication.
2. Should not be used with any tissue that will not fit within the confines of the specimen pouch to allow complete closure.
3. Not intended for use during procedures for which laparoscopic techniques are contraindicated.

Instructions for use:

1. Open the package using aseptic technique and 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,
   CAUTION: DO NOT push on the pushing cannula while inserting the introducer sheath into the trocar to prevent releasing of the bag inside the trocar cannula.
4. Deliver the retrieval bag into the body cavity by pushing on the pushing cannula until the retrieval bag is fully exposed.
5. 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.
6. Remove the pushing cannula and the introducer sheath.
7. Place the desired tissue inside the retrieval bag.
   NOTE: large tissue specimens may need to be cut into smaller pieces or morcelated for removal. If there is a suspicion that a malignant neoplastic process was taking place in the removed tissue, it should not be dismembered to avoid dissemination of neoplastic cells to neighbouring organs.
8. To remove, use grasper to grasp the closure loop located at the end of closure wire. 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.
   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, retrieval bag and grasper until the closed mouth of the retrieval bag is at the trocar incision site. 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. This should be done with care not to damage the bag wall
10. The contents of the retrieval bag may then be aspirated or removed with forceps.

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 in diameter 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. Once cinched, the specimen bag cannot be readily reopened in situ.
4. Do not attempt to remove the bag with specimen through the trocar as this may lead to bag rupture and spillage of contents.
5. If the specimen is too large for the size of the bag, it will not be possible to close it properly, which may lead to leakage of the contents into the body cavity.
6. If morcellator use is necessary do it with care, as morcellator can mechanically damage the wall of the Retrieval Bag, leading to leakage of the contents into the body cavity. Fragments from the damaged walls of the bag may remain in the body cavity an cause a foreign body reaction.
7. Care should be taken to avoid contact of the bag with sharp instruments, cutting devices, electrocautery and laser or other instruments as they may penetrate Retrieval Bag wall causing spillage of contents.
8. Excessive forces should be avoided during bag extraction to prevent the bag from bursting and spilling the contents.
9. If the 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.
10. If procedure described in clause 9 of instructions for use 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.
11. Dispose of all opened instruments whether used or unused to prevent accidental use of a contaminated device.
12. Use immediately after opening. Keeping the instruments post package opening leads to their contamination and creates a risk of an infection to the patient.
13. 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.
14. This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included.
15. 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	Consult electronic instructions for use	Manufacturer	Do not re-use
Caution	Do not resterilize	Do not use if package is damaged and consult instructions for use	Use-by date
Authorized Representative in the European Community	Catalogue number	Batch code	Quantity in package
Sterilized using irradiation	Medical device	Date of manufacture	Single sterile barrier system

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.