GLUTACK®

EN CE 1936

Catheter for controlled application of Glubran® 2 - REF GB-DS

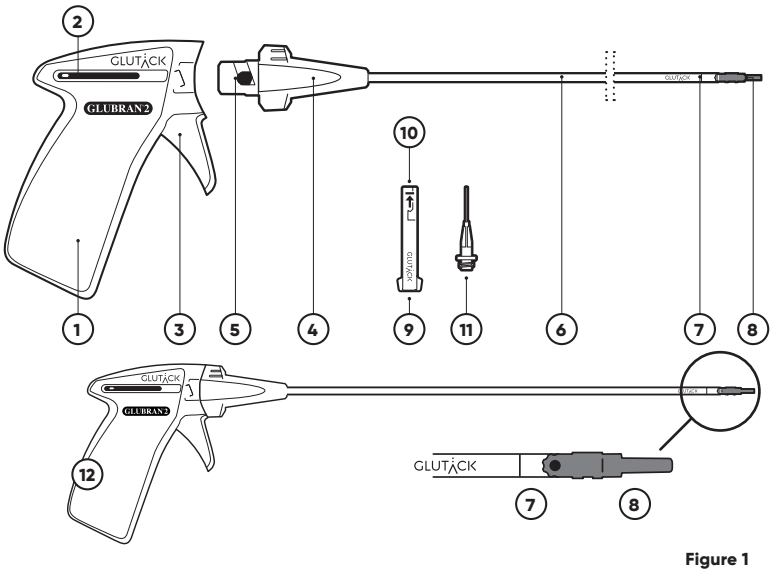


Figure 1

Features (Description of device)

GLUTACK® is a Class IIa medical device meeting the requirements of Regulation (EU) 2017/745. The GLUTACK® device enables the practitioner to apply Glubran® 2 in the form of drops (0.0125 ml - 12.5 mg/drop) in surgical procedures carried out during laparoscopy. Mainly designed for the application of Glubran® 2 in the fixation of prostheses during plastic surgery on hernias and incisional hernias. The sterile, latex-free, single-use device consists of the following components:

- **Handpiece** (Fig. 1, No. 1) with label stating the number of drops that can be dispensed; equipped with slider (Fig. 1, No.2), which displays the amount of Glubran® 2 dispensed during the procedure, and trigger (Fig. 1, No. 3) connected to the gear that forms the drop dispensing system.
- **Rigid catheter** (5 mm external diameter) consisting of:
  - **coupling base** (Fig. 1, No.4) and chamber for housing the loading cartridge (Fig. 1, No. 5);
  - **steel rod** (Fig. 1, No. 6) containing a small tube that allows Glubran® 2 to pass through:
  - **articulated and swivelling end** consisting of a white plastic part, (Fig. 1, No. 7), and a green tip with a special groove for easy grasping with surgical pliers/to grasp with surgical pliers, designed to be non-adhesive and non-obstructable (Fig. 1, No. 8).
- **Loading cartridge** for Glubran® 2 in transparent plastic (Fig. 1, no. 9), pre-marked with symbols indicating the direction of introduction into the chamber and the loading level (Fig. 1, No. 10).
- **Transfer tip** to be used for loading the cartridge with Glubran® 2 (Fig. 1, No. 11).

At the end of the assembly instructions, the device consists of a cannula with a handle and trigger at the proximal end and a swivel tip at the distal end (Fig. 1, No. 12). The distal end of the device can be swivelled to allow delivery of Glubran® 2 even in anti-gravity and anatomically difficult-to-reach positions.

Each individual device can be loaded with an appropriate amount of Glubran® 2, sufficient for at least, 30 or 60 drops, depending on the different formats. It is recommended to use of 0.5 ml Glubran®2 with 30 drops of Glutack® and the use of 1 ml Glubran® 2 with 60 drops Glutack. The green slider, visible from both sides of the handpiece, shows the amount of Glubran® 2 dispensed and the approximate amount remaining. Each time the trigger is pressed/released, one drop (approx. 0.0125 ml/drop - 12.5 mg/drop) is delivered from the distal end of the catheter. Read all the directions, precautions and warnings before use. These directions for use only provide information for the correct use of the GLUTACK® device manufactured by GEM S.r.l, Via dei Campi, 2; 55049 - Viareggio (LU) Italy, for the dispensing drops of Glubran® 2.

NOTE: the tip of the catheter can be orientated inside the abdominal cavity by grasping the articulated end in the groove on the green plastic part with pliers. **To extract the device, passing through the trocar, the tip of the catheter must be returned to its original linear position, i.E. 0°.**

In the specific case of wall surgery, the device allows to apply Glubran® 2 on the surface of herniated prostheses either on anatomical planes perpendicular to the catheter or, thanks to the orientability of the tip, on anatomical surfaces parallel to the catheter, in an anti-gravity position.

In cases involving mesh nets, drops of Glubran® 2 can be dispensed on a prosthesis already adjacent to the tissue, by placing the tip of the GLUTACK® directly into the desired point and gently pressing the trigger. With each click of the trigger, the drop of Glubran® 2 released penetrates the pores of the mesh and begins to polymerise on contact with the moist tissue below.

In cases involving prostheses with film, GLUTACK® can be used to dispense one or two drops of Glubran® 2 directly onto the mesh surface at the desired point, then bringing the mesh close to the tissue and waiting for complete polymerisation before repeating the application of Glubran® 2 on another area of the prosthesis in the same way.

Intended use

Controlled application of the Glubran® 2 surgical device in surgical procedures carried out during laparoscopy.

Target population

Adults

Warnings

⚠ The device must only be used by experienced medical practitioners who are suitably trained to use the device.

⚠ The device is sterile and intended for use on one patient only. Do not reuse, reprocess, clean, disinfect or resterilise the device, as this can lead to a risk of compromising the sterility and performance.

⚠ Do not use the product if the package has been damaged or tampered with.

⚠ Make sure that the device has been correctly assembled before use. Assemble according to the instructions in the section on "Directions for assembly and use".

⚠ Always check that the system is functioning correctly before use, by dispensing a test drop onto a surgical drape, keeping the tip in line with the steel catheter.

⚠ The device does not contain user-serviceable parts. Do not try to repair or dismantle the device. If, at any time, the device is found to be damaged or not functioning correctly, discard and replace with another.

⚠ Do not load the cartridge with fluid products other than Glubran® 2. The materials from which the GLUTACK® device is made have been tested with the Glubran® 2 medical device only.

⚠ Do not dilute or mix Glubran® 2 with other substances before loading the cartridge of the device.

⚠ The manufacturer will not accept any responsibility for damage caused by improper use or use other than what is shown on this Instruction Sheet.

⚠ When applying Glubran® 2 on the tissue, observe the polymerisation times as shown on the product data sheet.

⚠ At the end of the laparoscopic procedure still inside the abdomen, always return the pivoting tip to its original linear position (0°) by grasping it with the surgical pliers in the appropriate groove.

⚠ During the dispensing process, gently press the trigger and release it at the end of its stroke. Do not continue to increase the pressure on the trigger at the end of its stroke, as this can cause it to break.

Precautions

- When fixing prostheses in plastic surgery carried out on hernias or incisional hernias, the device must not be used if the prosthetic material is not compatible with cyanoacrylate-based adhesives.
- Do not use the Glutack catheter as a substitute for other surgical instruments. The device is designed for dispensing Glubran® 2 only. Any other surgical use may affect its functioning and safety.
- If the outlet hole of the tip is found to be partly obstructed, remove the device from the trocar and clean it by rubbing the green tip with dry, sterile gauze.

Disposal

Once used, dispose of the device according to local procedures and guidelines.

Storage

The device must always be stored in its original packaging. Always store between 5° C (41°F) and 30° C (86°F).

Expiry date

The expiry date is shown on the pack.

Sterility

This device is single-use and sterilised with ethylene oxide. STERILE EO

Contact

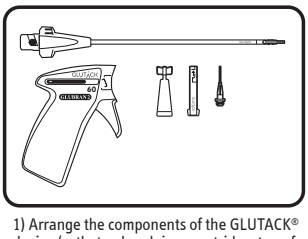
Any serious incident occurring with the device must be reported to the manufacturer GEM srl and to the competent authority of the Member State in which the user and/or patient is established.

Product Code

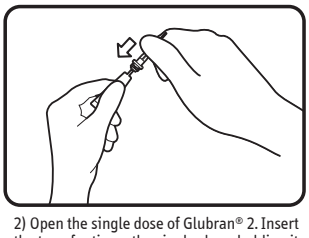
REF GB- DS 30 REF GB- DS 60

Directions for assembly and use

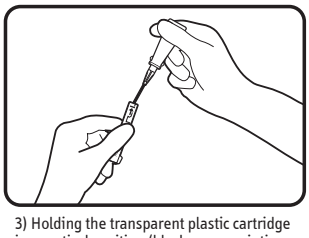
The device must be adequately prepared and activated to ensure correct functioning.



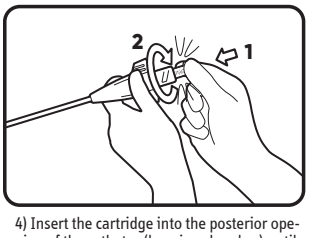
1) Arrange the components of the GLUTACK® device (catheter, handpiece, cartridge, transfer tip) and a single dose of the Glubran® 2 surgical device on the instrument table.



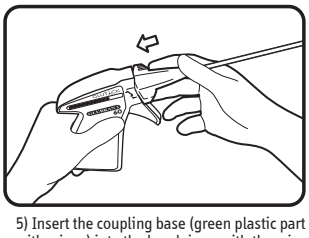
2) Open the single dose of Glubran® 2. Insert the transfer tip on the single-dose, holding it near the neck and applying enough pressure to allow the tip to be inserted. **Warning: do not press on the base of the single-dose to avoid leaking of the product.**



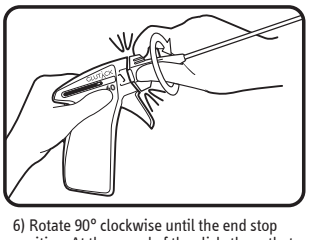
3) Holding the transparent plastic cartridge in a vertical position (black arrow pointing upwards), insert the transfer tip into the small opening. Gradually fill the cartridge by carefully pressing on the body of the single-dose until the product reaches the black line. **Once the cartridge is filled, check that it contains no air bubbles.**



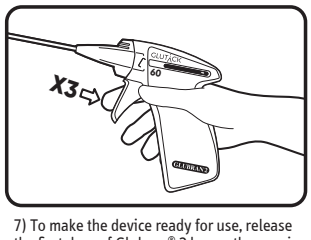
4) Insert the cartridge into the posterior opening of the catheter (housing chamber) until it reaches the end stop position. When fully inserted, rotate 90 ° clockwise until you hear a click.



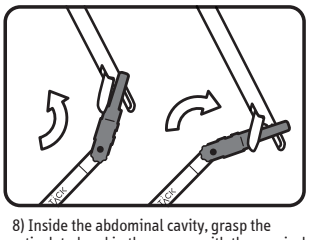
5) Insert the coupling base (green plastic part with wings) into the handpiece, with the wings perpendicular to the handpiece body.



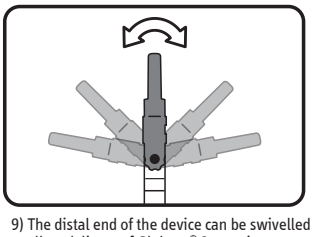
6) Rotate 90° clockwise until the end stop position. At the sound of the click, the catheter is correctly fitted and the trigger mechanism is automatically released.



7) To make the device ready for use, release the first drop of Glubran® 2 by gently pressing on the vacuum trigger 2-3 times.



8) Inside the abdominal cavity, grasp the articulated end in the groove with the surgical pliers when necessary, orientating it.
To extract the device, passing through the trocar, return the articulated end to a linear position at 0°.



9) The distal end of the device can be swivelled to allow delivery of Glubran® 2 even in anti-gravity and anatomically difficult-to-reach positions.

GEM SOLUTION COMES FROM EVOLUTION

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