GLUTACK® SHORT

ENG CE 1936

Catheter for the controlled application of Glubran® 2 in open surgery REF GB-DS SH

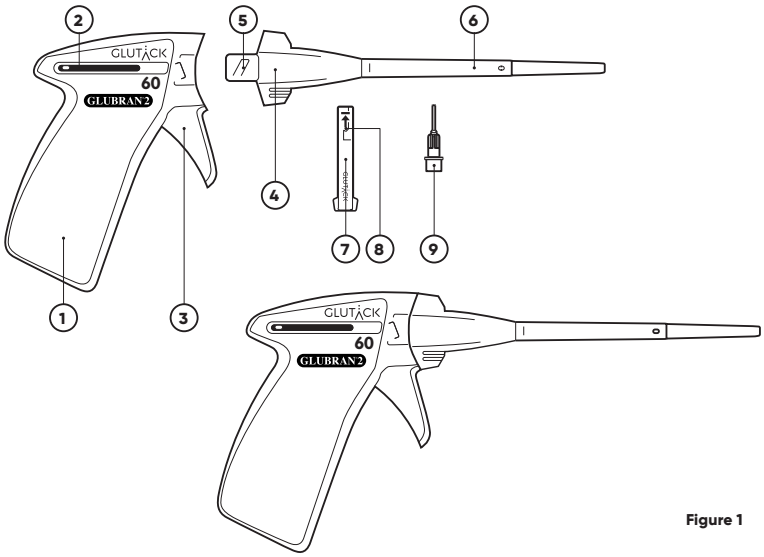


Figure 1

Features (Description of device)

The GLUTACK® SHORT catheter is a Class IIa medical device which complies with the requirements of Directive 93/42 and its subsequent updates. The GLUTACK® SHORT device enables the practitioner to apply Glubran® 2 in the form of calibrated drops (0.0125 ml/drop - 12.5 mg) in surgical procedures carried out during open surgery. Designed for the application of Glubran® 2 in the atraumatic fixation of prostheses during 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 calibrated drop delivery system.
  - **Catheter** consisting of:
  - **coupling base** (Fig. 1,N°4) and chamber for housing the loading cartridge (Fig. 1, N° 5);
  - **long polyethylene shaft,** 15 cm (Fig. 1, N° 6) containing a small tube that allows Glubran® 2 to pass through;
- **Cartridge** for Glubran® 2 made of transparent plastic (Fig.1,N°7), pre-printed with symbols showing the direction of insertion into the housing chamber and the loading level(Fig. 1,N°8).
- **Transfer tip** to be used for loading the cartridge with Glubran® 2 (Fig.1,N°9). At the end of the directions for assembly, the device is formed by a cannula with handle and trigger at the proximal end.

Each individual device can be loaded with the amount of Glubran® 2 that corresponds to the size shown on the package and handle; depending on the various sizes, the amount is therefore enough for at least 30 or 60 drops. 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 calibrated drop (0.0125 ml/drop - 12.5 mg) 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® SHORT device manufactured by GEM S.r.l, Via dei Campi, 2; 55049 - Viareggio (LU) Italy, for the dispensing calibrated drops of Glubran® 2.

In the specific case of wall surgery, the device enables the practitioner to apply drops of Glubran® 2 on the surface of hernia prostheses.

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® SHORT 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, the GLUTACK® SHORT can be used to dispense one or two drops of Glubran® 2 directly onto the tissue 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 tissue in the same way.

When correctly applied, Glubran® 2 begins to fix the mesh to the tissue after approximately 1-2 seconds, and is fully set after around 60-90 seconds. Once this time has elapsed, tissues or surgical gauzes can be positioned or juxtaposed without the risk of unwanted adhesion (see Glubran® 2 technical data sheet).

On completion of the procedure, the prosthesis is fixed to the tissue at the points of contact with Glubran® 2, which secures the mesh in place with maximum mechanical strength during the period in which it is incorporated into the abdominal wall, through the normal process of tissue fibrosis.

Intended use

Controlled application of the Glubran® 2 surgical device in the form of calibrated drops, during surgical procedures carried out in open surgery

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.

⚠ 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® SHORT 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.

⚠ During the dispensing process, gently press the trigger and release it at the end of its stroke on hearing a "click" sound. 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 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.
- If the outlet hole of the tip is found to be partly obstructed, clean by rubbing the 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

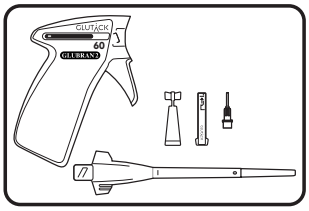
This device is single-use and sterilised with ethylene oxide. STERILE EO

Product Code

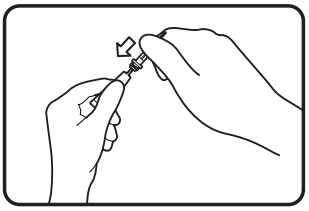
REF GB- DS SH 30 REF GB- DS SH 60

Directions for assembly and use

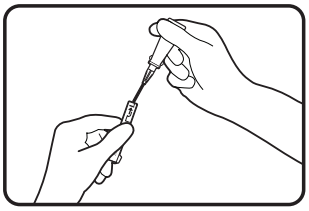
The device must be adequately prepared and activated to ensure correct functioning.



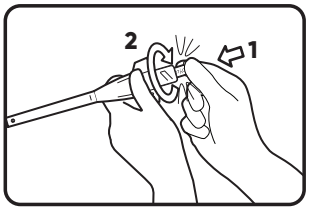
1) Arrange the components of the GLUTACK® SHORT device (catheter, handpiece, cartridge, transfer tip) and a single dose of the Glubran® 2 surgical device on the instrument table.



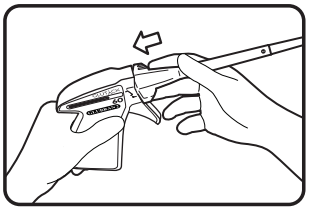
2) Open the single dose of Glubran® 2. Insert the transfer tip on the single-dose, holding it near the neck and applying enough pressure to allow the tip to be inserted.
Warning: do not press on the base of the single-dose to avoid leaking of the product.



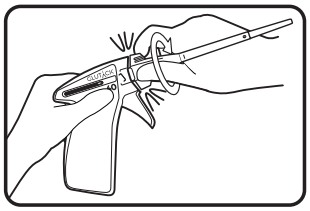
3) Holding the transparent plastic cartridge in a vertical position (black arrow pointing upwards), insert the transfer tip into the small opening. Gradually fill the cartridge by carefully pressing on the body of the single-dose until the product reaches the black line. **Once the cartridge is filled,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



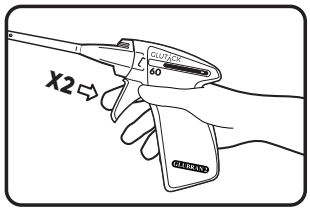
4) Insert the cartridge into the proximal opening of the catheter (housing chamber) until it reaches the end stop position. When fully inserted, rotate 90 ° clockwise until you hear a click.



5) Take the handpiece in your left hand and the catheter in your right. 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.

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