michbold

SOLUTION COMES FROM EVOLUTION.

GEM

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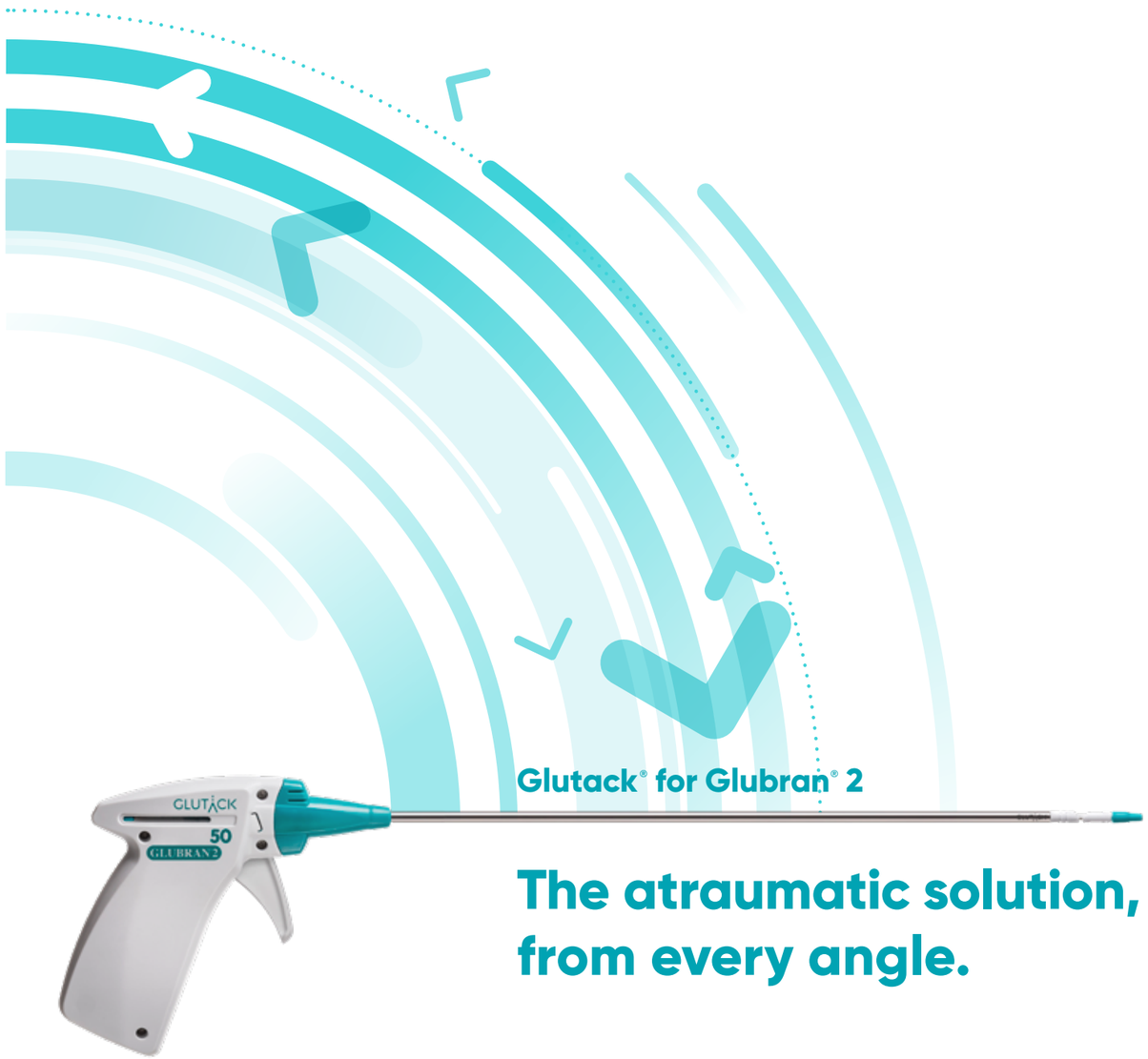
Vers. 00 - 14/12/2018

GLUTACK®



Glutack® for Glubran® 2

The atraumatic solution, from every angle.

GLUBRAN®2

GEM SOLUTION COMES FROM EVOLUTION.

GLUTACK®

A total evolution.

Designed with years of inherited experience of Glubran® 2 in atraumatic laparoscopic and laparotomic mesh fixation[1-29].

Glutack® is a user-friendly device for the atraumatic laparoscopic fixation of hernia mesh. Providing precise and consistent delivery of Glubran® 2 (NBCA+MS) with every pull of the trigger[24], to minimize surgical complications and the potential pain associated with the use of tacks and staples. Improving surgical outcomes and reducing healthcare costs[1-33].

One Glutack® is dispensed with every pull of the trigger

Glutack® + Glubran® 2 = 1 high performance adhesive tack

No change in clinical practice: delivery method is similar to traditional mesh fixation devices

Glubran® 2 is effective in repairing hernias with less post-op pain, less complications, less recurrences and cost-effective is largely documented [1-33]

Improves patient safety [1,2,6,8] and surgeon confidence [1]

Keeps the mesh in place respecting the natural tissue ingrowth [9,10]

BUILDING THE FUTURE

Atraumatic.

Versatile.

Multipurpose.

Glutack® + Glubran® 2 = 1 high adhesive tack

Synthetic biodegradable[11] cyanoacrylate adhesive modified by the addition of a monomer synthesized by the manufacturer GEM.

Polymerizes quickly in contact with live tissue and a wet environment[8] creating a thin and elastic film[12] having high tensile strength which guarantees strong adhesion to the tissues[10,13].

Ready for use[14-16] a high adhesive, sealant with haemostatic[17] and bacteriostatic properties. Effective antiseptic barrier against the most diffused infective and pathogenic agents during the surgical intervention[11,18,19].

Class III medical device authorized since 1998 in open, laparoscopic surgery and endovascular uses[20].

GLUTACK®

Evolution through revolution.

0º to 90º exclusive articulating tip

GLUTACK®

SAFE

- No clips or tacks: no tissue penetration, no nerve entrapment, no vessel damage [6,21] (Fig.1)
- Less post-op pain [6,33] (Fig.2)
- Reduces post-op complications [1,2,6,23]
- Adhesive delivery controlled at all times – no drips [24]
- Tip designed to avoid clogging and sticking [24]
- Fixation even in high risk anatomical locations: around the Triangle of Doom, Triangle of Pain and close to the Diaphragm

STRONG

- High shear strength equivalent to the current fixing methods: more than 9 N/cm^2 Glutack® [13] (Fig.3/5a)
- High peel force to remove the fixed mesh: 6N/cm^2 Glutack® [22] (Fig.5b)
- No significant difference in the strenght of parietal ingrowth between sutures [25], absorbable/ permanent tacks and Glubran 2® [10] (Fig.4)

FAST [24]

- Very quick device preparation < 1 min
- Rapid, controlled Glutack® delivery
- Each precision Glutack® adheres the mesh to the tissue immediately

PRECISE [24]

- Accurately controlled, repeatable Glutack® volume (0.0125 ml/drop)
- No product wastage

VERSATILE [24]

- 3 different sizes: containing 25, 40 or 50 Glutacks depending on mesh size / procedure requirement
- Articulating tip system to reach difficult areas

FLEXIBLE [24]

- Multiple angles of approach facilitated by articulating tip system (0° to 90°)
- Glutack® can be delivered at any angle
- Eliminates the need for controlateral ports

INTUITIVE [24]

- Simple "point and shoot" design
- Handle geometry provides user comfort and multiple grip options
- Audible and visual indicators confirm Glutack® delivery and number of Glutacks left
- Allowing you to deploy Glutacks perpendicular to the mesh and abdominal wall

The gentle power of the drop.

GLUTACK®

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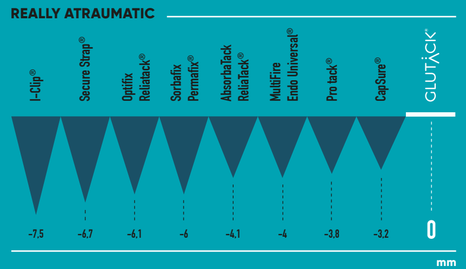
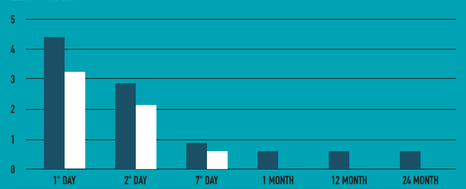
REALLY ATRAUMATIC



(Fig.1)

TISSUE PENETRATION (*mm*) [21, 30]

LESS PAIN



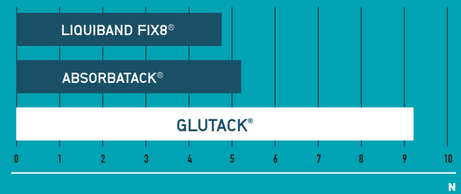
(Fig.2)

CLIPS

GLUBRAN®

EVALUATION OF POSTOPERATIVE PAIN INTENSITY BY VAS SCALE [6]
(modified by Burza A. et al. 2014).

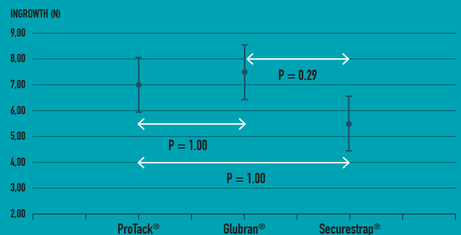
ONE GLUTACK COMPARED TO COMPETITOR DEVICE



(Fig.3)

PRE-CLINICAL SHEAR STRENGTH EVALUATION IN AN IN VITRO MODEL FOR PP-DYNAMESH FIXATION [13].

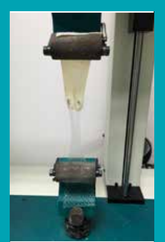
STRENGTH OF PARIETAL INGROWTH - 12 MONTHS



(Fig.4)

modified by Harslef S. et al. 2017 [10].

GLUTACK® STRENGTH TEST [13,22]



SHEAR 9N/CM²
(a)

PEELING 6N/CM²
(b)

(Fig.5a/5b)

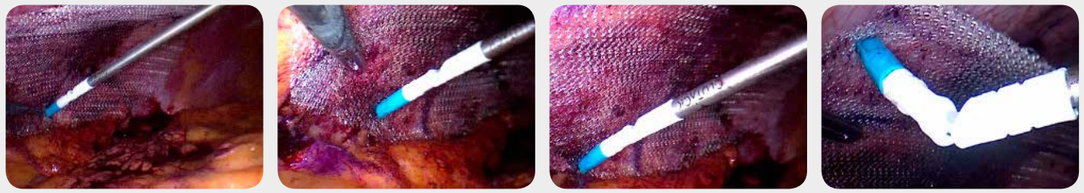
GLUTACK®

Proven Efficacy.

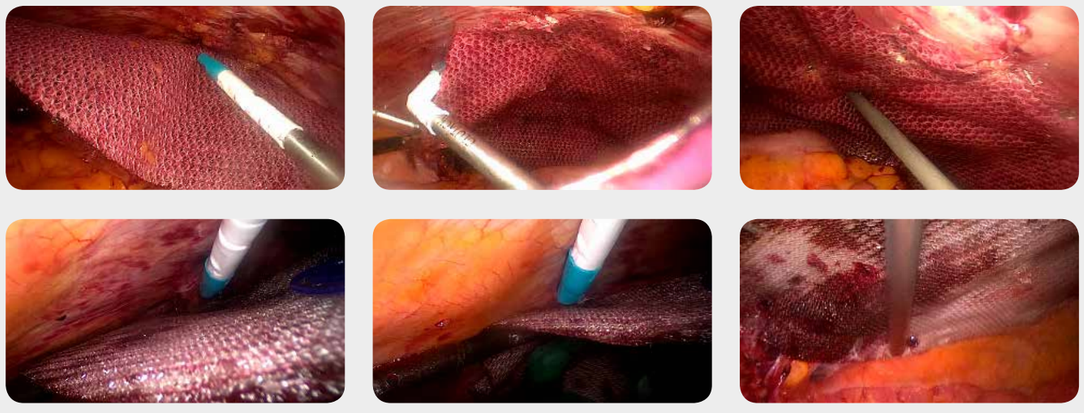
Glutack® in action.

Repair inguinal hernia

Laparoceles



Reduce trauma by a combined mesh fixation technique



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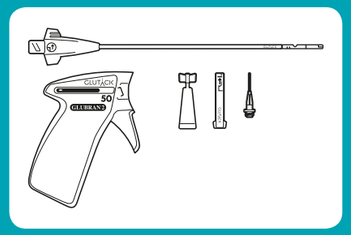
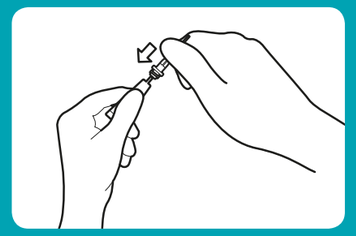
GLUTACK®

Assembly and use instructions

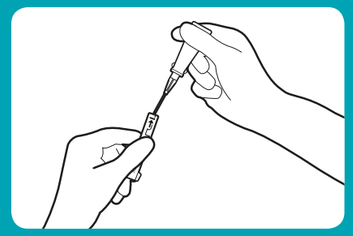
The device must be prepared and activated properly in order to ensure correct operation.



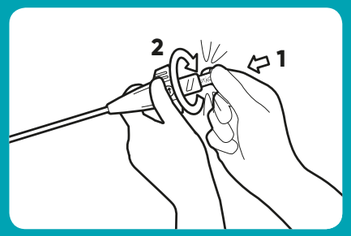
1) Place the components of the GLUTACK® device (catheter, handpiece, cartridge, transfer tip) and a vial of Glubran® 2 surgical device on the serving table.



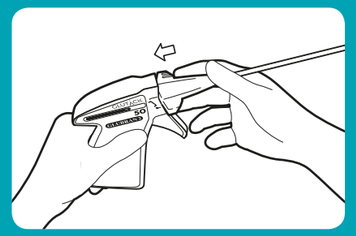
2) Open the vial of Glubran® 2. Insert the transfer tip onto the vial, grasping it close to the neck and applying an adequate pressure to allow the tip to be inserted.
Warning: do not press on the bottom of the vial to prevent the product from discharging.



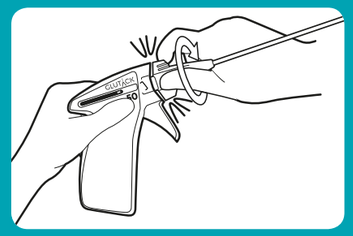
3) Holding the transparent plastic cartridge in an upright position (black arrow pointing upwards), insert the transfer tip into the small opening. Gradually fill the cartridge by carefully pressing on the body of the vial until the product reaches the black line. **When the filling is complete, check that there are no air bubbles inside the cartridge.**



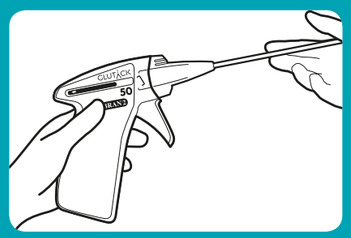
4) Insert the cartridge into the rear opening of the catheter (chamber) until it reaches the end of its travel. When fully inserted, turn it clockwise 90° until you hear a click.



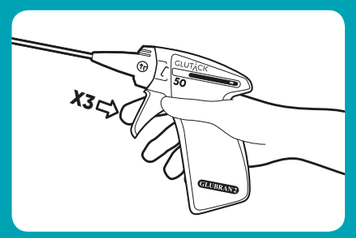
5) Take the handpiece with the left hand and the catheter with the right hand. Insert the connection base (the green plastic part with the wings) into the handpiece, with the wings perpendicular to the body of the handpiece. **Make sure that the arrow in the round symbol points upwards.**



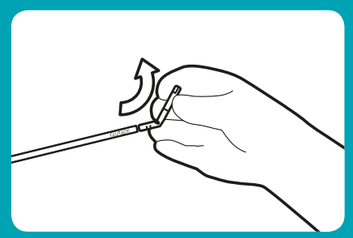
6) Turn 90° clockwise until the end of the stroke. At the sound of the click, the catheter is correctly assembled and the trigger mechanism automatically unlocks.



Warning: the device can no longer be disassembled.

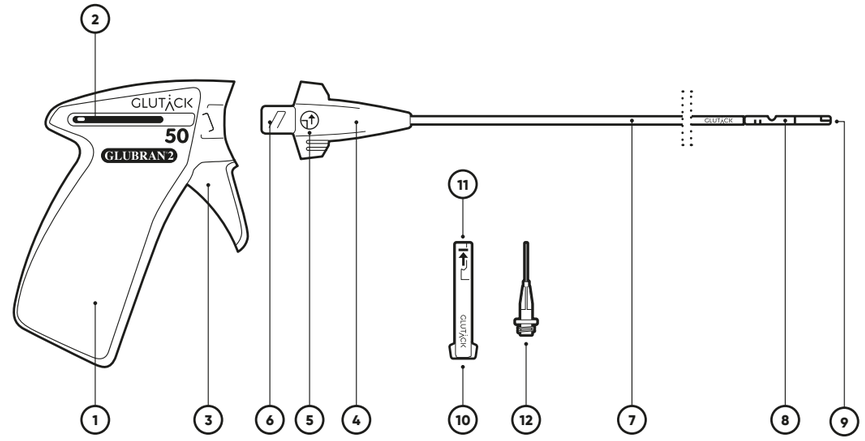


7) To make the device ready for use, release the first drop of Glubran® 2 by gently pressing the trigger 2-3 times.



8) Bend the articulated end of the catheter approximately 90° upwards and bring it back to 0° once or twice by gripping the flat section. The device is now ready for surgical use.

Note: tip can be damaged if not gripped carefully.



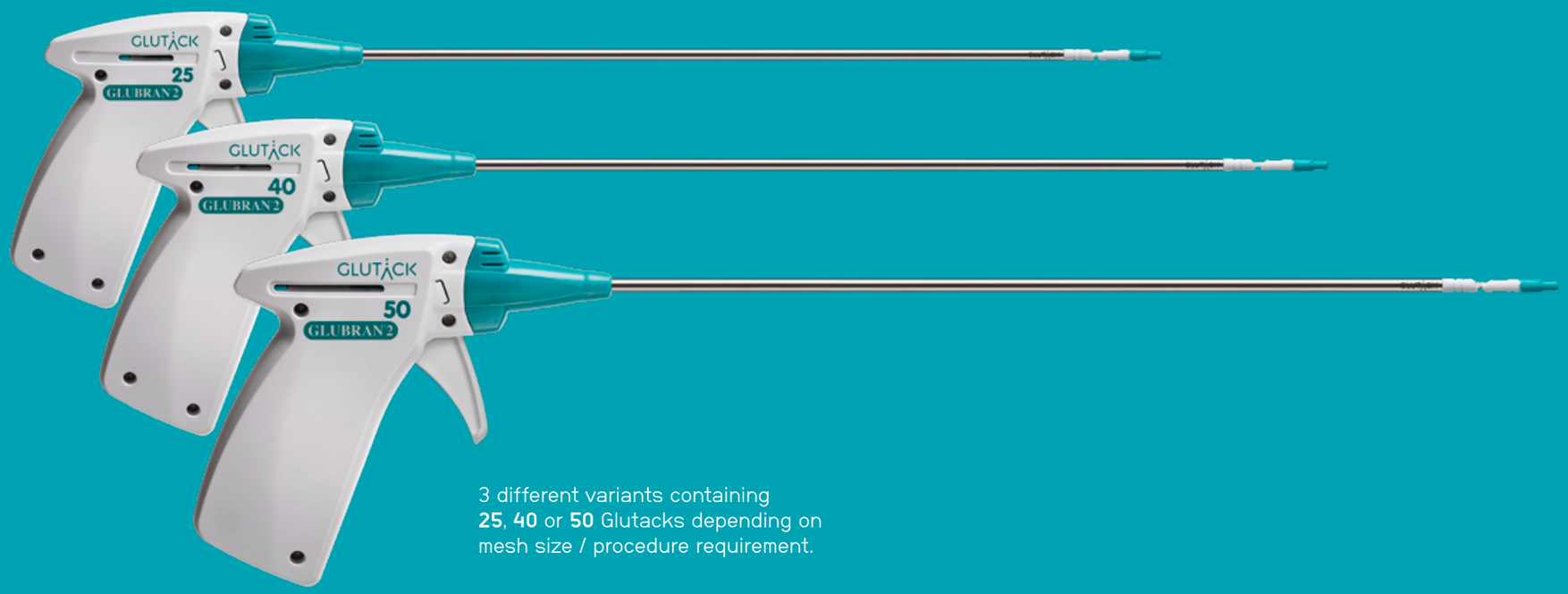
The sterile, latex free and single-use device consists of the following components:

- Handpiece (1) with label indicating the quantity of drops that can be dispensed; equipped with slider (2), which reveals the quantity of Glubran® 2 dispensed during the procedure, and the trigger (3) connected to the gear that comprises the precise delivery system of the drops.
- Rigid catheter (external diameter of 5 mm) composed of:
  - connection base (4) with the symbol showing the mounting direction (5) and loading chamber for the loading cartridge (6);
  - steel rod (7) inside which a small tube runs allowing the passage of Glubran® 2;
  - articulated and adjustable end, 0 ° to 90° (8), equipped with a tip, designed to be anti-adhesive and clog resistant (9).
- Loading cartridge for the Glubran® 2 in transparent plastic (10), pre-marked with symbols indicating the direction of insertion in the housing chamber and the loading level (11).
- Transfer tip to be used to fill the cartridge with Glubran® 2 (12).

Read always carefully the istructions for use (IFU) in the package leaflet.

GLUTACK®

For every single need.



3 different variants containing **25**, **40** or **50** Glutacks depending on mesh size / procedure requirement.