The gentle power of a drop.

Class III medical device, synthetic, CE certified for surgical and endovascular use.
Summary

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The evolution of GEM derives from its continuing commitment to research and efforts to improve products and demonstrate their effectiveness and quality, not only through the contribution of our expert professionals, but also through clinical studies on the most innovative devices.

25 years sustaining surgery.

Supporting the surgeon, with better results for patients.
ADHESIVE
SEALANT
HEMOSTATIC
BACTERIOSTATIC
SCLEROSING
EMBOLIZING
A REVOLUTION, IN A DROP.

Glufran 2 for minimally invasive surgery.

- Versatile, polymerizes quickly in contact with tissue and in a moist environment \( 59,98,100,159 \)
- Creates a thin, elastic, breathable film, firmly adhering to tissues or prosthetic materials \( 2,7,30,65,84,91 \)

**UNIQUE FORMULA** commercially available

- A second generation product modified by the addition of a monomer

N-Butyl 2 Cyanoacrylate (NBCA) + Methacryloxyisulfolane (MS)
SIX properties in ONE SINGLE product, for over 80 surgical indications.

**ADHESIVE**
High tensile strength: the minimum acceptable load is 435 N [approx. 18 kg/cm²]. 1,2,13,18

**SEALANT**
Applied using dedicated nebulizers, it forms a thin film with sealing and waterproofing properties, thanks to its synthetic nature and high adhesive power. 2,27,30,64-68,77,88,91,106-108

**HEMOSTATIC**
Reacts with blood, even when uncoagulated, inducing "mechanical" hemostasis at the site of bleeding. 7,62,63,90-97,116-119,121,127,131-134

**BACTERIOSTATIC**
Inhibits bacterial proliferation for an average of 7 days. 1,5,7,10,11,28,34,76,115

**SCLEROSING**
Injected into the lumen of the vessel/varix, it polymerizes, generating local thrombosis and resulting fibrosis and sclerosis. 5,113,128-132,135

**LIQUID EMBOLIZING AGENT**
Injected into the blood vessel it polymerizes, forming a tight-fitting mold to the walls of the vessel and occluding it. This generates a definitive occlusion, equivalent to a surgical ligature. 3,6,7,8,10,110,118,121,125,134,137,190
When it makes a difference.
It also interacts and reacts with liquids other than blood: serum, lymph, gastric and pancreatic juices, bile, saliva, urine.

Reacts with blood, even when uncoagulated, inducing "mechanical" hemostasis at the site of bleeding. 63-84,95,98-109,197

Hemostasis is ensured, even in anticoagulated patients or in patients with hereditary coagulopathies. 103,143,146,161

*1,2,5,7,10, 11,13,27,28,30,34,64–68,77,88,91,106–108,192
GLUBRAN 2 / CHEMICAL-PHYSICAL CHARACTERISTICS

RELIABLE BIOCHEMISTRY.

Appearance
TRANSPARENT

Smell
TYPICAL OF CYANOACRYLATES

Density
SIMILAR TO WATER

Ready to use
Does NOT polymerize in the presence of air
Storage between +2 and +8 °C
Can stay at room temperature (22.5+/−2.5 °C) for 48 hours
Effective in moist environment

The advantages of MS:

Polymerization temperature:
45 °C, much lower than 80-90 °C typical of pure monomeric cyanoacrylates

Biocompatibility

No tissue necrosis

Elasticity of the film at the end of polymerization
During polymerization a thin, elastic film is formed that adapts to the anatomy of the tissues. ¹⁰⁶-¹⁰⁸

At the end of polymerization, the surface of the film is no longer adhesive. ⁸

NOTE
Distilled water/glucose/mannitol do not activate polymerization ³,⁷,⁶,¹⁷²

In:
- Moist environments and tissues
- BLOOD or OTHER BODY FLUIDS (serum, lymph, gastric or pancreatic juices, bile, saliva, urine)
- Polymerizes after 1-2 seconds, complete after 60-90 sec
Zero residue, zero traces.
HYDROLYTIC DEGRADATION

Carboxylesterases circulating in the blood BIOGRADE Glubran® 2 by means of hydrolytic mechanisms, in a period ranging from 15 days to 6 months.

The degradation products are excreted from the body through the kidneys and pulmonary excretion.

In more vascularized tissues, elimination is faster.

Glubran® 2 does not stop the healing and tissue regeneration process.

The same newly formed tissue cells penetrate the film of Glubran® 2 and continue to colonize it and reproduce, until it is eliminated.

Histological samples of abdominal wall cross-sections of rats undergoing hernia repair with prosthesis fixation using Glubran® 2. Interaction between prosthetic mesh fibers and host tissues at 7, 15 and 30 days after surgery (Modified by Poli et Al. 2019).
BIOCOMPATIBILITY TEST

- Cytotoxicity
- Genotoxicity
- Mutagenicity

TISSUE TESTS

- Intracutaneous reactivity on rabbit
- Allergic sensitization on guinea pig
- Muscle implantation test in rabbit

RESULTS

The product causes moderate inflammation, typical of foreign body reactions such as suture threads. No chronic inflammation.

Once polymerization is complete, Glubran® 2 behaves like an inert biomaterial.

- Over 2 MLN treatments
- 25 years of safety
- Over 200 publications

*52,161,166,192,194,201
"Cyanoacrylate surgical glue as an alternative to suture stitches in fixing meshes for hernia repair."  

... No PMN (PolyMorphoNucleated), necrotic cells or apoptotic cells were observed.

"...when cyanoacrylates with longer alkyl chains (longer degradation) were finally synthesized, these began to be used clinically without histotoxicity..."  

Athens, Greece (November 2021)  

Image: Light micrographs of tissue samples treated with cyanoacrylate adhesive. (A) Glue residue. (B) Mesh threads. 

SAFETY
Constantly evolving solutions.

1 ml / 0.5 ml / 0.25 ml

10 sterile single-dose aluminum blister packs

Shelf life 2 years
Wide range of dedicated applicators.

- **Devices for drop-by-drop applications**
  - G2-DCD-210-8T
  - G-LLS

- **Tip for thin linear application**
  - G-DT

- **Laparoscopic catheters for drop-by-drop application**
  - G2-LPC
  - G2-LPC-RIG

- **Nebulizers for:**
  - **Laparoscopy**
    - G2-NBT
    - G2-NBT-SMALL
  - **Laparotomy**
    - G2-NBT-SHORT
    - G2-NBT RIG
    - G2-NBT SM SHORT

- **GLUTACK**
  - Laparoscopic atraumatic fixing device for hernia prostheses
  - GB-DS-25
  - GB-DS-50
GENERAL SURGERY

To prevent and reduce
Micro-leakage and extravasation of fluids with consequent formation of fistulae, seromas and lymphorrhoea.

To seal
- Anastomosis (vascular, gastrointestinal, biliary, urological) 2,5,7,29,192,194
- Sutures 7,9,19,26,28,42,67,68,95
- Manual and mechanical resection lines 15,63-66,82,106
- Resection surfaces of parenchyma and organs (liver, kidneys, pancreas, spleen, lungs) 69,70,81,82,91,95,97,192
- Surgical cavities following removal of organs or tumor masses 74,84,94,97

To treat
- Fistulae (biliary, anal, perianal, urinary, pharyngeal, liquoral, bronchial, pleural, esophageal, tracheoesophageal, gastric, gastrointestinal, duodenal and pancreatic) 22,32,75-80,88,90,92,99,110-115

THORACIC SURGERY

For aerostasis
Pulmonary resection interventions, lobectomies, pneumonectomies, bullectomies, volume reductions, tracheobronchial resections 85-92

NEUROSURGERY

To seal
- Sutures of cranial and spinal dural plastic surgery in combination with other products (gauze, hemostatic sponges) 20
- The transsphenoidal access of the Turkish saddle, for removal of pituitary adenomas 21

LIVER SURGERY

To prevent
The formation of bilomas and biliary leaks after liver surgery and cholecystectomy 81,82,152,159

BREAST AND GYNECOLOGICAL SURGERY

To close and seal
- Sectioned lymphatic vessels to prevent and reduce the formation of seromas and lymphorrhoea 84,94

AS A BACTERIOSTATIC SEALANT

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BREAST AND GYNECOLOGICAL SURGERY

To close and seal
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AS A SURGICAL ADHESIVE

SURGERY

To fix

- Hernia prostheses \(^4,7,9,37,60,93\)
- Prostheses in sacrocolpopexy \(^93\)
- In vaginal, perineal, uterine plastic surgery \(^24,25\)
- Omentum \(^106,108,204\)
- Fabric patches (biological and synthetic) \(^6,12,14,27,61,105\)

To replace sutures in

- Repair of small epicardial lacerations \(^14-16,208\)
- Timpanoplasty \(^24,25\)
- Uvuloplasty \(^28\)
- Circumcision, phimosis and frenulotomy \(^33-35,103\)
- Closing trocar insertion points
- Surgical wounds \(^10,11,26,67,192,207,20\)
- Dental surgery \(^22,26,27,193\)

To glue

- Damaged tissue \(^17,27,205,206\)
- Bone and osseocartilaginous fragments \(^207\)
- Tracheoesophageal phonation valves

To occlude

- Fistulae
- Ducts (biliary, pancreatic, etc.)
- Canals (lymphatic etc.) \(^22,32,75-80,88,90,92,99,110,115\)
AS A HEMOSTATIC

FOR ALL TYPES OF SURGERY

- Blocks punctate bleeding
- Adheres firmly to hemorrhage sites
- Adapts to micro folds of tissues

A simple and effective solution to achieve rapid hemostasis in 7,62,63,95-97-116-119,121-127,131-134

- Injuries with punctate bleeding after oncological surgery with partial or total removal of an organ
- Resection surfaces of various organs (liver, kidneys, spleen, pancreas, lung)
- Vascular and cardiac surgical anastomoses (arterial and venous bypass, arteriovenous, prosthetic-vascular fistulae, aneurysm repair)
- Bleeding oropharyngeal surfaces
- Parenchyma tissue on lacerations, hemorrhagic lesions
- Cholecystic bed, bladder bed
- Ovarian cysts, myomectomies, hysterectomies
- Gastro-duodenal ulcers, with endoscopic injection into the submucosa
AS A SCLEROSING AGENT

The endoscopists assistant 110–190

When injected into varices (Esophageal, Gastric, Duodenal) polymerizes and occludes the vessel, inducing sclerosis. 5,113,128–132,135

BLEEDING VARICES

1. Bleeding of Varices
2. Injection of Glubran® 2
3. Occluded Varix

Endoscopic treatment of gastric varices (Author Prof. G. Battaglia)

AS A LIQUID EMBOLIZING AGENT

Interventional radiologists assistant (body and head-neck) 3,6,77,87,110,118,121,125,134, 137–190

• Injected into the blood vessel, it polymerizes, forming a mold which adheres to the walls of the vessel, obstructing it and causing a definitive occlusion without recanalization.

VARICOCELES 142

Pre-embolization
Microcatheterization
Post-embolization

AVM EMBOLIZATION 142,190

Bleeding of AVM before and after injection of Glubran® 2 with complete obliteration and resolution.


52. J. F. Kukleta • C. Freytag • M. Weber. Efficiency and safety of mesh fixation in laparoscopic inguinal hernia repair using n-butyl cyanoacrylate: long-term biocompatibility in over 1,300 mesh fixations. Received: 18 August 2010 / Accepted: 1 October 2011.


**Thoracic surgery**


Gynecological surgery


Urological surgery


Bariatic surgery


Endoscopy


147. Chandra J, Anthony S, Uberoi R. Embolization of the internal iliac artery with Glubran®2 acrylic glue: initial experience with...


201. M. Foletto, L. Prevedello, G. Piatta, A. Albanese, D. Di Miceli. CYANOACRYLATE TO CLOSE MESENTERIC DEFECTS AFTER RYGB. Gastric bypass procedures including Roux-en-Y gastric bypass (RYGB) and One Anastomosis gastric bypass (OAGB)/ MGB. P.238. IFSO 2017 Abstract book.


204. M. Foletto, L. Prevedello, G. Piatta, A. Albanese, D. Di Miceli. CYANOACRYLATE TO CLOSE MESENTERIC DEFECTS AFTER RYGB. Gastric bypass procedures including Roux-en-Y gastric bypass (RYGB) and One Anastomosis gastric bypass (OAGB)/ MGB. P.238. IFSO 2017 Abstract book.


Thanks to the group efforts of a team of clinical and regulatory certification professionals, GEM’s quality system and production process has obtained the following certification.

ISO 13485:2016 and ISO 9001:2015. GEM is also MDSAP certified as the devices produced are authorized for sale in Canada, Brazil and Australia.

**EUROPEAN CERTIFICATIONS**

- CE 0373
- CE 1936
- CE 0476
SOLUTION COMES FROM EVOLUTION.