

TECHNICAL DATA SHEET AND INSTRUCTION SHEET

Composition:

Co-monomer NBCA - MS

FEATURES

Glubran[®] 2 is a class III surgical medical device (internal and external surgical use) that complies with current European Regulations. Glubran[®] 2 is a liquid of a synthetic nature with a cyanoacrylate base modified by the addition of a monomer synthesised by the manufacturer.

Glubran[®] 2 has pronounced adhesive, sealing and haemostatic properties; once cured, it provides an effective antiseptic barrier against the most common infectious or pathogenic agents in surgery. It is a ready-to-use, transparent, light-yellow liquid. On contact with living tissue and in a humid environment, it cures rapidly, creating a thin elastic film with high tensile strength that ensures solid tissue adhesion. Such a film naturally conforms to the anatomy of the tissues to which it is affixed, is impermeable and is not compromised/lysed/degraded by blood and body fluids. The film can easily be pierced by a suture needle. The curing time varies depending on the type of fabric Glubran[®] 2 comes into contact with, the nature of the liquids present and the amount of product applied. Under conditions of proper application Glubran[®] 2 starts to polymerize after about 1-2 seconds, completing its reaction around 60-90 seconds. At the end of this reaction, Glubran[®] 2 reaches its maximum mechanical strength. Once cured, Glubran[®] 2 no longer has any adhesive power, so that surgical fabrics or gauze can be placed side by side or juxtaposed without the risk of unwanted sticking. In normal surgical procedures, the Glubran[®] 2 film is removed by a process of hydrolytic degradation; the duration of this process varies depending on the type of tissue and the amount of Glubran[®] 2 applied. The polymerisation reaction can generate a temperature of around 45 °C.

Glubran[®] 2 shortens functional recovery time post-surgery and reduces pain treatment of hernias. Glubran[®] 2 reduces surgery time. Glubran[®] 2 prevents post-surgery complications, such as bleeding, fistula formation of various kinds and collection of biological fluids. Glubran[®] 2 stops arterial and venous haemorrhages in seconds. Glubran[®] 2 allows the minimally invasive treatment of different types of fistulas. Glubran[®] 2 is a palliative treatment of pain in bone metastases.

MODES OF APPLICATION

Surgical applications

Open the blister pack and take the single-dose product in sterile mode. Before opening the single-dose unit, check the state of fluidity of Glubran[®] 2 and its transparency. If the product is not very fluid and/or cloudy, it must not be used. Glubran[®] 2 must be withdrawn from the single-dose unit by means of a luer lock syringe with a 4-5 cm needle. Glubran[®] 2 can be applied with dedicated applicator devices or drop-by-drop directly with the same syringe with an insulin needle (approximately one drop of product per cm²). Before application, where possible, clean the area to be treated. In order to be effective, Glubran[®] 2 must come into direct contact with the tissues; for this reason, remove any collections/residues of blood, or any other liquid present, before application.

Glubran[®] 2 applied in small quantities with the dedicated applicator devices produces a thin adhesive film after polymerisation. Do not apply several drops on the same spot. Any excess product, within the first 5-6 seconds after application, can be removed with a dry pad or gauze. After application and until the polymerisation reaction is complete (60-90 sec), do not touch the product as it may come off or fail to produce the desired effect. The amount of excess product, after polymerisation, may result in the adhesive film peeling off and/or lead to the formation of small fragments that will tend to detach from the tissue and must always be removed. Excessive amounts of product prolong the polymerisation time and can lead to a lack of adhesion.

Glubran[®] 2 can be applied in sprayed form using the dedicated accessory devices (Ref. G2-NBT-xx) for both laparoscopic and laparotomic procedures; spraying the product allows an adequate amount of Glubran[®] 2 to be applied, forming a thin, elastic film that adheres to the tissue. In spray application, apply the product according to the relevant instructions for use of each spraying device.

Accessory devices for the correct application of Glubran[®] 2:

Syringe with insulin needle

Glubran[®] 2 is applied drop by drop using a syringe with an insulin needle. The product must be applied in an amount of approximately one drop per cm².

Drop-by-drop device (Ref. G2 DCD-210-8T)

This device allows a more accurate and controlled drop-by-drop application of Glubran[®] 2 compared to application with a syringe and insulin needle.

Applicator tip (Ref. G-DT)

The brush tip of the applicator tip allows a thin layer of Glubran[®] 2 to be applied directly onto the area to be treated.

Laparoscopic catheter (Ref. G2-LPC-xx)

This device allows the application of Glubran[®] 2 during laparoscopic surgery.

Spray device (Ref. G2-NBT-xx)

The system allows Glubran[®] 2 to be applied in sprayed form in laparotomic, laparoscopic, thoracoscopic and endoscopic surgeries.

Glutack (Ref. GB-DS xx)

This device allows the controlled application of Glubran[®] 2 in the form of calibrated drops in laparoscopic and laparotomic surgeries.

Skin application

Glubran[®] 2 can also be used for skin use. The product must be applied to the skin, externally, after the edges of the wound, which has been previously cleaned, have been brought together and made to fit perfectly. The wound edges should be held together for about 1 minute. Once polymerisation has taken place, no further correction is possible. After application, carefully check the treated fabrics for proper adhesion. Glubran[®] 2 will detach spontaneously 5-8 days after application. For this type of application, we recommend using the applicator tip.

CONTRAINDICATIONS

The product must not be applied in direct contact with brain tissue.

The product must not be applied within a vessel lumen, with the exception of treatments during digestive endoscopy, interventional radiology, venous sclerosis and embolization, and vascular neuroradiology.

The product must not be used in hypersensitive individuals and pregnant women.

The product must not be used on bleeding varices resulting from juvenile liver cirrhosis of unknown origin. The product must not be used in peripheral nerve anastomoses.

The product must not be dripped directly from the unit dose, but should be applied using one of the dedicated devices produced by the company or a syringe with an insulin needle.

PRECAUTIONS

Glubran® 2 has a slightly higher viscosity than water, so it must be applied very carefully to prevent the product from spreading into unwanted areas. If necessary, place gauze to protect the surrounding areas. Always check the compatibility of Glubran® 2 with other medical devices used during surgery, e.g. pure silicone or polycarbonate devices may affect the adhesion of the product (silicone) or trigger polymerisation (polycarbonate)

Glubran® 2 must always be applied in a minimum quantity: about 1 drop per cm², avoiding applying several drops on the same spot or a maximum of two passes with the spray device on the same part of the target tissue. A second layer of product may only be applied on top of the first after the latter has already cured.






















Any excess product, within the first 5-6 seconds after application, can be removed with a dry pad. The use of excess amounts of Glubran® 2 in areas at risk of infection (such as the uro-genital tract) has been associated with an increased risk of inflammation and/or infection.

The amount of excess product, after polymerisation, may result in the adhesive film peeling off and/or lead to the formation of small fragments that will tend to detach from the tissue and must always be removed. In addition, an excessive amount of product prolongs the polymerisation time and can lead to a lack of adhesion.

Avoid contact with the eyes. In case of accidental contact, wash immediately with water. If the product has polymerized, it will detach spontaneously after about 2-3 days.

Should the product come into contact with surgical instruments or anything else, it can be removed with acetone. Always check the compatibility of acetone with the material and the part to be treated.

WARNINGS

-  Glubran® 2 must only be used by qualified medical personnel. The manufacturer accepts no liability for damage caused by improper use compared with the indications of the following data sheet.
-  Any surgical and minimally invasive procedures should only be performed by persons who are adequately trained and familiar with such techniques. Consult the medical literature on techniques, complications and dangers before performing any surgical procedure.
-  Read all the information included in this instruction sheet carefully before use.
-  Do not use if the blister or single-dose is open or perforated. 
-  The product is disposable. 
-  The device is sterile and cannot be reused and resterilized after first opening. Reuse involves risks of infection for the patient due to loss of sterility of the contents and impairment of the product's bonding capacity and functionality. 
-  The product is ready for use.
-  Do not use Glubran® 2 with devices or accessories containing polycarbonate to avoid uncontrolled polymerisation of the product.
-  The product must not be diluted or mixed with dyes or other substances with the exception of tri-iodinated oil-based contrast media. Mixing with these substances has a proportionate effect on polymerisation times and the mixture must therefore be perfectly homogeneous and uniform.
-  In the case of endoscopic applications for sclerosis of gastric varices, the volume of Glubran® 2 must not exceed 1 ml per injection to avoid undesired effects such as embolism in districts not involved in the procedure. The total volume of product used to treat gastric varices may be more than 1 ml. In the case of endoscopic applications for sclerosis of oesophageal varices, the volume of Glubran® 2 must not exceed 0.5 ml per injection to avoid undesirable effects such as embolism in districts not involved in the procedure. The total volume of product used to treat oesophageal varices must not exceed 1 ml.
-  Always read the instructions of the applicator devices carefully before use
-  Do not use the adhesive if it has a viscous and/or cloudy appearance.
-  Any residual product must not be reused and must be disposed of.
-  The product cannot be re-sterilised. 
-  In rare cases, modest, temporary inflammatory reactions may occur after application.
-  When using Glubran® 2 as an adhesive for bonding large portions of fabric, it is recommended that the flaps be applied as quickly as possible so as not to lose part of the adhesive capacity in the first areas of product application.
-  When using Glubran® 2 as an adhesive for bonding portions/areas with considerable fatty tissue, it is recommended to apply a larger amount of product, always being careful not to overdo it in order not to create a rigid surface.

UNDESIRABLE EFFECTS

In rare cases, localised inflammatory reactions may occur in the area where the product is applied. Such reactions mainly occur when the amount of Glubran® 2 applied is higher than the recommended dose given in the section "Method of Application (Surgical Applications)".

In areas prone to infection (such as the uro-genital tract), too much of the product promotes the risk of inflammatory reactions that can progress into persistent infections.

In patients who are hypersensitive and/or tend to be allergic, use of the product may cause a strong allergic reaction, which in isolated cases may lead to anaphylaxis.

In some extravascular applications or during endovascular procedures, sensitive patients may experience a slight sensation of heat accompanied by a momentary pain that resolves spontaneously.

In endoscopic applications for sclerosis of gastric and oesophageal varices, embolisms may occur in districts not involved in the procedure if the indicated application quantities are not observed (see section Warnings).

STORAGE

The product must be stored between +2°C and +8°C. If it is necessary to store/transport the product outside this temperature range, it may be kept for a maximum of 5 days at temperatures no higher than 25°C.

VALIDITY

Properly stored, the product is valid for 2 years from the date of production. The product must not be used beyond its expiry date.

STERILITY

The product and its packaging (single-dose, trays and blisters) are sterile and do not contain latex or phthalates.

STERILE	A
---------	---

DISPOSAL

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

CONTACTS

Any serious incident that occurs, related to the device, should be reported to the manufacturer GEM srl at info@gemitaly.it and to the competent authority of the member state where the user and/or patient is established. In this case, a detailed description of the problem occurred is required, as well as the variable data of the medical device involved (sales code, batch number, UDI code).

PACKAGING AND PRODUCT CODES

See Table

REF.	Packaging	Format	GMDN	Basic UDI-DI
G-NB-2	10 single-dose/box	1 ml	58777	803190219X
G-NB2-75	6 single-dose/box	0.75 ml	58777	803190219X
G-NB2-60	6 single-dose/box	0.6 ml	58777	803190219X
G-NB2-50	10 single-dose/box	0.5 ml	58777	803190219X
G-NB2-35	6 single-dose/box	0.35 ml	58777	803190219X
G-NB2S-25	10 single-dose/box	0.25 ml	58777	803190219X

INTENDED USE AND INDICATIONS FOR USE

Glubran® 2 is intended for use on tissues with adhesive, sealing, haemostatic, sclerosing, embolising and bacteriostatic action.

It is indicated in traditional and laparoscopic surgery and in digestive endoscopy, interventional radiology and vascular neuroradiology.

Glubran® 2 can be applied to muscle, bone and cartilage tissue, endothelial, adipose, connective tissue, internal epithelia, parenchyma, mucous membranes and serous membranes (peritoneum, pleura, etc.).

Glubran® 2 reacts with all body fluids, such as blood, lymph, bile, gastric juice, pancreatic juice, etc.

Glubran® 2 also has haemostatic action on patients treated with anticoagulant drugs or suffering from congenital coagulation defects, as the polymerisation process is independent of the coagulation factors involved in haemostasis.

Below are some applications of the product in various surgical procedures. In order to learn the correct way to apply Glubran® 2 in all surgical applications, it is necessary to contact our company or authorised distributor and learn the appropriate technical instructions and professional medical literature.

Cardiac Surgery

- As a haemostatic and suture-reinforcing sealant on the myocardium.
- As a haemostatic and suture-reinforcing sealant on anastomoses (vessel-vascular and prosthetic-vascular).
- As a patch adhesive on the myocardium or to glue the dissection plane in aortic dissections.

Vascular surgery

- As a haemostatic and suture-reinforcing sealant on anastomoses (vessel-vascular and prosthetic-vascular).
- As an adhesive for the treatment of iatrogenic pseudoaneurysms, via percutaneous injections.
- As a filler and sclerosing agent for the treatment of varicose and insufficient veins of the lower limbs, by endovascular injection.

Neurosurgery

- As an adhesive and sealant for bonding patches on dural tissue.
- As a sealant to prevent liquor fistulas for trans-sphenoidal closure of the sella turcica.
- As an adhesive and sealant for bonding and bone and osteocartilaginous fragments.

Otolaryngology/Maxillofacial Surgery

- As a sealant for the treatment of CSFs in nasal-paranasal and pituitary surgery.
- As a sealant for the treatment of pharyngocutaneous and oroantral fistulas.
- As an adhesive in nose and paranasal sinuses surgery.
- As a sealant of palatal sutures in cleft lip and palate surgery.
- As an adhesive for bonding bone-cartilage fragments.
- As an adhesive to promote skin engraftment.

Odontostomatology

- As an adhesive for stabilising the bone window in sinus lift surgery.
- As an adhesive for the stabilisation of bio-filler materials in guided bone regeneration procedures.
- As an adhesive for closing endodontic-oral incisions.

Ophthalmology

- As an adhesive for fixation of the conjunctival flap in pterygioplasty surgery.
- As a sealant and adhesive for closing corneal perforations.

Paediatric surgery

- As a haemostatic on resections or lesions of parenchymatous organs (liver, kidney, pancreas, spleen).
- As a sealant and haemostatic on lung biopsies.
- As a suture substitute in circumcision and hypospadias.
- As a sealant and haemostatic in closing organ perforations.
- As a sealant in the treatment of fistulas.
- As a sclerosant in the treatment of gastro-oesophageal varices.
- As an adhesive and sealant in the closure of the patent processus vaginalis.

General surgery

- As an adhesive in the plasticisation of hernias and incisional hernias with patch/mesh in both traditional and laparoscopic surgery.
- As a sealant in the treatment of proctological fistulas.
- As sealant and reinforcement of gastrointestinal and rectal anastomoses.
- As a sealant in the treatment of gastrocutaneous fistulas.
- As sealant for prevention of bilomas and biliary fistulas following liver resection.
- As a haemostatic on parenchymal tissues (liver, pancreas, spleen, etc.) on internal epithelial, muscle and adipose tissue.

Bariatric surgery

- As an adhesive for bonding adipose tissue in omentoplasty procedures after sleeve gastrectomy.
- As sealant and suture reinforcement after Sleeve Gastrectomy or Roux-en Y Gastroenterostomy.

Plastic surgery

- As an adhesive, haemostatic for skin flap adhesion in abdominoplasty procedures.
- As a sealant in the prevention and treatment of seroma in abdominoplasty.
- As an adhesive and haemostatic in rhinoplasty surgery.
- As an adhesive in breast reconstructive surgery.

Thoracic surgery

- As a reinforcing sealant for immediate aerostasis and increased mechanical sealing.
- As a sealant for bronchial and bronchopleural fistulas.

Gynaecological surgery

- As an adhesive and haemostatic in vaginal and perineal plastics.
- As a sealant for the prevention and treatment of inguinal lymphocele and lymphorrhoea.
- As a surgical mesh bonding agent for the treatment of prolapse.

Breast surgery

- As a sealant for the prevention and treatment of seroma and lymphorrhoea following mastectomy, quadrantectomy and axillary lymphadenectomy procedures.

Urological surgery

- As a haemostatic and sealant during kidney transplant.
- As a sealant and haemostatic on lacerations and haemorrhagic renal injuries.
- As a sealant and haemostatic of the excretory route in partial nephrectomy surgery.
- As a sealant in the treatment of urinary fistulas.
- As a sealant in the treatment of post-surgery lymphorrhoea.
- As a suture substitute in phimosis, circumcision and frenulotomy surgery.
- As a graft adhesive in urethroplasty procedures.
- As a haemostatic on endoscopic resections of bladder tumours.


















Digestive endoscopy

- As a sealant in the endoscopic treatment of oesophageal, gastric, gastrointestinal, duodenal and pancreatic fistulas.
- As a hemostat and sealant in the endoscopic treatment and prevention of bleeding following gastrointestinal mucosal and submucosal resection.
- As a haemostatic in the endoscopic treatment of bleeding gastroduodenal ulcers.
- As a sclerosant in the endoscopic treatment of oesophageal, gastric and duodenal varices.

Interventional radiology and vascular neuroradiology

- As an embolysers in embolisation and sclerosis of arteries and veins.
- As an embolysers in the treatment of vascular malformations and fistulas.
- As an embolysers in the treatment of endoleak.
- As a sealant in the treatment of postsurgical fistulas.
- As a prostatic artery embolysers in the treatment of prostate adenoma.

SYMBOLS USED

	Manufacturer's data		Do not re-sterilise
	Medical Device, the item is a medical device		Do not use if the packaging is damaged
	CE mark and Notified Body identification number		Single-dose / Do not reuse
	Code/catalogue number		See the Instructions for Use
	Expiry date		Unique device identifier
	Batch code		Production date
	Sterilised using aseptic techniques		Keep dry
	Sterile double barrier system		Keep out of direct sunlight
	Upper and lower temperature limits to which the medical device can be safely exposed		

Definitions

Incident: Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Serious incident: Any incident that directly or indirectly led, might have led or might lead to any of the following: Death of a patient, user or other person; Serious deterioration, temporary or permanent, of the health of a patient, user or other person or a serious threat to public health.

Serious public health threat: an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

SSCP: Safety and Clinical Performance Summary (SSCP) Available on the Eudamed portal once active.