GLUBRAN®2

CE 0373

PATIENT LEAFLET

WHAT IS GLUBRAN®2 AND WHAT IS IT USED FOR?

Glubran 2 is a class III medical device (for internal and external surgical use) that complies with the applicable European Regulations.

Glubran 2 is a synthetic cyanoacrylate liquid (NBCA - MS Co-monomer) modified by addition of a monomer synthesised by the manufacturer.

Glubran 2 has outstanding haemostatic and adhesive properties, and once set (solidified), it provides an effective antiseptic barrier against infectious agents or pathogens commonly encountered in surgical settings. It is a pale yellow, transparent liquid supplied ready for use.It polymerises rapidly in contact with viable tissue and in moist environments, to create a thin elastic layer with a high tensile strength that ensures firm adhesion to tissues. This layer adjusts naturally to the anatomy of the underlying tissues, it is waterproof and is not adversely affected by blood or other body fluids. Once set (solidified), the layer can be easily perforated by a suture needle as the polymerisation of the product does not generate glass-like aggregates. The polymerisation time depends on the type of tissue with which Glubran 2 comes into contact, the nature of the fluids present and the amount of product applied. When applied correctly, the glue starts to set after 1-2 seconds and completes its setting reaction in approximately 60-90 seconds. Glubran 2 reaches its maximum mechanical strength on completion of this reaction. Once set, Glubran 2 no longer possesses adhesive properties, so tissues or surgical gauzes may be placed over or in contact with it without any risk of unwanted adhesion. The polymerisation reaction generates a temperature of approximately 45°C.

PACKAGING AND PRODUCT CODES

See Table The glue and its primary packaging are sterile and do not contain latex.

REF	Packaging	Volume
G-NB-2	10 single-dose vials/box	1 ml
G-NB2-75	6 single-dose vials/box	0,75 ml
G-NB2-60	6 single-dose vials/box	0,6 ml
G-NB2-50	10 single-dose vials/box	0,5 ml
G-NB2-35	6 single-dose vials/box	0,35 ml
G-NB2S-25	10 single-dose vials/box	0,25 ml

GLUBRAN®2 IS USED BY QUALIFIED PHYSICIANS IN PEDIATRIC POPULATION AND ADULTS FOR THE FOLLOWING INDICATIONS:

Glubran 2 must be used only by qualified physicians with experience using the product.

Glubran 2 has an adhesive, sealant, haemostatic, sclerosing, embolic and bacteriostatic effect on tissues.

It is used in conventional and laparoscopic surgery and in digestive endoscopy, interventional radiology and vascular neuroradiology procedures.

It may be used alone or in combination with sutures, even in patients treated with heparin and patients with hypothermia. Examples of application in various type s of surgery are provided below. There are no contraindications to the use of this device in pediatric and adult polpulation.

Attention is drawn to the Warnings, Precautions, and Special Patient Populations.

Skin Application

In sterile environments, Glubran 2 can be used also on the skin.

The product must never be applied inside wound flaps, rather it must be applied to the skin once the margins of the previously cleansed wound have been brought together and perfectly aligned.

The wound margins must be held firmly together for about one minute. Once polymerisation has taken place, no further modifications are possible.

After application, carefully check the correct adhesion of the treated tissues. Glubran 2 will detach spontaneously 5-8 days after application.

Cardiac surgery

- Consolidation of aortic and other vascular sutures.
- Repair of minor epicardial tears without use of sutures.
- Haemostasis and reinforcement of coronary by-pass anastomoses and as an adhesive to optimise and secure coronary by-pass grafting.
- Coating of perianeurysmal tissue in ventricular aneurysm surgery.
- Reinforcement of sutures and patch adhesion in left ventricular reduction (LVR) procedures.
- As an adhesive to secure the dissection plane in acute aortic dissections.
- As a haemostatic agent in the prevention of proximal and distal anastomotic bleeding in acute aortic dissections.
- As an adhesive for bonding patches to reinforce dissected aortas.
- As a haemostatic agent in aortic valve surgery anastomoses, particularly in the presence of calcific or atheromatous aortas.
- Haemostasis and reinforcement of sutures after aortic aneurysm repair.
- In re-operations, as a haemostatic adhesive on ventricular tears caused by re-sternotomy or adhesions.

Paediatric cardiac surgery

- Consolidation of aortic and other vascular sutures.
- As a haemostatic agent on suture lines between biological and/or synthetic tissue in the reconstruction of cardiac and vascular walls.
- In re-operations, as a haemostatic agent on suture lines and in areas of oozing bleeding.

Vascular surgery

- Haemostasis and reinforcement of anastomoses in general, particularly in the presence of fragile vascular walls or those subjected to endarterectomy.

- Haemostasis and reinforcement of anastomoses in vascular-prosthetic and/or vasculo-vascular by-passes.
- As a haemostatic agent on bleeding suture lines after carotid endarterectomy with patch angioplasty.
- As a haemostatic agent in vascular bleeding sites.
- Haemostasis and reinforcement of anastomoses after aortic aneurysm repair.
- Haemostasis and reinforcement of anastomoses in the construction of arterio-venous fistulas.
- As an antiseptic barrier in all anastomosis sites.
- Treatment of varicose veins and venous insufficiency of the lower limbs.
- Treatment of iatrogenic pseudoaneurysms.
- Treatment of prosthetic-cutaneous fistulas.
- Treatment of osteocutaneous fistulas in limb amputation stumps.

Neurosurgery

- As an external sealant in cranial and spinal dural plastic surgery to prevent CSF fistulas in combination with resorbable haemostatic gauzes and sponges used to protect the cerebral parenchyma.
- As a sealant in dural plastic surgery, in the residual cavities following tumour removal.
- As a sealant in dural tears during hemilaminectomy procedures.
- Closure of the sella turcica via the transsphenoidal route.
- Bonding of bone and osteocartilaginous fragments.
- Bonding of intercostal and cervical muscles.
- Bonding in elective of bone opercula

Ophthalmology

- Pterygium procedures
- Sealing of corneal tears and lesions
- Closure of leaks caused by eye injuries
- Scleral-fixated IOL surgery
- Keratoplasty
- Closure of the scleral opening in trabeculectomy procedures

ENT/Maxillofacial surgery/Odontostomatology

- Sealant for CSF fistulas in nasal/paranasal sinus and pituitary gland surgery.
- Sealing of pharyngocutaneous and oroantral fistulas.
- Sealant for protection against salivary contamination in oral and rhino-pharyngeal surgery.
- Sealing of palatal sutures in cleft lip and palate and uvulopalatoplasty procedures.
- Sealant for post-traumatic or post-ear surgery oto-liquorrhoea.
- Treatment of seromas, laterocervical-supraclavicular lymphorrhagia after lymph node removal.
- Haemostasis of bleeding surfaces of the oral and pharyngeal cavities.
- Haemostasis in muscle dissection areas (i.e. skin flaps)
- Haemostasis of osteotomy stumps.
- Stabilisation of the bone window in maxillary sinus lift procedures.
- Stabilisation of bio-filler material in guided bone regeneration procedures.
- Closure of retroauricular wounds during tympanoplasty procedures.
- Closure of endoral incisions.
- Bonding of osteocartilaginous fragments.
- To promote the sealing of tracheoesophageal voice prostheses in cases of leaks between the prosthesis and the trachea.
- To promote skin graft attachment.

Paediatric surgery

- Haemostasis during liver resection surgery.
- Bonding, repair and haemostasis of parenchymal tissue for tears or haemorrhagic lesions of the liver, kidney, pancreas, or spleen.
- Haemostasis of margins after laparoscopic wedge biopsies of the liver.
- Hepatic vascular bed haemostasis after conventional or laparoscopic cholecystectomy.
- Sealing and reinforcement of digestive tract anastomoses after bowel resection.
- Sealing of anastomoses in biliary tract reconstruction.
- As an adhesive in laparoscopic closure of the peritoneo-vaginal canal in congenital inguinal hernias.
- Sealing of surgical sutures to prevent extravasation of urine after construction of anastomoses in urological disorders.
- Aerostasis of parenchymal tissue after laparoscopic lung biopsy.

General surgery/Plastic surgery

- As an adhesive in both conventional and laparoscopic inguinal hernia repair surgery and laparoceles repair using patches.
- Haemostasis in liver resections.
- Haemostasis of the gallbladder vascular bed in conventional and laparoscopic surgery.
- Bonding, repair and haemostasis of parenchymal tissue for tears or haemorrhagic lesions of the liver, kidney, pancreas, or spleen.
- Sealing and reinforcement of gastrointestinal and rectal anastomoses.
- Sealing and haemostasis of gastric sutures.
- Bonding of adipose tissue in omentoplasty procedures after sleeve gastrectomy and for the closure of Petersen's defects after gastric by-pass surgery.
- Treatment of gastrocutaneous fistulas.
- Haemostasis, prevention and treatment of seromas and skin flap adhesion in abdominoplasty procedures.
- Haemostasis of portacaval anastomoses.
- Sealant for appendix stumps.
- Sealant in rectovaginal septum reconstruction.
- Sealant for anastomoses in biliary tract and pancreatic duct reconstruction.

- Treatment of anal and perianal fistulas.
- Prevention of bilomas and biliary fistulas following liver resection.

Thoracic surgery

- Sealing and reinforcement of sutures or staples in lung resections, lobectomies, pneumonectomies, bullectomies, volume reduction procedures and tracheobronchial resections, to obtain immediate aerostasis and an improved mechanical seal.
- Sealing and reinforcement of vascular sutures during lung transplants.
- Sealing and reinforcement of sutures after tracheal resection.
- Haemostasis of oozing bleeding after detachments and dissections e.g. decortications, pleural cavity obliterations due to adhesions, tumours and mediastinal masses.
- Sealing of bronchial and bronchopleural fistulas.

Gynaecological/Breast surgery

- As a bonding and haemostatic agent in cervical trauma.
- As a bonding and haemostatic agent in vaginal and perineal plastic surgery.
- Vaginal haemostasis after hysterectomy and urethrocystopexy.
- Sealing and haemostasis of oozing haemorrhages.
- Sealing and haemostasis in reconstructive surgery after destructive oncological procedures.
- Prevention and treatment of seroma and lymphorrhoea following mastectomy, quadrantectomy and axillary lymphadenectomy procedures.
- Prevention and treatment of lymphocele and inguinal lymphorrhoea.
- As a surgical mesh bonding agent for the treatment of prolapse.

Urological surgery

- Sealing of surgical sutures to prevent extravasation of urine.
- Haemostasis during kidney transplants and nephrolithotomies.
- Sealing and haemostasis of kidney tears and haemorrhagic lesions.
- Sealing and haemostasis of the excretory pathways in partial nephrectomy procedures.
- Treatment of urinary fistulas.
- Treatment of postoperative lymphorrhoea.
- As suture in phimosis, circumcision and frenulotomy procedures.

Digestive endoscopy

- Endoscopic treatment of oesophageal and oesophagotracheal, gastric, gastro-intestinal, duodenal, and pancreatic fistulas.
- Endoscopic treatment and prevention of bleeding following gastrointestinal mucosal and submucosal resection.
- Endoscopic treatment of gastric, duodenal and peptic ulcers.
- Endoscopic treatment of oesophageal, gastric and duodenal varices.

International radiology and vascular neuroradiology

- Arterial and venous embolisation and sclerosis.
- Treatment of vascular malformations and fistulas.
- Treatment of endoleaks.
- Treatment of postsurgical fistulas.
- To ensure haemostasis after removal of vascular introducers in femoral endovascular procedures.

International radiology and vascular neuroradiology

- To ensure haemostasis after removal of vascular introducers in femoral endovascular procedures.

ADVERSE EFFECTS

Although rare, inflammatory reactions may occur at the product application site.

These reactions mainly occur when the amount of Glubran 2 applied exceeds the recommended dose indicated in the section"Method of Use (Surgical Applications)." In areas prone to infection (such as the urogenital system), an excessive amount of product increases the risk of inflammatory reactions that may cause persistent infections.

In hypersensitive and/or allergic patients, use of the product may cause a severe allergic reaction and, in rare cases, anaphylaxis. In some extravascular applications or during endovascular procedures, sensitive patients may experience a slight burning sensation accompanied by temporary pain, which will subside spontaneously.

For any other adverse effect unmentioned, please contact your health professionals.

CONTRAINDICATIONS

Do not apply the product directly to cerebral tissue.

Do not apply the product inside a vessel lumen, except in the case of treatment during digestive endoscopy, interventional radiology and vascular neuroradiology procedures.

When used for skin closure applications, never apply the product inside wound margins, but only to the surface of the skin, once the thoroughly cleansed wound margins have been perfectly aligned.

Do not use the product in particularly sensitive subjects or pregnant women.

Do not use the product on bleeding varices caused by juvenile liver cirrhosis of unknown origin.

Do not use the product for peripheral nerve anastomoses.

PRECAUTIONS

The viscosity of the Glubran 2 is only slightly greater than that of water, and therefore the product must be applied very carefully to prevent it from spreading to unwanted areas; when necessary, apply gauzes to protect the surrounding areas.

Always apply in minimal amounts, i.e. approximately one drop per square centimetre, and do not apply more than one drop in the same point. A second layer of Glubran 2 can be applied over the first once it has polymerised.

Any excess product may be removed using a dry swab within 5-6 seconds after application.

Use of excess amounts of Glubran 2 in areas prone to infection, such as the vagina, has been associated with an increased risk of inflammation and/or infection. After polymerisation, any excess product may lead to detachment of the adhesive layer and/or result in the formation of small fragments that tend to detach from the tissues and should always be removed.

An excessive amount of product prolongs the setting time and can prevent adhesion.

Avoid contact with the eyes. In case of accidental contact, wash with water immediately. If the product has polymerised, it will detach spontaneously after about 2-3 days.
Should the product come into contact with surgical instruments or other materials, it can be removed using acetone.
Consult your doctor about possible side effects.

WARNINGS

⚠ Glubran 2 must be used only by qualified physicians with experience using the product. The manufacturer shall not be liable for damage caused by any use other than those outlined in this technical data sheet.

⚠ The product is for single use only.

⚠ Do not reuse the device after the first opening. Reuse involves a substantial risk of infection for the patient due to lack of content sterility, failure of adhesive properties and impaired product efficacy due to contact with the air.

⚠ The product is supplied ready for use.

⚠ 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 case of endovascular application, the volume of Glubran 2 used must not exceed 1 mL per injection, in order to prevent adverse effects, such as embolism, in areas not concerned by the procedure.

⚠ Do not use Glubran 2 with devices or accessories containing silicone or polycarbonate. Always make sure that any devices used are sterile and compatible with the product, in order to prevent any induction of polymerisation or degradation of Glubran 2.

⚠ Do not use the product if it is viscous and/or cloudy.

⚠ Any leftover product must be discarded.

⚠ The product cannot be re-sterilised.

⚠ Although rare, temporary local inflammatory reactions may occur after application.

⚠ When used for application on the skin, although the exothermal reaction that occurs during polymerization does not exceed 45°C, it may cause a slight burning sensation in particularly sensitive patients (e.g. children and elderly subjects) at the Glubran 2 application site.

⚠ Please see the full list of precautions and contraindications in the instruction for use.

SHELF LIFE

During normal surgical procedures, the layer of Glubran 2 is eliminated by hydrolytic breakdown, a process whose duration varies according to tissue type and the quantity of Glubran 2 applied. In embolisation procedures, Glubran 2 persists for a longer period of time.

STERILITY

The glue and its primary packaging are sterile and do not contain latex.

DISPOSAL METHOD

After use follows the local procedures and guidelines of the place.

CONTACT

Any serious incident that occurs in relation to the device should be reported to the manufacturer GEM SRL and to the Therapeutic Goods Administration www.tga.gov.au.

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List of symbols

Patient Name or patient ID

Information website for patients

Date of implantation

"Use By." This symbol shall be adjacent to the expiration date

Name and Address of the implanting healthcare institution/provider

Lot Number/Batch Code

Name and Address of the manufacturer

STERILE A

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