

GLUBRAN® 2

Surgical Glue – Rif. G-NB-2

TECHNICAL CARD

CE 0373

Composition:

NBCA - MS Co-monomer

CHARACTERISTICS

GLUBRAN 2 Surgical Glue is a class III medical-surgical product (for internal and external surgical use) which fulfils the requirements of the European Directive on Medical Devices 93/42/EEC. GLUBRAN 2 is a synthetic cyanoacrylic surgical glue modified by addition of a monomer synthesized by the manufacturer. GLUBRAN 2 surgical glue has outstanding haemostatic and adhesive properties, and once set (solidified), the glue produces an effective antiseptic barrier against infectious agents or pathogens commonly found in surgical settings. It is a pale yellow, transparent liquid ready for use. It polymerises rapidly in contact with living tissue and in moist environments, to create a thin elastic film of high tensile strength that ensures firm adherence to tissues. The film conforms naturally to the anatomy of the tissue on which it has been applied, it is waterproof and is not impaired by blood or organic fluids. Once set, the film may be easily perforated by a suture needle as the product polymerization does not generate glass-like aggregates. The polymerization time depends on the type of tissue with which the glue comes into contact, the nature of the fluids present and the amount of product applied. When applied properly, the glue starts to set after 1-2 seconds and completes its setting reaction after about 60-90 seconds. The glue reaches its maximum mechanical strength on completion of this reaction. Once set, the glue no longer possesses adhesive properties so that tissues or surgical gauzes may be placed in contact with it without any risk of unwanted adhesion. In normal surgical procedures, the film of glue is eliminated by hydrolytic breakdown, a process whose duration varies according to tissue type and quantity of glue applied. In embolization procedures, the glue remains for a longer period of time. The polymerization reaction generates a temperature of approximately 45°C.

METHOD OF USE

Surgical Applications

Open the blister and pour the sterile single-dose vial directly on the surgical table in a sterile field.

Before opening the single-dose vial, check transparency and fluidity of the glue. If the product appears cloudy and/or thickened, it should not be used. Draw the glue out of the single-dose vial with a sterile 4-5 cm needle luer lock insulin syringe. The glue can be directly applied a drop at a time using the same syringe with an insulin needle (approximately one drop per sq.cm). Whenever possible, clean the area to be treated before applying the glue. The glue applied in minimum amount will form, with polymerization, a thin adhesive film. For this purpose, it is essential not to apply more than one drop in the same spot. Any second layer of glue may be applied over the first only when this has already polymerized. Any excess product may be removed with a dry swab within the first 5-6 seconds after its application. After application and until the polymerization reaction is complete, do not touch the glue as it may detach or not produce the effect desired. After polymerization, the amount of product in excess may lead to detachment of the adhesive film and/or give rise to the formation of small fragments which tend to become detached from the tissues and which should always be removed. Moreover, an excessive amount of product, in addition to prolonging setting time, can prevent adherence. The glue can be sprayed; in this case it is advisable to protect the areas surrounding those to be treated.

Skin Closure Applications

The glue can be used in a sterile environment on the skin. The glue must not be applied into the wound but only on the skin after having made sure that the wound is perfectly clean and the two damaged sides of the tissue perfectly fit together. The edges of the wound must be kept firmly joined for about one minute. When polymerization occurs no other modifications are possible. After application, carefully check that the treated edges of the wound properly stick together. The glue will spontaneously detach after 5-8 days after application.

CONTRAINDICATIONS

Do not apply the glue directly to cerebral tissue.

Do not apply the glue inside a vessel lumen, except in the case of treatments during digestive tract endoscopy, interventional radiology and vascular neuroradiology.

When used in skin closure applications, the glue should never be applied inside wound margins, but only

to the skin surface, after the margins of the wound have been joined perfectly and previously cleaned thoroughly.

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

Do not use the glue on bleeding varices caused by juvenile liver cyrrhosis of unknown origin.

Do not use the glue for anastomoses of peripheral nerves.

PRECAUTIONS

The viscosity of the glue is only slightly greater than that of water, so the glue should be applied very carefully to prevent its spread to unwanted areas; when necessary, apply gauzes to the protect surrounding areas. The glue should always be applied in minimal amounts, i.e. approximately one drop per square centimetre, avoiding the application of more than one drop in any given spot. A second layer of glue can be applied over the first only after its full polymerization.

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

After polymerization, any excess product may lead to detachment of the adhesive film and/or give rise to the formation of small fragments which tend to become detached from the tissues and which should always be removed.

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

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

Should the glue come into contact with surgical instruments or other materials, it can be removed with acetone.

WARNING

The glue must be used only by qualified physicians who have experience in using this product. The manufacturer shall not be liable for damages caused by any uses other than those outlined in this technical data sheet.

The glue is a disposable product.

The glue is ready for use.

The glue is not meant to be diluted or mixed with other substances, except for substances used to make it radio-opaque. However, such mixing shall proportionally change polymerization times.

Do not use the glue with instruments or accessories containing silicone or polycarbonate. Always make sure that instruments and accessories are sterile and compatible with the product to prevent any induction of polymerization or breakdown of the glue.

Do not use if thickened and/or cloudy.

Any glue remaining in the single-dose vial should not be re-used and should be discarded.

The glue cannot be re-sterilised.

In rare cases, after application, a temporary local inflammatory reaction may occur.

When used for skin applications, the exothermal reaction during polymerization, though not exceeding 45°C, may sometimes cause a slight sensation of heat in particularly sensitive patients (e.g. children and elderly subjects) at the glue application site.

STORAGE: The product should be stored at temperatures between 0°C and +4°C.

SHELF LIFE: When properly stored, the product has a shelf life of 2 years from the date of manufacture. The product should not be used after its expiration date.

STERILITY: The glue is sterile.

PACKAGING: One package contains 6 1-ml single-dose vials.

PRODUCT CODE: G-NB-2

INDICATIONS

GLUBRAN 2 Surgical Glue has an adhesive and haemostatic action on tissues. It is used in traditional and laparoscopic surgery and in digestive tract endoscopy treatments, interventional radiology and vascular neuroradiology. It may be applied alone or in combination with sutures, even in patients being treated with heparin and in hypothermia.

Given below are examples of applications in various types of surgery:

Cardiac Surgery

- Consolidation of aortic and vascular sutures in general.
- Repair of minor epicardial lacerations without the use of sutures.
- Haemostasis and reinforcement of coronary by-pass anastomoses and as an adhesive to optimise and secure the path of coronary by-passes on the heart.
- Coating of perianeurysmal tissue in ventricular aneurysm surgery.
- Reinforcement of sutures and patch adhesion in left ventricle 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 anastomosis bleeding in acute aortic dissections.
- As an adhesive to glue 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 lacerations of the ventricle caused by re-sternotomy or adhesions.

Paediatric Cardiac Surgery

- Consolidation of aortic and vascular sutures in general.
- As a haemostatic agent on suture lines between biological and/or synthetic tissues 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 vascular walls subjected to endarterectomy.
- Haemostasis and reinforcement of anastomoses in vascular-prosthetic and/or vasculo-vascular by-passes.
- As a haemostatic agent at bleeding points of suture following carotid endarterectomy with patch angioplasty.
- 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 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 liquor (CSF) fistulas in combination with absorbable hemostatic gauzes and sponges used to protect the cerebral parenchyma.
- As a sealant in dural plastic surgery in residual cavities following tumour removal.
- As sealant in dural lacerations in hemi-laminectomy operations.
- Closure of the sella turcica through trans-sphenoidal route.
- Gluing of bone and osteocartilaginous fragments.
- Gluing of intercostal and cervical muscles.
- Gluing in election of bone opercula.

ENT Surgery

- Sealing of CSF fistulas in operations in nose/paranasal sinus and hypophysis surgery.
- Sealing of pharyngocutaneous fistulas.
- Salivary sealing in oral and rhino-pharyngeal cavity surgery.
- Sealing of 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 dissected muscle areas (i.e. skin flaps).
- Haemostasis of osteotomy stumps.
- Closure of retroauricular wounds in tympanoplasty operations.
- Gluing of osteocartilaginous fragments.
- To promote sealing of oesophago-tracheal phonatory valves in cases of leakage between the valve and the trachea.
- To promote attachment of skin grafts.

Paediatric Surgery

- Haemostasis of liver sections.
- Gluing, repair and haemostasis of parenchymal tissue on lacerations or haemorrhagic lesions of the liver, kidney, pancreas, or spleen.
- Haemostasis of sections after laparoscopic liver wedge biopsies.
- Haemostasis of liver bed after traditional surgical 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 peritoneal-vaginal canal in congenital inguinal hernias.
- Sealing of surgical sutures to prevent urine extravasation after construction of anastomoses in urological disorders.
- Aerostasis of parenchymal tissue after laparoscopic lung biopsy.

General Surgery

- As an adhesive in both traditional and laparoscopic inguinal hernia repair surgery with patches.
- Haemostasis of liver sections.
- Haemostasis of the bleeding gallbladder bed in traditional and laparoscopic surgery.
- Gluing, repair and haemostasis of parenchymal tissue on lacerations or haemorrhagic lesions of the liver, kidney, pancreas, or spleen.
- Sealing and reinforcement of gastrointestinal anastomoses.
- Haemostasis of portacaval anastomoses.
- Sealing of appendix stump.
- Sealing in recto-vaginal septum reconstruction.
- Sealing of anastomoses in biliary tract and pancreatic duct reconstruction.
- Treatment of axillary and inguinal lymphorrhoea.

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 improved mechanical sealing.
- 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 cavities obliterated by adhesions, tumours and mediastinal masses.
- Sealing of bronchial and bronchopleural fistulas.

Gynaecological Surgery

- As an adhesive and haemostatic agent in cervical trauma.
- As an adhesive 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 oncological demolition procedures.

Urological Surgery

- Sealing of surgical sutures to prevent urinary extravasation.
- Haemostasis in the course of kidney transplants and nephrolithotomies.
- Sealing and haemostasis of kidney lacerations and haemorrhagic lesions.
- Sealing and haemostasis of excretory pathways in partial nephrectomy operations.
- Treatment of urinary fistulas.
- Treatment of postoperative lymphorrhoea.

Digestive Tract Endoscopy

- Endoscopic treatment of oesophageal and oesophagotracheal, gastric, gastro-intestinal, duodenal, and pancreatic fistulas.
- Endoscopic treatment of gastric, duodenal and peptic ulcers.
- Endoscopic treatment of oesophageal, gastric and duodenal varices.

Interventional Radiology and Vascular Neuroradiology

- Arterial and venous embolizations.



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