

Two Component Skin Adhesive and applicator tip Ref. G-NBOC2

TECHNICAL CARD

Composition:

NBCA (n- butyl 2 cyanoacrylate)

OCA (2- octyl cyanoacrylate)

CHARACTERISTICS

GLUBRAN TISS 2 Skin Adhesive is a class II medical-surgical device, which meets the European Regulations in force.

GLUBRAN TISS 2 is a second generation, two component skin glue. It is supplied together with its single-use applicator tip in a blister pack.

GLUBRAN TISS2 is ready to use, sterile, cyanoacrylate-based.

It is a pale yellow liquid that polymerizes quickly when in contact with tissues, creating a thin elastic waterproof film of high tensile strength to ensure a firm adherence to tissues. Its fluidity and its applicator characteristics allow the controlled release of the adhesive even in areas difficult to treat. Once polymerised (60 – 90 sec.), it has no longer any adhesive properties.

The polymerized adhesive produces an effective antiseptic barrier against infectious bacteria responsible for the most common infections.

The product is compatible with most catheters used for central and peripheral venous accesses (CVC, PICC and Midline).

The product is available in 0.25 ml, 0.35 ml and 0.5 ml. Each case contains 10 blisters with sterile single vial and applicator tip.

INTENDED USE

Treatment of skin lacerations and cuts no longer than 7-8 cm.

The device can be applied in all skin lesions caused by trauma or by surgical incisions.

The device can be applied in the insertion sites of catheters used for central and peripheral venous accesses in order to reduce dislocations, to protect them from bacterial infections by barrier effect and to make hemostasis even in patients with, congenital and not congenital, coagulation defects.

Indicated also for use in pediatrics.

Recommended for the sealing of surgical wounds in case of dental implant operations, oral and maxilla-facial surgery.

It can be also applied on lesions of the oral mucosa caused by traumas or surgical cuts.

METHOD OF USE

Glubran Tiss 2 is easy and rapid to apply:

1. Open the blister and pull out the vial and the tip.
2. Drain the product at the bottom of the vial by keeping it upright with the cap facing upwards.
3. Turn and remove the cap of the vial
4. Insert the applicator tip onto the neck of the vial, by making sure it is correctly fixed before proceeding to apply the adhesive.
5. Turn the vial upside down, so that the adhesive is drained off at its end. Exert a slight pressure on the body of the vial to let the adhesive tip soak. Be careful not to press excessively to prevent the product from leaking.
6. Make sure that the margins of the lesion are approximated; apply a thin layer of adhesive to the wound. Excessive product quantity delays the curing time, reduces the tensile strength of the adhesive at the point of application, and induces an incorrect wound healing.

The edges of the wound must be kept joined for about one minute. When polymerization occurs, no other correction is possible. The detachment of the adhesive will spontaneously occur about 5-8 days following the application.

CONTRAINDICATIONS

The adhesive must never be applied inside the flaps of a wound, but only onto the skin after having approached the edges of the wound, previously cleaned and dried.

Do not apply on infected, chronic, gangrenous, or subsequent to pressure ulcers wounds.

The adhesive must not be used in hypersensitive subjects to the product.

Do not use the product if the tissue is inflamed or oedematous.

Do not use in the case of pus or purulent exudates because of an infectious process.

PRECAUTIONS

Before using the product, check the fluidity and the transparency of the glue inside the vial. If the product is thickened and/or cloudy, it should not be used.

The product should always be applied in a minimum quantity. A second layer of adhesive can be applied over the first, only when the latter has polymerized.









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

Do not let the adhesive to come into contact with your eyes. In case of accidental contact wash immediately with water. If the product had polymerized its detachment will occur spontaneously after about 2-3 days.

Should the adhesive come into contact with surgical instruments, it can be removed with acetone.

Avoid prolonged contact with water and detergents in the days following the application. Do not rub the treated surface and dry by gently wiping with a soft cloth.

WARNING

-  Only qualified physicians experienced in using the product can use the adhesive. The user is responsible for the correct use of the product.
-  GLUBRAN TISS2 is suitable for the treatment of recent wounds of the skin which have been cleaned thoroughly and when its edges can be easily joined together. In case of margin tension it will be necessary to perform a subcutaneous suture.
-  Do not use the adhesive if thickened and/or cloudy.
-  The adhesive is a single use product.
-  Do not reuse or resterilize the device after its first opening. Its reuse involves risks of Infection to the patient for loss of sterility of the content.
-  Discard any remaining glue.
-  Rarely, after application, a slight but temporary local inflammatory reaction may occur. The exothermic reaction during the polymerization, though not exceeding 50°C, may sometimes cause a slight sensation of heat in hypersensitive patients (e.g.: children or elderly subjects) at the glue application site.
-  It is not advisable to use the product for fixing catheters consisting of silicone only.

STORAGE

The product should be stored at temperatures between +2 °C and +8°C.

In the event that the product has to be stored outside this temperature range, it can be stored for up to 48 hours at 22.5°C ± 2.5°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 product is sterile.

PACKAGING AND PRODUCT CODES

See the chart:

REF	PACKAGING	VOL.	CND	GMDN
G-NBOC2	10 single dose with tip/pack.	0.50 ml	H90010102	34164
G-NBOC2-35	10 single dose with tip/pack.	0.35 ml	H90010102	34164
G-NBOC2-25	10 single dose with tip/pack.	0.25 ml	H90010102	34164

