

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory



n-Butyl 2-Cyanoacrylate

SURGBOND

Sterile Bio - Adhesive



COMPOSITION

Each ampoule of Surgbond contains

n-Butyl 2-Cyanoacrylate.....0.25 ml / 0.50 ml & 1.0 ml

CLINICAL INFORMATION

INDICATIONS

Surgbond topical skin adhesive is intended for tropical application, only to hold closed, easily approximated skin edges of wounds from surgical incisions, and

- Closure of external surgical and Post-traumatic wounds.
- Closure of external incisional wounds i.e., in appendectomy; cholecystectomy; GI resections: biopsy; gastro jejunostomy; other abdominal surgeries; surgery on exposed body areas; laparoscopic incisions.
- Closure of Gynaec and Obstetric external incisional wounds i.e., in episiotomy; caesarean section; hysterectomy; oophorectomy ; laparoscopy.
- Plastic & Cosmetic surgery including all facial surgeries; surgery to remove scars; earlobe repairs; corrective breast surgery.
- Closure of external incisional wounds in family planning surgeries.
- Closure of post-traumatic wounds i.e., cuts and lacerations.
- As a sealant in obliterating bleeding varices in gastroendoscopy.

Wound closure with Surgbond leads to significantly better wound healing because the polymeric film binds the edges strongly and seals the wound precisely, allowing a perfect wound closure under Surgbond bacteriostatic cover. Wound inflammation is curtailed to a large extent when treated with Surgbond.

In a clinical study, n-Butyl 2-Cyanoacrylate injected endoscopically into the varix is reported to stop the bleeding in upto 93% of cases with a single session. n-Butyl 2-Cyanoacrylate was also found to be effective in ocular surgeries for temporary or permanent closure of an impending or frank corneal perforation .

DOSAGE

The dose depends on the severity and area of the wound. An ampoule of Surgbond containing 0.25 ml closes wound upto 5 cms; ampoule containing 0.50 ml closes wound upto 10 cms and ampoule containing 1.00 ml closes wound upto 20 cms. Surgbond may be used in conjunction with, but not in place of subcuticular sutures. For deeper wounds, absorbent suture need to be applied in addition to Surgbond.

Method of Use

- When you are ready to use Surgbond, first clean the oozing blood and dry the wound area as far as possible.
- Approximate the wound edges precisely. For larger wounds, forceps may be used to hold the edges of skin. Take out the applicator tube.
- Take out the ampoule and cut off at the tip holding it vertically. Draw the whole Surgbond from the ampoule into the applicator.
- After holding the skin in approximation, apply few droplets of Surgbond from the applicator at intervals to facilitate holding.
- Apply a thin layer of Surgbond throughout the approximated wound and allow it to dry for about two minutes. The applied film should extend to at least $\frac{1}{2}$ a cm on either side of the approximated wound (i.e. on the healthy skin on either side).
- For better adhesion, do not apply Surgbond into the wound, but apply on top of the approximated area, as a bridge.
- Intermittent temporary supportive sutures may be applied for wounds larger than 7 cms.
- As practiced, internal absorbable sutures should be applied for deeper wounds before the final closure with Surgbond
- Contact with water should be avoided for at least 4 days after closure with Surgbond
- One ampoule is for single use only. Left over adhesive must be discarded.

NOTE

- Correction of skin edges cannot be done once the adhesive has dried.
- Surgbond should not be used to close infected wounds.
- Any surgical instruments soiled with Surgbond can be cleaned with dimethylformide or acetone.
- Surgbond must be used only when in liquid form. The condition of Surgbond can be assessed before opening the adhesive ampoule. If found viscous, discard the product.
- Do not use Surgbond after the expiry date.

CONTRAINDICATIONS

- Do not use on any wounds with evidence of active infection, gangrene or wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g. oral cavity, lips) or on skin which may be regularly exposed to body fluids or with dense natural hair (e.g. scalp)
- Do not use on the surface of the brain or on the nervous system. Application on the intima and media of blood vessels also to be avoided due to the risk of thrombosis.
- Do not use on patients with a known hypersensitivity to cyanoacrylate or formaldehyde.

WARNINGS AND PRECAUTIONS

Surgbond is a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.

Surgbond should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction. If unintended bonding of intact skin occurs, peel, but do not pull the skin apart. Petroleum Jelly or acetone may help loosen the bond. Other agents such as water, saline, betadine, soap, are not expected to immediately loosen the bond.

Surgbond should not be used in high skin tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint will be immobilized during the skin healing period.

Surgbond treated wounds should be monitored for signs of infection. Wounds with signs of infection, such as erythema, edema, warmth, pain, and pus, should be evaluated and treated for infection accordingly.

Surgbond should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction. Polymerization of Surgbond may be accelerated by water or fluids containing alcohol. Hence, Surgbond should not be applied to wet wounds.

Surgbond should only be used after wounds have been cleaned and debrided in accordance with standard surgical practice. Local anesthetic should be used when necessary to ensure adequate cleansing and debridement.

Surgbond polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying Surgbond in multiple thin layers (at least three) onto a dry wound and allowing time for polymerization between application, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if Surgbond is applied, so that large droplets of liquid are allowed to remain unspread, the patient may experience sensation of heat or discomfort.

Surgbond should not be restrained Exposure of Surgbond after its final manufacture to excessive heat (as in autoclaves of ethylene oxide sterilization) or radiation (such as gamma or electron beam) is known to increase its viscosity and may render the product unusable.

Do not apply liquid or ointment medications or other substances to the wound after closure with Surgbond as these substances can weaken the polymerized film and allow for wound dehiscence. Surgbond's permeability by topical medications has not been studied. Surgbond's permeability by fluids is not known and has not been studied.

Surgbond should be used immediately after drawing it into the applicator, as the liquid adhesive will not flow freely after a few minutes. Surgbond is a free flowing liquid slightly more viscous than water. To prevent inadvertent flow of liquid Surgbond to unintended areas

(1) the wound should be held in a horizontal position with Surgbond applied from

above, and (2) Surgbond should be applied in multiple (at least 3) thin layers rather than few large droplets.

Safety and effectiveness of Surgbond on wounds of patients with peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, burst stellate lacerations have not been studied.

Safety and effectiveness of Surgbond on animal or human bites, puncture or stab wounds and on wounds in vermilion surfaces has not been studied.

UNDESIRABLE EFFECTS

Surgbond is inert, biocompatible and nontoxic. Side effects are very rare and local in nature and may sometimes occur due to improper application. Except for occasional allergic reactions, there are no other local or systemic side effects.

PHARMACOLOGICAL INFORMATION

Surgbond is a sterile blue colour topical adhesive. It is a liquid in its monomer form and polymerizes instantaneously when it comes in contact with water or body moisture. The polymeric matter forms a thin film, which holds the wound edges together, tightly. Because of this property, it is specifically suitable for the adhesion of skin.

Storage :

Store protected from light at a temperature not exceeding 30°C

Presentation

Surgbond in a sterile ampoule, packed in an outer container along with an applicator. Available in ampoules of 0.25ml, 0.50ml & 1.0ml.

Marketed by:


Surgeway

For Further Information, Please write to:

SURGEWAY BIOSCIENCES

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