



C-SEAL

CLOSES INCISION IN A CLEAN & FASTER WAY

➤ **PRODUCT BRIEFS:**

C-SEAL is sterile tissue adhesive. Closing the surgical wound is an important step in the surgical procedure. The success of surgery is sometimes compromised by the suturing techniques or improper suturing material. Black silk sutures are more or less most often used material in the day today surgical procedures, but these sutures demand more time and effort from the surgeon and there is need to substitute these material with more user friendly closing materials (1) such as NBCA.

NBCA belongs to the group of tissue adhesives called as cyanoacrylates and is considered to be superior to other members of this class. N-butyl cyanoacrylate has unique properties compared to other cyanoacrylates like octyl cyanoacrylate (2) **C-SEAL** is bio-compatible, haemostatic, anti bacterial, non-histotoxic, non-allergic and devoid of complications such as secondary inflammatory reactions which can be associated with percutaneous suture procedures.

➤ **CLINICAL BENEFITS:**

- Closes incision in a clean and faster way- saves surgeon's time
- Strong adhesion- only one application required.
- Easy to use and apply- violet tint for enhanced visibility.
- Assured cosmetic healing of incision- for satisfied patients.
- Lowers chances of ugly marks of sutures & incision

➤ **USES:**

C-SEAL TOPICAL SKIN ADHESIVE is indicated for topical application only, to hold closed EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM SURGICAL INCISIONS, including punctures from minimally invasive surgery and, simple, thoroughly cleaned, trauma induced lacerations. **C-SEAL** may be used in conjunction with, but not in place of, deep dermal



stitches. **C-SEAL** can be used as skin adhesive in many medical specialties and surgical procedures like:

1. **UROGENITAL SURGERY**- Reanastomosis of ureter, Repair of injured kidney.
2. **GENERAL SURGERY**- Biopsy sites, Laparotomy, Hernia, Appendicitis.
3. **ENT**- To close tympanic membrane perforations.
4. **PLASTIC SURGRY**- Skin grafts in burns, Corrections of ear lobe punctures. Exicision of scar.
5. **OBSTECTRIC & GYNAECOLOGY**- Episiotomy wound closure, Caesarian section, Tubectomy, Laparotomy.
6. **G.I.SURGERY**- Bleeding gastric varies, intestinal anastomosis by invagination, wounds of liver & pancreas.
7. **ORTHOPAEDIC SURGERY**- Tandon repair, Cartilage binding.
8. **OPHTHALMOLOGY**- Ptosis, Corneal perforation, Corneal transplant.
9. **PAEDIATRIC SURGERY**- Hernia, Small lacerations.

➤ **Uses of different strengths of C-SEAL:**

C-SEAL is available in 3 different packs because of different needs of doctors.

0.15 ml is the right choice for very small incisions like during laproscopic surgery / keyhole surgery where the hole is very small & just few drops are required.

0.25 ml would be right choice for little elongated incisions like during cesarion section where the cut is longer than 4 inches.

0.50 ml is a good choice when **C-SEAL** has to be used in gastric varies. Because in gastric varices. **C-SEAL** is to be injected via a catheter during the endoscopic procedure. Here more liquid is required to block the internal bleeding as the doctor may have to put the drug for longer duration of time so as to put it very precisely & accurately.

Generally, 0.15 ml will be enough to seal keyhole incisions. Since it is single use ampoule, it is better and advisable to opt for 0.15 ml ampoule.



➤ **ABRIDGED PRESCRIBING INFORMATION:**

• **CONTRA INDICATIONS:**

Hypersensitivity to n-Butyl cyanoacrylate & D & C violet -2 colour, Contaminated wounds, Application on Brain & Neuronal Surfaces, decubitus ulcers, animal or human bites, or stab wounds.

• **ADVERSE REACTIONS :**

Clinical use of cyanoacrylate-based topical skin adhesives has suggested that the following adverse events may occur. Wound dehiscence, acute infection including erythema, oedema, and drainage, bonding to unintended tissue such as the eye, thermal discomfort during polymerization, allergic reactions, foreign body reaction and chronic non-healing of a wound. is generally well tolerated. Thick application of **C-SEAL** tissue adhesive should be avoided as it may cause injury to the adjacent tissue and delays the process to healing. Thick applications do not enhance bonding and tend to crack and loosen prematurely.

➤ **PRECAUTIONS :**

Each ampoule of **C-SEAL** is for single use only. Discard the ampoules containing viscous state of liquid tissue adhesive. Do not allow the contact of **C-SEAL** with surgical instruments, gloves or fingers during the procedure of application. **C-SEAL** is not absorbable and therefore should not be used below the skin as it may cause a foreign body reaction. **C-SEAL** should be used on wounds that have easily apposed edges which have been thoroughly cleaned, debrided and otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to assure adequate cleansing and debridement. **C-SEAL** should always be applied sparingly, either as minute drops or as a thin film bridging the wound and the aligned wound edges. **C-SEAL** polymerizes through an exothermic reaction in which a small amount of heat is produced. With the proper technique of applying **C-SEAL** sparingly in minute drops or a thin film onto a dry wound, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if **C-SEAL** is applied so that large droplets of liquid are allowed to remain unspread, the patients may experience a sensation of heat or discomfort. **C-SEAL** should not be used in areas with or increased skin tension, such as knuckles, elbow, or knees, unless the joint will be immobilized during the skin healing period or the skin tension has been decreased by application of another wound closure



device (e.g. sutures or skin staples) prior to application of **C-SEAL**. If unintended bonding of intact skin with **C-SEAL** should occur, removal may be accomplished by using either acetone or petroleum jelly. Typical cleansers such as soap, and other agents such as water, saline, povidone iodine or chlorhexidine are not expected to loosen the bond.

➤ **PRECAUTIONS FOR OPHTHALMOLOGISTS:**

When closing facial wounds near the eye using **C-SEAL**, adjust the patients position so that any flow of the adhesive is away from the eye. The eye should be closed and protected with gauze. Strategic placement of petroleum jelly near the eye can be effective at preventing inadvertent flow of the adhesive into the eye. If contact with the eye occurs, flush the eye copiously with saline or water. Use of the adhesive near the eye has inadvertently caused some patient's eyelids to be sealed shut. In some of these cases general anesthesia and surgical intervention has been needed to open the eye.

C-SEAL can be removed by applying Acetone in case of accidental adhesion.

➤ **APPLICATION:**

C-SEAL is for local application used for the closure of surgical wounds. **C-SEAL** may be used in conjunction with, but not in place of, deep dermal stitches. Although NBCA is colorless liquid, **C-SEAL** contains blue coloured liquid (due to D& C violet 2 color) so that **C-SEAL** is clearly visible during the wound closing procedure. But the color will fade as the wound heals.

C-SEAL is applied in a drop wise manner, which spreads to form a thin film and than polymerizes with in 20-30 seconds, closing the wound.

➤ **PROCEDURE OF C-SEAL APPLICATION:**

C-SEAL is applied only to outside surfaces to bridge over edges. Do not apply it directly to raw surfaces. Wound edges should be straight and lie together naturally. Insert a tampon, clean the wound thoroughly and dry the skin adequately. Stabilize the wound edges from top to bottom. Insert



C-SealTM 0.15 ml
0.50 ml
0.25 ml

the finger between the edges and pull it out to bring them forward slightly. This is to ensure the wound edges are not rolled inward, but meets perfectly. Two surfaces of wound to be held in place with a tissue forcep. Take required amount of **C-SEAL** with the help of syringe and needle. Apply **C-SEAL** as minute drops or as a very thin film along the edges of the wound. Avoid heavy application. Maintain manual approximation of the apposed wound edges for approximately 30 seconds to allow the topical skin adhesive to polymerize. **C-SEAL** is expected to be completely polymerized and at full strength in approximately 1 minute, when the topical skin adhesive is no longer tacky. Adhesive will stiffen when dry. Dry dressing can be applied over the dosed wound but should not be too tight. Liquid, ointment, or cream medications should not be applied onto wounds following closure with **C-SEAL**.

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