

N-BUTYL-2-CYANOACRYLATE
TOPOCRYL[™]
Topical Tissue Adhesive



Room Temperature Storage

High Purity & Product Stability

Great Cosmetic Outcomes

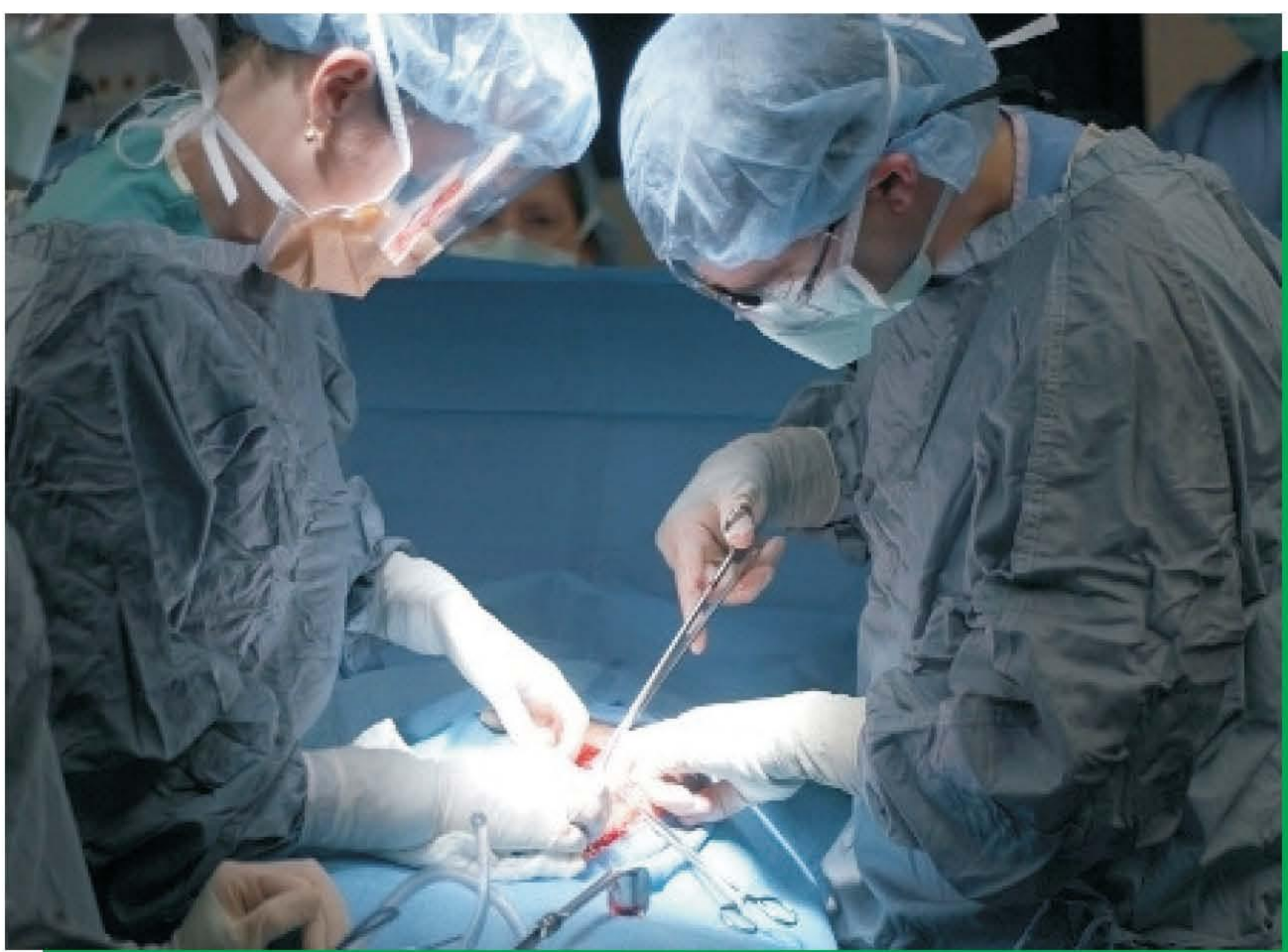
Easy Application

Soft Polymer Micro Tip Delivery

Versatile Indicative Uses

Minimal Post Surgical Infection

Patented Micro Delivery System



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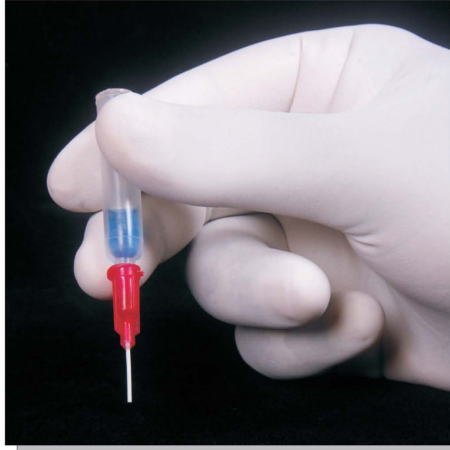
n-butyl-2-cyanoacrylate

Cyanoacrylate gets polymerized very quickly and becomes in-effective when it gets in contact even with trace moisture content generally present in the atmosphere.

This sensitivity of cyanoacrylate tissue adhesive towards atmospheric moisture has been a insurmountable problem for manufacturers as well as for the doctors.

The patented micro delivery system package of **TOPOCRYL**, solves the problems in handling of cyanoacrylate both in shipping and handling and as well as in the final usage.

N-BUTYL-2-CYANOACRYLATE TOPOCRYL™ Topical Tissue Adhesive



Advantages

Micro Delivery of cyanoacrylate at the wound site helps to just add the right amount to close the wound. Accidental excess application is kept to a minimum when using **TOPOCRYL** which in turn helps in quick healing and decrease in tissue damage due to heat of polymerization.

Micro Delivery system provides an option to apply tissue adhesive at hard to reach places as well as on very small incisions and cuts.

The crushable ampule system helps to keep the product from solidifying due to atmospheric moisture. This guarantees the product to remain in liquid form and hence effective and active at time of application.

A great convenience to doctors as they have a world class product in their hands.

Product is delivered via a soft polymer micro tip thus reducing accidental injuries that may happen while applying the product over the wound site.

Patented Micro Delivery System

Applying cyanoacrylate at the site of wound has been a problem with product packaged in plastic ampule. The product is drawn using a syringe from the container and then the plunger is pushed to release drops of cyanoacrylate over the two edges of the skin.

TOPOCRYL has a patented micro delivery system which is built into the package itself.

When pressed on the plastic jacket firmly between two fingers, the glass ampule inside is crushed which releases butyl cyanoacrylate into the plastic container.

The plastic container contains a built-in filter to stop glass particle debris.

The product comes out through the needle as micro drops. The flow is easily controlled by applying required pressure on the plastic jacket between the two fingers.



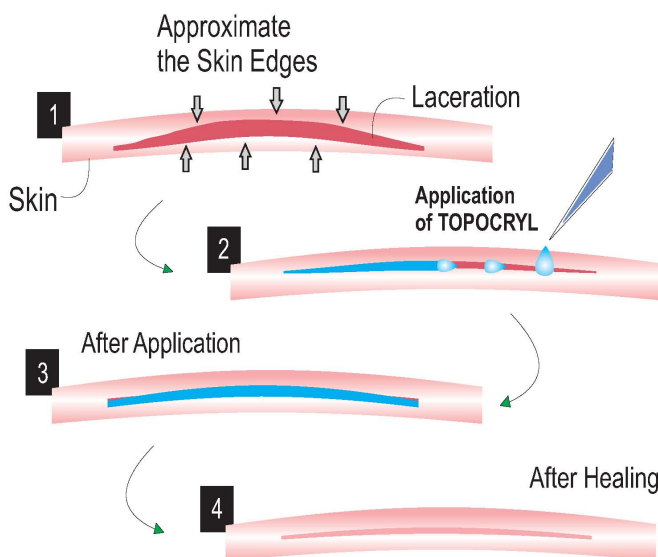
Long Term Stability

Some products were known to get polymerized (and hence rendered ineffective), within couple of months of shelf life. It has been also observed some packages getting solidified within days of shipment to the distributors from the manufacturing site.

TOPOCRYL is stable with respect to temperature, dust and moisture. The active component, monomer form of n-butyl-2-cyanoacrylate, remains as a clear blue liquid even when left at room temperature.

The much needed stability is due to the filling of cyanoacrylate in a hermetically sealed crushable glass ampule. As the glass walls are impermeable to moisture the product remains in liquid form for a long time even at room temperature storage.

The surrounding sheath jacket made up of a polymer gives mechanical strength to the device and doubles as a product usage and handling system.





N-BUTYL-2-CYANOACRYLATE TOPOCRYL™ Topical Tissue Adhesive

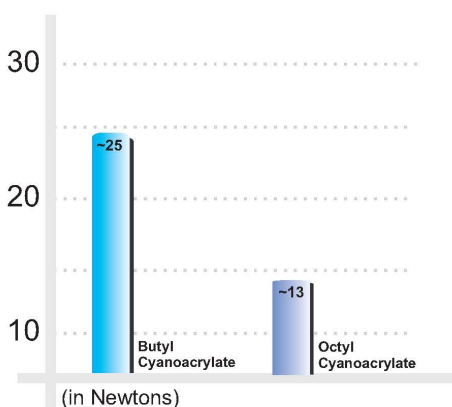
Suggested Indications

- Ophthalmic surgery : Corneal perforations
- ENT surgery : Tympanic perforations
- Dental surgery : Dental implants, Periodontal surgery, Gingivectomy, extracting sites.
- General surgery : Laparotomy, Hernia, Appendicitis.
- Plastic surgery : Cleft lip, Excision of scars, Skin graft
- Gynaecology : Episiotomy, Cesarean section, Tubectomy
- Gastroenterology : Varices, Wounds in Liver and Pancreas.
- Orthopaedic : Tendon repair, bone graft, Cartilage binding
- Surgical oncology : Thyroid & Breast malignancy surgery.
- Pediatric : Lacerations, Hernia, Cleft palate, cleft lip.

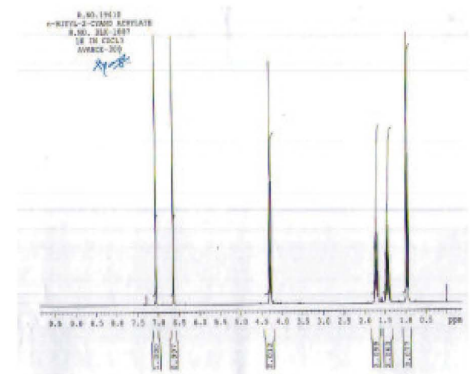
References

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Tensile Strength Comparison



Product Purity: N.M.R Chart



N-BUTYL-2-CYANOACRYLATE TOPOCRYL™ Topical Tissue Adhesive

WARNING

TOPOCRYL IS NOT AN INJECTION

NOT FOR INTRAVENOUS USE

NOT FOR INTRA-MUSCULAR USE

ONLY TO BE USED BY SURGEON OR A
REGISTERED MEDICAL PRACTITIONER

TOPOCRYL IS A SINGLE USE MEDICAL DEVICE



Product Information

INDICATIONS

TOPOCRYL is indicated for the closure of topical skin cuts, wounds and incisions including laproscopic incisions which have easily approximated edges with minimal tension and are thoroughly cleansed and without any evidence of infection.

CONTRA-INDICATIONS

TOPOCRYL should not be used internally (under the tissue or skin) as it may lead to foreign body reaction as the product is not absorbed in the tissues.

TOPOCRYL should not be used or applied on any internal organs or vascular bodies or brain tissue.

TOPOCRYL is not to be used to close wounds or cuts that show signs of infection.

TOPOCRYL is not used on patients that are allergic or hypersensitive to tissue adhesives and any products containing cyanoacrylates and formaldehyde.

TOPOCRYL is not to be used in patients that have diseases or conditions that are known to interfere in healing process.

TOPOCRYL is not to be used on cuts and wounds where extreme skin tensions occur like elbows and knees.

WARNINGS

TOPOCRYL is not an injection and not to be used for intravenous or intramuscular purposes.

Apply TOPOCRYL sparingly over the cut or wound as excess application may lead to tissue damage due heat of polymerization.

Do not introduce TOPOCRYL into the cut or wound as it may hinder wound healing.

TOPOCRYL is a free flowing liquid. If the product appears solidified or not free flowing, discard the device.

TOPOCRYL is a single use medical device.

STORAGE

Store below 40°C in cool and dry place.

PRECAUTIONS

As TOPOCRYL bonds to many surfaces, care should be taken so that gloves, surgical instruments, hands do not come in contact during application.

Spilt product can be flushed with water which solidifies the product.

Care should be taken not to accidentally introduce the product into the eyes as it may lead to bonding of the eye lids.

In case of accidental bonding, do not pull apart the bonded edges. Use copious amount of water to flush out the product.

If the bonding already occurred, use petroleum products like acetone, dimethyl formamide to dissolve the polymerized product.

Usually separation occurs due to moisture and tears in the eyes.

USE OF TOPOCRYL

TOPOCRYL device is held between forefinger and thumb. Firm pressure is applied on the cylindrical plastic jacket to crush the glass ampoule inside. The adhesive is released into the plastic jacket inside.

The edges of the laceration or cut or wound are closely approximated with the help of holding tongs.

The device is turned upside down and brought near the site of application.

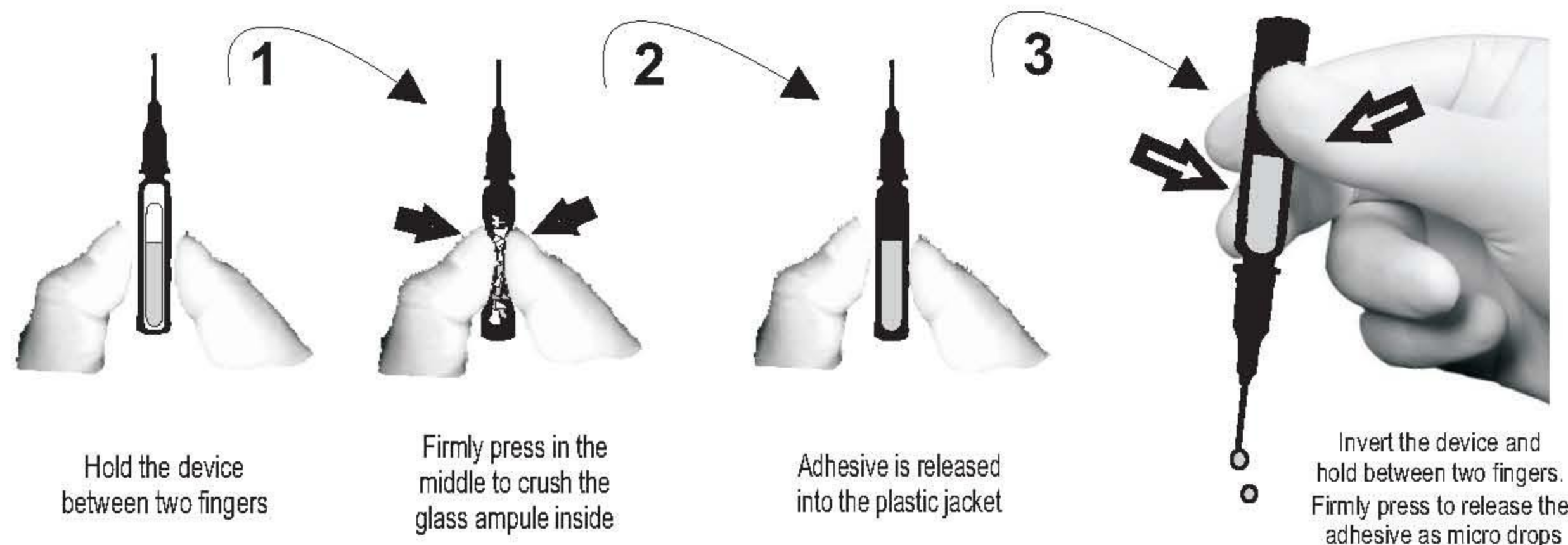
By applying firm pressure on the jacket, micro drops of the product are forced out of the soft polymer needle.

Fine drops of the product are applied along the cut or laceration.

The tip of the white polymer needle is not allowed to get in contact with the skin or tissue or the open wound during the whole closure procedure.

Bonding is complete within a minute.

The closed wound or cut can be supplemented with wound tapes or sutures in necessary to supply additional strength as required by the surgeon especially on a long cut or laceration or a possibility of stretching.



Device Usage Drawing

DESCRIPTION

TOPOCRYL is a topical skin adhesive containing of n-butyl-2-cyanoacrylate (also known as enbucrilate). For better visibility at the applied surface and to have a better approximation of quantity applied, the adhesive is dyed blue.

CONTENTS

One ampoule of TOPOCRYL contains 0.25ml / 0.5ml / 1.0ml n-butyl-2-cyanoacrylate.

INDICATIONS

TOPOCRYL is indicated for the closure of topical skin cuts, wounds and incisions including laparoscopic incisions, which have easily approximated edges with minimal tension and are thoroughly cleansed and without any evidence of infection and for embolization of gastric varices.

CONTRA-INDICATIONS

TOPOCRYL should not be used internally (under the tissue or skin) as it may lead to foreign body reaction as the product is not absorbed in the tissues.

TOPOCRYL should not be used or applied on any internal organs or vascular bodies or brain tissue.

TOPOCRYL is not to be used to close any wounds or cuts that show infection.

TOPOCRYL is not to be used on patients that are allergic or hypersensitive to tissue adhesives and any products containing cyanoacrylate products and formaldehyde.

Tissue Adhesives are not to be used in patients that have diseases or conditions that are known to interfere in healing process.

TOPOCRYL is not to be used on cuts and wounds where extreme skin tensions occur like elbows and knees.

WARNINGS

TOPOCRYL is not an injection and is not to be used for intravenous or intra-muscular purposes.

TOPOCRYL is to be applied on thoroughly cleansed cuts or wounds that do not show any evidence of infection.

Use TOPOCRYL sparingly as excess application it may lead to tissue damage due to heat of polymerization.

Do not introduce TOPOCRYL into the wound as it may hinder the wound healing.

TOPOCRYL is a free flowing blue liquid. If the product appears solidified or not free flowing please discard the package immediately.

TOPOCRYL is a single use device.

TOPOCRYL should be used within five minutes of opening the blister package.

PRECAUTIONS

As TOPOCRYL bonds to many surfaces, care should be taken so that gloves, surgical instruments does not come into contact during applications.

Spilt product can be flushed with water which solidifies the product.

Care should be taken not to introduce the product into the eyes as it can bond the eye lids.

In case of accidental bonding, do not pull apart the bonded edges. Use copious amount of water to flush out the product.

If bonding already occurred, use petroleum products like acetone or dimethyl formamide to dissolve the polymerized product.

Usually within three to four days separation occurs due to the moisture and tears in the eyes.

USE OF THE DEVICE

The device is held between forefinger and thumb. Firm pressure is applied on the middle of cylindrical plastic jacket to crush the glass ampule inside. The adhesive is released into the plastic jacket.

The device is turned upside down and moved near the site of application. By applying firm pressure using the fingers, micro drops of adhesive are delivered on to the closely approximated skin edges. The tip of the device is not allowed to get in contact with the skin, tissue or open wound during the whole procedure.


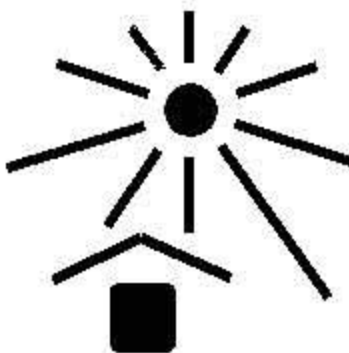
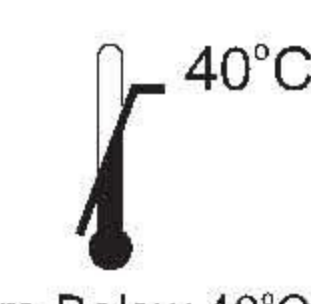



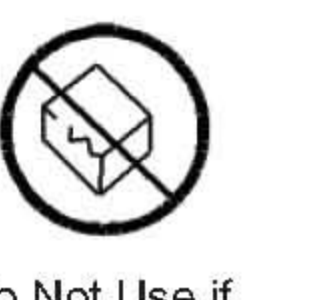


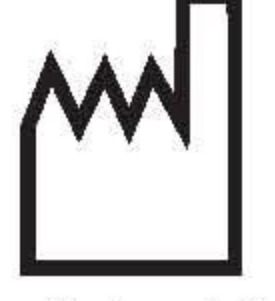
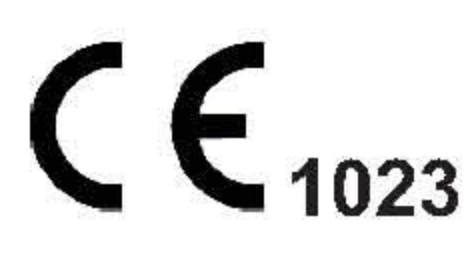

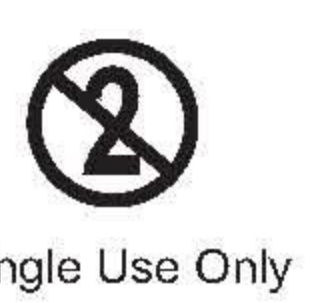
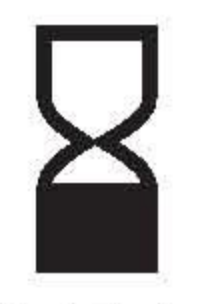

Wait for a minute for the polymerization and bonding to complete.

The closed cut or wound can be supplemented with wound tapes or sutures if required especially in case of a long cut or there is a possibility of stretching exists.

PRODUCT RANGE

Pack of 10 units of 0.25ml / 0.5ml / 1.0ml n-butyl-2-cyanoacrylate Brand: TOPOCRYL

SYMBOLS USED ON THE LABELING

 Caution! Consult accompanying document inserts in the package	 Keep away from sunlight	 Store Below 40°C	 Manufactured by	 European Representative
 Do Not Resterilize	 Do Not Use if Package is damaged	 Catalogue Number	 Batch No./Lot No:	 Manufactured Date:
 CE Mark including ITC (notifying body) identification number. Product conforms with the essential requirements in the European Medical Devices Directive 93/42/EEC then amended by 2007/47/EEC	 Read Instructions inside before Use	 Single Use Only	 Use By / Expiry Date:	 Sterile using Asoptic Filling

WARNING
 NOT AN INJECTION
 NOT FOR INTRAVENOUS USE
 TOPICAL USE ONLY
 TO BE USED BY SURGEON OR
 A REGISTERED MEDICAL
 PRACTITIONER



Hold the device between two fingers

1



Firmly press in the middle to crush the glass ampule inside

2



Adhesive is released into the plastic jacket

3



Invert the device and hold between two fingers. Firmly press to release the adhesive as micro drops