

TopoCryl

Topical Skin Adhesive

n-Butyl-2-Cyanoacrylate

DESCRIPTION

TopoCryl is a topical skin adhesive containing of n-butyl-2-cyanoacrylate.

CONTENTS

One unit of TopoCryl contains 0.25ml / 0.5ml / 5.0ml 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.

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 medical device is not intended for extensive wounds requiring healing by secondary intent.

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

TopoCryl is not 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.

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

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

WARNINGS

TopoCryl is not an injection and not for intravenous or intra-muscular use.

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.

TopoCryl is a free flowing violet 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 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.

Do not 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 (REFER TO DRAWINGS ON THE BACK)

The device is held between two hands using both forefingers and thumbs as illustrated in the box insert. Firm pressure is applied on the presser clip to to crush the glass ampule inside the soft polymer jacket. The adhesive is released into the jacket. Slip out the presser clip through the bottom of the device.

The device is turned upside down so that the needle is facing down and the adhesive is allowed to collect near the bottom of the device. Tapping few times on the device to clear the debris will help to the liquid to collect rapidly. Bring the device 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.

ONLY APPLY TOPICALLY.

Do not let adhesive seep into the wound as it can hinder wound healing and can lead to dehiscence.

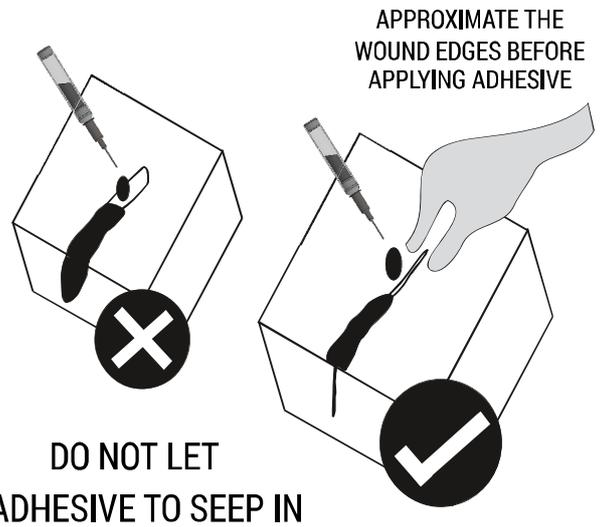
Wait for 30 to 60 seconds for the polymerization and bonding to complete. The closed cut or wound can be supplemented with wound tapes or sutures if required especially in case of a long cut or there is a possibility of stretching exists. Discard the device as a medical waste, along with any un-used liquid, once the procedure is complete.

STORAGE

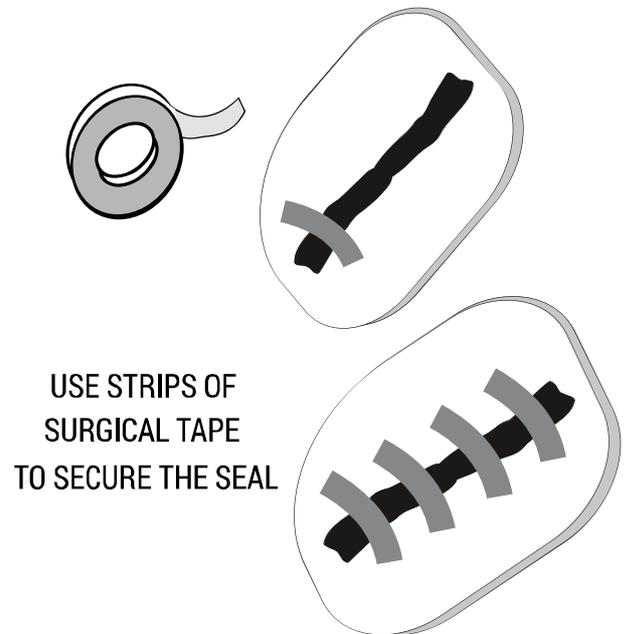
TopoCryl should be stored below 40 °C / 104 °F. Refrigeration not required.

Keep away from moisture and direct heat.

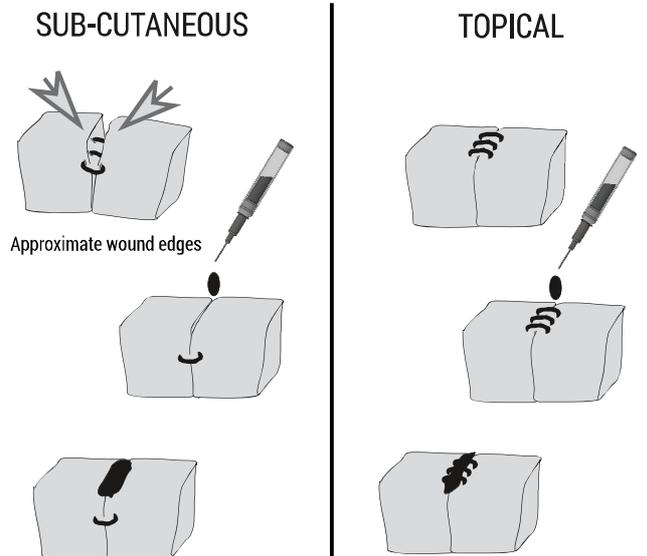
WOUND SEALING TECHNIQUE



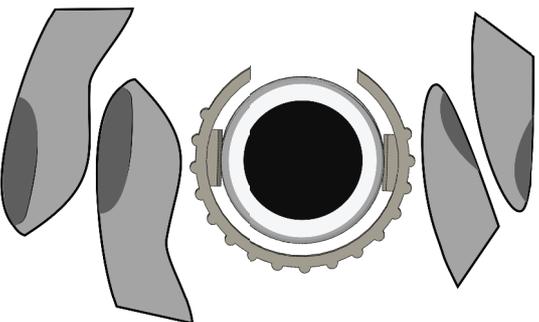
SECURING THE SEAL



USAGE WITH SUTURES

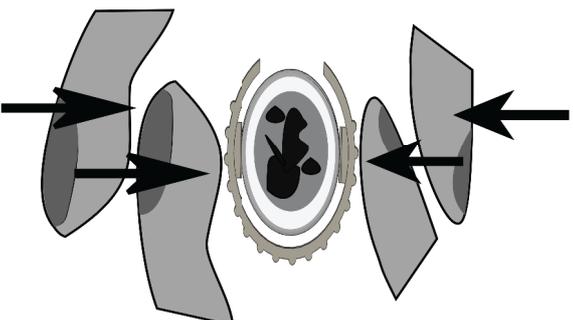
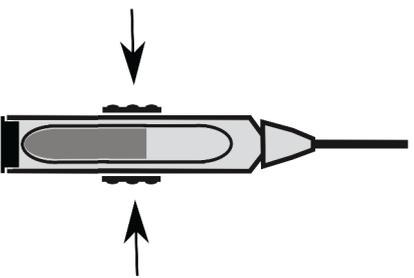


PREPARING THE SKIN ADHESIVE DEVICE FOR USE



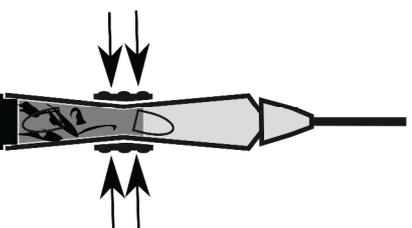
1

Using both hands, hold the device over the PRESSER RING using both fore fingers and thumbs.



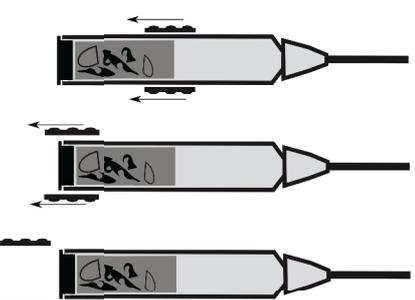
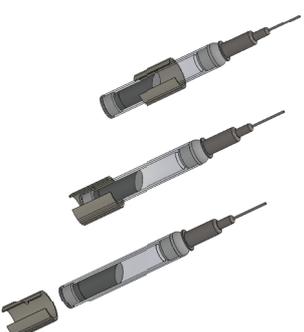
2

Firmly press over the PRESSER RING to crush the ampule inside.



3

Slide off the PRESSER RING via the bottom of the device.



Device is ready to use.

