

DESCRIPTION

XOIN 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 XOIN contains 0.15ml / 0.25ml / 0.5ml / 1.0ml n-butyl-2-cyanoacrylate.

INDICATIONS

XOIN 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

XOIN 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.

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

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

XOIN 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 be used in patients that have diseases or conditions that are known to interfere in healing process.

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

WARNINGS

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

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

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

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

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

XOIN is a single use device.

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

PRECAUTIONS

As XOIN 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

Open the pouch. Use a blunt end of a forceps to sharply tap the jacket of the device thus crushing the glass ampule inside. The adhesive is now released. Take the device out of the pouch, invert the device and give a few taps on the jacket with fingers so that the adhesive collects at the bottom near the needle. The device is ready to seal the wound. Bring the device near the closely approximated wound edges and apply firm pressure using the fingers to deliver small drops of adhesive over the length of the wound. Do not allow the device to contact the skin during the application procedure. Wait for a minute for the bonding to complete. Do not pull apart the sealed edges.

SUPPLEMENT THE SEALED WOUND WITH STRIPS OF SURGICAL HOLDING TAPE FOR STRENGTHENING THE SEAL

Do not let the adhesive enter the wound while applying as it hinders wound healing.

Keep the wound horizontal in order to prevent run off into other areas.

Gauze bandage can be applied for protection against mechanical injury.

WARNING

KEEP AWAY FROM EYES

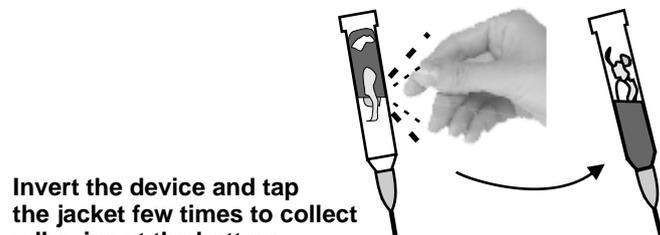
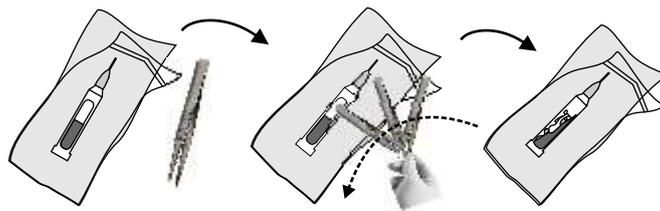
IN CASE OF ACCIDENTAL ADHESION USE ACETONE OR NAIL POLISH REMOVER TO DISSOLVE SOLIDIFIED PRODUCT

NOT AN INJECTION - NOT FOR INTRAVENOUS USE

TO BE USED BY REGISTERED MEDICAL PRACTITIONER

DEVICE PREPARATION

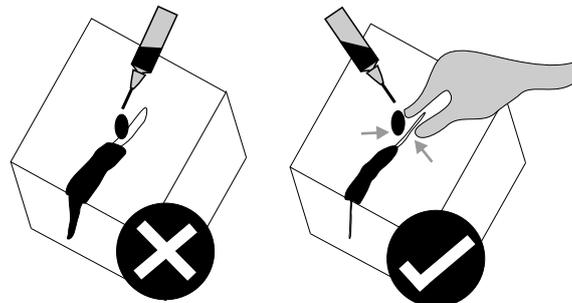
Sharply tap the device on the jacket using a blunt edge like the back of a forceps to crush the glass ampule inside.



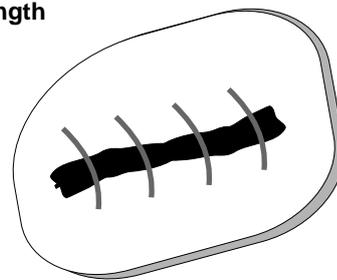
Invert the device and tap the jacket few times to collect adhesive at the bottom

WOUND SEALING

Closely approximate the wound edges using forceps or fingers and apply adhesive along the surface without introducing into the wound

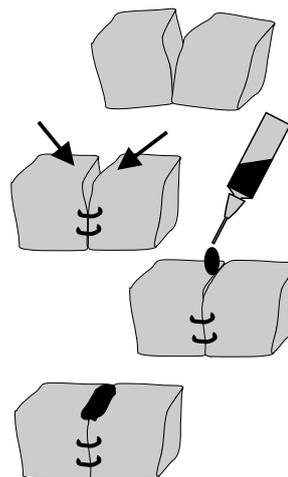


After sealing, apply strips of surgical tape along the length to improve seal strength



USAGE WITH SUTURES

PER-CUTANEOUS



TOPICAL

