exofin fusion®
SKIN CLOSURE SYSTEM

2-Octyl Cyanoacrylate

INSTRUCTIONS FOR USE

SourceMark™ Medical

REF	M1222	22cm
REF	M1230	30cm
REF	M1244	60cm

BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

DESCRIPTION

exofin fusion® Skin Closure System is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2. It is provided in a single-use applicator packaged in a rigid blister. As applied to skin, the liquid topical skin adhesive is slightly more viscous than water and polymerizes within minutes. In vitro studies have shown that **exofin fusion®** acts as a barrier to microbial penetration as long as the liquid topical skin adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

exofin fusion® also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment to an incision up to 20cm for product M1222, 28cm for product M1230, and 58cm for product M1244 until the liquid topical skin adhesive is applied to achieve skin closure.

INDICATIONS

exofin fusion® is intended 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 cleansed, trauma-induced lacerations.

exofin fusion® should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

CONTRAINDICATIONS

- Do not use on any wounds with evidence of infection, gangrene, or on wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin that may be regularly exposed to body fluids or with dense natural hair (e.g., scalp).
- Do not use on patients with a known hypersensitivity to cyanoacrylate, formaldehyde, benzethonium chloride, or pressure-sensitive adhesive.

WARNINGS

- **exofin fusion®** incorporates a fast-setting liquid topical skin adhesive capable of adhering to most body tissue and to 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.
- Polymerization of the **exofin fusion®** liquid topical skin adhesive component may be accelerated by water or fluids containing alcohol. **exofin fusion®** should not be applied to wet wounds.
- **exofin fusion®** should not be applied to the eye. If contact of the liquid topical skin adhesive with the eye occurs, flush the eye copiously with saline or water. If residual liquid topical skin adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with **exofin fusion®** position the patient so that any run-off of the liquid topical skin adhesive is away from the eye. The eye should be closed and protected with gauze. Prophylactic placement of petroleum jelly around the eye to act as a mechanical barrier or dam can be effective in preventing inadvertent flow of liquid topical skin adhesive into the eye. **exofin fusion®** will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where **exofin fusion®** is intended to adhere. Use of topical skin adhesive near the eye has inadvertently caused some patients' eyelids to be sealed shut. In some of these cases, general anesthesia and surgical removal has been required to open the eyelid.
- **exofin fusion®** liquid topical skin adhesive should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- **exofin fusion®** should not be used in high skin tension areas or across areas of increased skin tension, such as joints, unless the area will be immobilized during the skin healing period or unless skin tension has been removed by application of another wound closure device (e.g. sutures or skin staples) prior to application of **exofin fusion®**.
- **exofin fusion®** 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 according to standard practice for infection.
- **exofin fusion®** should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- **exofin fusion®** should only be used after wounds have been cleaned, debrided, and are otherwise closed in accordance with standard surgical practice. Local anesthetic should be used when necessary to ensure adequate cleansing and debridement.
- Excessive pressure of the applicator tip against the wound edges or surrounding skin can force the wound edges apart and allow liquid topical skin adhesive into the wound. Liquid topical skin adhesive within the wound could delay wound healing or result in adverse cosmetic outcome, or both. Therefore, **exofin fusion®** liquid component should be applied with a very light brushing motion of the applicator tip over the mesh.
- **exofin fusion®** liquid topical skin adhesive polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying **exofin fusion®** liquid adhesive in a single layer onto a dry wound, heat is released slowly and the sensation of heat or pain experienced by the patient is minimized. However, if **exofin fusion®** liquid topical skin adhesive is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- **exofin fusion®** is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize **exofin fusion®**. Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to product failure or infection or transmission of bloodborne pathogens to patients and users. Do not place **exofin fusion®** in a procedure pack/tray that is to be sterilized prior to use without prior written authorization from manufacturer.
- Exposure of **exofin fusion®** after its final manufacture to excessive heat (as in autoclaves or ethylene oxide sterilization) or radiation (such as gamma or electron beam), is known to increase its viscosity and may render the product unusable.
- For children less than 10kg, the length of wounds that the **exofin fusion®** system is used for should not exceed 20 cm.

PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with **exofin fusion®**, as these substances can weaken the polymerized film and allow for wound dehiscence. **exofin fusion®** permeability by topical medications has not been studied. Prior to application, cleanse the application site thoroughly to remove any remaining blood, fluids or topical medications/anesthetics.
- **exofin fusion®** permeability by fluids is not known and has not been studied.
- **exofin fusion®** liquid topical skin adhesive, as a liquid, is slightly more viscous than water. To prevent inadvertent flow of liquid topical skin adhesive to unintended areas: (1) the wound should be held in a horizontal position, with **exofin fusion®** liquid adhesive applied from above, and (2) **exofin fusion®** liquid adhesive should be applied in a single layer. Any excess liquid adhesive can be quickly wiped off with sterile gauze.
- Safety and effectiveness of **exofin fusion®** on wounds of patients with peripheral vascular disease, insulin-dependent diabetes mellitus, blood clotting disorders, personal or family

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history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of **exofin fusion®** on the following wounds have not been studied: animal or human bites, puncture or stab wounds.
- Safety and effectiveness on wounds that have been treated with **exofin fusion®** and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of **exofin fusion®** liquid adhesive on wounds in vermilion surfaces have not been studied.

ADVERSE REACTIONS

Adverse reactions related to either the wound closure procedure or the use of **exofin fusion®** are possible. The following events have been identified as potentially associated with wounds closed with **exofin fusion®**.

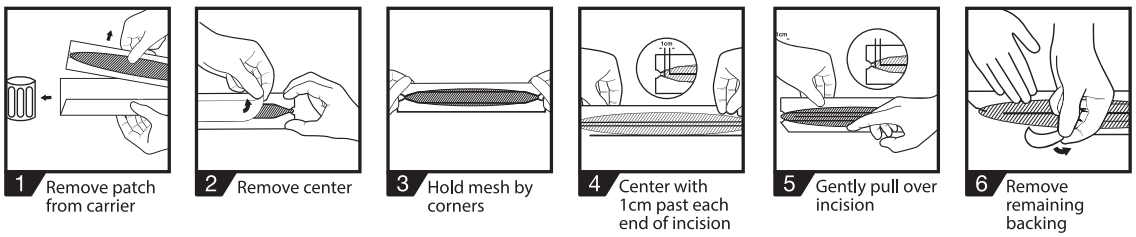
Infection (redness more than 3-5 mm from the wound margin, swelling, purulent discharge, pain, increased skin temperature, fever) | Acute inflammation (erythema, edema, pain, warmth) | Dehiscence | Bleeding | Skin edge necrosis | Excessive itching | Skin blistering | Seroma | Hematoma

DIRECTIONS FOR USE

exofin fusion® is intended for single patient use. The mesh patch or patches and liquid topical skin adhesive applicators should only be used for wound closure of a maximum of 20cm for product EF70401, 28cm for product EF70430, and 58cm for product EF70466 on a single patient. After wound closure has been achieved, any excess mesh patch and adhesive applicators should be discarded and not reused on other patients.

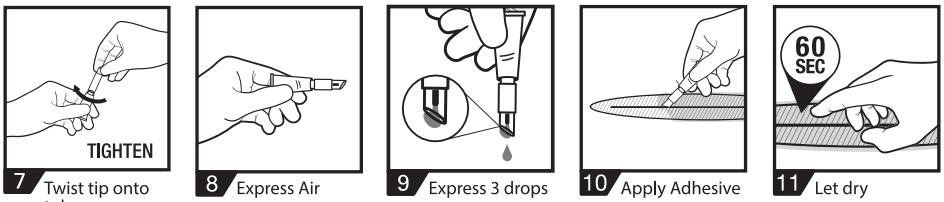
1. The application of **exofin fusion®** system requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of **exofin fusion®** (i.e., cleanse, irrigate, debride, obtain hemostasis, and close deep layers such that there is no tension on the skin). The skin edges must be closely approximated prior to application of the mesh, such that significant manual approximation is not required during mesh application.
2. Pat the wound dry with sterile gauze to assure direct tissue contact for adherence of the mesh and the liquid skin adhesive to the skin.
3. Remove the formed tray from the sealed bag and aseptically transfer the entire tray to the sterile field. Remove the lid from the tray to access the device components.
4. **exofin fusion®** is applied in a 2-step process with either 1 mesh patch and 2 applicators, or 2 mesh patches and 3 applicators for dispensing the liquid skin adhesive. Steps for application of **exofin fusion®** are illustrated below. Remove the mesh patch from the mesh carrier (Fig. 1). Remove the center section of the release backing paper from the mesh (Fig. 2). Hold the mesh by the corners of the backing paper, ensuring the pressure-sensitive adhesive (PSA) will be on the mesh side that will be adhered to the patient's skin (Fig. 3).
5. Position the mesh so one half is on either side of the incision, ensuring that at least 1 cm of mesh extends from each end of the incision (Fig. 4).

Mesh Application



6. Press gently to ensure intimate contact of the mesh to the selected side of the incision.
7. Gently pull the mesh perpendicularly over the incision while adjusting with fingers or forceps to achieve skin edge approximation and affix the remainder of the mesh to the other side of the incision (Fig. 5). Ensure the mesh is placed at least 1 cm from each of the ends of the incision. Use sterile scissors to trim any excess mesh, if necessary.
8. Remove the remaining paper backing/frame (Fig. 6).
9. Ensure that the mesh is in full contact with the skin prior to application of the liquid skin adhesive. If there are areas where the mesh is loose, gently pass a gloved finger or instrument over the affected area to ensure complete adherence of the mesh to the skin. If the mesh is still not adhered to the skin, carefully cut any affected segments of the mesh and remove them from the skin. Ensure the skin edges are clean and dry and reapply new mesh according to the directions for use, overlapping the end of the existing mesh by approximately 1cm. The liquid skin adhesive should be applied over the entire mesh and slightly over on to the surrounding skin. The adhesive should be applied immediately after the mesh has been properly placed over the incision. **Pat the deployed mesh dry gently with dry sterile gauze in the event of bodily fluid seepage without disturbing skin edge approximation prior to spreading the adhesive over the mesh.**

Adhesive Application



10. Activate the liquid topical skin adhesive by twisting the connector containing the applicator tip onto the tube to break the sterile seal (Fig. 7). DO NOT OPEN ADHESIVE UNTIL READY TO APPLY.
11. While holding the tube in a horizontal position, squeeze the tube at the "X" near the crimped end to release the pressure and air from the tube (Fig. 8). Activate the adhesive by pointing applicator tip down and expressing three drops onto a surgical drape (Fig. 9). Now that adhesive is flowing from applicator tip, continue squeezing and applying pressure to the tube while painting the surface of the mesh, including slightly off the mesh to the surrounding skin, until the entire mesh surface is fully covered (Fig. 10).
12. In the event the glue runs out before fully covering the mesh and surrounding skin, simply open another tube of adhesive that is supplied in the package and follow Steps 8 and 10.
13. Once complete coverage is achieved, do not touch any part of the mesh or surrounding skin for approximately 60 seconds.
14. After 60 seconds has past, lightly touch the surface with a clean gloved finger to ensure the adhesive has fully polymerized/dried before applying any other dressing or covering of any kind (including gown or sheet) (Fig. 11).
15. Mesh should remain in place on the patient up to 14 days after application with proper aftercare.

NOTE: DO NOT APPLY A SECOND COAT OF ADHESIVE TO MESH PATCH WITH ADHESIVE.

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Finally, inspect the incision for any blood or fluid accumulation under the mesh, including areas where fluid may be seeping through the mesh.

If such areas exist, carefully cut any affected segments of the mesh and remove them from the skin. Ensure the skin edges are clean and dry, and reapply new mesh and liquid topical skin adhesive according to the directions for use, overlapping the ends of existing mesh by approximately 1 cm.

A protective, dry wound dressing such as gauze may be applied only after the liquid topical skin adhesive has completely polymerized and **exofin fusion®** is no longer tacky to the touch. If the liquid topical skin adhesive is not allowed to fully polymerize prior to application of a dressing, **exofin fusion®** may adhere to the dressing, causing it to become loose or be pulled away from the skin when the dressing is removed, which can result in dehiscence (skin edge separation).

Patients should be advised that **exofin fusion®** will need to remain in place until the wound/incision is properly healed (typically 7 to 14 days). During this time, **exofin fusion®** should be kept dry. If directed by the health care practitioner, the wound may be briefly wet in a shower if dried immediately thereafter by gently blotting with a soft towel. The wound should not be soaked or scrubbed. Patients should not swim or otherwise immerse the wound in water for prolonged periods. If a protective wound dressing is being used over **exofin fusion®**, it should be replaced with a dry dressing after showering or bathing.

Patients should also be instructed not to scratch, rub or pick at **exofin fusion®** and reminded not to apply topical ointments, lotions, or liquids to the wound while **exofin fusion®** is in place. This may loosen **exofin fusion®**, causing it to peel away from the skin before the wound has fully healed. Patients should be instructed not to engage in strenuous physical activity that may cause tension on the wound or cause perspiration to wet **exofin fusion®**.

exofin fusion® is designed to naturally slough off or it can be removed by following removal instructions below:

REMOVAL INSTRUCTIONS

1. Slowly peel the mesh patch until it begins to lift from the skin. Pull **exofin fusion®** away from the skin along the line of the wound. Do not pull the mesh straight up from the skin. **exofin fusion®** should be pulled back along the line of the wound close to the skin. Use the other hand to stabilize the wound as the mesh is peeled off.
2. Once the entire length of **exofin fusion®** has been removed, discard the device in an appropriate medical waste container.
3. Any residual adhesive and/or dried wound exudate can be cleaned from the skin, according to institutional standard of care for skin cleansing.

HOW SUPPLIED

exofin fusion® is supplied sterile, in single patient use components:
(1) mesh patch for product versions M1222 and M1230 or (2) mesh patches for product version M1244, (2) tubes of liquid adhesive for M1222 and M123 and (3) tubes for liquid adhesive for M1244. The components are packaged in a rigid blister tray to maintain the sterility of the device until opened or damaged. **exofin fusion®** is supplied in boxes of 2 systems each.

STORAGE
Recommended storage conditions: below 30 °C (86 °F), away from moisture, direct heat, and direct sunlight. Do not use after expiry date.

STERILITY
exofin fusion® is originally sterilized by dry heat and ethylene oxide gas. Do not resterilize. Do not use if package is opened or damaged. Discard any unused materials following completion of medical procedure.

STERILE SINGLE USE ONLY

REPORTING — Healthcare Professional should use the following number 844-633-4583, when reporting adverse reactions or potentially threatening complications involving **exofin fusion®**.

CAUTION — This product is meant for external dermal application only and should not contact the eyes.This product should not be ingested, applied internally, or injected intravascularly.

Federal (U.S.A.) Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Manufactured by CHEMENCE MEDICAL, INC.

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