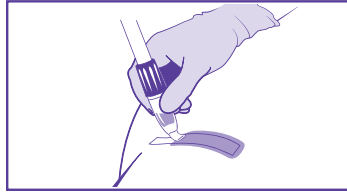




- Spread the liquid adhesive smoothly and evenly over the entire length of the mesh and surrounding skin area using the flexible liquid adhesive applicator tip. Apply the liquid adhesive using short strokes and moving from one end of the mesh to the other, making sure that the mesh is saturated as the liquid adhesive is applied along the entire length. The liquid adhesive should also be applied slightly over the edge of the mesh covering a small margin of surrounding skin. Any excess liquid adhesive can be wiped off quickly with sterile gauze. NOTE: DO NOT APPLY A SECOND COAT.



- Repeat application steps to close additional wound/incision sites on which mesh has been applied.

Once applied to the mesh, the liquid adhesive will polymerize within approximately 60 seconds. After 60 seconds, check that polymerization is complete by gently dabbing along the length of the DERMABOND™ PRINEO™ System with a gloved finger, checking for tackiness. When no liquid or tackiness is apparent, the polymerization process is complete. Once the liquid adhesive is polymerized, the wound is closed and sealed.

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 adhesive according to the directions for use, overlapping the ends of the existing mesh by approximately 1 cm.

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

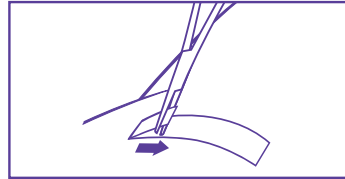
Patients should be advised that DERMABOND™ PRINEO™ System will need to remain in place until the wound/incision is properly healed (typically 7 – 14 days). During this time DERMABOND™ PRINEO™ System should be kept dry. If directed by the health care practitioner, the wound may be briefly wet in a shower or bath, 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 DERMABOND™ PRINEO™ System, it should be replaced with a dry dressing after showering or bathing.

Patients should also be instructed not to scratch, rub, or pick at the DERMABOND™ PRINEO™ System, and reminded not to apply topical ointments, lotions, or liquids to the wound while DERMABOND™ PRINEO™ System is in place. This may loosen the DERMABOND™ PRINEO™ System causing it to come 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 the DERMABOND™ PRINEO™ System.

DERMABOND™ PRINEO™ System is designed to naturally slough off or it can be removed by following removal instructions below:

REMOVAL INSTRUCTIONS

- Gently grasp the edge of the DERMABOND™ PRINEO™ System at one end of the wound. If the edge of the device is still adhered to the skin, gently pick at the edge until it begins to peel away from the skin.
- Slowly peel the DERMABOND™ PRINEO™ System away from the skin along the line of the wound. Do not pull the mesh straight up from the skin. The DERMABOND™ PRINEO™ System 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.



- Once the entire length of the DERMABOND™ PRINEO™ System has been removed, discard the device in an appropriate medical waste container.

Any residual adhesive and/or dried wound exudate can be cleaned from the skin according to the institutional standard of care for skin cleansing.

HOW SUPPLIED

DERMABOND™ PRINEO™ System is supplied sterile, for single patient use. The system is packaged in a rigid blister tray to maintain the device sterile until opened or damaged.

STORAGE

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

STERILITY

DERMABOND™ PRINEO™ System 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 material following completion of medical procedure.

Rx only	CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Caution
30°C 86°F max	Upper Limit of Temperature	Batch number
Use by		Manufacturer
Do not reuse		Sterilized using ethylene oxide
Do not resterilize		Sterilized using steam or dry heat
Catalogue number		

DESCRIPTION

DERMABOND™ PRINEO™ 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. The applicator is composed of a crushable glass ampule contained within a liquid adhesive applicator with attached applicator tip. As applied to skin, the liquid adhesive is slightly more viscous than water and polymerizes within minutes. *In vitro* studies have shown that DERMABOND™ PRINEO™ System acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

DERMABOND™ PRINEO™ System also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment until the liquid adhesive is applied to achieve skin closure.

INDICATIONS

DERMABOND™ PRINEO™ System 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. DERMABOND™ PRINEO™ System 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 wound with evidence of infection, gangrene, or wounds of decubitus etiology.
- Do not use on mucosal surfaces or across mucocutaneous junctions (e.g., oral cavity, lips), or on skin which 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, benzalkonium chloride, or pressure-sensitive adhesive.

WARNINGS

- DERMABOND™ PRINEO™ System incorporates a fast-setting liquid topical skin adhesive capable of adhering to most body tissue and many other materials, such as surgical 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 DERMABOND™ PRINEO™ System liquid adhesive component may be accelerated by water or fluids containing alcohol. DERMABOND™ PRINEO™ System should not be applied to wet wounds.
- DERMABOND™ PRINEO™ System should not be applied to the eye. If contact of the liquid adhesive with the eye occurs, flush the eye copiously with saline or water. If residual liquid adhesive remains, apply topical ophthalmic ointment to help loosen the bond and contact an ophthalmologist.
- When closing facial wounds near the eye with DERMABOND™ PRINEO™ System, position the patient so that any run-off of the liquid 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 adhesive into the eye. DERMABOND™ PRINEO™ System will not adhere to skin pre-coated with petroleum jelly. Therefore, avoid using petroleum jelly on any skin area where DERMABOND™ PRINEO™ System is intended to adhere. Use of DERMABOND™ PRINEO™ System liquid adhesive component 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.
- DERMABOND™ PRINEO™ System should not be used below the skin because the polymerized material is not absorbed by tissue and can elicit a foreign body reaction.
- DERMABOND™ PRINEO™ System should not be used in high skin-tension areas or across areas of increased skin tension, such as knuckles, elbows, or knees, unless the joint 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 DERMABOND™ PRINEO™ System.

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- DERMABOND™ PRINEO™ System 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.
- DERMABOND™ PRINEO™ System should not be used on wound sites that will be subjected to repeated or prolonged moisture or friction.
- DERMABOND™ PRINEO™ System 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 liquid adhesive applicator tip against wound edges or surrounding skin can force the wound edges apart and allow liquid adhesive into the wound. Liquid adhesive within the wound could delay wound healing and/or result in adverse cosmetic outcome. Therefore, DERMABOND™ PRINEO™ System liquid adhesive component should be applied with a very light brushing motion of the liquid adhesive applicator tip over the mesh and surrounding skin area.
- Excessive pressure of the mesh dispenser against the skin during application may result in (1) fluid discharge from the wound, preventing sufficient adherence of the mesh to the skin, (2) gaping of the wound edges, or (3) stretching of the mesh. All of these situations may result in sub-optimal skin closure.
- DERMABOND™ PRINEO™ System liquid adhesive component polymerizes through an exothermic reaction in which a small amount of heat is released. With the proper technique of applying DERMABOND™ PRINEO™ System liquid adhesive component 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 DERMABOND™ PRINEO™ System liquid adhesive component is applied so that large droplets of liquid are allowed to remain unspread, the patient may experience a sensation of heat or discomfort.
- DERMABOND™ PRINEO™ System is packaged for single patient use. Discard remaining opened material after each wound closure procedure.
- Do not resterilize DERMABOND™ PRINEO™ System.
- Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.
- Do not place DERMABOND™ PRINEO™ System in a procedure pack/tray that is to be sterilized prior to use. Exposure of DERMABOND™ PRINEO™ System, 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.

PRECAUTIONS

- Do not apply liquid or ointment medications or other substances to the wound after closure with DERMABOND™ PRINEO™ System, as these substances can weaken the polymerized film and allow for dehiscence (skin edge separation). Prior to application, cleanse the application site thoroughly to remove any remaining blood, fluids or topical medications/anesthetics. DERMABOND™ PRINEO™ System permeability by topical medications has not been studied.
- DERMABOND™ PRINEO™ System permeability by fluids is not known and has not been studied.
- DERMABOND™ PRINEO™ System liquid adhesive component is slightly more viscous than water. To prevent inadvertent flow of liquid adhesive to unintended areas: (1) the wound should be held in a horizontal position, with DERMABOND™ PRINEO™ System liquid adhesive component applied from above, and (2) DERMABOND™ PRINEO™ System liquid adhesive component should be applied in a single layer. Safety and effectiveness of DERMABOND™ PRINEO™ System on wounds of patients with peripheral vascular disease, insulin-dependent diabetes mellitus, blood clotting disorders, personal or family history of keloid formation or hypertrophy, or burst stellate lacerations, have not been studied.
- Safety and effectiveness of DERMABOND™ PRINEO™ System 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 DERMABOND™ PRINEO™ System and then exposed for prolonged periods to direct sunlight or tanning lamps have not been studied.
- Safety and effectiveness of DERMABOND™ PRINEO™ System on wounds in vermilion surfaces have not been studied.

ADVERSE REACTIONS

Adverse reactions related to either the wound closure procedure or to the use of the DERMABOND™ PRINEO™ System are possible. The following events have been identified as potentially associated with the wounds closed with the DERMABOND™ PRINEO™ System.

- 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 (Skin Edge Separation)
- Excessive itching
- Skin blistering

Events potentially associated with the wound closure procedure include bleeding, skin edge necrosis, seroma, and hematoma.

CLINICAL STUDY COMPARING THE DERMABOND™ PRINEO™ SKIN CLOSURE SYSTEM TO HIGH VISCOSITY DERMABOND® ADHESIVE FOR CLOSURE OF TRAUMA-INDUCED LACERATIONS

Description: A prospective, randomized, controlled, unmasked study was conducted to evaluate the safety and effectiveness of closing the approximated skin edges of trauma-induced lacerations using DERMABOND™ PRINEO™ System in comparison to the currently marketed High Viscosity DERMABOND® Topical Skin Adhesive, with or without sutures placed below the skin surface according to investigator judgment.

The study population included patients at least one year of age, in good general health, who signed informed consent and agreed to follow-up visits. Patients were excluded if presenting with: significant multiple trauma, peripheral vascular disease, insulin-dependent diabetes mellitus, blood clotting disorder, keloid formation or hypertrophy history (patient or family), cyanoacrylate or formaldehyde allergy, burst or stellate lacerations due to crush or hard blow, animal or human bite, and decubitus ulcer. One unit of either DERMABOND™ PRINEO™ System or DERMABOND® Adhesive was used to close the wound. Wound length was measured in millimeters; wound depth and width were not measured according to the study protocol. Most wounds in the study were small, superficial lacerations, which did not require dermal suture placement (average wound length = 15 mm).

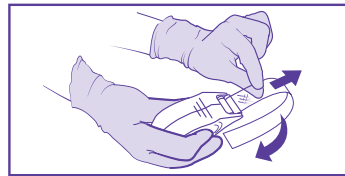
Follow-up was at 14 days (± 2 days) and at 30 days (± 5 days). The Modified Hollander Cosmesis Scale (MHCS), a validated scale, was used to evaluate cosmesis at the 30-day (± 5 days) follow up visit. This scale evaluates step-off borders, edge inversion, contour irregularities, excess inflammation, wound margin separation, and overall wound appearance.

Results: The primary measure of device effectiveness in the study was wound closure at day 14, defined as continuous approximation of wound margins from the time of wound closure until the day of evaluation without dehiscence (skin edge separation) or need for reclosure. Results indicate that DERMABOND™ PRINEO™ System was equivalent to the DERMABOND® Adhesive control for effectiveness of wound closure at day 14. Results for the 30-day cosmesis evaluation also indicate that results for DERMABOND™ PRINEO™ System were equivalent to control.

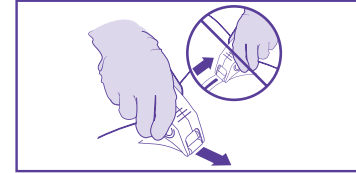
DIRECTIONS FOR USE

DERMABOND™ PRINEO™ System is intended for single patient use. The mesh dispenser and liquid adhesive applicator should only be used for wound closure on a single patient. After wound closure has been achieved, both liquid adhesive applicator and mesh dispenser should be discarded and not reused on other patients.

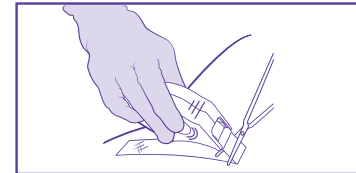
1. The application of DERMABOND™ PRINEO™ System requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of DERMABOND™ PRINEO™ System (i.e., cleanse, irrigate, debride, obtain hemostasis and close deep layers such that there is no tension on the skin edges). 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 dry, sterile gauze to ensure direct tissue contact for adherence of the mesh and the liquid adhesive to the skin.
3. Remove the lid of the formed tray containing the two device components and aseptically transfer the components to the sterile field.
4. DERMABOND™ PRINEO™ System is applied in a 2-step process with a liquid adhesive applicator and a mesh dispenser. Steps for application of DERMABOND™ PRINEO™ System are illustrated below.
5. Hold the mesh dispenser and pull the leader from its storage position. Gently pull to begin dispensing the mesh, exposing ~1 cm of mesh past the roller. Position the hand leader under the mesh dispenser. Position the mesh dispenser with the arrow visible on the top of the dispenser.



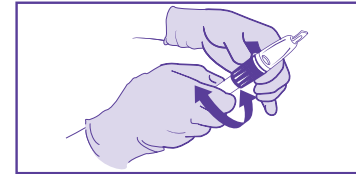
6. Position the mesh dispenser approximately 1 cm prior to the beginning of the wound/incision. Pressing gently with the roller, affix the mesh to the skin along the approximated skin edges by pushing the mesh dispenser forward with one hand, while using the other hand to temporarily hold the hand leader or the starting edge of mesh. Once the leading edge of the mesh is adhered to the skin, fingers or forceps may be used to approximate the skin edges just in front of the mesh roller if needed to maintain approximation. Advance the mesh dispenser to apply the mesh along the length of the approximated skin edges, and at least 1 cm past the end of the incision.



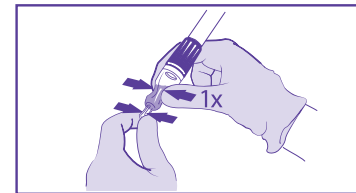
7. Once the incision is fully covered and the mesh extends at least 1 cm beyond the length of the incision, use sterile scissors to cut the mesh from the dispenser and to cut the leader from the leading edge of the mesh. If additional mesh is needed to accommodate wound dimensions or additional wounds/incisions, apply the additional mesh to the wound in the same manner prior to application of the liquid adhesive.
8. Ensure that the mesh is in intimate contact with the skin prior to application of the liquid 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 1 cm.



9. The liquid adhesive should be applied to mesh immediately after the mesh has been placed using the following steps.
10. Activate the liquid adhesive applicator by twisting the purple dial until a snap is heard.

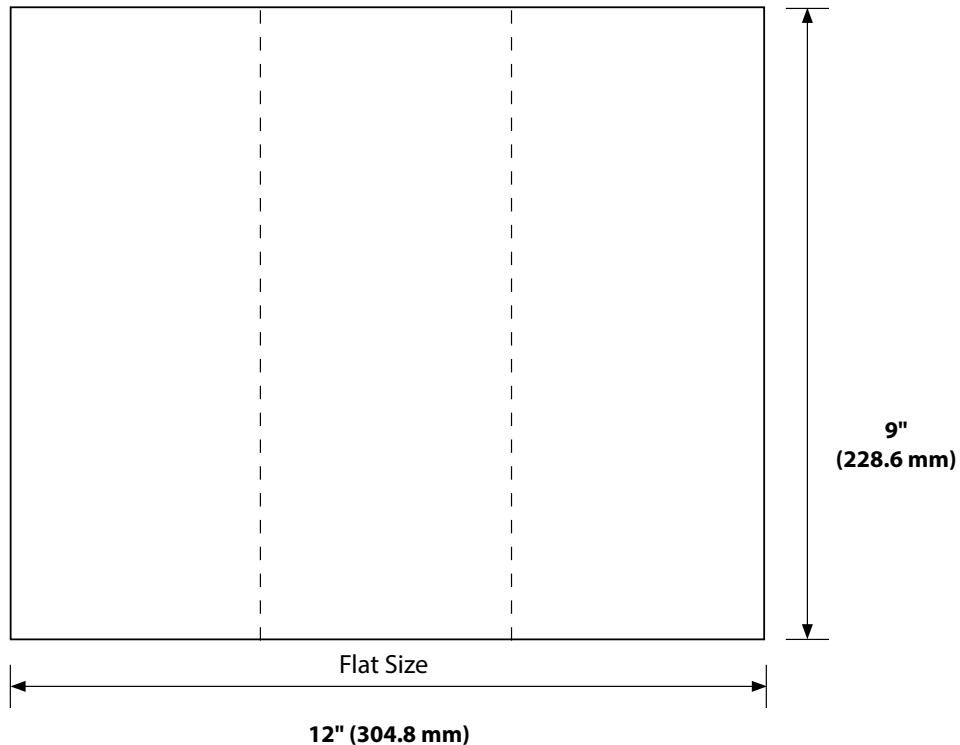


11. Position the liquid adhesive tip straight down and away from the application area. Pinch the tip of the applicator and squeeze the flexible bulb one time. Once the pressure in the bulb is released, it will partly or completely fill with liquid adhesive. This primes the applicator for dispensing the liquid adhesive. No additional priming is required.

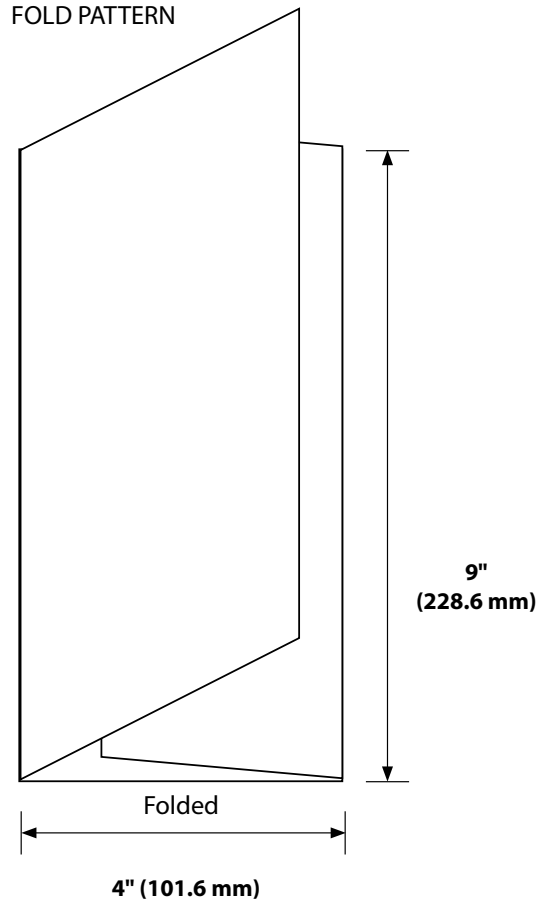


IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



FOLD PATTERN



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STOCK 40 lb. Finch Opaque					DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK. This document or data herein or herewith is not to be reproduced, used or disclosed in whole or part without the permission of Ethicon, Inc.				
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