

DERMABOND® PRINEO® Skin Closure Systems **Discussion Guide**



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Product Specifications

Q: Is DERMABOND® PRINEO® Skin Closure System just DERMABOND ADVANCED® Topical Skin Adhesive with a self-adhering mesh?

A: No. DERMABOND PRINEO System consists of a self-adhering mesh and a 2-octyl cyanoacrylate liquid adhesive formulation (which is similar to but not the same as DERMABOND ADVANCED Adhesive). These two components must be used together to close easily approximated skin edges of surgical incisions and simple lacerations. DERMABOND PRINEO System is approximately 32% stronger than DERMABOND ADVANCED Adhesive with subcuticular sutures.^{1,5*}

Q: Is DERMABOND PRINEO System available in more than one length?

A: Yes. In order to accommodate a variety of incision lengths, DERMABOND PRINEO System is available in 22-cm, 42-cm, and 60-cm lengths, each of which is trimmable, self-adhering, and must be used in combination with the supplied liquid adhesive.^{1,3}

Q: What is the chemical composition of the adhesives in DERMABOND PRINEO System?

A: The liquid adhesive in DERMABOND PRINEO System is 2-octyl cyanoacrylate. The adhesive on the mesh component is an acrylic pressure-sensitive adhesive.^{1,3}

Q: Is the liquid adhesive in DERMABOND PRINEO System a high-viscosity formula?

A: No. The liquid adhesive in DERMABOND PRINEO System is only slightly more viscous than water. The liquid adhesive in DERMABOND ADVANCED Adhesive is a high-viscosity formula.^{1,4}

Q: Can the liquid adhesive in DERMABOND PRINEO System be used alone (without the mesh) for skin closure?

A: No. The liquid adhesive component of DERMABOND PRINEO System must be used only in combination with the self-adhering mesh component. If used without the mesh, the liquid adhesive in DERMABOND PRINEO System will not polymerize as expected.^{1,3}

Q: What is the initiator on the mesh component and how does it work?

A: The initiator on the mesh component is benzalkonium chloride. Once the liquid adhesive is applied to the mesh, the initiator acts to initiate and accelerate polymerization in a reliable, consistent manner. Polymerization occurs within approximately 60 seconds.^{1,3}

*Study performed ex vivo

Q: What are the key differences between DERMABOND® PRINEO® Skin Closure System and DERMABOND ADVANCED® Topical Skin Adhesive?

A: See chart below.

	DERMABOND PRINEO System¹⁻³	DERMABOND ADVANCED Adhesive⁴
Number of components	Two (2): a liquid adhesive and a self-adhering mesh that must be used in combination	One (1): a liquid adhesive
Viscosity of liquid adhesive	Low (slightly more viscous than water; 7-8 centipoise)	Higher (syrup-like; 200 centipoise)
Polymerization of liquid adhesive	Begins polymerization only after contact with an “initiator” on the self-adhering mesh	Begins polymerization as it passes through the applicator tip, which contains the initiator
Expected polymerization time	Approximately 60 seconds	Full apposition strength is expected to be achieved within minutes after the adhesive is applied. Full polymerization is expected when the DERMABOND ADVANCED Adhesive layer is no longer sticky.
Product components	<ul style="list-style-type: none"> • 22 cm: 22-cm long x 4-cm wide self-adhering mesh patch + liquid adhesive applicator • 42 cm: Two 22-cm long x 4-cm wide self-adhering mesh patches + liquid adhesive applicator • 60 cm: 60-cm long x 2-cm wide self-adhering mesh + liquid adhesive applicator 	Pen-style applicator consisting of a crushable ampoule contained within a plastic applicator

Application

Q: Will the initiator in the self-adhering mesh clog the liquid adhesive applicator tip after the surgeon starts expressing the liquid adhesive onto the mesh?

A: No. The initiator for DERMABOND® PRINEO® Skin Closure System is on the surface of the self-adhering mesh, not within the liquid adhesive applicator, so the applicator tip will not clog. This allows for a 2-hour working time of the liquid adhesive.^{1,3}

Q: How does the surgeon know if the right amount of liquid adhesive has been applied?

A: When the entire length of mesh appears purple in color and there are no visible areas of the original “clear” mesh. Since the initiator is located in the mesh, it is very important that the mesh be fully covered with a single layer of liquid adhesive, including going slightly beyond the edges of the mesh, covering a small margin of surrounding skin.^{1,3}

Q: What would happen if more than a single layer of the liquid adhesive were applied to the self-adhering mesh?

A: Remember that the liquid adhesive begins polymerization after it contacts the initiator on the surface of the mesh. If more than a single layer of liquid adhesive is applied to the mesh, the second layer of adhesive will not be able to contact the initiator on the mesh (which is now covered by the first layer of adhesive), and therefore the second layer will not be able to polymerize, resulting in a “sticky” film.^{1,3}

Q: What is the longest incision length that can be closed with the DERMABOND PRINEO System?

A: Given the fact that the mesh should be extended 1 cm beyond each end of the incision (per the IFU), the “usable” length of the mesh will be less than the total length of the mesh as packaged. There may also be variability in how the mesh is applied, such as overlapping in keyhole incisions, which could result in decreasing the usable length. Therefore, the longest incision that can be closed with DERMABOND PRINEO System (22 cm) is 20 cm, with DERMABOND PRINEO System (42 cm) is 40 cm, and with DERMABOND PRINEO System (60 cm) is 58 cm.^{1,3}

Q: Can the DERMABOND PRINEO System mesh component be overlapped or cut into multiple segments and used on multiple incisions or wounds on the same patient?

A: Yes. The self-adhering mesh can be cut and applied to multiple incisions on the same patient or in overlapping segments over adjoining incisions, provided that at least 1 cm of mesh is extended beyond each end of each incision and the mesh is overlapping the end of the existing mesh by approximately 1 cm.^{1,3}

Q: Can the self-adhering mesh be removed and repositioned?

A: Yes. As long as the liquid adhesive has not yet been applied, the self-adhering can be removed, adjusted, and repositioned.

Q: What are the contraindications for DERMABOND PRINEO System?

A: DERMABOND PRINEO System is contraindicated for^{1,3}:

- Any wound with evidence of active infection, gangrene, or wounds of decubitus etiology (e.g., bedsores or pressure ulcers)
- 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)
- Patients with a known hypersensitivity to cyanoacrylate, formaldehyde, benzalkonium chloride, or pressure-sensitive adhesive

Q: I am considering using DERMABOND® PRINEO® Skin Closure System on high-tension areas (such as the knee); what changes, if any, are necessary for my wound closure technique?

A: DERMABOND PRINEO System is designed for topical skin closure in conjunction with, but not in place of, deep dermal stitches. When DERMABOND PRINEO System is used in high skin-tension areas, the user should ensure that the skin tension has been relieved by applying another wound closure device (e.g., deep dermal or subcuticular sutures) prior to application. During a total knee arthroplasty, best practice is to apply the DERMABOND PRINEO System while the knee is at the same angle of flexion that the joint capsule is closed at, without relaxing the knee.^{1,3}

Q: Do skin preps such as Betadine®, ChloroPrep®, and HIBICLENS® have any effect on the DERMABOND PRINEO System?

A: Skin preps will have no effect on DERMABOND PRINEO System as long as the IFU application instructions are followed. Per the IFU, DERMABOND PRINEO System requires thorough wound cleansing prior to application. The application site should be cleansed thoroughly with saline or isopropyl alcohol to remove any remaining blood, fluids, or topical medications/anesthetics, including skin preps, and then patted dry. Any liquid remaining on the application site may delay polymerization time and compromise the effectiveness of DERMABOND PRINEO System.^{1,3}

Q: Can the DERMABOND PRINEO System be extended more than 1-2 cm beyond the ends of the incision?

A: According to the IFU, the mesh should be trimmed so that at least 1 cm extends beyond the ends of the incision. There should be no issue with the mesh being extended greater than 1-2 cm beyond the ends of the incision, although patient comfort should be considered.^{1,3}

Q: Can surgeons cut the self-adhering mesh along the long axis in order to cover longer incisions?

A: Per the IFU, the mesh may be cut or trimmed in length; however, the mesh should NOT be “split” or altered in width. If your incision is longer than the mesh, you should use another length or additional unit of the length you have.^{1,3}

Q: Can DERMABOND PRINEO System be used in a “clean-contaminated” designated case?

A: A clean-contaminated (or Class II) wound is a surgical wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, surgical procedures involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection is encountered and no major break in technique occurs. 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. It is not contraindicated on clean-contaminated wounds, but is contraindicated on any wound with evidence of infection, gangrene, or on wounds of decubitus etiology, per the IFU.^{1,3}

Removal

Q: When should DERMABOND® PRINEO® Skin Closure System be removed?

A: DERMABOND PRINEO System is designed to naturally slough off the skin; however, it can also be removed when there is adequate wound healing as determined by a healthcare practitioner. This is typically 7 to 14 days after the procedure, in accordance with the natural wound healing process. Please refer to the product labeling for proper removal instructions.^{1,3}

Q: Can DERMABOND PRINEO System be removed prior to wound healing completion, if the surgeon suspects an infection?

A: Yes. A healthcare practitioner can remove the DERMABOND PRINEO System at any time, in accordance with the proper removal instructions outlined in the IFU.^{1,3}

Q: What is the best way to quickly remove DERMABOND PRINEO System if there are complications with surgery and the wound needs to be re-opened?

A: Please follow the removal instructions as outlined in the IFU. Topical ointments or petrolatum may help loosen the adhesive bond to the skin.^{1,3}

Reactions

Q: Does DERMABOND® PRINEO® Skin Closure System cause any allergic reactions?

A: As noted in the contraindications section of the IFU, some patients may be hypersensitive to certain components of DERMABOND PRINEO System, including cyanoacrylate, formaldehyde, benzalkonium chloride, or pressure-sensitive adhesive. This hypersensitivity may manifest clinically as redness, rash, blistering, or itching. Such reactions are more commonly classified as irritant contact dermatitis or allergic contact dermatitis.^{1,3}

Q: Can DERMABOND PRINEO System cause blistering?

A: As noted in the contraindications section of the IFU, some patients may be hypersensitive to certain components of DERMABOND PRINEO System including cyanoacrylate, formaldehyde, benzalkonium chloride, or pressure-sensitive adhesive. This hypersensitivity may manifest clinically as redness, rash, blistering, or itching. Blistering may also be caused by inelastic post-surgical dressings, especially if post-operative edema is present.^{1,3}

Q: What steps should be taken if a patient experiences a local reaction or hypersensitivity to DERMABOND PRINEO System?

A: You should report the adverse reaction to Ethicon at 1-877-384-4266. Adverse events may also be forwarded to the FDA MEDWATCH program by phone at 1-800-FDA-1088 or fax at 1-800-FDA-0178. The patient's physician should determine any treatment of a local reaction. Some reactions may resolve with no treatment or may require topical treatment, depending on severity and physician judgment.

Q: If a patient has an adhesive or tape allergy, can they still use DERMABOND PRINEO System?

A: If a patient has had reactions to other adhesives or tapes in the past, it is possible that they could be sensitive to the pressure-sensitive adhesive on the DERMABOND PRINEO System mesh component.

Q: If a patient has blistered from butterfly skin closures, will the same effect happen with DERMABOND PRINEO System?

A: If a patient has experienced blisters when treated with butterfly skin closures, it could be due to the adhesive or inelasticity of the product, especially if edema was present. There is no reliable way to know if the same thing could happen with DERMABOND PRINEO System.

Q: By sealing the wound with DERMABOND PRINEO System, does this increase the risk of a hematoma?

A: Wound hematoma, a collection of blood and clot in the wound, is one of the most common surgical wound complications and is almost always caused by imperfect hemostasis. In none of our three randomized controlled clinical trials comparing DERMABOND PRINEO System to either intradermal sutures or to DERMABOND® Topical Skin Adhesive for skin closure was there any difference in incidence of hematoma among the treatment groups.^{1,3,6,7}

Q: By sealing the wound with DERMABOND PRINEO System, does this increase the risk of a seroma?

A: A seroma is an accumulation of fluid in a tissue or organ that can occur after surgery, or sometimes after an injury such as blunt trauma. Seromas develop as a result of damage to blood and lymphatic vessels that occurs during surgery or as the result of an injury. In our three randomized controlled clinical trials comparing DERMABOND PRINEO System to either intradermal sutures or DERMABOND Adhesive for skin closure, the DERMABOND PRINEO System was found to be equivalent with regards to safety.^{1,3,6,7}

Q: Does DERMABOND PRINEO System decrease the severity of keloid scarring in any way?

A: Ethicon has not studied the safety and effectiveness of DERMABOND PRINEO System on wounds of a patient with a personal or family history of keloid formation. Keloid scarring can manifest either in the presence or absence of a surgical procedure.

Oozing/Drainage

Q: If exudates or fluid under a wound can ooze or seep out, how can DERMABOND® PRINEO® Skin Closure System provide a microbial barrier?

A: While DERMABOND PRINEO System polymerizes into a film that adheres to skin and is impermeable to bacteria, the film is not impermeable to moisture vapor or other gases (e.g., oxygen and carbon dioxide). In effect, any fluids produced beneath the film may eventually pass through the film as moisture vapor. However, if fluid is oozing or seeping out, the microbial barrier may be disrupted or compromised. In order to minimize any oozing, it is important to apply DERMABOND PRINEO System properly, including closing deeper tissue layers first to relieve wound tension and eliminate dead space; ensuring that the wound is clean and dry; good hemostasis is achieved; and fully covering the self-adhering mesh with the liquid adhesive. If the liquid adhesive is not applied to some areas of the mesh, those areas will not adhere tenaciously to the skin; and over time, exudates or fluid may ooze or seep out. 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 IFU, overlapping the ends of the existing mesh by approximately 1 cm.^{1,3}

Q: What should surgeons do if they notice blood or fluid accumulating under DERMABOND PRINEO System while in the operating room?

A: While in the operating room, surgeons should inspect DERMABOND PRINEO System for any blood or fluid accumulation under the mesh, including areas where fluid may be seeping through the mesh. One possible cause of this is failure to fully achieve hemostasis prior to application. If such areas exist, carefully cut any segments of the mesh from the affected area(s). Ensure the incision is clean and dry, and reapply new mesh and liquid adhesive per product IFU, ensuring adequate overlap onto existing mesh and surrounding skin.^{1,3}

Q: DERMABOND PRINEO System acts as an occlusive wound dressing, but isn't it better to let a wound "breathe"?

A: Topical skin adhesives such as the DERMABOND PRINEO System help support a healthy wound with occlusive characteristics. They provide a low-oxygen environment, which can positively influence the formation of new blood vessels, since the main source of oxygen during wound closure is through capillaries under the surface of the skin. Topical skin adhesives allow moisture vapor to pass through wound while keeping environmental bacteria out; and additionally, they function as a microbial barrier and create a moist environment that is optimal for wound healing.^{1,3,8,9}

Q: Can DERMABOND PRINEO System be used in conjunction with negative-pressure wound therapy (NPWT)?

A: Ethicon has not conducted any studies on the use of DERMABOND PRINEO System in conjunction with NPWT, and the effect NPWT would have on DERMABOND PRINEO System is unknown.

Post-surgical Care

Q: How should patients treated with DERMABOND® PRINEO® Skin Closure System care for their wound after surgery?

A: A protective, dry wound dressing, such as gauze, may be applied only after the liquid topical skin adhesive has completely polymerized and the DERMABOND PRINEO System is no longer tacky to the touch. If the liquid topical skin adhesive is not allowed to fully polymerize prior to the 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.^{1,3}

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 healthcare 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.^{1,3}

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 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 the DERMABOND PRINEO System.^{1,3}

Q: Are postoperative dressings required with DERMABOND PRINEO System?

A: No. However, compression garments or other coverings can be used if the surgeon prefers. If dressings are used, care should be taken when changing or removing these coverings. Due to natural compressive forces, coverings that are in contact with DERMABOND PRINEO System may stick to the mesh, and removing them should be done carefully to ensure that DERMABOND PRINEO System is not accidentally pulled away from the skin along with the dressings.^{1,3}

Q: After DERMABOND PRINEO System is applied, how will the surgeon assess whether the wound is healing or detect any potential complications?

A: Any wound healing complications should be detectable by assessing the area around the incision for erythema, edema, elevated temperature, or pain.

Q: Can you use AQUACEL® Dressings on top of DERMABOND PRINEO System, even though it is not necessary?

A: DERMABOND PRINEO System does not require a dressing, but if one is used, it should be a dry wound dressing, as liquids or prolonged exposure to moisture can weaken the polymerized DERMABOND PRINEO System adhesive film before the wound is properly healed (typically 7-14 days). Ethicon has not conducted specific compatibility testing of DERMABOND PRINEO System with AQUACEL® Ag Surgical. The hydrofiber wound dressing contours to the wound bed, and along with the gelling action of the sodium carboxymethylcellulose, a moist environment is created at the site. This could potentially alter the physicochemical properties of the DERMABOND PRINEO System film, including permeability to oxygen, carbon dioxide, and moisture vapor, which could interfere with wound healing and the DERMABOND PRINEO System microbial barrier. Since AQUACEL® Ag Surgical is designed to be in intimate contact with the wound surface, it is not known if the silver ions would penetrate the polymerized film of the DERMABOND PRINEO System. It should also be noted that the adhesive in the border of AQUACEL® Ag Surgical dressing may adhere to the DERMABOND PRINEO System, causing it to lift during removal of the dressing.^{1,3,10}

Q: Can DERMABOND® PRINEO® Skin Closure System be submerged in water for an extended period of time (i.e., if the surgeon prescribes hydrotherapy starting at 3-4 days post-total knee replacement)?

A: No. Prolonged exposure to liquids may loosen the bond to the skin and compromise wound closure. Note from the IFU, under Directions for Use Step 13: 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.^{1,3}

Q: Can patients remove DERMABOND PRINEO System by themselves when wound healing is complete? If so, what instructions should they be given?

- A: The DERMABOND PRINEO System is designed to naturally slough off, or it can be removed by following removal instructions below per the IFU^{1,3}:
1. 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.
 2. Slowly peel the DERMABOND PRINEO System away from the skin along the lines of the wound. Do not pull the mesh straight up from the skin. The DERMABOND PRINEO System should be pulled back along the lines of the wound close to the skin. Use the other hand to stabilize the wound as the mesh is peeled off.
 3. Once the entire length of the DERMABOND PRINEO System has been removed, discard the device in an appropriate medical waste container.
 4. Any residual and/or dried wound exudate can be cleaned from the skin according to usual practice.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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