

DERMABOND™ PRINEO™ Skin Closure System (22 cm)

Device Performance Quick Guide¹



Patient Selection

DO NOT use on patients with known hypersensitivity to cyanoacrylate, formaldehyde, benzalkonium chloride, or pressure-sensitive adhesive. Use of DERMABOND™ PRINEO™ System on patients with hypersensitivity to one of these components may lead to skin reaction. 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).

Wound Preparation

The skin edges must be closely approximated prior to application of the mesh, such that significant manual approximation is not required during mesh application. DERMABOND™ PRINEO™ System should not be used in high skin-tension areas or across areas of increased skin tension, such as joints, e.g., knuckles, elbows, or knees, 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 DERMABOND™ PRINEO™ System.



Mesh Application



Position the mesh so one half is on either side of the incision, ensuring that at least 1 cm of mesh extends from the beginning of the incision. Use sterile scissors to trim any excess mesh, if necessary. Press gently to ensure intimate contact of the mesh to the selected side of the incision. 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.

Liquid Adhesive Application



Spread the liquid adhesive smoothly and evenly over the entire length of the mesh and surrounding skin area using the flexible 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.

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Skin/Wound Preparation¹

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.

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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.



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Mesh Application¹



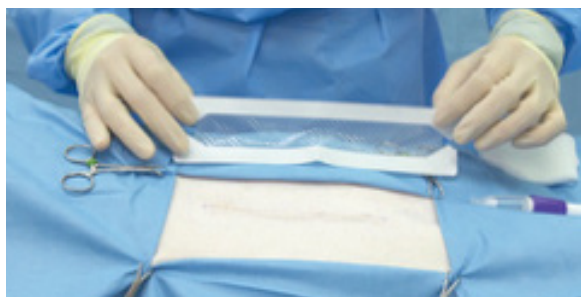
Step 1

Remove the mesh patch from the mesh carrier and dispose of the mesh carrier.



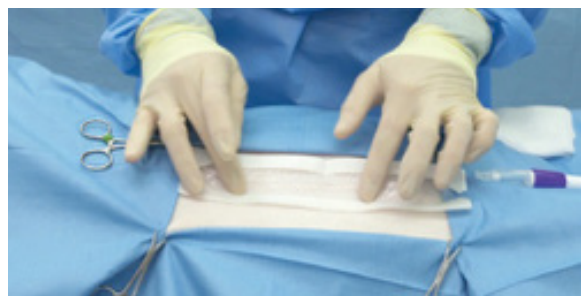
Step 2

Flatten the mesh patch at the crease gently. Remove the center section of the release backing paper from the mesh.



Step 3

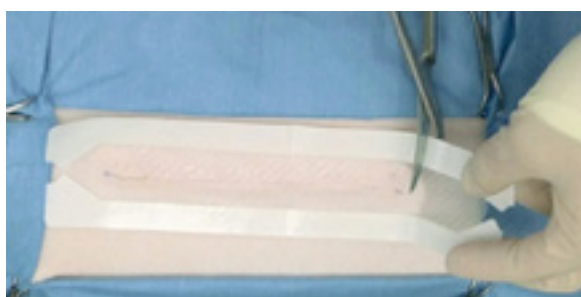
Hold the mesh by the corners of the backing paper, ensuring the pressure-sensitive adhesive (PSA) will be on the mesh side that will be adhered to the patient's skin.



Step 4

Position the mesh so one half is on either side of the incision, ensuring that at least 1 cm of mesh extends from the beginning of the incision. Use sterile scissors to trim any excess mesh, if necessary. Press gently to ensure intimate contact of the mesh to the selected side of the incision.

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.



Step 5

Use sterile scissors to trim any excess mesh, if necessary. 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. Remove the remaining paper backings/frames.

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Liquid Adhesive Application¹

Ensure the mesh is in intimate contact with the skin prior to application of the liquid adhesive. The liquid adhesive should be applied over the mesh immediately after the mesh has been placed.



Step 6

Activate the liquid adhesive applicator by twisting the purple dial until a snap is heard.



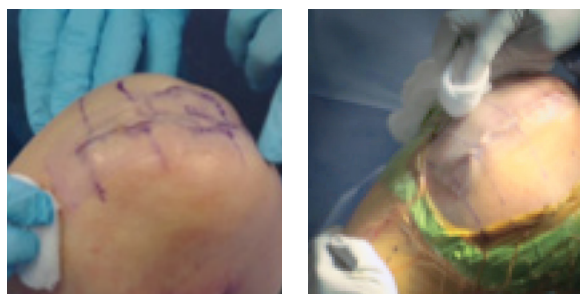
Step 7

Position the applicator 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.



Step 8

Spread the liquid adhesive smoothly and evenly over the entire length of the mesh and surrounding skin area using the flexible applicator tip.



Step 9

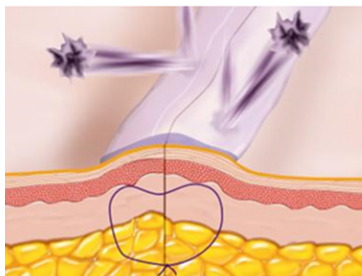
The liquid adhesive should also be applied slightly over the edge of the mesh, covering a small margin of surrounding skin. Any excess liquid adhesive can be wiped off quickly with sterile gauze.

NOTE: DO NOT APPLY A SECOND COAT.

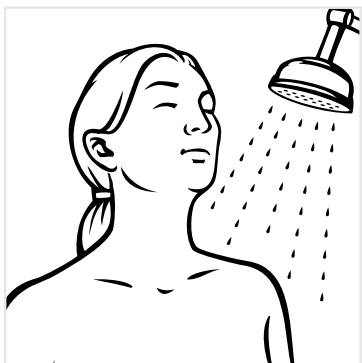
A protective, dry wound dressing such as gauze may be applied only after the liquid adhesive has completely polymerized and the DERMABOND™ PRINEO™ System is no longer tacky to the touch.

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Postoperative Care¹



DERMABOND™ PRINEO™ Skin Closure System provided a flexible microbial barrier with 98.43% protection in vitro for 72 hours against organisms commonly responsible for SSIs.^{2*†}



Patients should be advised that DERMABOND™ PRINEO™ System will need to remain in place until the wound/incision is properly healed (typically 7 to 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 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.



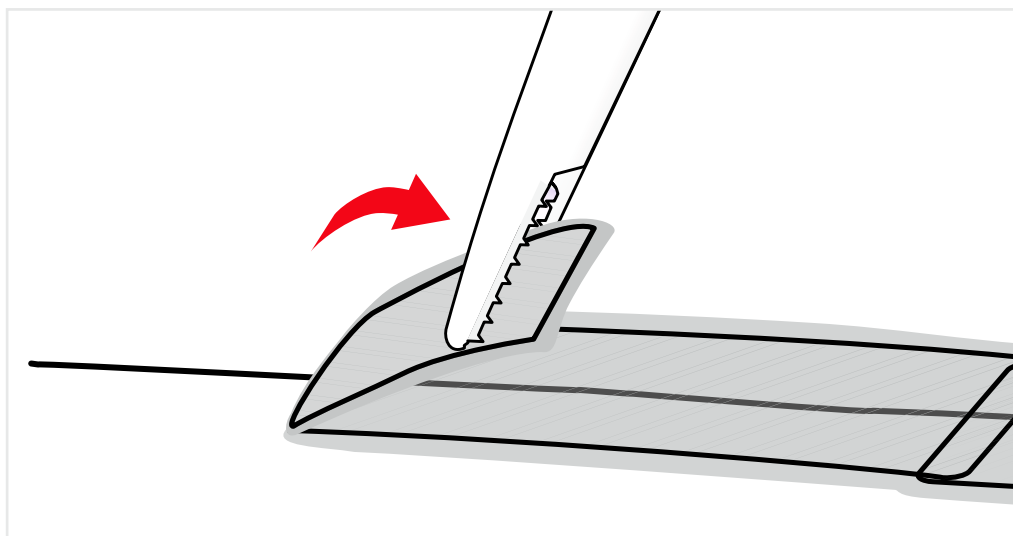
^{*}*Staphylococcus epidermidis, Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, and Enterococcus faecium.*

[†]*Pre-clinical test data are not necessarily indicative of clinical performance*

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Removal Instructions¹

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



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 (Fig. 11). Use the other hand to stabilize the wound as the mesh is peeled off.

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

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

References

1. Ethicon, 100926837 DERMABOND™ PRINEO™ Skin Closure System 22cm. Instructions For Use. 15 November 2023. ADAPTIV Document 380457. Data on File.
2. Ethicon, 09TR016 Technical Report: Study Report for In-Vitro Evaluation of the Microbial Barrier Properties of Improved PRINEO™ Skin Closure System. March 2009. Data on File. (EM_ETH_WOUN103663)