DERMABOND™ PRINEO™
Skin Closure System (22 cm)

Optimal Device Performance Quick Guide[1]

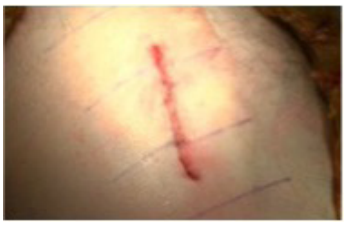
Patient Selection

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.

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). Do not use on any wound with evidence of infection, gangrene, or wounds of decubitus etiology.

Wound Preparation

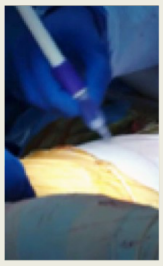
The skin edges must be closely approximated prior to application of the mesh, so that no significant manual approximation is required during mesh application. When used in high-tension areas, ensure skin tension has been removed by application of another wound-closure device (e.g., sutures or skin staples) prior to application of DERMABOND PRINEO System, or ensure that the area will be immobilized during the skin-healing period.

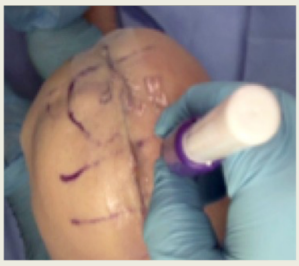


Mesh Application

Position the mesh so one half is on either side of the incision, ensuring that at least 1 cm of mesh extends from each end of the incision. Press gently to ensure intimate contact of the mesh to the 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.

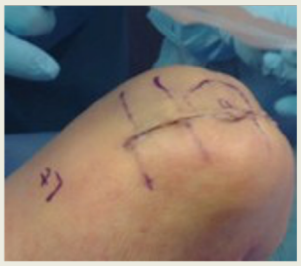
Liquid Adhesive Application





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. Spread the adhesive smoothly and evenly over the entire length of the mesh using the flexible applicator tip. DO NOT APPLY A SECOND COAT.

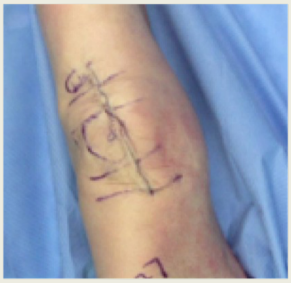
Knee Application

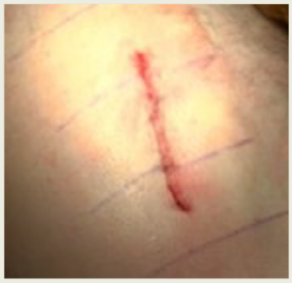


During a total knee arthroplasty, best practice is to apply the DERMABOND PRINEO System while the knee is at the same angle of flexion as the joint capsule closure, without relaxing the knee.

Skin/Wound Preparation[1]

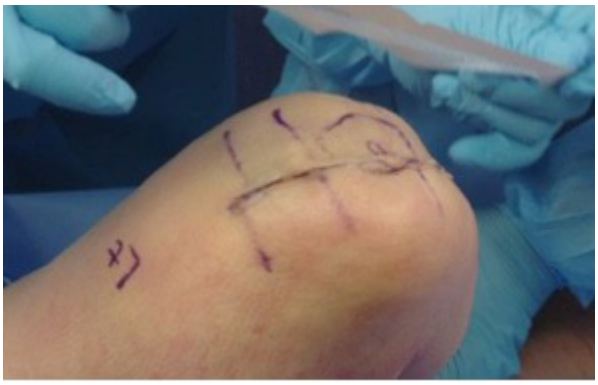
The application of DERMABOND PRINEO System requires thorough wound cleansing. Follow standard surgical practice for wound preparation before application of DERMABOND PRINEO System (i.e., cleanse, irrigate, debride, obtain hemostasis, and close deep layers such that there is no tension on the skin edges).



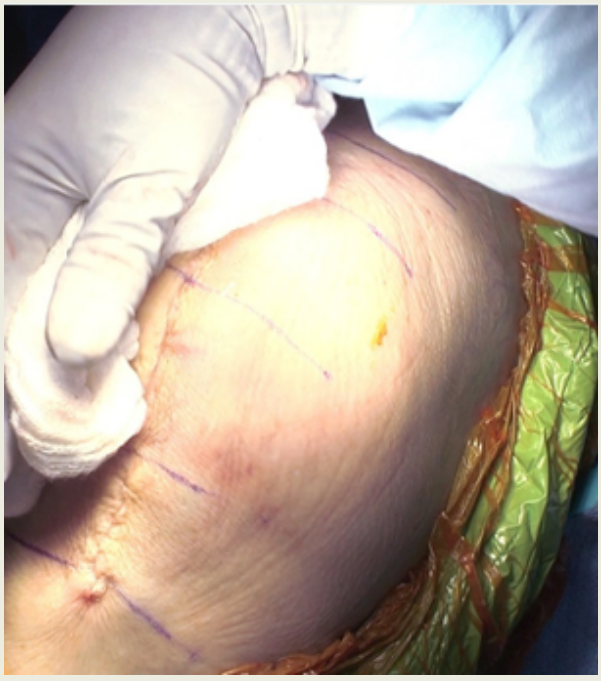


The skin edges must be closely approximated prior to application of the mesh, so that no significant manual approximation is required during mesh application.

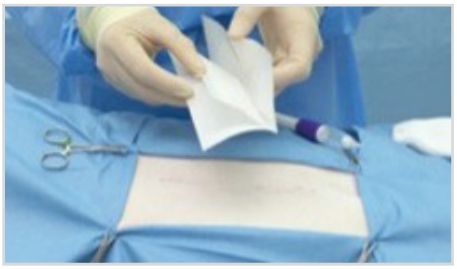
When used in high-tension areas, ensure skin tension has been removed by application of another wound-closure device (e.g., sutures or skin staples) prior to application of DERMABOND PRINEO System, or ensure that the area will be immobilized during the skin-healing period.



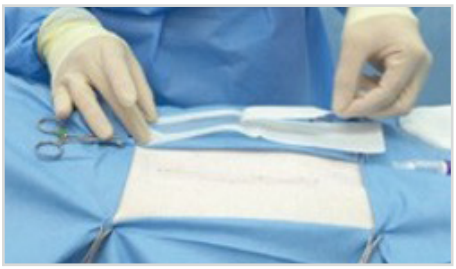
Pat the wound dry with dry, sterile gauze to ensure direct tissue contact for adherence of the mesh and the liquid topical skin adhesive to the skin.



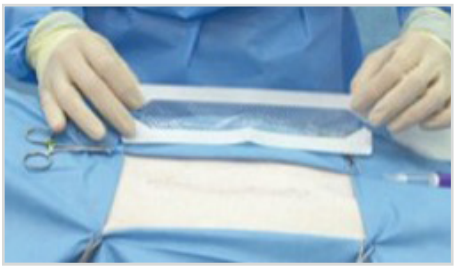
Mesh Application[1]



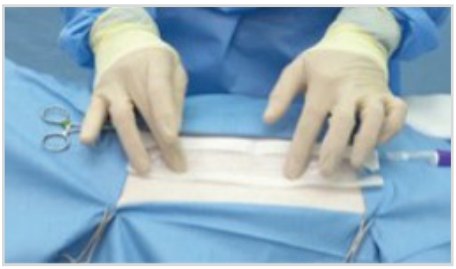
1. Remove the mesh patch from the mesh carrier and dispose of the mesh carrier.



2. Flatten the mesh patch at the crease gently. Place the mesh patch flat on a surface so the mesh is facing down. Remove the center paper liner by peeling from the tab while the patch is flat, with the mesh side facing downward.

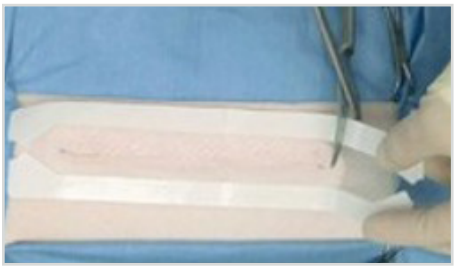


3. Hold the mesh by the proximal (closest to you) corners of the backing paper, ensuring the pressure-sensitive adhesive will be on the mesh side that will be adhered to the patient's skin.



4. 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. Press gently to ensure intimate contact of the mesh to the selected side of the incision.

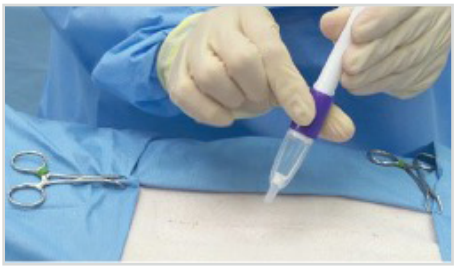
Gently pull the mesh perpendicularly over the incision while adjusting with fingers or forceps to achieve skin-edge approximation, and affix the remainder of the mesh to the other side of the incision.



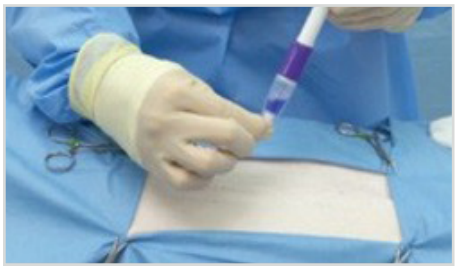
5. Use sterile scissors to trim any excess mesh, if necessary. Remove the remaining paper backing/frames.

Liquid Adhesive Application[1]

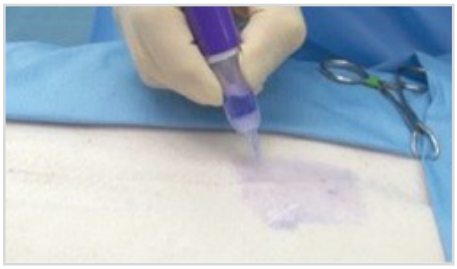
Ensure the mesh is in intimate contact with the skin prior to application of the liquid adhesive. The liquid adhesive should be applied over the mesh immediately after the mesh has been placed.



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

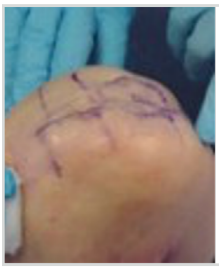


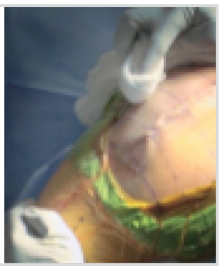
7. Position the applicator tip straight down and away from the application area. Pinch the tip of the applicator, and squeeze the flexible bulb one time. Once the pressure in the bulb is released, it will partly or completely fill with liquid topical skin adhesive.



8. Spread the liquid adhesive smoothly and evenly over the entire length of the mesh 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.





9. The 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. **DO NOT APPLY A SECOND COAT.**

Although not necessary, a protective, dry wound dressing such as gauze may be applied only after the liquid adhesive has completely polymerized (approximately 60 seconds), and the DERMABOND PRINEO System is no longer tacky to the touch.

Postoperative Care[1]

Once polymerized, DERMABOND PRINEO System provides a flexible microbial barrier with 99% protection in vitro for 72 hours against organisms commonly responsible for surgical site infections (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.

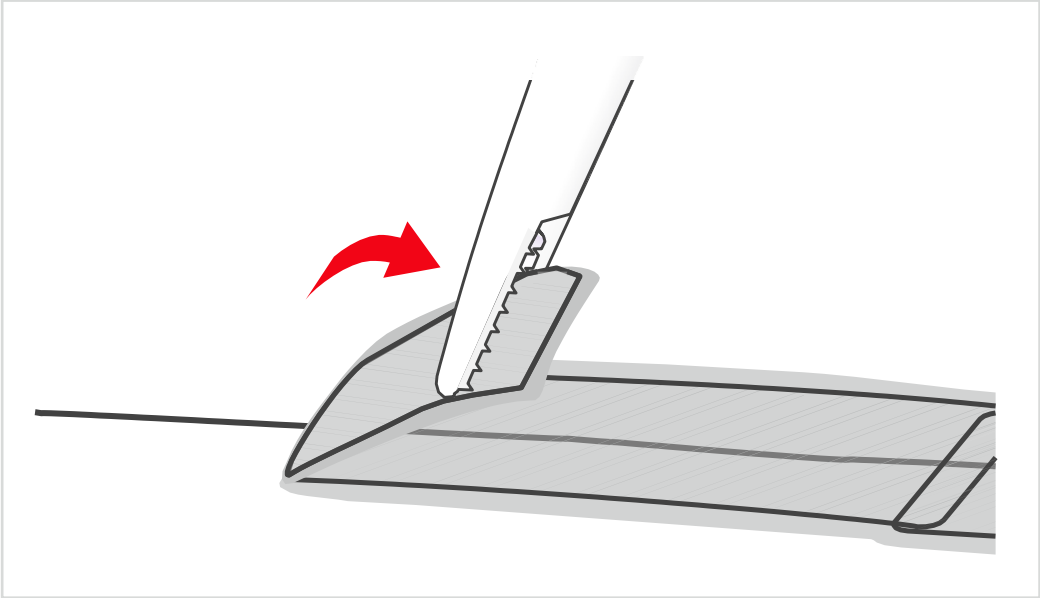
Patients should also be instructed not to scratch, rub, or pick at the DERMABOND PRINEO System and reminded **not to apply topical ointments, lotions, or liquids** to the wound while DERMABOND PRINEO System is in place. This may loosen the DERMABOND PRINEO System, causing it to peel away from the skin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

*Clinical significance unknown

Removal Instructions[1]

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, close to the skin. Do not pull the mesh straight up from the skin. Use the other hand to stabilize the wound as the mesh is peeled off. If required, petroleum jelly may be applied to aid in removal.

Any residual adhesive 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.

References
1. DERMABOND® PRINEO® Skin Closure System (22 cm) Instructions for Use. Ethicon, Inc.
2 Su W. Study report for in vitro evaluation of microbial barrier properties of DERMABOND ProTape. 06TR071. December 4, 2006. Ethicon, Inc.

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