Dermabond®

DERMABOND® PRINEO®

Skin Closure System

Protection • Strength • Patient Satisfaction

The Dermabond Prineo family continues to grow, offering a closure solution for more surgical wounds

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Wound Burden

- Wound complications are common in hip and knee arthroplasty and can include dehiscence, infection, inflammation, necrosis, abscess, and blistering[1-3]
- Meta-analyses have reported that the rate of wound dehiscence ranges from 1.3% to 4.8%[1,2]
- Reported Surgical Site Infection (SSIs) Rates:[4,5]

Procedure	Mean Reported SSIs	Range of Reported SSIs
THA	2.1%	0.05% to 28%
TKA	1.3%	0.05% to 19%
Spine	Unknown	0.7% to 16%

- Infection at the wound site prolongs inflammation and immune response, potentially leading to the wound becoming chronic and non-healing[6,7]
- Surgical site infections (SSIs) have been reported to be a key reason for readmissions in total hip arthroplasty (THA) and total knee arthroplasty (TKA)[8]

Unmet Need

- There are several types of wound dressings used in conjunction with wound closure methods such as staples or sutures. Application of a wound dressing is necessary for proper wound management.[9] However, wound dressings are not intended for wound closure, and, do not have the strength necessary to close wounds
- Wound dressings are typically changed 3-5 times in hip and knee arthroplasty.[3,10]
  Dressings changes are associated with:
  - Pain, time, and cost consumption[9,11]
  - Potential risk for introducing pathogens into the wound[9,11]
  - Patient dissatisfaction[9,11]
  - With each dressing change, it takes 3-4 hours for cellular activity to resume[9]
- There is a need for an all-in-one wound closure treatment that provides the ideal healing environment and skin-holding strength[12]

Protection

How does Dermabond® Prineo® protect the wound?

- Provides a flexible microbial barrier with 99% protection in vitro against organisms commonly responsible for surgical site infection, including *S. aureus, P. aeruginosa, E. coli, E. faecium, and S. epidermidis*[13,14]
- Demonstrates in vitro inhibition of bacteria (Methicillin-resistant Staphylococcus aureus, Methicillin-resistant *Staphylococcus epidermidis, Escherichia coli)*[15]
- In a retrospective study comparing Dermabond® Prineo® and skin staples in Total Knee Arthroplasty, Dermabond® Prineo® is associated with significantly reduced readmission rates within 30, 60, and 90 days[16]

Strength

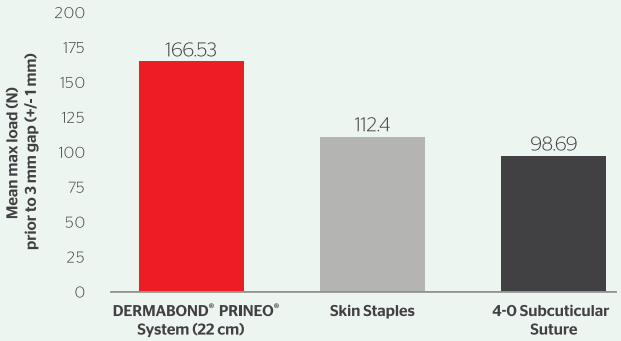
How does Dermabond® Prineo® add strength to the wound?

Technology that provides superior strength compared to skin staples or 4-0 suture[17,18]

The average strength of Dermabond® Prineo® Skin Closure System (22 cm) was shown to be*:

- ~33% stronger when compared to the average strength of staples
- ~40% stronger when compared to the average strength of 4-0 suture

COMPARATIVE SKIN-HOLDING STRENGTHS

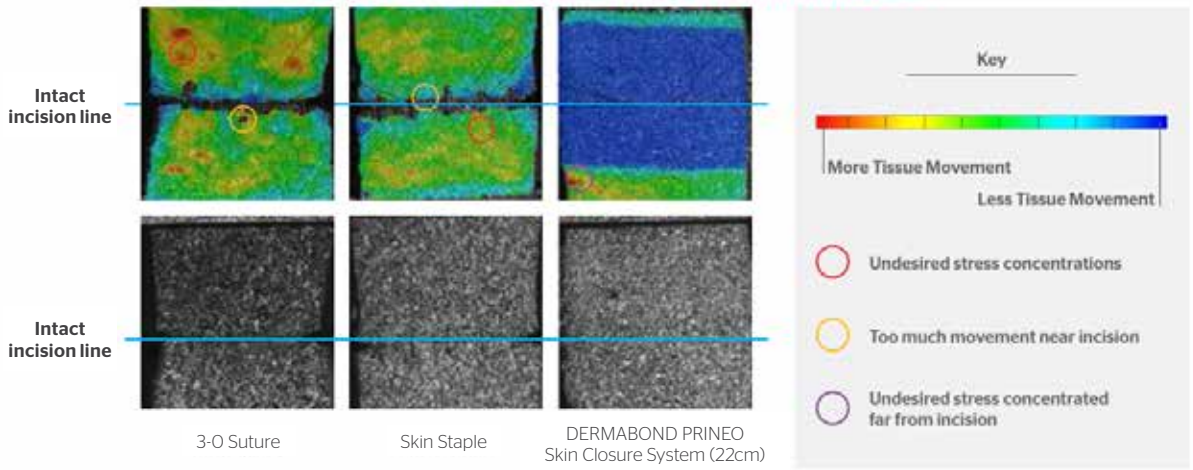


*In an ex vivo study, more load in N was required to create a 3-mm gap between skin edges appoximated with DERMABOND® PRINEO® System than with subcuticular 4-0 MONOCRYL™ (poliglecaprone 25) Suture or PROXIMATE® Ethicon Endo-Surgery skin staples (p<.001).

Superior distribution of tension versus staples or suture[19]

In a head-to-head study vs staples and subcuticular suture, incised tissue samples were approximated using 3-0 suture, skin staples, or Dermabond® Prineo® System (22 cm), respectively. Samples were then placed in a device and tensioned mechanically. Digital Image Correlation (DIC) technology was used to map strain (as revealed by tissue movement).

MAPPING OF TISSUE MOVEMENT UNDER 1 LB OF TENSILE LOAD



The mesh framework and adhesive of Dermabond® Prineo® System (22 cm) provides better distribution of tension than suture or staples[19]

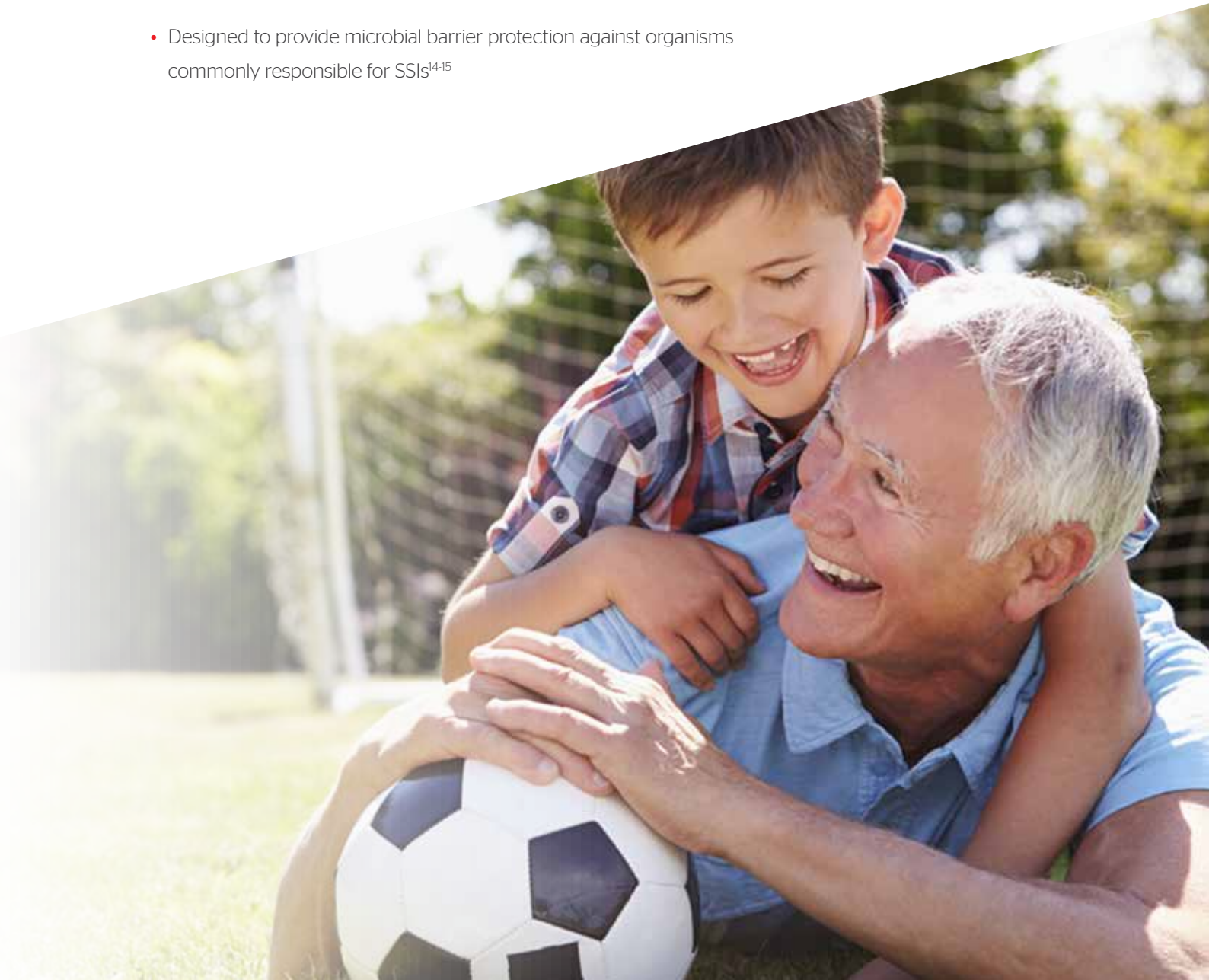
- Sutures and staples create individual points of tension or stress points along the incision
- Dermabond® Prineo® (22cm) has a more uniform distribution of tension

Patient Satisfaction

How does Dermabond® Prineo® benefit the patient?

Dermabond® Prineo® has numerous benefits that can help enhance patient satisfaction including:

- The ability for patients to shower immediately after procedure, if directed by their healthcare practitioner[20]
- Easy mesh tape removal when the wound is sufficiently healed[21]
- Good cosmetic results[21,22]
- Less pain at removal vs. other wound closure methods[21,23]
- Easier self-care as post-surgical dressings are not needed (i.e., no dressing changes required)[24,25]
- Designed to provide microbial barrier protection against organisms commonly responsible for SSIs[14-15]

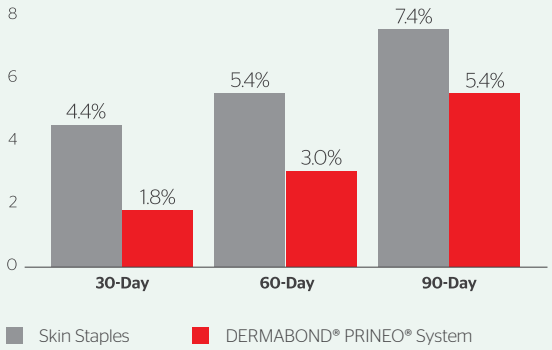


Economic value of the Dermabond® Prineo® Skin Closure System

Dermabond® Prineo® System may improve total knee arthroplasty (TKA) outcomes

Based on a retrospective analysis of 1,942 TKA procedures, Dermabond® Prineo® System was associated with statistically significant **reduced length of hospital stay, reduced probability of discharge to skilled nursing facility (SNF) or other non-home setting,** and **reduced readmission rates** when compared to skin staples[16]

30, 60, 90-DAY ALL-CAUSE READMISSION RATES[16]



12% reduction

in length of stay with Dermabond® Prineo® System[16]

31% reduction

in discharge to non-home setting with Dermabond® Prineo® System[16]

Dermabond® Prineo® System may result in costs savings due to elimination of staple or suture removal and dressing changes

Wound dressings are typically changed 3 to 5 times in hip and knee arthroplasty

- Multiple dressing changes results in the additional burden of increased staff time, potential risk for introducing SSI-causing pathogens to the wound, and material costs[3,9,10]
- Evidence demonstrates that in hip and knee arthroplasty, use of a wound dressing that lowers the frequency of dressing changes and wound complications may be cost effective despite additional upfront cost[3]

Results of an economic model showed that the Dermabond® Prineo® System may provide cost savings within hip and knee Arthroplasties

- The results showed Dermabond® Prineo® System could achieve cost savings of $56.70 to $79.62 per patient when standard or premium wound dressings are used[26^]
- Based on these results, it is anticipated that the Dermabond® Prineo® System may provide cost savings due to decreases in resource utilisation in the post-acute care setting.

^ dollar amounts in USD

A family of products to address your wound closure needs

Dermabond® Prineo® is a specifically formulated 2 component skin closure device containing:

- A proprietary 2-octyl cyanoacrylate topical skin adhesive
- A flexible, self-adhesive polyester mesh that conforms to the contours of the body[13]

Product Code	Description	Length of wound covered	Prostheses List Billing Code*
CLR222	4cm x 22cm mesh patch & 3.8ml topical skin adhesive	up to 20cm[20]	MN230
CLR422	x2 4cm x 22cm mesh patches & 3.8ml topical skin adhesive	up to 41cm[28]	MN230
CLR602	2cm x 60cm mesh strip & 3.8ml topical skin adhesive	up to 58cm[27]	MN230

*for applicable procedures only

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

1. Zhang W, Xue D, Yin H, et al. Barbed versus traditional sutures for wound closure in knee arthroplasty: a systematic review and meta-analysis. Sci Rep 2016;6:19764.
2. Krishnan R, MacNeil SD, Malvankar-Mehta MS. Comparing sutures versus staples for skin closure after orthopaedic surgery: systematic review and meta-analysis. BMJ Open 2016;6 (1): e009257.
3. Ravenscroft MJ, Harker J, Buch KA. A prospective, randomised, controlled trial comparing wound dressings used in hip and kneesurgery: Aquacel and Tegaderm versus Cutiplast. Ann R Coll Surg Engl 2006;88 (1): 18-22.
4. Patel H, Khoury H, Girgenti D, Welner S, Yu H. Burden of Surgical Site Infections Associated with Arthroplasty and the Contribution of Staphylococcus aureus. Surg Infect (Larchmt) 2016;17 (1): 78-88.
5. Parchi PD, Evangelisti G, Andreani L, Girardi F, Darren L et al. (2015) Postoperative Spine Infections. Orthop Rev (Pavia) 7 (3): 5900.
6. Enoch S, Leaper D. Basic science of wound healing. Surgery 2008;26 (2): 31-37.
7. Menke MN, Menke NB, Boardman CH, et al. Biologic therapeutics and molecular profiling to optimize wound healing. Gynecol Oncol 2008;111 (2 Suppl): S87-91.
8. Minhas SV, Kester BS, Lovecchio FC, et al. Nationwide 30-Day Readmissions After Elective Orthopedic Surgery: Reasons and Implications. J Health Qual 2017; 39(1): 34-42.
9. Chowdhry M, Chen AF. Wound dressings for primary and revision total joint arthroplasty. Ann Transl Med 2015;3 (18): 268.
10. Singh B, Mowbray M, Nunn G, et al. Closure of hip wound, clips or subcuticular sutures: does it make a difference? Eur J Orthop Surg Traumatol 2006;16 (2): 124-129.
11. Langlois J, Zaoui A, Ozil C, et al. Randomized controlled trial of conventional versus modern surgical dressings following primary total hip and knee replacement. Int Orthop 2015;39 (7): 1315-1319.
12. Smith TO, Sexton D, Mann C, Donell S (2010) Sutures versus staples for skin closure in orthopaedic surgery: meta-analysis. BMJ 340 c1199.
13. Data on File, ETHICON Inc. Kolata R, Study Protocol 06VA001
14. Bhende S, et al. In Vitro Assessment of Microbial Barrier Properties of DERMABOND® Topical Skin Adhesive. Surgical Infections; 2002;3:251-257
15. Data on File, ETHICON Inc. Bhende S, In-vitro study to evaluate the ability of Dermabond™ Prineo™ Skin Closure System to kill bacteria on contact. 2012
16. Sutton N, et al. Economic and clinical comparison of 2-octyl cyanoacrylate/polymer mesh tape with skin staples in total knee replacement. Journal of Wound Care 2018; 27(4) S12-S22
17. Data on File, Ethicon Inc. Kumar A. AST-2014-0246. Study to compare the tissue holding strength of Dermabond Prineo 22cm Skin Closure System to conventional wound closure techniques. 2014
18. Data on File, Ethicon Inc. Kumar A. AST-2012-0290. Study to compare the tissue holding strength of Prineo Skin Closure System with conventional wound closure techniques. 2012
19. Data on file, Ethicon Inc. Augustin J. Report for mapping strains in Dermabond Prineo Skin Closure System 22 cm comparative study. 2014
20. Ethicon Inc. Dermabond PRINEO Skin Closure System 22cm IFU –Instructions For Use
21. Parvizi D, et al. Use of 2-Octyl Cyanoacrylate Together with a Self-Adhering Mesh (Dermabond Prineo) for Skin Closure Following Abdominoplasty: An Open, Prospective, Controlled, Randomized, Clinical Study. Aesth Plast Surg. 2013;37:529-537
22. Huemer GM, et al. Effective wound closure with a new two-component wound closure device (Prineo) in excisional body-contouring surgery: experience in over 200 procedures. Aesthetic Plast Surg. 2012;36(2):382-386.
23. Blondeel PN, et al. Evaluation of a New Skin Closure Device in Surgical Incisions Associated With Breast Procedures Annals of Plastic Surgery. 2014;73(6):631-637
24. van Nooten F, De Cock E, Fagre J, et al. Comparing time and supplies usage associated with a new skin closure device vs. standard of care wound closure for abdominoplasty surgery in The Netherlands. International Society for Pharmacoeconomics and Outcomes Research, 11th Annual European Congress.Athens, Greece. 2008.
25. De Cock E, van Nooten F, Mueller K, et al. Changing the surgical wound closure management pathway: Time and supplies with PRINEO™ vs. standard of care for abdominoplasty surgery in Germany. International Society for Pharmacoeconomics and Outcomes Research, 11th Annual European Congress. Athens,Greece. 2008.
26. Sadik, K, Flener J, Gargiulo J, et al. A U.S. Hospital Budget Impact Analysis of a Skin Closure System Compared with Standard of Care in Hip and Knee Arthroplasty Poster Presented at the ISPOR 22nd Annual International Meeting, May 20-24, 2017
27. Ethicon Inc. Dermabond PRINEO Skin Closure System 60cm IFU –Instructions For Use
28. Ethicon Inc. Dermabond PRINEO Skin Closure System 42cm IFU –Instructions For Use

For further information please contact your local Ethicon representative, or call customer service in Australia on 1800 252 194 or New Zealand on 0800 803 988.

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