The DERMABOND® Portfolio Difference

CAN-112308-190418

Benefits that make the difference

There are many topical skin adhesives (TSAs) to choose from. Trust DERMABOND® to deliver consistent results you can count on.

Protection

Demonstrated in vitro to **kill 99.9% of bacteria** (MRSA, MRSE, and *E. coli*) on direct contact[1]

Strength

Provided strength to maintain barrier and **wound closure integrity** especially during critical wound healing period (48 hours)[2]

Patient Satisfaction

Offered **comfort and convenience** and led to excellent cosmesis[3-5]

Economic Benefits

Reduced length of stay by more than 25% in CABG surgery when used in addition to conventional sutures[6]

Reduced hospitalization costs by $500 for C-sections when compared with staples or sutures alone[7]

Efficacy can only be proven through clinical trials and **real-world patient studies**

Competitors have claimed similar benefits to DERMABOND Portfolio products. However, many of these competitors use studies of DERMABOND® Topical Skin Adhesive to support their efficacy claims, instead of providing their own clinical evidence.[8,9] This is partially due to changes in FDA classification of TSAs in 2008.

As first to market in 1998, DERMABOND Adhesive was considered a Class III device, requiring substantial evidence to prove its own efficacy and safety before FDA approval. But in 2008, the FDA reclassified TSAs to Class II,[10] which meant new TSAs could obtain market clearance by proving equivalence to previously-approved devices. This means **TSAs introduced after 2008 were held to fewer regulations than DERMABOND Adhesive, and as a result, did not need to provide as much evidence regarding their own efficacy and safety.**

PROVEN clinical results no other TSA can match

The DERMABOND® Portfolio of products is backed by an extensive body of evidence, including **57 published, randomized controlled trials** evaluating 6,173 patients and has more clinical experience, outcomes data, and publications than any other TSA.*†

*Based on published literature in PubMed and SCOPUS, using only RCTs that evaluated the use of the product in a manner consistent with intended indication.

†DERMABOND ADVANCED® Topical Skin Adhesive and DERMABOND® PRINEO® Skin Closure System test equivalent or superior to DERMABOND Adhesive in head-to-head testing for microbial barrier, wound-bursting strength, tensile strength, flexibility, durability, viscosity, drying time, water vapor transmission rate, water resistance, and physician satisfaction.

A precisely-balanced formulation—**unique to DERMABOND®**

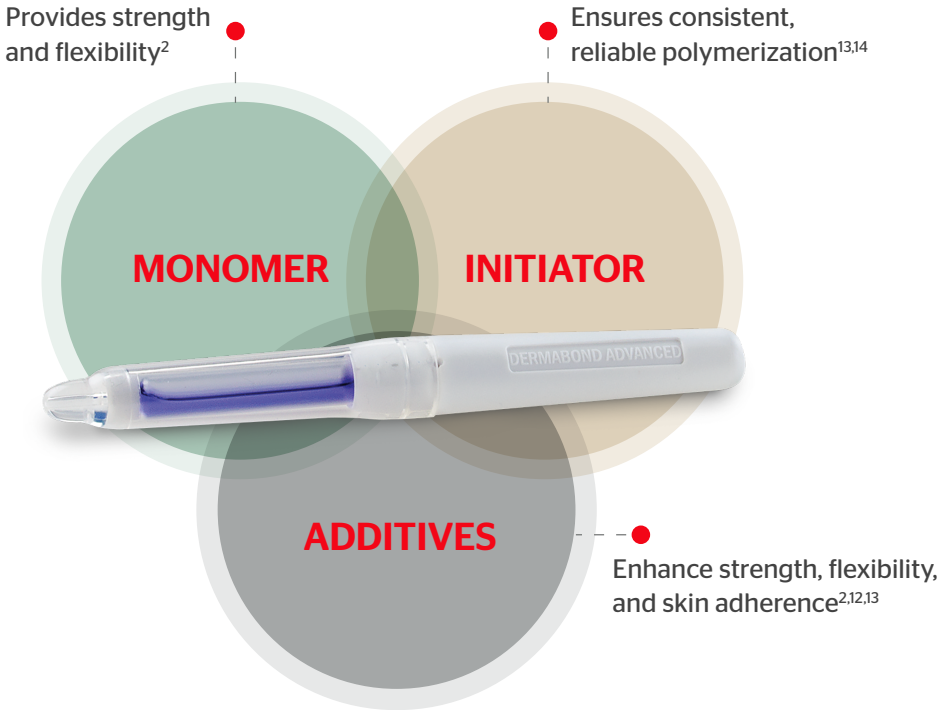
DERMABOND ADVANCED® Topical Skin Adhesive has a formulation unlike any other TSA. The base is the monomer—a highly purified, 2-octyl cyanoacrylate (2-OCA)—which provides strength and flexibility.[2,3] Some competitors, such as Swiftset™ Topical Skin Adhesive, use a butyl-based monomer in their formulations, which is not as strong or flexible as a 2-OCA monomer.[2]

2-OCA monomer has demonstrated significantly greater strength and flexibility than butyl-based adhesives.[2]

In addition to a highly purified 2-OCA, DERMABOND ADVANCED Adhesive is developed with **specific ratios** of an initiator and additives, that **together**, provide **strong, flexible closure with microbial barrier protection** that set it apart from the competition.[1,11,12]

TSAs: More than a monomer

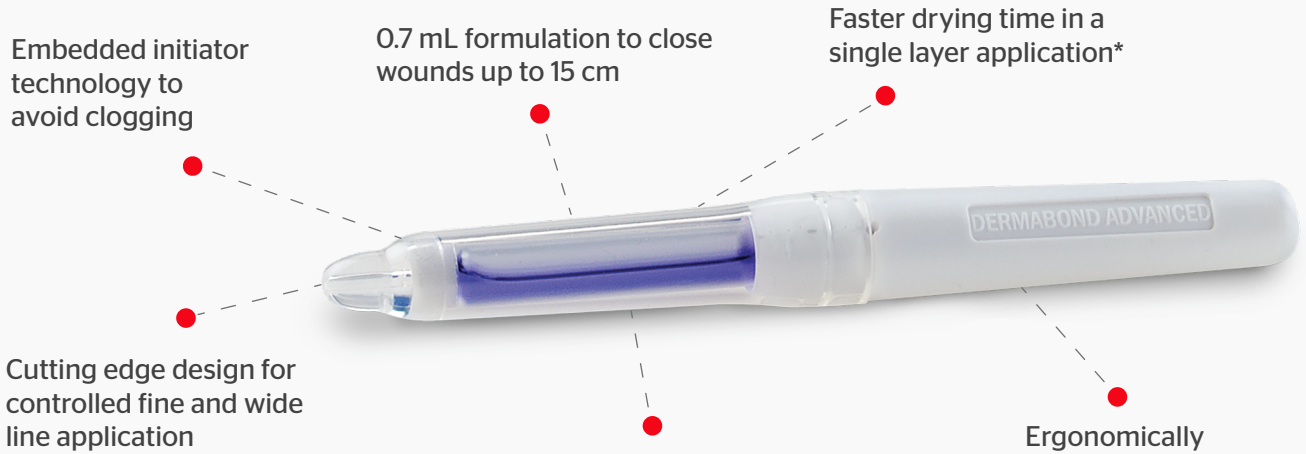
Competitors have claimed similar benefits just because they share the same 2-OCA monomer, and some have even used studies of DERMABOND® Topical Skin Adhesive to support their efficacy claims.[8,9] However, **no competitor has the same formulation as DERMABOND ADVANCED Adhesive, which means they cannot be expected to provide the same clinical results!**



Tried, tested and trusted for 20 years

Harnessing two decades of TSA expertise, every feature of the DERMABOND® applicator is designed to optimize surgeon experience and enhance product delivery.

DERMABOND ADVANCED® Topical Skin Adhesive Applicator



Held to the highest of standards

As the first-to-market, DERMABOND Topical Skin Adhesive was held to high standards. And for **the last 20 years**, Ethicon has continued to focus on quality—manufacturing millions of units each year while providing every customer with a product that meets strict quality guidelines.

*Compared to DERMABOND® Topical Skin Adhesive.

The only skin closure portfolio that delivers **the DERMABOND® difference**

Sustained innovation has given rise to a diverse family of skin closure products for a wide variety of clinical needs. From small laparoscopic incisions to high-tension wounds from open surgery, the DERMABOND® Portfolio has a skin closure device designed to replace skin sutures and staples* for optimal healing, excellent cosmesis and patient satisfaction.[4]

Choose the Right DERMABOND® for You

DERMABOND ADVANCED® Topical Skin Adhesive

Trusted quality and proven efficacy for mid-to-large incisions—up to 15 cm in length[2,11]

DERMABOND® Mini Topical Skin Adhesive

Proprietary DERMABOND® formulation in an economically efficient size for small incisions—up to 4 cm in length

DERMABOND® PRINEO® Skin Closure System

Greater skin holding strength than skin sutures and staples in 22—60 cm sizes for longer, open incisions[15]

(22 cm)

(42 cm)

(60 cm)

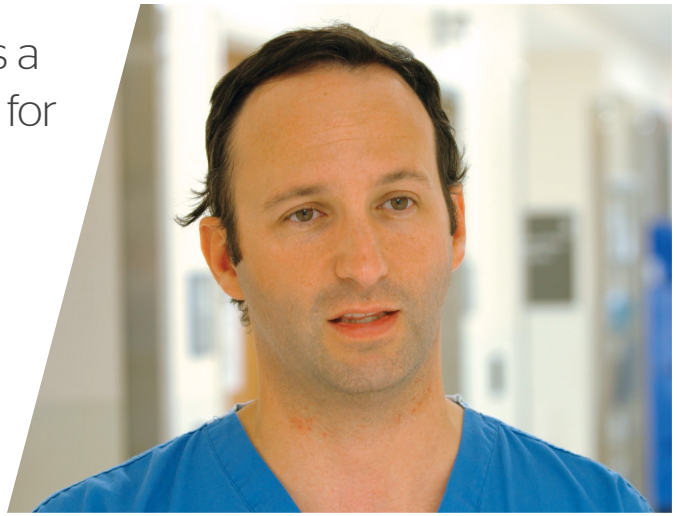
*In wounds approximated with deep dermal sutures

DERMABOND® PRINEO® Skin Closure System

Strength, Protection, and Patient Satisfaction

- Supports skin closure with strength equivalent to 3-0 MONOCRYL® (poliglecaprone 25) Suture (shown ex-vivo)[16]
- Provides a flexible microbial barrier with 99% protection in vitro for 72 hours against organisms commonly responsible for surgical site infections[17†]
- Leads to greater overall satisfaction for surgeons and patients when compared to skin staples[18‡]

> I like DERMABOND PRINEO System, because I think it creates a water tight skin closure of the arthrotomy, which is important for addressing some of the risk factors for surgical site infections and is also nice for the patient. With DERMABOND PRINEO System, the patient may start showering soon after the procedure and feel like a normal person again, and mentally I think this helps them achieve a faster recovery period.
>
> – Dr. Ryan Nunley, Orthopedic surgeon, St. Louis, MO



The quote is the opinion of Dr. Nunley, a real surgeon who used DERMABOND PRINEO System. Post-surgical interview was October 6, 2015. Dr. Nunley is a paid consultant of Ethicon.

> After the DERMABOND PRINEO System came off it was wonderful... I was so anxious to actually see the scar line... It's such a fine scar line!
>
> – Diane McGaw, Total Knee Replacement patient
>
> Diane is a real patient whose doctor used DERMABOND PRINEO System in her surgery. Post-surgical interview was May 8, 2017.

DERMABOND® Portfolio Difference vs other TSAs

Monomer	OCTYL								BUTYL	
Manufacturer	**ETHICON**			**CHEMENCE MEDICAL**		**ADHEZION BIOMEDICAL**	**ADVANCED MEDICAL SOLUTIONS**			
Products	DERMABOND ADVANCED® Topical Skin Adhesive	DERMABOND® Mini Topical Skin Adhesive	DERMABOND® PRINEO® Skin Closure System	exofin® High Viscosity Tissue Adhesive	exofin fusion® Skin Closure System	SurgiSeal Stylus® Topical Skin Adhesive† (Distributed by Pfizer)	LiquiBand Exceed®	Skin Affix™ Topical Skin Adhesive (Medline private label)	LiquiBand® Topical Skin Adhesive	LiquiBand® Flow Control Topical Skin Adhesive/Swiftset™ Topical Skin Adhesive
Proprietary Formulation Additives	Strength, flexibility, durability	Strength, flexibility, durability	Strength, flexibility, durability	Flexibility, Strength	Flexibility, Strength	None	Flexibility	Flexibility	None	None
Initiator for Consistent Polymerization	Yes[14]	Yes[14]	Yes[14]	Yes[25]	Yes[25]	Minimal	None	None	None	None
Thickener for Higher Viscosity	Yes[8,12]	Yes[8,12]	Yes[8,12]	Yes[25]	Yes[25]	None	None	None	None	None
Performance										
Wound Bursting-Strength (3-D)	431.2 mmHg[19]	274 mmHg[2]	Shown to provide significantly greater skin-holding strength than skin staples or subcuticular 4-0 MONOCRYL® (poliglecaprone 25) Suture (P<0.01)[15*]	Unknown	Unknown	Unknown	Unknown	Unknown	140.8 mmHg[19]	140.8 mmHg[19]
Tensile Strength (2-D)	10.13 lbf[20]	9.86 lbf[22]		Unknown	Unknown	5.44 lbf[28]	6.40 lbf[31]	Unknown	2.46 lbf[34]	3.95 lbf[36]
Fatigue Failure Cycles	15.5[20]	15.3[22]		Unknown	Unknown	2.4[29]	Unknown	Unknown	1.25[34]	1.25[34]
Product Details										
Packaging	DNX12 12 units/box DNX6 6 units/box[21]	DHVm12 12 units/box[21]	CLR222US 2 units/box CLR602US 2 units/box[21]	6 units/box or 10 units/box[26]	2 units/box[27]	12 units/box[30]	6 units/box[32]	12 units/box[33]	12 units/box[35]	12 units/box[35]
Volume/ Applicator	0.7 mL[21]	0.36 mL[21]	22 cm or 60 cm[21]	1 mL[9]	22 cm or 44 cm[27]	0.5 mL[30]	0.8 g[32]	0.4 mL[33]	0.5 mL[35]	0.5 mL[35]
Application	Single Layer[3]	At least 2 layers[23]	Single layer over mesh[24]	Single layer[26]	Single layer over mesh and anchors[27]	1–2 layers[30]	Unknown	Unknown	Unknown	Unknown

*In an ex-vivo study, more load in N was required to create a 3±1 mm gap between skin edges approximated with DERMABOND PRINEO System, than with subcuticular 4-0 MONOCRYL™ Suture or PROXIMATE Ethicon Endo-Surgery skin staples (P=0.00).

†SurgiSeal Stylus® Topical Skin Adhesive has the equivalent formulation of SecureSeal™ Octyl Topical Skin Adhesive.

Strong, protected skin closure is critical for optimal surgical outcomes

Don't compromise your closure— choose **the DERMABOND® Difference**

Products in the DERMABOND® Portfolio provide microbial protection,[11] excellent cosmetic outcomes,[4,18] and deliver greater overall satisfaction for both surgeons and patients when compared to staples.[18*]

*Double-blinded quantitative market research study comparing surgeon experience with DERMABOND PRINEO System and skin staples in total knee arthroplasty. N=88 patients; N=83 orthopaedic surgeons. 90% c.l. Fielded June/July 2017

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

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Shaping the future of surgery