

LiquiBand® Exceed™ Topical Skin Adhesive Summary of Effectiveness Data

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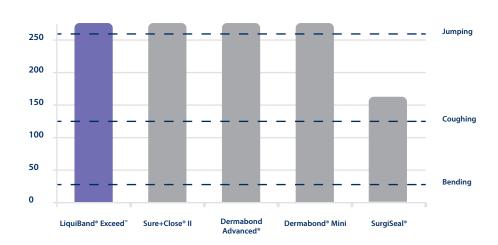
Introducing LiquiBand® Exceed™, A Next Generation 2-Octyl Cyanoacrylate Topical Skin Adhesive

Cyanoacrylate adhesives have been extensively evaluated as alternatives to conventional topical wound closure devices such as sutures and staples. Cyanoacrylates provide strong wound closure with good cosmetic outcomes and speed of use which is why they have become commonplace for medical applications. Recent studies have found the microbial barrier properties of cyanoacrylates protects wounds from microbial contamination.^{1,2}

LiquiBand®Exceed™, a next generation 2-octyl-cyanoacrylate adhesive device developed by Advanced Medical Solutions (Plymouth) Ltd. has recently gained regulatory approval for topical wound closure. Here we present results following extensive testing of LiquiBand® Exceed™ by in vitro laboratory assessments and in vivo skin model evaluations. These assessments include evaluating the strength and flexibility of topical wound closure, ease of use and barrier properties to microbial contamination.

- ▶ High Wound Burst Strength
- ▶ Low Weight of Adhesive per Centimeter of Wound Coverage
- ▶ Flexible and Water Resistant Wound Closure
- ▶ Controlled Application of Adhesive
- ▶ Safe and Effective Wound Closure
- ▶ Low Exothermic Reaction
- ▶ Effective Barrier to Microbial Contamination

Proven Strength Provides Confidence In Wound Closure...



In a porcine wound model study comparing topical wound closure by commercially available medical adhesives³, LiquiBand® Exceed™ withstood pressures experienced from common activities such as bending (30mmHg), coughing (127mmHg) and jumping (252mmHg) (chart 1).⁴

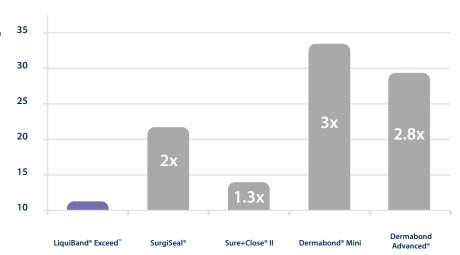
Chart 1: Two centimeter incisions closed by various commercially available adhesives were subjected to increasing pressure (mmHg) using a biomechanical test system (BTC- 2000™, Surgical Research Laboratory Inc.).

...While Using Less Adhesive

Only 10µg of LiquiBand® Exceed™ adhesive were required to confidently close each cm of wound, up to three times less than comparative devices.³
One device can be used for topical closure of wounds up to 30cm (chart 2).³

Additional standardized strength testing (ASTM F2255-05, F2458-05, F2256-05) demonstrated similar tensile, lap-shear and t-peel strength as Dermabond Advanced*.³

Chart 2: Devices were weighed before and after application as per manufacturer's instructions to determine amount of adhesive used (μg) per cm of wound length.



A Safety Profile That Offers Peace Of Mind

Extensive standardized biocompatibility testing (ISO 10993: biological evaluation of medical devices) demonstrates that LiquiBand® Exceed™ is non skin-sensitizing and non toxic.³ *In vivo* wound model (porcine) testing and *ex vivo* histological analysis demonstrates that topical wound closure with LiquiBand® Exceed™ does not interfere with the natural wound healing process or adversely affect intact skin.³

A Device Designed For Controlled Application Of Adhesive

Laboratory testing³ demonstrated that the novel broad felt tip design and winged applicator body of LiquiBand® Exceed™:

- Optimizes coverage & yield of adhesive,
- ▶ Helps to avoid stuttering and
- Provides consistent coat weight compared to Dermabond Advanced®

LiquiBand® Exceed™ was able to be applied consistently in an even layer across more than two times the area compared to Dermabond Advanced® (Figure 1).



Figure 1: An example of application of one LiquiBand® Exceed™ applicator compared to one Dermabond Advanced® applicator.

Additionally, LiquiBand® Exceed™ has been designed to be easy to activate and apply adhesive, without dripping or squirting.³

Formulated For Low Heat On Application

With only a 0.34°C measured increase in temperature during the polymerization reaction, LiquiBand® Exceed™ adhesive avoids the burning sensation commonly experienced following application of other topical skin adhesive wound closure devices.³

Effective Barrier To Microbial Contamination



Figure 2: Percentage of agar plates layered with LiquiBand® Exceed™ that remained uncontaminated following 3 and 7 days incubation with 8 different pathogenic microorganism species.¹

Standardized testing of microbial barrier properties found LiquiBand® Exceed™ to provide:

- Protection against 8 different species of pathogenic fungi (C. albicans, Asp. brasiliensis), and bacteria species (E. coli, S. aureus, S. epidermidis, Ps aeruginosa, E. cloacae), including MRSA, commonly implicated in SSI (Surgical Site Infections) as long as the adhesive film remains intact³
- ▶ Once polymerized, LiquiBand® Exceed™ provides an instant barrier to contamination, allowing for the innate process of wound healing previously shown to generate a natural microbial barrier at 48- 72hrs post wound closure^{5,6}

Flexible And Water Resistant Wound Closure

When subjected to standardized testing for flexibility (ASTM D4338-97), LiquiBand® Exceed™ was found to be as flexible as Dermabond Advanced® without cracking or blushing following flexion.³

Light showering does not affect wound closure strength of LiquiBand® Exceed™ as evaluated following standardized strength testing (ASTM F2458-05).³

Conclusion

LiquiBand® Exceed™, a regulatory approved 2-octyl cyanoacrylate adhesive, was subjected to multiple testing methodologies for the topical closure of wounds. LiquiBand® Exceed™ adhesive was found to have high tensile strength in standardized ASTM testing and also in a wound simulation model where wounds closed with LiquiBand® Exceed™ adhesive withstood pressures experienced from everyday activities including jumping, coughing and bending. While this strength of wound closure was found to be similar to other wound closure devices, LiquiBand® Exceed™ required up to three times less volume of adhesive to close the same length of wound as Dermabond Advanced®. Only one LiquiBand® Exceed™ device was required to close wounds up to 30cm in length.

Additionally, the broad tip applicator and winged design of LiquiBand® Exceed™ was found to provide users with controlled and consistent application of adhesive.

Standardized safety testing found that LiquiBand® Exceed™ adhesive is non-toxic or skin-sensitizing, which was also demonstrated following *ex vivo* histological analysis of wounds closed with the adhesive.

While strong and durable closure and ease of use are primary requirements for topical adhesives, protecting wounds from microbial contamination may prevent potential SSI. LiquiBand® Exceed™ was demonstrated to be an effective barrier to high titre challenge from 8 different pathogenic microbial species including MRSA, commonly implicated in SSI.

These results demonstrate that LiquiBand® Exceed™ is a proven choice for strong and durable topical wound closure that protects against microbial contamination and provides users with control and precision of application.



- References:

 1. Grimaldi L, et al. Octyl-2-cyanoacrylate adhesive for skin closure: eight years experience. In Vivo. 2015 Jan-Feb;29(1):145-8.

 2. Ando M, et al. Surgical site infection in spinal surgery: a comparative study between 2-octyl-cyanoacrylate and staples for wound closure. Eur Spine J. 2014 Apr; 23(4):854-62.

 3. Data on File at Advanced Medical Solutions (Plymouth) Ltd.

 4. Cobb WS, et al. Normal Intra-abdominal Pressure in Healthy Adults. Journal of Surgical Research. 2005. 129:231-235.

 5. Rosevear C, et al. Reducing Risk Of Post-Operative Complications After Joint Replacement Surgery, Nurse Unit Manager Periopertive Services, Geelong Private Hospital, Geelong, Victoria 3220, Australia. 6. Nursing Times, Surgical wound care: current views on minimizing dressing-related pain (September, 2004).

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