Count on Cortiva® allograft dermis
for a predictable graft experience

Cortiva®

ALLOGRAFT DERMIS

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Cortiva® allograft dermis is a non-crosslinked acellular dermal matrix (ADM). It is a safe and natural biologic option for the repair, replacement, reconstruction, or augmentation of soft tissues including plastic and reconstructive surgery procedures.[1] With precise tolerances for thickness and size[1], Cortiva® allograft dermis delivers exceptional handling predictability that you can depend on every time you open the package.

Cortiva® allograft dermis, processed using a proprietary method that maintains the native dermal structure, has demonstrated rapid revascularization and remodeling to support graft incorporation.[1,6,7,*,†]

Maintaining the highest standards of quality, from donor screening to terminal sterilization, Cortiva® allograft dermis provides surgeons with an ADM they can depend on for a consistent and excellent graft experience.[1]

- **Exceptional handling predictability**
- **Proprietary gentle processing**
- **Rapid graft incorporation**
- **Comprehensive portfolio**
- **Proven commitment to quality**

Exceptional handling predictability

Dermis thickness impacts handling characteristics such as pliability and conformability. The Cortiva® allograft dermis portfolio features a uniform thickness throughout the graft and tight thickness specification tolerances to provide a consistent and predictable handling experience for surgeons.[1,‡]

Conformable and pliable, with a consistent handling experience.[1,‡]

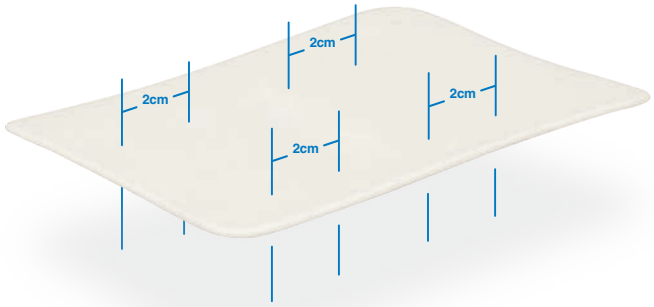
Inter- & intra-graft thickness and shape consistency with tight tolerances

Precise thickness consistency of ± 0.1–0.125mm.[1]

Measured every 2cm for consistent thickness.[1]

Length and width confirmed twice with a laser-calibrated ruler.[1]

Conforms to specifications without deviation. Graft measurements are not averaged.

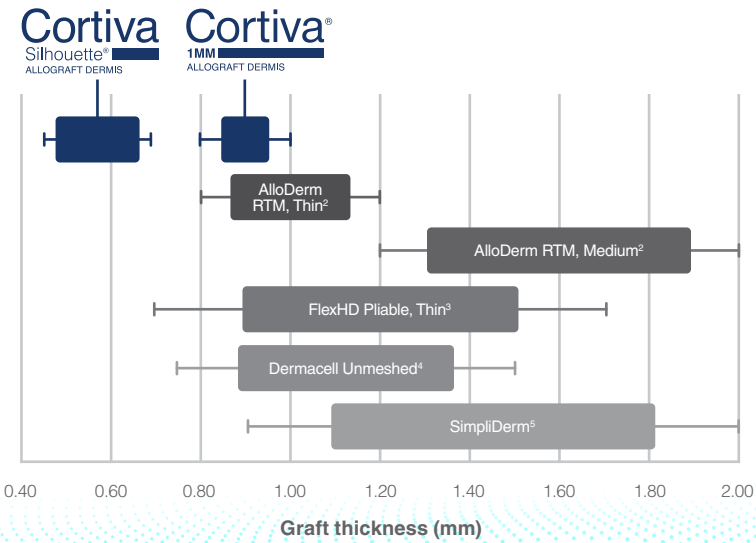


Uniform intra-graft predictability

Predictability is our focus. Cortiva® allograft dermis grafts are precisely controlled to ± 0.1–0.125mm, measured every 2cm increment.[1]

Exceptional inter-graft thickness consistency

Cortiva® allograft dermis grafts feature a precise thickness consistency range compared to other leading acellular dermal matrixes of similar thickness.[1] Comparison based on publicly available specifications.



Proprietary gentle processing

The proprietary sterilization process used for Cortiva® allograft dermis achieves a Sterility Assurance Level (SAL) of 10^{-6} while preserving the graft's native dermal structure and biomechanical characteristics.[1]

Sterility assurance level of 10^{-6}

U.S. Food and Drug Administration (FDA) recommendation for medical devices: The sponsor should state the Sterility Assurance Level (SAL) of 10^{-6} for devices labeled as sterile. FDA recommends a SAL of 10^{-3} for devices intended only for contact with intact skin.[8]

10^{-6} Cortiva® ALLOGRAFT DERMIS

1 in 1,000,000 chance a viable microorganism survives the sterilization process

10^{-3} Most used ADMs

1,000 times more likely to contain microorganisms than SAL 10^{-6}

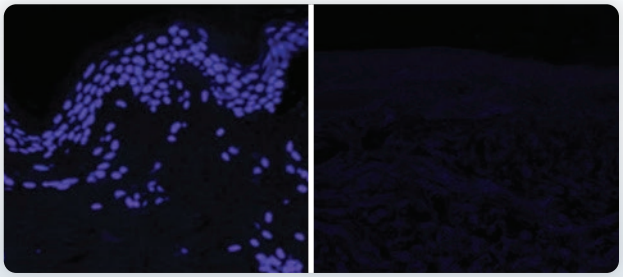
Aseptic, No SAL Some ADMs

Up to 1,000,000 times more likely to contain microorganisms than SAL 10^{-6}

Preserved dermal structure

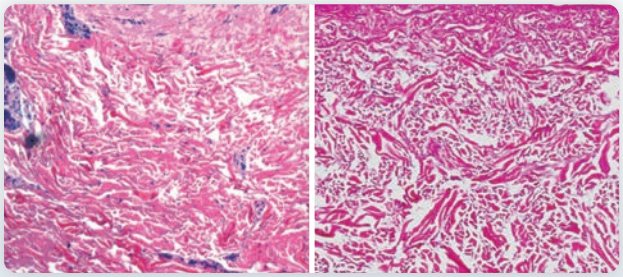
The proprietary processing used across the Cortiva® allograft dermis portfolio is validated to inactivate or remove a broad panel of viruses, bacteria, fungi, and spores, while preserving the native dermal structure and biomechanical characteristics.[1,*]

Unprocessed human dermis[1] | Cortiva® ALLOGRAFT DERMIS



Processing removes cellular and DNA content (DAPI nuclear DNA stain. 20× magnification.)

Unprocessed human dermis[1] | Cortiva® ALLOGRAFT DERMIS



H&E staining shows the preserved native structure in Cortiva® allograft dermis. Cells removed. Processing leaves native tissue intact (H&E Stain. 50× magnification.)

The Cortiva® allograft dermis difference

Our strict approach to dermal processing takes all the necessary steps to ensure the best outcomes. Our tissue sterilization process sterilizes tissue safely and effectively while maintaining native characteristics.

Please refer to the labeling for complete instructions for use.

- **Preservative free**[1]
- **Normal immune response**[1,6,9,†]
- **Up to 5-year shelf life**[1]
- **30 second rehydration**[1]

Rapid graft incorporation

Cortiva® allograft dermis, processed using a proprietary method that maintains the native dermal structure, has demonstrated rapid revascularization and remodeling to support graft incorporation into the host.[1,6,7,9,*,†]

Rapid revascularization

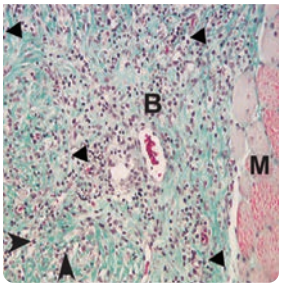
Pre-clinical studies

In pre-clinical studies, cellular infiltration and capillary formation were observed as early as 7 days post implantation along with a favorable immune response consistent with normal wound healing.[1,*]

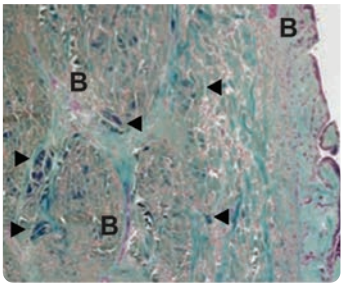
Clinical studies

In a clinical setting, 13 patients underwent a second planned procedure where the graft was biopsied, and robust revascularization and incorporation were observed.[6,†]

Pre-clinical results[1,*] (100×)



Clinical results[6,†] (100×)

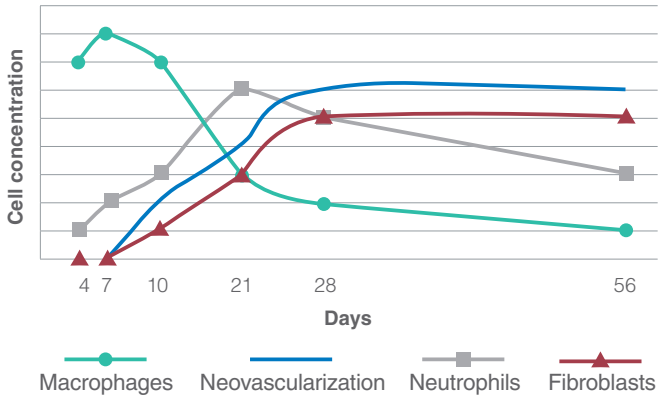


B Blood vessels **M** Muscles ▶ Cellular infiltration

Images: Representative Masson's Trichrome histology.

Favorable healing response

This graph illustrates the qualitative healing response to implanted Cortiva® allograft dermis in a pre-clinical study. Plotted as a concentration of various types of cells present in the explanted tissue as a function of time, the graph is consistent with the temporal sequence of normal wound healing.[1,*]



Level 1 clinical evidence results

In a prospective randomized controlled trial of 302 patients, outcomes with Cortiva® 1mm allograft dermis (151 patients) were compared to outcomes with AlloDerm RTM (151 patients). The study noted that the odds of seroma formation were nearly twice as high with AlloDerm RTM than with Cortiva® 1mm allograft dermis (p=0.047) after adjustment for relevant covariates.[7,†]

	Seroma	Hematoma	Infection	Necrosis	Dehiscence	Reconstructive failure
Cortiva® 1MM ALLOGRAFT DERMIS	**21 (7.6%)**	4 (1.4%)	24 (8.7%)	17 (6.1%)	14 (5.1%)	23 (8.3%)
AlloDerm RTM	**33 (12%)**	10 (3.6%)	26 (9.3%)	22 (7.9%)	16 (5.7%)	26 (9.3%)
p-Value	**0.09**	0.17	0.80	0.43	0.73	0.68

Comprehensive portfolio

Surgeons can choose the thickness, size and shape of dermis to fit their surgical approach.

Cortiva Silhouette® ALLOGRAFT DERMIS

The thinnest cut for exceptional pliability

One of the thinnest and most pliable ADMs available, processed from the middle dermal layer to closely conform to contoured and complex surfaces.[1,‡]

Thickness	0.45–0.7 mm
Tolerance	± 0.125 mm
Size	2×4 cm to 16×20 cm
Dermis	Dermis without basement membrane (no orientation)

Cortiva® 1MM PERFORATED TAILORED ALLOGRAFT DERMIS

Unique hexagonal perforation

Combines a preshaped graft design with hexagonal perforations to provide ease of use and versatility across dynamic, patient-centric procedures.[11]

Thickness	0.8–1.0 mm
Tolerance	± 0.1 mm
Size	Small (15.1×7.3cm–87 cm^2), Medium (19.2×9.2cm–140 cm^2) Large (21.1×10.2cm–170 cm^2)
Dermis	Perforated dermis without basement membrane (no orientation)

Cortiva® 1MM TAILORED ALLOGRAFT DERMIS

For patient centric customization

Optimized for better fit, featuring a preshaped design that supports surgical precision and patient-centered customization.[11]

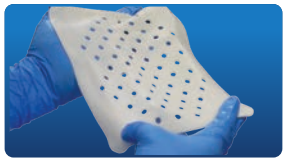
Thickness	0.8–1.0 mm
Tolerance	± 0.1 mm
Size	Small (15.1×7.3cm–87 cm^2), Medium (19.2×9.2cm–140 cm^2), Large (21.1×10.2cm–170 cm^2)
Dermis	Dermis without basement membrane (no orientation)

Cortiva® 1MM PERFORATED ALLOGRAFT DERMIS

Unique hexagonal perforation

Features a distinctive pattern of hexagonal perforations. In an animal model, hexagonal perforations demonstrated greater multi-directional expansion compared to other perforation shapes.[10,*]

Thickness	0.8–1.0mm
Tolerance	± 0.1mm
Size	16×20 cm
Dermis	Perforated dermis with basement membrane



Cortiva® 1MM ALLOGRAFT DERMIS

Consistent thickness for predictable graft handling‡

Offers predictable graft handling across diverse surgical applications, with precise thickness uniformity and multiple size options.[1,6,7,12,†,‡]

Thickness	0.8–1.0mm
Tolerance	± 0.1mm
Size	4×12 cm to 16×20 cm
Dermis	Dermis with basement membrane

Proven commitment to quality

Evergen is a leading provider of tissue-based implants with a commitment to scientific integrity, safety, and quality. Continuous investments in new technologies and surgeon engagement allow for the processing of reliable, high-quality implants that ultimately enhance patients' lives and our healthcare partner's experience. By choosing Cortiva® allograft dermis, you prioritize quality above all else.

We deliver:

Highest standards of quality

- Precise tolerances for allograft thickness and size.[1]
- To ensure each measurement meets our strict specifications, graft measurements are not averaged and processes include relevant controls to ensure graft consistency.[1]
- Tissue processors and donor chart reviewers have an average of 10+ years of experience and are supported by two medical directors who are licensed physicians.[1]

Proven safety

- More than 8.8 million tissue-based implants, including Cortiva® allograft dermis, have been processed using the same proprietary, validated sterilization method with zero confirmed cases of implant-associated infection.[1]
- We maintain the highest level of sterility (SAL 10^{-6}) for Cortiva® allograft dermis, without impacting the native structure of the dermis.[1,*]
- Clinical studies demonstrate an excellent safety profile.[6,7,12,†]

Exceptional supply reliability

- Significant investments in processing capacity and operational excellence support a +99% on-time delivery rate for Cortiva® allograft dermis.[1]
- Long standing partnerships with leading tissue procurement organizations and tissue bank certifications seamlessly integrate our supply chain with implant processing.[1]
- Investments in state-of-the-art technology enable us to maximize the gift of tissue donation.

Unwavering scientific integrity

- 80,000 square feet of laboratory and processing space dedicated to researching new applications of human tissue, and improving and validating new tissue processing methods.[1]
- Proudly hosts numerous healthcare practitioner education programs, including peer-to-peer round tables to foster discussions among surgeons nationwide, regardless of their product preferences or preferred techniques.
- Evergen Donor Services supports tissue procurement partners through in-depth technical training to optimize recovery outcomes and maximize the gift of tissue donation.[1]

Coordinate implant ordering with your local representative:
800.624.7238 | **customerservice@evergenbio.com**

	Cortiva Silhouette® ALLOGRAFT DERMIS	Cortiva® 1MM PERFORATED TAILORED ALLOGRAFT DERMIS	Cortiva® 1MM TAILORED ALLOGRAFT DERMIS	Cortiva® 1MM PERFORATED ALLOGRAFT DERMIS	Cortiva® 1MM ALLOGRAFT DERMIS
Thickness	0.45–0.7 mm thick	0.8–1.0 mm thick	0.8–1.0 mm thick	0.8–1.0 mm thick	0.8–1.0 mm thick
Dermis	Dermis without basement membrane (no orientation)	Perforated dermis without basement membrane (no orientation)	Dermis without basement membrane (no orientation)	Perforated dermis with basement membrane	Dermis with basement membrane
Description	**Code**	**Code**	**Code**	**Code**	**Code**
2×4cm	UTD0204	–	–	–	–
4×7cm	UTD0407	–	–	–	–
4×12cm	UTD0412	–	–	–	DH2412
4×16cm	UTD0416	–	–	–	DH2416
5×8cm	UTD0508	–	–	–	DH2508
6×12cm	UTD0612	–	–	–	DH2612
6×16cm	UTD0616	–	–	–	DH2616
7×10cm	UTD0710	–	–	–	DH2710
8×12cm	UTD0812	–	–	–	DH2812
8×16cm	UTD0816	–	–	–	DH2816
8×20cm	UTD0820	–	–	–	DH2820
10×15cm	UTD1015	–	–	–	DH3015
16×20cm	UTD1620	–	–	DP1620	DH3620
Small 15.1×7.3cm–87cm^2	–	DMS087P	DMS087	–	–
Medium 19.2×9.2cm–140cm^2	–	DMM140P	DMM140	–	–
Large 21.1×10.2cm–170cm^2	–	DML170P	DML170	–	–

For more information, visit **CortivaADM.com**

Cortiva®
ALLOGRAFT DERMIS

Description
Cortiva® 1mm, Cortiva® 1mm Tailored, Cortiva® 1mm Perforated Tailored, and Cortiva Silhouette® allograft dermis are dehydrated dermis from donated human tissue processed through the Tutoplast® Tissue Sterilization process. The implants are preserved by the Tutoplast® tissue sterilization process which retains the three-dimensional collagen structure responsible for the multidirectional, mechanical properties of the original dermal tissue. These implants are regulated as 361 human cell and tissue product (HCT/Ps) as defined in US FDA 21 CFR 1271 and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). These implants are provided sterile and require rehydration prior to use.

Warnings
Cortiva Silhouette® Cortiva® 1mm, Cortiva® 1mm Perforated, Cortiva® 1mm Perforated Tailored: The same potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, it is not possible to guarantee freedom from transmission of infectious agents or other adverse reactions such as hypersensitivity, allergic or immune response.

Cortiva® 1mm Tailored: The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant. Successful treatment is dependent upon the patient's host tissue response. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function.

Cortiva Silhouette®, Cortiva® 1mm Perforated, Cortiva® 1mm Perforated Tailored: Do not use the implant for abdominal wall repair, hernia repair or for other procedures that require substantial tensile strength. The implant should be used only where it is under minor to moderate tension.

Cortiva Silhouette®: Do not perforate the implant. Perforations may affect implant performance.

Cortiva® 1mm Perforated, Cortiva® 1mm Perforated Tailored: Do not further perforate the implant. Additional perforations may affect implant performance.

Precautions
Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant; as such conditions may compromise outcomes. The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determines that the clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to the success of the surgical procedure.

References

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* Performance data from animal models may not be representative of performance in humans.
† Clinical cases are unique and individual results may vary.
‡ Lab data may not be representative of effects or performance in humans.

All Cortiva® and Cortiva Silhouette® allograft dermis implants are processed by RTI Surgical, Inc. (Alachua, FL).
Please refer to the labeling for complete instructions for use. Regulatory approvals vary by country. Therefore, we kindly ask you to contact the representative in your region regarding the availability of specific grafts in your country.

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Evergen
11621 Research Circle
Alachua, FL 32615 USA
T 800.624.7238
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