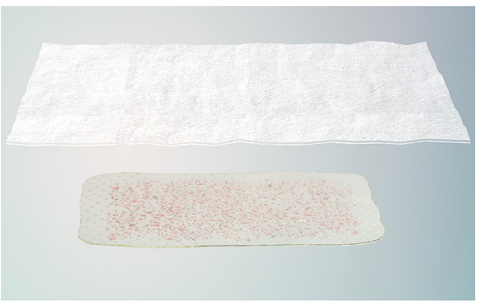
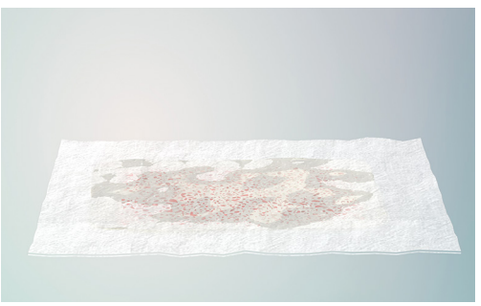
StrataGraft®
allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat

Postoperative care

DRESSING STRATAGRAFT





Please adhere to the following recommendations when changing dressings:

- A porous, nonadherent contact dressing should be placed over StrataGraft® and left in place for 1 week before changing
- Place a second layer of dressing that does not contain silver
- Placement of an outer bolster or wrap that keeps StrataGraft from moving as clinically appropriate is at the discretion of the physician

If you are caring for a patient treated with StrataGraft and have questions or concerns about the wound, it is important to reach out to the treating physician before taking further action.

Dressings and topical products not recommended for use with StrataGraft

StrataGraft is composed of viable cells, and because of this, some dressings and topical products are not recommended.

- **Mafenide acetate** is not recommended following the application of StrataGraft as this topical antimicrobial has been shown to reduce keratinocyte viability and disrupt the integrity of the tissue
- **Silver-containing antimicrobials or dressings** are not recommended because in vitro data suggest silver may decrease the viability of keratinocytes and human dermal fibroblasts
- **Chlorhexidine solution** is not recommended on the wound following application of StrataGraft as this material has been shown to be toxic to keratinocytes and human dermal fibroblasts

INDICATION

StrataGraft® is an allogeneic cellularized scaffold product indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use in patients with known allergies to murine collagen or products containing ingredients of bovine or porcine origin.

Warnings and Precautions

- StrataGraft contains glycerin. Avoid glycerin in patients with known sensitivity (irritant reaction) to glycerin.
- Severe hypersensitivity reactions may occur. Monitor for both early and late symptoms and signs of hypersensitivity reaction following StrataGraft application, and treat according to standard medical practice.
- StrataGraft contains cells from human donors and may transmit infectious diseases or infectious agents, eg, viruses, bacteria, or other pathogens, including the agent that causes transmissible spongiform encephalopathy (TSE, also known as Creutzfeldt-Jakob disease [CJD or variant CJD]).

Please see additional Important Safety Information on next page and full Prescribing Information, including complete instructions.

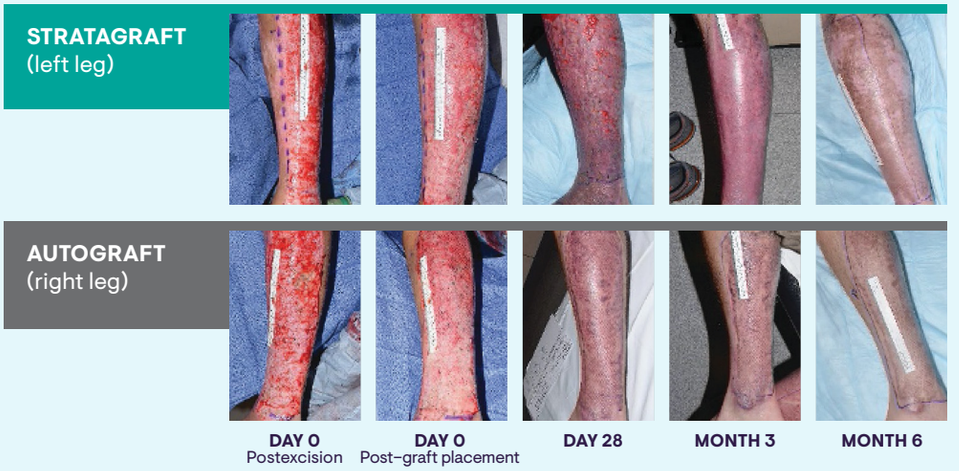
A DIFFERENT PICTURE OF HEALING

While StrataGraft and autograft ultimately provide clinically similar cosmesis outcomes, the path to getting there may appear different from what you are accustomed to seeing, particularly during the first few weeks of healing.

CLINICAL TRIAL PATIENT A

The patient sustained a 17% TBSA thermal burn and was treated on the lower extremities.

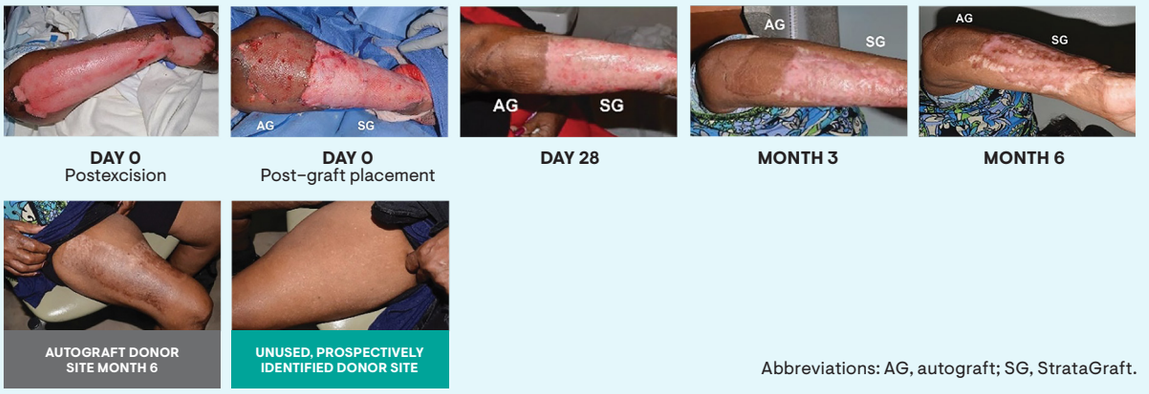
SINGLE PATIENT SIDE-BY-SIDE COMPARISON



CLINICAL TRIAL PATIENT B

The patient sustained a 14% TBSA thermal burn and was treated on the forearm.

SINGLE PATIENT SIDE-BY-SIDE COMPARISON



Abbreviations: AG, autograft; SG, StrataGraft.

Both patients were treated with autograft and StrataGraft and served as their own comparators.[1]

If you have any additional questions about postoperative care with StrataGraft, please call 1-877-647-2239.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

StrataGraft is a xenotransplantation product because of an historic exposure of the keratinocyte cells to well-characterized mouse cells. The cell banks have been tested and found to be free of detectable adventitious agents, and mouse cells are not used in the manufacture of StrataGraft; however, these measures do not entirely eliminate the risk of transmitting infectious diseases and disease agents.

Transmission of infectious diseases or agents by StrataGraft has not been reported.

- Because StrataGraft is a xenotransplantation product, StrataGraft recipients should not donate whole blood, blood components, plasma, leukocytes, tissues, breast milk, ova, sperm, or other body parts for use in humans.

Adverse Reactions

- The most common adverse reactions (incidence ≥2%) were itching (pruritus), blisters, hypertrophic scar, and impaired healing. Other adverse events reported are included in the full Prescribing Information.

Pediatric Use

- The safety and effectiveness of StrataGraft in pediatric patients (<18 years) have not been established.

Please see additional Important Safety Information on previous page and full Prescribing Information, including complete instructions.

Reference: 1. Gibson ALF, Holmes JH IV, Shupp JW, et al. A phase 3, open-label, controlled, randomized, multicenter trial evaluating the efficacy and safety of StrataGraft construct in patients with deep partial-thickness thermal burns. *Burns*. 2021. doi:10.1016/j.burns.2021.04.021.

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