



## About StrataGraft®

### What Is StrataGraft®?

StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen – dsat) is a viable, bioengineered, allogeneic, cellularized scaffold product comprised of keratinocytes grown on gelled collagen containing dermal fibroblasts. It was approved by the U.S. Food and Drug Administration (FDA) on June 15, 2021, and is indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns). StrataGraft is the first approved donor site-free alternative to autograft for this patient population.

### What Are Deep Partial-Thickness Burns?

Deep partial-thickness burns are complex skin injuries in which the damage extends through the entire epidermis (outermost layer of skin) and into the lower part of the dermis (innermost layer of skin).

**Each year, approximately 40,000 patients in the United States require hospitalization for the treatment of severe burns,<sup>1</sup> including deep partial-thickness burns.**

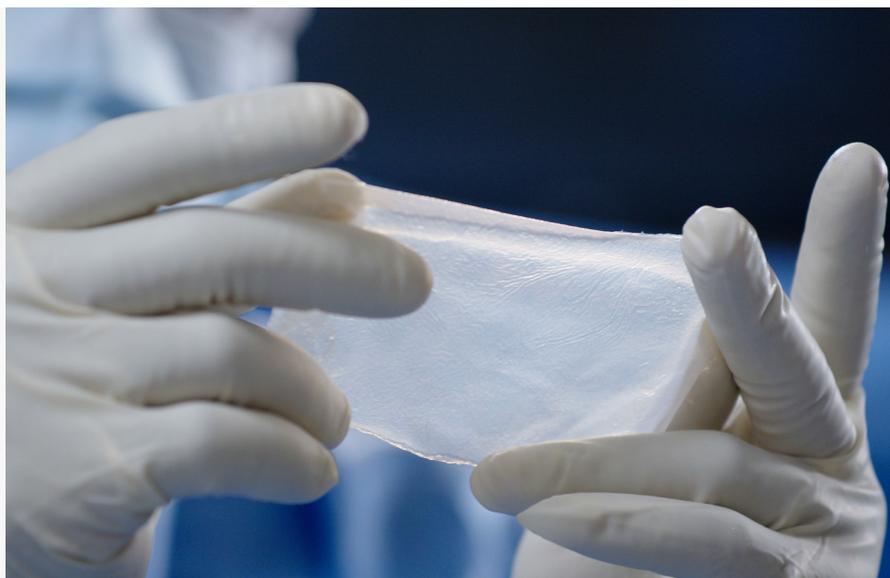
The current standard of care for deep partial-thickness burns is autograft, which involves the surgical harvesting of healthy skin from an uninjured site on the patient and transplanting the skin graft to the injury, leaving the patient with two wounds requiring care. Patients who receive an autograft may experience pain,<sup>2,3</sup> itching, scarring and discoloration,<sup>2,3</sup> increased risk of infection,<sup>2,4</sup> and possible compromised tissue function at the donor site.<sup>5</sup> In addition, the amount of healthy skin available for harvesting is frequently limited in those with large burns, necessitating sequential re-harvesting of available donor sites.

### How Does StrataGraft Work?

**Designed with both dermal and epidermal layers composed of well-characterized human cells, StrataGraft delivers viable cells to support the body's own ability to heal.**

StrataGraft contains metabolically active cells that produce and secrete a variety of growth factors and cytokines. Growth factors and cytokines are known to be involved in wound repair and regeneration. StrataGraft does not remain permanently engrafted, but is replaced by the patient's own cells over time.

Right: StrataGraft dimensions: off-white rectangular sheet of approximately 100 cm<sup>2</sup>



#### Media Contact

Ben Rickles | Real Chemistry | 404-502-6766 | [brickles@realchemistry.com](mailto:brickles@realchemistry.com)

StrataGraft and the StrataGraft logo are trademarks of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owners.

©2021 Mallinckrodt. US-2001785 06/21



## How Is StrataGraft Used?

Now that StrataGraft is approved for use in the United States, it will be available to burn surgeons for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns). StrataGraft is intended to be applied in appropriate aseptic conditions, such as the operating room, and can be sutured, stapled or secured with a tissue adhesive.

**StrataGraft is cryopreserved in order to deliver viable cells upon application.**

## What Data Support the Use of StrataGraft?

The efficacy and safety of a single application of StrataGraft in the treatment of deep partial-thickness burns were evaluated in the pivotal Phase 3 STRATA2016 clinical trial (NCT03005106). The multicenter study enrolled 71 adult participants age 18 and older at U.S. burn centers. **Results showed the study met both co-primary endpoints with statistical significance:**

### Autograft sparing

The difference in the percent area of StrataGraft and control autograft treatment sites that required autografting by three months was 98% ( $p < 0.0001$ ). Donor site harvest was eliminated for 96% (68 of 71) of the StrataGraft-treated burn sites. As a result, pain and scarring were significantly reduced at these potential donor sites that were spared and remained intact ( $p < 0.0001$ ).<sup>6</sup>

### Durable wound closure

The proportion of patients achieving durable wound closure of the StrataGraft treatment site at three months without autograft replacement was 83% (95% CI: 74, 92). The proportion of patients achieving durable wound closure of the autograft control treatment site at three months without additional autograft placement was 86% (95% CI: 78, 94).<sup>6</sup>

## 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).

## 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]).

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  $\geq 2\%$ ) 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 full Prescribing Information.**

## Media Contact

**Ben Rickles**  
Real Chemistry  
404-502-6766  
brickles@realchemistry.com

StrataGraft and the StrataGraft logo are trademarks of a Mallinckrodt company. Other brands are trademarks of a Mallinckrodt company or their respective owners.

©2021 Mallinckrodt. US-2001785 06/21

## References

- American Burn Association. Burn Incidence Fact Sheet. <http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/>. Accessed May 15, 2020.
- Sinha S, Schreiner AJ, Biernaskie J, Nickerson D, Gabriel VA. Treating pain on skin graft donor sites: review and clinical recommendations. *J Trauma Acute Care Surg*. 2017;83(5):954-964.
- Burnett LN, Carr E, Tapp D, et al. Patient experiences living with split thickness skin grafts. *Burns*. 2014;40(6):1097-1105.
- Weber RS, Hankins P, Limitone E, et al. A randomized prospective trial comparing a hydrophilic polyurethane absorbent foam dressing with a petrolatum gauze dressing. *Arch Otolaryngol Head Neck Surg*. 1995;121(10):1145-1149.
- Serebrakian AT, Pickrell BB, Varon DE, et al. Meta-analysis and systematic review of skin graft donor-site dressings with future guidelines. *Plast Reconstr Surg Glob Open*. 2018;6(9):e1928.
- StrataGraft Prescribing Information. June 2021.

To learn more about  
StrataGraft, visit  
[StrataGraft.com](http://StrataGraft.com).

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