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

# A quick reference guide to workflow integration

**Please refer to the full Prescribing Information for thorough instructions on preparation, placement, and postoperative care**

## 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.

**Please see Important Safety Information throughout and full Prescribing Information, including complete instructions.**

# Preparing

This guide is intended to be a quick reference for staff members who have already received training on properly preparing StrataGraft®. See the full Prescribing Information for detailed instructions, including aseptic technique.

**READY IN APPROXIMATELY 20 MINUTES**

**PERSONNEL** Scrub tech + circulator

## MINIMAL REQUIREMENTS


StrataGraft


Gloves or atraumatic forceps


Water bath or warming oven set at 35°C to 39°C (95°F to 102°F)

- Place the Hold Solution in a warming oven for 45 minutes or a water bath for 15 minutes. Other preparations may begin during the warming process

## READY TO USE IN APPROXIMATELY 20 MINUTES

- Remove StrataGraft from ultracold storage; once it is removed, the Insert Tray must be placed into the Hold Solution within 10 minutes
- Open the sterile Hold Dish; **then** aseptically pour the warmed Hold Solution into the dish
- Transfer and aseptically place the Insert Tray containing StrataGraft into the Hold Solution for at least 15 minutes but no longer than 4 hours
- Ready to mesh and place

See full Prescribing Information for detailed instructions.

## SELECT IMPORTANT SAFETY INFORMATION

### 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.

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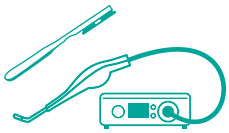
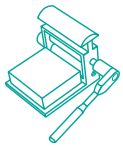
# Placing

**MESH AND PLACE WITHIN 4 HOURS**

**PERSONNEL** Burn surgeon + scrub tech

| | | |
|---|---|---|
| ✓ Prepare the wound bed as per usual |  | Excision/ debridement tools |
| ✓ Estimate the amount of StrataGraft required | 8 cm × 12.5 cm | Each StrataGraft sheet is ~100 $cm^2$ |
| ✓ Mesh StrataGraft up to a 1:1 ratio. Do not allow StrataGraft to dry |  | Mesher |
| ✓ Place StrataGraft with the dermal (shiny) side down on the prepared wound bed, and anchor using your preferred method. If using fibrin glue, apply prior to placing StrataGraft |  | Staples, sutures, or tissue adhesive, such as cyanoacrylate or fibrin glue |
| ✓ Apply a porous, nonadherent contact dressing |  | Dressings |

See full Prescribing Information for detailed instructions.

## SELECT IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

- 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]).

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# Postop

**KEEP INITIAL DRESSING IN PLACE FOR 1 WEEK**

**PERSONNEL** Burn surgeon + nursing staff

## RECOMMENDATIONS WHEN CHANGING DRESSINGS

- A porous, nonadherent contact dressing should be placed over StrataGraft
- 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

Dressings and topical products not recommended for use with StrataGraft:

- Mafenide acetate
- Silver-containing antimicrobials or dressings
- Chlorhexidine solution

**See full Prescribing Information for detailed instructions.**

## 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.

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# Visit **StrataGraft.com** to learn more.

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  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 full Prescribing Information, including complete instructions.**

**Reference:** StrataGraft. Package insert. Stratatech Corporation; 2021.

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