

Before starting with StrataGraft

Before you begin any procedure with StrataGraft®, read the entire [Prescribing Information](#). These instructions are for preparing 1 sheet of StrataGraft. Preparation should take approximately 20 minutes.

StrataGraft components

- A single ~100 cm² rectangular sheet of StrataGraft in a Product Dish inside a laminated foil pouch
- 1 bottle of Hold Solution inside a laminated foil pouch. Note: The bottle will not be full. Do not use the Hold Solution if the contents of the bottle appear cloudy or turbid
- 1 sterile Hold Dish in a clear pouch

StrataGraft must be maintained in ultracold conditions (ie, in a freezer at -70°C to -90°C or on dry ice) during transport, storage, and transfer to the OR until initiation of the thaw process.

Following excision/debridement, determine the number of StrataGraft sheets that need to be thawed.

STRATAGRAFT PREPARATION

1. WARM THE HOLD SOLUTION

Use 1 bottle of Hold Solution for each sheet of StrataGraft to be prepared for placement. Remove the Hold Solution from the pouch and warm using 1 of the following options.

Option 1: Place into a warming oven/cabinet set at a temperature of 35°C to 39°C or 95°F to 102°F for AT LEAST 45 minutes prior to use.

Option 2: Place the Hold Solution in a sterile or nonsterile water bath set at a temperature of 35°C to 39°C or 95°F to 102°F for AT LEAST 15 minutes prior to use without submerging the cap or threads of the bottle.

If using a sterile water bath, ensure proper steps are taken to transfer the Hold Solution to the sterile field. Dispose of any unused Hold Solution that has been warmed.

3. GATHER STRATAGRAFT

Remove the number of StrataGraft sheets to be prepared from ultracold storage. Once StrataGraft is removed from ultracold storage conditions, it must be placed into the Hold Dish containing warmed Hold Solution within 10 minutes.

- Use 1 Hold Dish for each sheet of StrataGraft

2. TRANSFER THE HOLD DISH

Aseptically transfer the empty sterile Hold Dish to the sterile field. The nonsterile operator peels open the seal of the pouch and aseptically presents the Hold Dish to the sterile operator for placement in the sterile field (A).



4. OPEN STRATAGRAFT

Open the carton and remove the foil pouch. Peel the foil pouch open, and carefully remove the closed Product Dish. The unopened Product Dish containing StrataGraft can be placed on a flat surface outside of the sterile field. StrataGraft should not remain at room temperature for more than 10 minutes.

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]).

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.

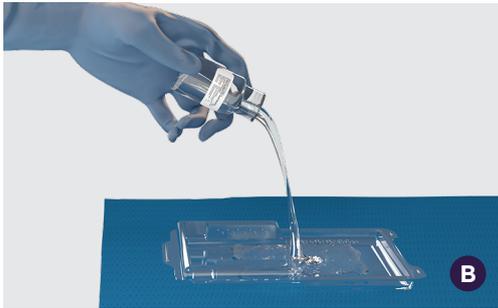
Please see additional Important Safety Information on next page and full [Prescribing Information](#), including complete instructions.

STRATAGRAFT PREPARATION (CONTINUED)

5. POUR WARMED HOLD SOLUTION

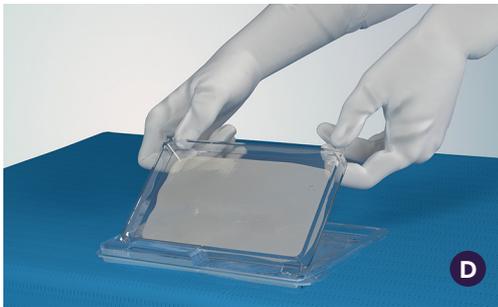
The nonsterile operator pours 1 entire bottle of warmed Hold Solution into 1 sterile Hold Dish (B) using aseptic technique per institutional procedures (eg, wearing sterile gloves) immediately after removing the warmed Hold Solution from the warming device.

Ensure proper steps are taken to maintain the integrity of the sterile field.



7. PLACE INSERT TRAY

Place the Insert Tray into the Hold Dish (D) with the warmed Hold Solution. Using sterile, gloved fingers or a pair of atraumatic forceps, place the Insert Tray into the Hold Dish, beginning with 1 edge and lowering it to the opposite edge to minimize trapping bubbles beneath the Insert Tray.



If bubbles do become trapped beneath the Insert Tray, gently lift the Insert Tray and place it slowly back down into the Hold Solution.

Maintain StrataGraft in the Hold Solution for a minimum of 15 minutes to a maximum of 4 hours.

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

- 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

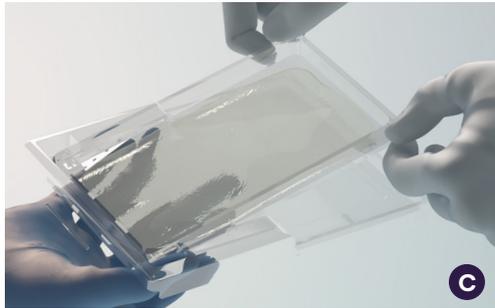
- The safety and effectiveness of StrataGraft in pediatric patients (<18 years) have not been established.

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

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

6. OPEN PRODUCT DISH

Open the Product Dish, and present the Insert Tray containing StrataGraft to the sterile field (C). The nonsterile operator removes the Product Dish lid and holds the Product Dish without touching the Insert Tray. The sterile operator aseptically removes the Insert Tray from the Product Dish using sterile, gloved fingers or a pair of atraumatic forceps.



8. MESH STRATAGRAFT

StrataGraft can be meshed up to a 1:1 ratio prior to placement.

- While maintaining sterility, remove StrataGraft from the Insert Tray and mesh
- Hold Solution, sterile 0.9% normal saline, or lactated Ringer's solution may be used to moisten the mesher/tissue board
- StrataGraft may be meshed with either side up; note which side is the dermis (shiny) and which side is the epidermis (matte) prior to meshing and placement
- Do not allow StrataGraft to dry

STRATAGRAFT PLACEMENT

Place StrataGraft directly on the prepared wound bed

- The meshed StrataGraft should be placed with the dermal (shiny) side down in contact with the patient's prepared wound bed. The epidermal (matte) side should be facing up
- Abut the sheets when placing multiple StrataGraft sheets. Overlapping the edges of StrataGraft is not required. StrataGraft may be trimmed to fit the shape and size of the wound area
- StrataGraft should have contact across the entire surface of the wound bed. Do not stretch or expand StrataGraft, as doing so may degrade its structural integrity

Anchoring StrataGraft

Anchor StrataGraft with staples, tissue adhesive (such as cyanoacrylate or fibrin glue), or sutures to keep StrataGraft from dislodging.

- If using fibrin glue, apply prior to placing the meshed StrataGraft on the prepared wound bed

Dressing the wound

- Place a porous, nonadherent contact dressing over StrataGraft and leave the dressing in place for 1 week before changing
- It is not recommended to use or have dressings that use mafenide acetate, silver-containing antimicrobials, or chlorhexidine following application of 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


allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen - dsat

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