

STRATAGRAFT®

allogeneic cultured keratinocytes and dermal fibroblasts
in murine collagen-dsat

Patient Information

This guide is to help you understand STRATAGRAFT and its use for the treatment of burns. This guide does not take the place of talking with your healthcare provider about STRATAGRAFT. If you have questions about STRATAGRAFT, talk to your healthcare provider.

STRATAGRAFT is a biologic drug approved by the Food and Drug Administration (FDA) for use in adult patients who have a specific type of burn. STRATAGRAFT is placed onto your burn by your healthcare provider. Over time, your skin cells should grow to replace the skin cells lost to the burn.

STRATAGRAFT is available by prescription only.
U.S. License Number: 2144

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Glossary/Definitions of Terms

Autograft: a piece of your own skin tissue used to replace skin lost to burn.

Bilayer construct: product containing two different layers of skin cells in a format similar to human skin.

Biologic drug: a drug product that is produced from living organisms or contains components of living organisms.

Bovine: relating to cattle.

Dermal fibroblasts: a type of cell from the inner layer of skin that helps the skin to recover from injury.

Hypersensitivity: condition in which there is an exaggerated response by the body to something foreign.

Infectious agent: organisms that might cause an infection or infectious disease; includes bacteria, fungi, viruses, and parasites.

Keratinocytes: cells that make up the outer surface of the skin that helps the skin to recover from injury.

Murine: relating to rodents.

Porcine: relating to pigs.

Skin grafts: a piece of tissue used for replacing skin lost to burn.

Xenotransplantation product: human cells that have been exposed to animal cells are considered to be a xenotransplantation product. One of the human cell types in STRATAGRAFT was grown with mouse cells early in the development of STRATAGRAFT. Even though mouse cells are no longer used in the manufacture of STRATAGRAFT, FDA considers STRATAGRAFT to be a xenotransplantation product.

What is STRATAGRAFT?

STRATAGRAFT construct is produced from two kinds of human skin cells (keratinocytes and dermal fibroblasts). To produce STRATAGRAFT, the cells are allowed to grow together to make a bilayered construct that is similar to skin.

Mouse cells are no longer used in the STRATAGRAFT manufacturing process. In the past, one of the cell types used to make STRATAGRAFT was grown with mouse cells. There have been no identified health concerns associated with these mouse cells.

No infectious agents have been detected in STRATAGRAFT.

Who should use STRATAGRAFT?

Adults may need STRATAGRAFT if they have a deep burn(s). Your doctor will evaluate if STRATAGRAFT may be right to treat your burn(s).

Why may STRATAGRAFT help your condition?

For many deep burns, one treatment type is the removal of the damaged, burned skin, and replacement with a skin graft. These skin grafts may be taken from your own healthy skin on your body and moved to the burned area to help it heal. When skin grafts are taken from your body, it is called an autograft. This procedure leaves a new wound where the healthy skin was taken.

If your doctor recommends that your burn wound be treated with STRATAGRAFT, then your healthcare provider will place STRATAGRAFT on your burn instead of using a piece of your own healthy skin. In most cases, treatment with STRATAGRAFT avoids or greatly decreases the amount of healthy skin that is taken for grafting.

STRATAGRAFT will likely allow your own skin cells to grow and heal the burned area over time.

When should STRATAGRAFT not be used?

You should not be treated with STRATAGRAFT if you have an allergy to STRATAGRAFT or any of the components of STRATAGRAFT, including murine collagen or bovine or porcine products.

What are the risks associated with STRATAGRAFT?

- STRATAGRAFT contains glycerin. In patients who have a glycerin sensitivity, there is a risk of an allergic reaction.
- Because STRATAGRAFT contains human cells, there is the possibility of transmission of an infectious agent.
- Because STRATAGRAFT is a xenotransplantation product, there is the possibility of infection from the previous exposure to mouse cells.

The safety of STRATAGRAFT was similar to that of autografting in clinical studies.

To report SUSPECTED ADVERSE REACTIONS, contact Customer Care at 1-877-647-2239 or <http://www.mallinckrodt.com/stratatech> or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What is xenotransplantation and what are the issues related to xenotransplantation?

FDA considers STRATAGRAFT to be a xenotransplantation product because one of the human cell types in STRATAGRAFT was grown with mouse cells in the past. The mouse cells and human cells have been thoroughly tested and no infectious agents were found. No infections from mouse cells were reported in clinical trials. However, there is a very low possibility for infection from the mouse cells.

STRATAGRAFT contains no mouse cells; however, you should be aware that:

- At any time in the future, if you develop unexplained symptoms, notify your treating physician.
- STRATAGRAFT recipients should not donate whole blood, blood components, plasma, leukocytes, tissues, breast milk, ova, sperm, or body parts for transplantation. This restriction does not extend to your intimate contacts or the medical team taking care of you.
- A small amount of blood (around 5 mL, or about 1 teaspoon) will be collected prior to treatment with STRATAGRAFT. This sample could be used as a baseline sample to assess health issues that may be related to the treatment. These samples will not be used for any purpose other than responding to a request by the FDA. Blood samples and patient information will be stored and used as required and allowed by law.
- Although not required, consider allowing an autopsy to be performed in the event of your death, regardless of the cause of death.

Why do we track your personal information?

FDA requires Stratatech to track the patients who receive STRATAGRAFT, so Stratatech can notify the patients and their health care professionals promptly if a safety concern associated with the product is identified.

Thus, we will collect information about you and the STRATAGRAFT you received. This information will be provided to the FDA on a periodic basis. Your information will be kept confidential consistent with applicable laws.

What are the potential complications of burns and skin grafting?

Severe burns may cause many complications to both the skin and other parts of the body. These complications can be very serious and life-threatening.

In the clinical studies, complications seen after treatment with STRATAGRAFT were typical of severe burns. Patients experienced itching, blisters, scarring, and impaired healing at the treatment site.

To help avoid complications after surgery, follow these instructions:

- Leave the dressing(s) in place unless instructed otherwise by your healthcare provider. Contact your healthcare provider if STRATAGRAFT gets shifted out of place.
- Avoid touching the dressing or treated areas until instructed otherwise by your healthcare provider.
- Keep the dressing(s) dry.
- Expect itching, redness, swelling, bruising, and/or pain after the surgery. **Contact your healthcare provider if you develop fever, increased drainage, pain and/or swelling, or any other adverse effect at or around the treatment site.**

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