

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

**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

Manufactured by:  
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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.

*ex-vivo*: outside of the living body.

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: product that contains live cells, tissues, or organs from a non-human animal source or human body fluids, cells, tissues, or organs that have come into *ex-vivo* contact with live non-human animal cells, tissues, or organs.

## **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.

STRATAGRAFT is a xenotransplantation product because in the past, one of the cell types used to make STRATAGRAFT was grown with mouse cells. The cell banks have been tested and found to be free of detectable infectious agents and mouse cells are no longer used in the manufacture of STRATAGRAFT.

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.

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](http://www.fda.gov/medwatch).**

Recipients of xenotransplantation products are generally not eligible to donate whole blood, blood components, source plasma or source leukocytes. However, individual blood banks may request an exception, so if you wish to donate blood or blood products check with your donation center.

STRATAGRAFT recipients who otherwise meet the donor requirements are eligible to donate human cells, tissues, breast milk, ova, sperm, or body parts for transplantation.

### **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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