Epicel®
(cultured epidermal autografts)

HDE# BH990200

Patient Information

This leaflet is designed to help you understand Epicel (cultured epidermal autografts) and its use for the treatment of burn wound. This leaflet does not take the place of talking with your health care provider about Epicel. If you have questions about Epicel, talk to your health care provider.

Epicel is a Humanitarian Device: Authorized by Federal law for use in adult and pediatric patients who have deep dermal or full thickness burns comprising a total body surface area of greater than or equal to 30%. It may be used in conjunction with split-thickness autografts, or alone in patients for whom split-thickness autografts may not be an option due to the severity and extent of their burns. The effectiveness of the device for this use has not been demonstrated.

For more information, please see Instructions for Use available at Epicel.com.

Federal Law restricts this device to sale by or on order of a physician.

Manufactured By:
Vericel Corporation
64 Sidney Street
Cambridge, MA 02139 USA

VERICEL®

www.Epicel.com

Glossary/Definitions of Terms

Anaphylaxis: Immediate, transient kind of allergic reaction.

Autograft: A tissue transferred from one place on the body to a new location.

Autologous: When a tissue is moved from one place on the body to another location on the same body, the tissue is referred to as autologous.

Cultured: The maintenance or growth of cells in an incubator after removal from the body.

Cultured Epidermal Autograft: A tissue grown from one's own skin cells for use in placing on the person's own body.

Epidermis: The outer cell layers of the skin.

Epidermal: Relating to the outer cell layers of the skin.

Dermal: Relating to the skin.

Dermis: Skin, the layer of skin lying under the epidermis, it contains blood vessels, nerves, sweat glands, and hair follicles.

Full thickness burn: A burn of the skin that involves all of the layers of skin, i.e., epidermis and dermis, down to the underlying muscle and fat tissues. A full thickness skin burn is a third degree burn.

Harvest: Word used to indicate removal of skin tissue for use in covering burns on other parts of the body.

Hypersensitivity: Condition in which there is an exaggerated response by the body to a foreign agent.

Irradiated or Irradiation: The use of or process of using gamma-ray energy to inactivate cells used in the manufacture of Epicel®; cells treated with this process cannot reproduce but remain alive.

Media or Medium: Liquid or solid reagents used for the growth of cells outside of the body.

Mouse cells (3T3 cells): Cells from mice used to help the patient's keratinocytes/skin cells grow.

Regeneration: Growth of skin cells to replace the patient's own skin lost to burn.

Skin grafts: Skin used for replacing skin lost to burn; also can refer to skin cells grown outside of the body to replace skin lost to burn.

Split-thickness autograft: Process of removing part of patient's own skin for immediate placement onto burned areas of the patient's own body.

Tissue: A collection of similar cells grown or growing together.

Tissue culture: The process of growing cells outside of the body in an incubator.

Xenogeneic: Referring to being derived or obtained from an organism of a different species, e.g., tissue grafts.

Xenotransplantation: Used to refer to tissues being placed from one species to another species, e.g., from mouse to human; the process of placing tissues from one species onto another species.

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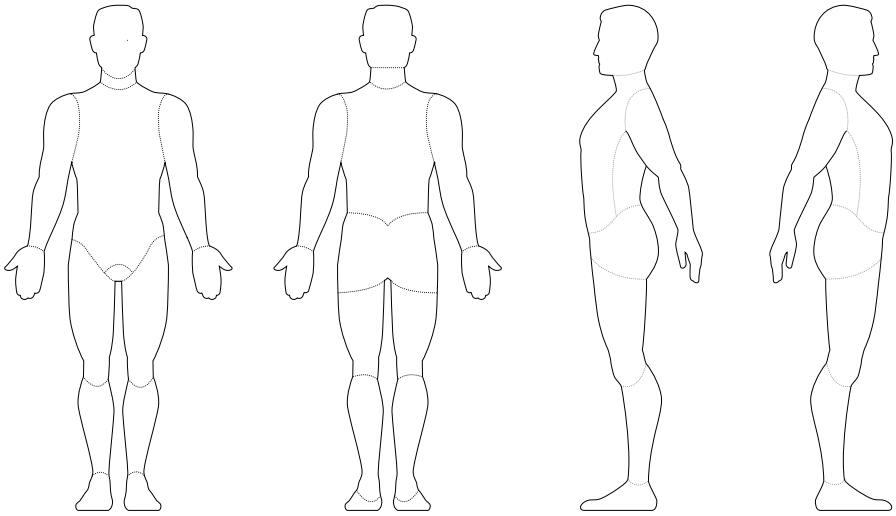
Important Safety Information Epicel is contraindicated in patients with a history of anaphylaxis following exposure to vancomycin, amikacin, and amphotericin, as trace quantities of these anti-infective agents may remain in the Epicel autograft. Epicel should not be used in patients with known sensitivities to materials of bovine or murine origin. It is contraindicated for use on clinically infected wounds.

For more information, please see Instructions for Use available at www.Epicel.com

Total Body Surface Area (TBSA): A percent estimate of the total surface of the body that is burned. Burns are judged by the size of the burn in relation to the whole body and by the depth of the burn injury. Different methods exist to calculate the extent or size of a burn injury. It is important to know the percentage of the total skin surface involved in the burn. One method to determine the percentage of total skin surface involved in a burn is to divide the adult body into regions. Each region represents approximately nine percent of the total body surface. These regions are the head and neck, each upper limb, the chest, the abdomen, the upper back, the lower back and buttocks, the front of each lower limb, and the back of each lower limb. This makes up 99 percent of the total body surface area. The remaining one percent is the genital area.

Epicel Placement Diagram: Adult



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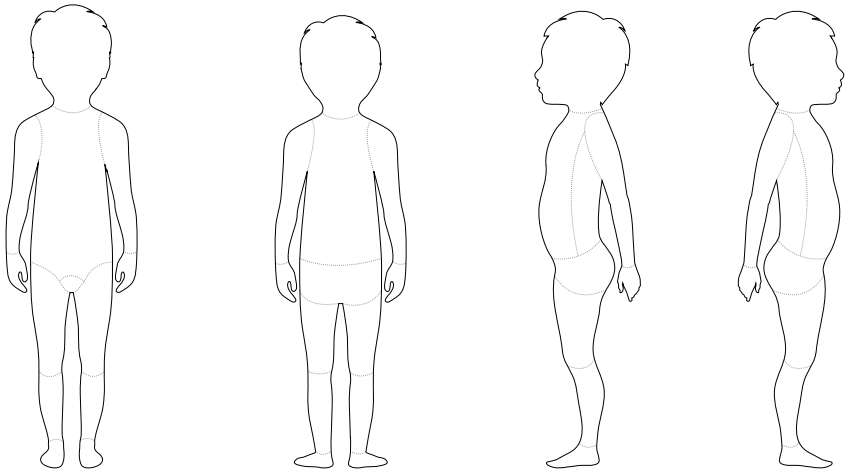
Epicel Placement Diagram: Pediatric



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Important Safety Information Because Epicel is manufactured with and contains residual amounts of murine cells, FDA considers it a xenotransplantation product. Therefore, recipients should not donate whole blood, blood components, source plasma, source leukocytes, tissues, breast milk, ova, sperm, or other body parts for use in humans because there is a potential risk of carrying an infection that is transmitted from mouse cells to humans.

For more information, please see Instructions for Use available at www.Epicel.com

What is Epicel®?

Epicel grafts are sheets of skin cells ranging from 2 to 8 cell layers thick. The grafts are grown or cultured from a postage stamp sized sample of your own healthy skin. During this culture process, irradiated mouse cells, also referred to as 3T3 cells, are used to promote cell growth and to ensure that there will be a sufficient number of grafts available as soon as possible for treatment.

The mouse cells used in the culture process have been extensively tested for the presence of infectious agents such as bacteria, fungi, and viruses. The mouse cells are irradiated before their use in the process to prevent them from multiplying.

Other substances used during the manufacture of Epicel include: antibiotics such as vancomycin, amikacin or amphotericin B; bovine (cow) serum; hormones such as insulin, triiodothyronine, hydrocortisone, epidermal growth factor; and also cholera enterotoxin.

Who should use Epicel?

You may need Epicel if you have deep burns over a total body surface area of greater than or equal to 30%. A doctor may use Epicel together with your own skin graft, or use Epicel alone to cover your burn wound when your own graft is not available or sufficient due to the severity and extent of your burn wound. Epicel can be used for adults and pediatrics.

Why Epicel may help your condition

In deep burns, the outermost layer of the skin and all of the inner layer of the skin is destroyed. Due to the depth of the injury, regeneration of the skin is greatly reduced. The usual treatment for these deep wounds is removal of the damaged tissue and placement of a fresh skin graft. These skin grafts are taken from an area of the individual's unburned skin. This donor skin is placed on the burn wounds. Wound healing may occur fairly rapidly in patients with small total body surface area burns where there is enough unburned skin to harvest for a graft. In a larger total body surface area (usually greater than 30%) the patient does not have enough donor skin available to cover the wounds. The provider may need to consider another means of permanent wound closure, such as Epicel. The Epicel graft replaces the top layer of the skin. This layer of skin is required to close or heal your wounds. This permanent wound coverage must be performed in a timely fashion to avoid the many complications of the burn wound injury.

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Important Safety Information Squamous cell carcinoma (SCC) has been reported in patients with burn injury after being grafted with Epicel. Although SCC is a known complication of burn scars, the role of Epicel in the causation of SCC cannot be excluded.

For more information, please see Instructions for Use available at www.Epicel.com

Using Epicel®

When Epicel Should Not be Used

You should NOT get Epicel if you have any of the following problems or conditions:

- severe allergy to substances used in the manufacture of Epicel
- severe allergy to antibiotics, vancomycin, amikacin or amphotericin because Epicel is grown in media containing these antibiotics
- severe allergy to materials of cow or mouse origin
- infected wounds

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

Although Epicel is grown from your own skin cells, it is grown together with mouse cells and contains residual mouse cells. Therefore, FDA considers it a xenotransplantation product. **If you receive Epicel, you should never donate blood or blood parts, tissue, breast milk, egg, sperm, or other body parts for use in humans because of the potential risk of carrying an infection that is transmitted from mouse cells to humans.** This restriction does not extend to your intimate contacts and the medical team taking care of you.

A small amount of blood (around 20 ml, which is equivalent to about 4 teaspoons) may be drawn from you before Epicel surgery. This blood sample will be used as a baseline blood sample to assess any possible public health issues related to the treatment.

You may consider allowing autopsy to be performed after death, regardless of the cause of death, which may help in the event of a public health concern. If this is decided, share this information with your family and/or legal entity.

To date, there has been no identified public health hazard associated with the use of xenogeneic cells in the Epicel manufacturing process.

Why we track your personal information

FDA requires manufacturers of certain medical devices to track those devices, and the patients who receive them, so they can notify the patients and their health care providers promptly if a safety concern associated with the device is identified. The FDA has determined that Epicel is a medical device that must be tracked. Therefore, you should provide your contact information, such as your name, address, phone number, and information about your next of kin.

You should notify your health care provider immediately of any symptoms of an infection or allergic reaction.

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Important Safety Information The Epicel product is intended solely for autologous use. Patients undergoing the surgical procedure associated with Epicel are not routinely tested for transmissible infectious diseases. Discontinue use if the patient shows evidence of allergic reaction.

For more information, please see Instructions for Use available at **www.Epicel.com**

Using Epicel®

What are the Potential Complications of Burns and Skin Grafting?

Deep and extensive burns may cause many complications to both the skin and other parts of the body. These complications can be very serious and life threatening. The following outcomes were reported in the past clinical experience: infection, sepsis, drainage, multi-organ failure, and death.

Complications associated with skin grafting include: blister formation, graft tearing, graft detachment, graft contracture, or skin tightening, and skin graft failure.

Squamous Cell Carcinoma (SCC), one type of skin cancer, is a possible long-term complication of extensive burns. SCC has been reported in <1% of burn patients after treatment with Epicel®. SCC in these cases developed in more than one area on the body approximately 11 to 23 years from the time of grafting.

How to Take Long-Term Care of Your Healed Burn Wound

After your burn wound has healed, your health care provider will decide on the best long term care for you, including:

- bathe with mild soaps and moisturize with mild lotions
- use pressure garments approximately six weeks post grafting
- conduct activity of daily living as tolerated

SCC has been reported in patients who have received Epicel. You may have risk for the development of skin cancers such as SCC over the burn scars. This skin cancer may look like growing lumps, often with a rough, scaly, or crusted surface. It may also look like flat reddish patches in the skin that grow slowly. You should see your health care provider for any skin changes in a timely manner.

To help protect your skin, consider the following whenever you are in the sun, even for short periods of time:

- wear long clothing to cover your skin
- apply sunscreen to all exposed areas
- wear a hat and sunglasses

In addition:

- avoid tanning beds and sun lamps
- avoid harmful chemicals

If you notice any changes in your skin, see your health care provider.

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Important Safety Information If clinical signs of infection are present or develop, do not apply Epicel until the infection is adequately treated. The effectiveness of Epicel has not been proven in clinical studies. The long-term safety of Epicel is unknown. Over the past 27 years, the mortality from all causes was 13% before hospital discharge.

For more information, please see Instructions for Use available at www.Epicel.com

Additional Information and Questions

Please refer to the Epicel® package insert for additional information. This can be obtained from your provider or by contacting Vericel Corporation 24 hours/day @ **800-CEA-SKIN** or 1-800-232-7546 (USA only) or from **www.epicel.com**.

For any concerns regarding treatment with Epicel please contact your provider.

For any product-related questions, please contact Vericel Corporation 24 hours/day @ **1-800-CEA-SKIN** or 1-800-232-7546 (USA only).

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Important Safety Information Men and women who intend to have children should be advised that the effects, if any, of Epicel on fetal development have not been assessed. In addition, the safety of Epicel has not been studied in pregnant and nursing women.

For more information, please see Instructions for Use available at www.Epicel.com

Important Safety Information Patient information supplied by attending burn teams from 1989 to 1996 reported the adverse events of highest incidence as: death (13%), infection (13.8%), graft tear (7.8%) or graft blister (4.2%) and drainage (3.3%). Some of these events may have been due to the underlying burn injury and not the device itself. From June 1998 through September 2015 adverse events received by Genzyme Biosurgery (predecessor in interest to Vericel) and Vericel Corporation were similar to the previously identified adverse events. Events that were reported in ≥ 1% of patients included multi-organ failure (6.6%), sepsis (5.2%) infection (4%) and skin graft failure/graft complication (2.7%). The relationship of these events to Epicel has not been established.

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For any product-related questions, please contact Vericel Corporation 24 hours/day

1-800-CEA-SKIN (1-800-232-7546)

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