HUMANITARIAN DEVICE: Epicel® (cultured epidermal autografts) is authorized for use in adults and pediatric patients who have deep dermal or full thickness burns comprising a total body surface area 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.

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. 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.

Please see Important Safety Information on last page and Directions for Use and Patient Information.

BIOPSY PROCUREMENT

An Epicel biopsy taken within the first **24-48 hours** can increase treatment options

Two full-thickness 6cm x 2cm diamond-shaped biopsies should be obtained. The biopsies should be taken from different sites of undamaged, non-diseased skin preferably within **24-48 hours** of admission.

There is **no financial obligation** for the Epicel Biopsy Kit or for taking the biopsy and starting the initial cell culture process.
Biopsy Considerations

• **Local or general anesthesia** may be utilized for biopsy harvest. Local anesthetic should be injected circumferentially, not directly into the biopsy site. If the initial excision surgery is delayed, the biopsy can be taken at bedside under local anesthesia.

• **The biopsy site** should be shaved to remove hair, thoroughly washed, and swabbed with 70% alcohol, followed by a sterile normal saline rinse.

• **The prep sequence may be repeated** to remove the excessive bacterial bioburden if it is suspected that the biopsy site is highly contaminated.

• **If contamination remains** the biopsy may be lost and a repeat biopsy may be needed, causing delays in the total cell culturing process.

• **Biopsies should be placed** into individually labeled biopsy media tubes and returned to the original packaging container for shipment.

• **Instructions for biopsy procurement**, packaging and shipping the biopsy are in the Epicel Biopsy Kit Directions for Use.

• **There is no financial obligation** for the Epicel Biopsy Kit or for taking the biopsy and starting the initial cell culture process.

Biopsy Overview

Epicel is derived from two small, full-thickness biopsies of skin taken from different sites on the burn patient’s undamaged, non-diseased skin, recommended within the first **24-48 hours** of admission.

A single Epicel order can cover an area up to **4,800 cm²** in a single treatment (about the size of an average adult torso).

Epicel is expanded at a **400:1** ratio and further expansion can occur without additional biopsy.

Biopsy site suggestions include the **axilla** and **groin**, but any non-burned area may serve as a biopsy site.

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Please see Important Safety Information on last page and Directions for Use and Patient Information.
Indication

Epicel® (cultured epidermal autografts) is indicated for use in adults and pediatric patients who have deep dermal or full thickness burns comprising a total body surface area 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.

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.

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.

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.

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.

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. 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.

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.

Please see Directions for Use and Patient Information.