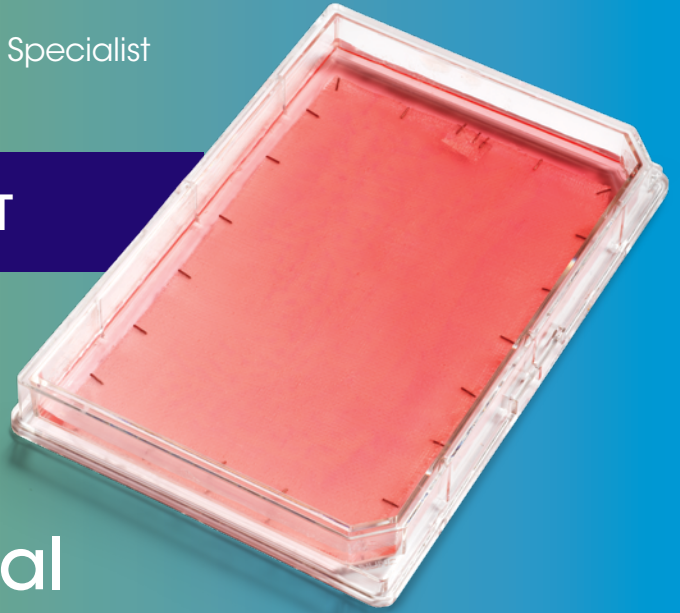


For biopsy support please contact your Burn Therapy Specialist
or call **1-800-CEA-SKIN** (1-800-232-7546)

BIOPSY PROCUREMENT



There is never a financial charge from Vericel for taking or processing an Epicel biopsy

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

To order an Epicel biopsy kit, call **1-800-CEA-SKIN** (1-800-232-7546) or contact your Burn Therapy Specialist



Epicel[®]
(cultured epidermal autografts)

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](#).

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

Biopsy Overview

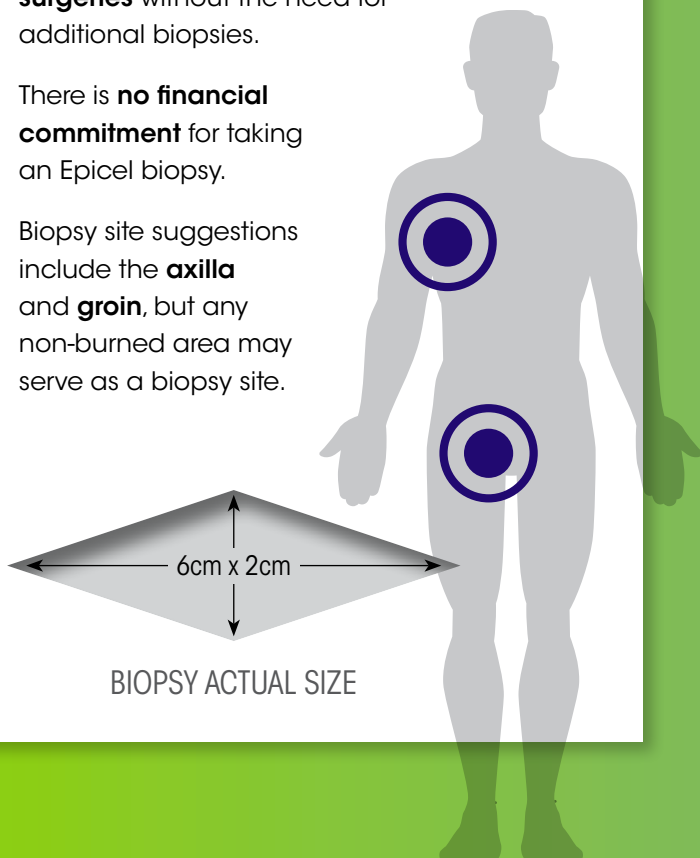
Epicel is derived from two full-thickness 6cm x 2cm diamond-shaped biopsies of skin taken from different sites on the burn patient's undamaged, non-diseased skin preferably within **24-48 hours** of admission.

A single Epicel order can cover an area up to **7,200 cm²** in a single treatment.

Epicel can be ordered for **subsequent surgeries** without the need for additional biopsies.

There is **no financial commitment** for taking an Epicel biopsy.

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



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.

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Please see Important Safety Information on last page and [Directions for Use](#) and [Patient Information](#).

To order an Epicel biopsy kit, call **1-800-CEA-SKIN** (1-800-232-7546) or contact your Burn Therapy Specialist

Vericel Corporation
64 Sidney Street, Cambridge, MA 02139
800-CEA-SKIN (800-232-7546)

Biopsy Transmittal Notice for EPICEL® (Cultured Epidermal Autografts)

PLEASE PRINT CLEARLY

PATIENT INFORMATION

| | | | |
|-----------------|---|--|---------|
| First Name | Last Name | Middle Initial | DOB/Age |
| Hospital ID No. | Admission Date | Injury Date | |
| Height (cm) | Weight (kg) | Epicel is indicated for \geq 30% Total Body Surface Area (TBSA) deep dermal or full thickness burns. Is this a burn patient? | |
| Sex | Male <input type="checkbox"/> Female <input type="checkbox"/> | <input type="checkbox"/> Yes, State TBSA Affected (%): <input type="checkbox"/> No, State Diagnosis & TBSA Affected (%): | |
| Patient Insured | Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> | Insurance Carrier | |

MEDICAL/ALLERGY INFORMATION (It is very important that this section be completed.)

Vancomycin Allergy Yes No Amikacin Allergy Yes No Amphotericin B Allergy Yes No

Please note any significant dermatological history

HOSPITAL INFORMATION (Please be sure to identify the primary hospital contact.)

Complete Hospital Name with Center or Division

Complete Hospital Address

Hospital City Hospital State Hospital Zip Code

Attending Physician(s) Phone Number

Designated Hospital Contact Phone Number

SPECIFIC BIOPSY INFORMATION (Please remember to label tubes with patient name and biopsy site.)

| | | |
|--------------------------|--------------------------|----------------------------|
| Date of Biopsy | Time of Biopsy | Expiration Date (On Tubes) |
| Biopsy Site (Tube No. 1) | Biopsy Site (Tube No. 2) | |

INFECTION INFORMATION

| | |
|---|--|
| Wound Infection Microbial: Yes <input type="checkbox"/> No <input type="checkbox"/> | Systemic Infection Microbial: Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Organism(s): Fungal: Yes <input type="checkbox"/> No <input type="checkbox"/> | Organism(s): Fungal: Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Current Topical Antimicrobial or Antifungal Medication(s) | Current Systemic Antimicrobial or Antifungal Medication(s) |

NAME OF PERSON FILLING OUT THIS FORM

Name: _____ Date: _____

TO ENSURE PROPER HANDLING, PLEASE DO NOT SHIP ON YOUR OWN.

- CALL VERICEL CUSTOMER CARE AT 800-CEA-SKIN (232-7546) FOR BIOPSY PICK-UP.
- KEEP THIS TRANSMITTAL NOTICE AVAILABLE WHEN CALLING OUR CUSTOMER CARE REPRESENTATIVE.
- PLACE THIS FORM AND THE EPICEL TRACKING FORM INSIDE THE BOX PRIOR TO PICK-UP.

65014.F 03/2015

VERICEL™ Epicel® (cultured epidermal autografts) Tracking Form
(Please Print AND Return with Skin Biopsy Kit)

Patient Full Name _____ Patient Date of Birth (MM/DD/YYYY) _____

Address _____

City _____ State _____ Zip Code _____

Telephone Number _____ Social Security Number _____

Next of Kin or Primary Contact

Name of Next of Kin/Primary Contact _____

Address _____

City _____ State _____ Zip Code _____

Telephone Number _____

Primary Care Physician (other than EPICEL Surgeon)

Name of Primary Care Physician _____

Address _____

City _____ State _____ Zip Code _____

Telephone Number _____

Name of Person Completing Form _____ Relationship to Patient _____

For questions, please contact:
Vericel Customer Care at 1-800-CEA-SKIN (232-7546)
TEL: (617) 588-5678 FAX: 1-844-333-2847

| For Vericel Use Only | |
|--------------------------|-------|
| EPICEL Lot ID # | _____ |
| Date of Surgery | _____ |
| Surgeon Name | _____ |
| Hospital | _____ |
| Surgeon Telephone Number | _____ |

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65609.B 03/2015

Biopsy Transmittal Notice

The Biopsy Transmittal Notice for Epicel must accompany the biopsy in the Epicel Biopsy Kit. Complete at time of biopsy and return with the Epicel Tracking Form in the Epicel Biopsy Kit.

Epicel Tracking Form

The Epicel Tracking Form collects information needed to fulfill the FDA Medical Device Tracking requirements.

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.

Please see Important Safety Information on last page and [Directions for Use](#) and [Patient Information](#).

To order an Epicel biopsy kit,
call 1-800-CEA-SKIN (1-800-232-7546)
or contact your Burn Therapy Specialist

There is **no cost** for the Epicel biopsy kit or for biopsy processing, even if a case moves forward



Epicel[®]
(cultured epidermal autografts)

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.

Please see [Directions for Use](#) and [Patient Information](#).

Important Safety Information

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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 $\geq 1\%$ 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.

 VERICEL

64 Sidney Street, Cambridge, MA 02139 | 800-232-7546

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