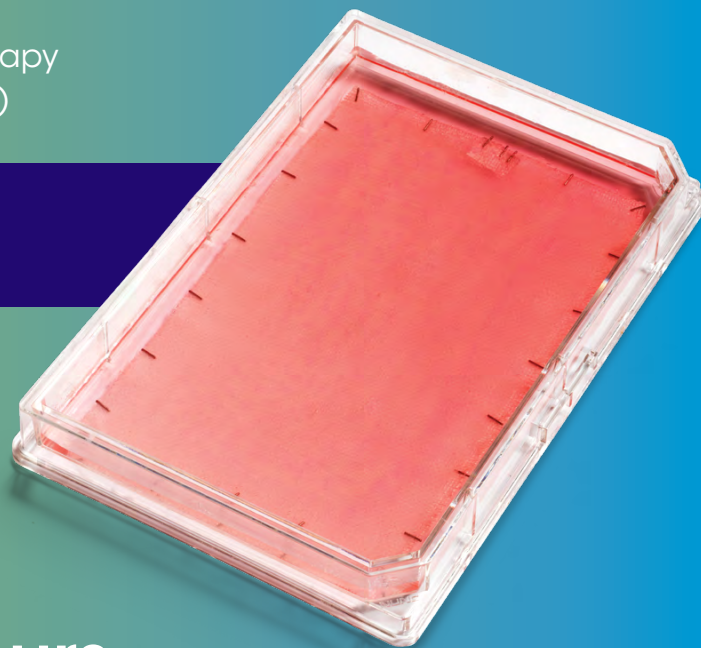
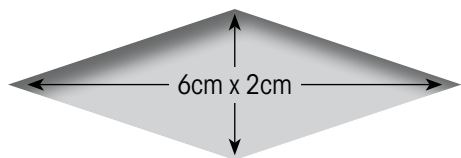


For biopsy support please contact your Burn Therapy Specialist or call **1-800-CEA-SKIN** (1-800-232-7546)

BIOPSY PROCUREMENT



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



BIOPSY ACTUAL SIZE

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.

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](#).

Epicel Biopsy Procurement Guidelines

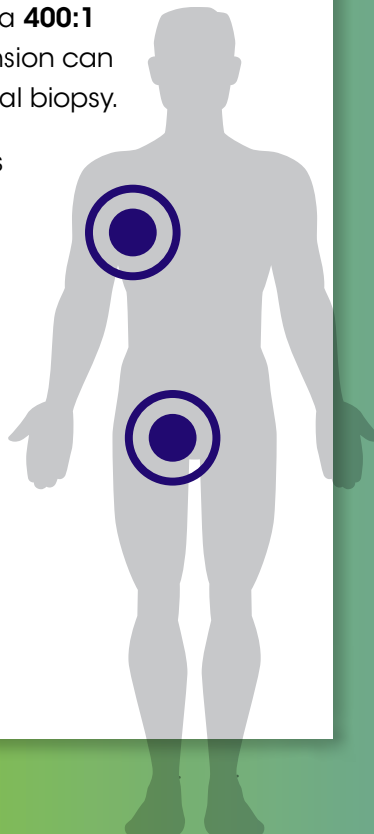
Biopsy Overview

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.



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](#).

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

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)	Epical 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 <input type="checkbox"/> No <input type="checkbox"/>	Amikacin Allergy	Yes <input type="checkbox"/> No <input type="checkbox"/>	Amphotericin B Allergy	Yes <input type="checkbox"/> No <input type="checkbox"/>
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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 EPICAL TRACKING FORM INSIDE THE BOX PRIOR TO PICK-UP.

65014F 03/2015

VERICEL® Epical® (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 EPICAL 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	
EPICAL Lot ID #	_____
Date of Surgery	_____
Surgeon Name	_____
Hospital	_____
Surgeon Telephone Number	_____

www.vericel.com
Vericel Corporation
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65609B 03/2015

Biopsy Transmittal Notice

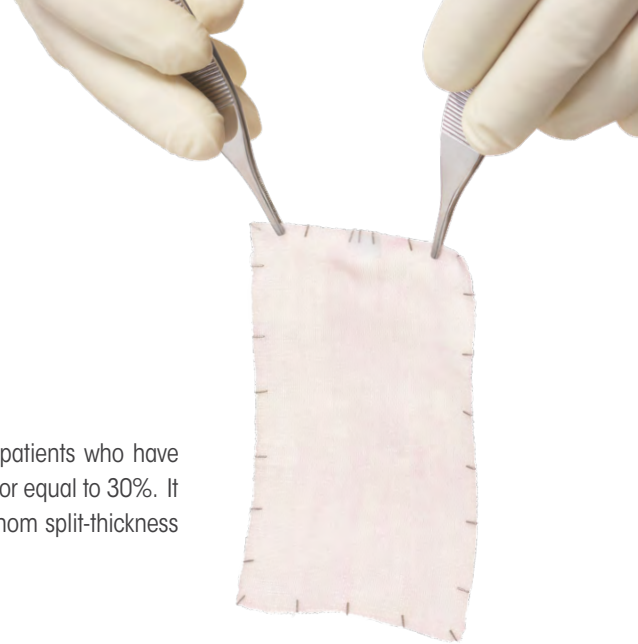
The Biopsy Transmittal Notice for Epical must accompany the biopsy in the Epical Biopsy Kit. Complete at time of biopsy and return with the Epical Tracking Form in the Epical Biopsy Kit.

Epical Tracking Form

The Epical Tracking Form is the primary source of information for your Epical order. Complete and return it with the biopsy and the Biopsy Transmittal Notice in the Epical Biopsy Kit.

IMPORTANT SAFETY INFORMATION: Epical 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 Epical autograft. Epical 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 Epical 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](#).



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 $\geq 1\%$ 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.

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



64 Sidney Street
Cambridge, MA 02139
800-232-7546
www.epicel.com

Epicel[®]
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