Epicel®
(cultured epidermal autografts)

COMMUNICATIONS RESOURCES

Materials and recommendations to support communications related to treatment with 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.

Please see Important Safety Information on page 10.

VERICEL

EPICEL® Communications Resources

Materials and recommendations to support communications related to treatment with Epicel® (cultured epidermal autografts)

Introduction

Since it was first introduced more than 25 years ago, the use of Epicel® (cultured epidermal autografts) in the treatment of deep dermal or full thickness burns has been of interest to media, patients, clinicians and others. Burn centers have provided information and stories about Epicel to local media through a range of platforms, including websites, social media and printed materials.

This kit includes information and template materials that can be used to support your communications related to your use of Epicel in many ways, including participation in local media stories and development of content for your burn center website or patient education resources. These materials are designed to help you provide information about Epicel that is accurate and easy to understand for all audiences. Additional information about Epicel can be found at Epicel.com

We hope you find these materials useful. Please feel free to reach out any time if we can provide additional information or support for your communications strategies related to Epicel.

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Media Interest in Epicel

Treatment of burns continues to be among the most challenging and compelling issues in healthcare. As a result, many burn centers have opportunities to work with local media to develop stories about the prevention and treatment of burns, including stories about treatment with Epicel. There continues to be interest in the production process used to develop Epicel and in profiles of patients who have been treated at leading burn centers across the United States.

This kit includes recommendations on how to reach out to your local media to suggest a story about your center and its use of Epicel. It also includes a range of template materials that you can easily customize to develop media opportunities about your burn center and Epicel, including:

- a draft letter that can be used to suggest a story about your burn center to a local reporter;
- an Epicel fact sheet to help you provide clear and easy to understand information to reporters and others;
- copies of available product graphics that you can offer to reporters or use in communications materials; and,
- a draft article about Epicel that might be appropriate for websites, blogs, newsletters and patient education materials.

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How to Send a Story Suggestion to Local Media Outlets

In considering a story about treatment with Epicel, reporters are often interested in learning about how the product is developed and used in patient care. They also often want information about local patients who have been treated. For a burn center that is performing its first procedure with Epicel, this event can often be positioned as a local "first" in outreach to media that cover local important news in healthcare.

You can send a story suggestion to a reporter at any time throughout the year. In most cases, the preferred way to reach out to a reporter is via email (with no attachments to reduce the risk of getting caught in a spam filter). You might consider reaching out to reporters to highlight a first procedure involving EPICEL or an especially compelling example of a patient treated at your center. It can also be advantageous to suggest a story related to burn prevention and treatment during periods when reporters might be especially interested in this topic. Some examples include:

- prior to Burn Awareness Week (first full week in February), when many reporters will be preparing stories about prevention and treatment; and,
- early summer, when many reporters might be interested in developing stories about safety and burn risk related to outdoor fires, barbecues and use of fireworks.

In your communication, you should provide a brief description of the story you are suggesting and indicate the resources and spokespersons available. (See example of a media letter on page 5.)

Arranging interviews

Reporters will often want to speak with a clinician and if possible a patient or family member about treatment with Epicel. In some cases, patients themselves may be unable to speak to reporters. In these cases, a parent or other family member may be available to offer perspectives that will be of interest.

You should confirm in advance any personal details that media spokespersons will want to discuss or not discuss in interviews, and you should ask patients or family members to sign a release form granting you permission to share information about their health and treatment with reporters.

Interview strategy

Every interview presents an opportunity to deliver important information about your practice and burn treatment to the public. The following techniques and recommendations are designed to help you handle any interview with better control and deliver your messages with maximum impact:

- **Identify the messages you want to deliver <u>in advance</u>.** You should prepare 3-4 messages about the case, including the use of Epicel, that you feel are important to include in your interview, and work to provide those messages in response to a reporter's questions.
- **Use clear and simple language the audience can understand.** Try not to use too many complex clinical or medical terms.

Please see Important Safety Information on page 10.

General Timeline for Contacting Local Media

WEEK 1	▶ Prepare media contact list and customize email and backup materials. Prepare materials for each media contact. Note that you should not include information as an attachment in email to reporters. This increases the risk that an email will be blocked by a spam filter. ▶ Distribute materials (via email in most cases).
WEEK 2	▶ Follow up via phone with the reporters on your list. In general, it is best to try to contact reporters in the late morning or early afternoon. ▶ You will often need to leave voicemail messages for reporters. In doing so, it is appropriate to call again if you do not hear back from them within a few days. ▶ Try to reach all of the reporters on your list within the week after you distribute materials. Keep your spokespersons updated on your progress and any media opportunities that seem likely.
WEEKS 3 - 6	▶ Many reporters may require additional information or ask you to call them back when their schedule is less hectic. You may find that some reporters are not ready to do your story until several weeks or months after your mailing. You may need to re-contact and work with some reporters over several weeks to provide all the support necessary for a story.
WEEKS 6 - 8	▶ Follow-up with reporters to determine whether they need any additional information prior to completing a story.

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Sample Letter to Reporters

Below is an example of a letter you might use to suggest a story about treatment with Epicel to reporters. The letter should be no longer than a few paragraphs and should clearly identify the story idea and the spokespersons who are available for interviews.

Dear **[Editor / Health Reporter]:**

Thousands of people each year experience severe burns known as deep dermal or full thickness burns that can be difficult to treat. For patients who experience these severe burns over much of their body, the use of traditional skin grafting can be difficult or impossible. The team at **[Burn Center Name]** in **[Location]** recently used a treatment option which cultures a patient's skin in a laboratory using two small biopsies of skin taken from the patient. The cultured skin was then used to cover the affected area.

The treatment – known as Epicel – is available in the United States for patients who have deep dermal or full thickness burns comprising a total body surface area greater than or equal to 30% of their body. In **[month], [Burn Center Name]** treated a **[description of patient – age, sex]** who had burns over **[XX%]** of his/her body.

[Burn Center Name] is now using this procedure to treat burn victims. **[Doctor Name]** is available for interviews and can describe how the process works to culture skin and how the new skin is then applied to areas affected by a burn. **[Patient Name and or his/her RELATIONSHIP/NAME]** are also available to discuss their experience as one of the first patients in our area treated with Epicel.

We hope you find this story of interest. I can be reached at **[phone and email].**

Sincerely,

[Dr. Name]
[Address]
[Affiliation]

Please see Important Safety Information on page 10.

About Epicel® (cultured epidermal autografts)

- Epicel is a cultured epidermal autograft (CEA), which is a skin graft cultured in a laboratory from a biopsy of the patient's own skin cells.
- Grafts developed using Epicel can provide skin replacement using a patient's own skin cells for patients who have deep dermal or full thickness burns comprising a total body surface area of greater than or equal to 30%.
- Epicel is derived from small full-thickness biopsies of skin taken from an unaffected area on the burn patient.
- Two individual biopsies about 6 cm long and 2 cm wide are taken from different sites on the patient's undamaged, non-diseased skin so that Epicel can be prepared.
- The patient's skin cells are placed into a culture medium, nutritionally supported and allowed to grow together to form new cells that can be used in skin grafts. In the culture the cells grow rapidly, often producing grafts that are 10,000 times the size of the original biopsy taken from the patient. Grafts can be cultured in as little as 17 days.
- A clinical study done at the Baltimore Regional Burn Center of Johns Hopkins University compared the outcomes of therapy in patients with massive burns with or without cultured CEAs. The study found that people in the CEA group had significantly higher survival rates than those in the control group.[1, 2]
- Over the past 25 years, Epicel has been used in over 1,500 patients.
- Epicel is the only cultured epidermal autograft approved by the Food and Drug Administration (FDA). For additional information, see Important Safety Information included in this kit.
- Epicel is produced for each patient by highly trained professionals in a state of the art facility using technologies pioneered by researchers at the Massachusetts Institute of Technology (MIT) and Harvard University.[3]
- Because Epicel is a humanitarian use device, Vericel does not sell Epicel for a profit – i.e., the amount charged does not exceed the costs of the research, development, fabrication, and distribution of the product. However, as a global leader in cell therapy manufacturing, Vericel continues to provide Epicel as part of its commitment to serve patients in need.

References

1. Munster AM. Cultured skin for massive burns: a prospective, controlled trial. Ann Surg 1996; 224:372–5.
2. Epicel Directions for Use; Page 8.
3. Rheinwald JG, Green H. Serial cultivation of strains of human epidermal keratinocytes: the formation of keratinizing colonies from single cells. Cell. 1975;6:331-43.

Please see Important Safety Information on page 10.

Images

The following high-resolution images related to Epicel are available for use in media outreach.

The images can be downloaded from the [Epicel Communications Resources Image Library](#).

1 Epicel Biopsy Kit.jpg

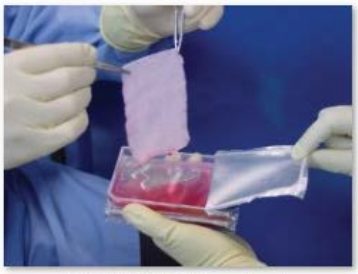

2 Prep for Biopsy.jpg


3 Epicel Culturing Process.jpg


4 Epicel Graft Manufacturing.jpg


5 Epicel Skin Graft.jpg


6 Epicel Skin Graft.jpg


7 Epicel Skin Graft Procedure.jpg

Please see Important Safety Information on page 10.

Draft Article

This section includes information about Epicel that your burn treatment center can use to describe the product to patients, surgeons, nurses and others. This content is designed for use in multiple platforms, including websites, blogs, newsletters and patient education materials. This content can be presented in conjunction with the Epicel fact sheet or independently.

Draft article/blog post

Using Epicel (cultured epidermal autografts) to treat full thickness burns

Each year in the U.S., more than 400,000 people are affected by burns that require medical attention, and an estimated 30,000 patients seek treatment at a dedicated burn center. In many cases, these patients experience full thickness or deep dermal burns (also sometimes referred to as third- or fourth-degree burns) that destroy all layers of skin and extend into subcutaneous tissue, muscle, or bone. Full-thickness or deep dermal burns are typically associated with significant scarring.

Patients who experience severe burns are often treated with autologous skin grafts, which are sections of skin removed from unaffected areas of their body and then transplanted to cover a burn area. The removal of a skin graft involves a surgical procedure that can cause pain and additional scarring. In addition, use of autologous skin grafts may not be an option for patients with severe burns over a large percentage of their body.

Epicel is a cultured epidermal autograft (CEA), which is a skin graft grown in a laboratory using two small biopsies of the patient's own skin. In this process, the Epicel grafts can provide skin replacement for patients who have deep dermal or full thickness burns comprising a total body surface area of greater than or equal to 30%. The new skin grafts are grown using two postage stamp-sized biopsies of the patient's skin. Using these biopsies, the patient's skin cells are placed into a culture medium, nutritionally supported and allowed to grow together to form new cells that can be used in skin grafts. In the culture the cells grow rapidly, often to 10,000 times the size of the original biopsy taken from the patient. Grafts can be cultured in as little as 17 days.

A clinical study conducted at the Baltimore Regional Burn Center of Johns Hopkins University compared the outcomes of therapy in patients with massive burns with or without cultured CEAs. The study found that people in the CEA group had significantly higher survival rates than those in the control group.[1, 2]

Over the past 25 years, Epicel has been used in over 1,500 patients. It is the only cultured epidermal autograft approved by the Food and Drug Administration (FDA).

Epicel is produced for each patient by highly trained cell therapy professionals in a state of the art facility using technologies pioneered by researchers at the Massachusetts Institute of Technology (MIT) and Harvard University.[3]

References

1. Munster AM. Cultured skin for massive burns: a prospective, controlled trial. Ann Surg 1996; 224:372–5.
2. Epicel Directions for Use; Page 8.
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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 Epicel Directions for Use and Patient Information.

VERICEL

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