

SPRAY-ON SKIN™ CELLS

DRESSING GUIDELINES

FOR THE HEALTHCARE PROFESSIONAL

Please see back page for Important Safety Information.



THE PATIENT HAS BEEN TREATED WITH SPRAY-ON SKIN™ CELLS

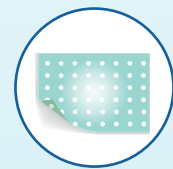
a regenerative epidermal suspension including keratinocytes, fibroblasts and melanocytes. These isolated skin cells are not visible to the naked eye. Care should be taken when assessing the treated areas so that the developing epidermis is not accidentally disturbed by removal of the patient’s dressings. The following information, precautions and notes provide dressing management guidance.

DURING WOUND HEALING¹

Dressings Post-application of Spray-On Skin Cells

PRIMARY DRESSING

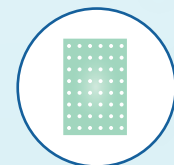
After the Spray-On Skin Cells have been applied, all treated areas will have been covered with a:



NON-ADHERENT



NON-ABSORBENT



SMALL PORE DRESSING, SUCH AS TELFA™ CLEAR

This dressing may have been fixed to the wound with surgical glue, sutures, or staples, as necessary.

This dressing protects the wound bed and provides an ideal environment for regeneration of the epidermal layer.*

*Always follow the instructions as set by the dressing manufacturer.

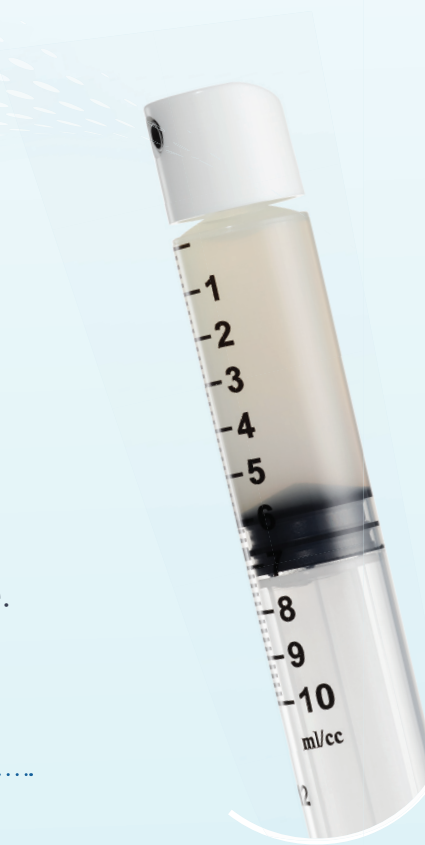
SECONDARY AND OUTER DRESSING

A secondary dressing should provide protection to the wound and absorb any exudate.

- This should be a moderately absorbent, minimally adherent, low shear, readily removable dressing (such as Xeroform™, Cuticerin™, or Adaptic™).

A bulky gauze and an outer wrap bandage should be placed to provide additional protection to the wound and absorb any exudate.

Use of known cytotoxic agents (for instance, silver sulfadiazine) are contraindicated for areas treated using Spray-On Skin™ Cells.



SIGNS AND SYMPTOMS OF INFECTION

Containment of infection within treatment areas is crucial.

- If infection is suspected, then treat per standard of care.



Cytotoxic agents are contraindicated for areas treated with Spray-On Skin Cells.

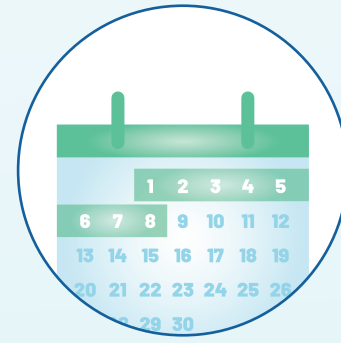
DURING WOUND HEALING¹

Dressings Post-application of Spray-On Skin™ Cells

DRESSING CHANGES

Initial Dressing Change

Change outer dressings and compression bandages if exudate levels are high. If a secondary dressing change is required, take care to protect the primary dressing and keep it dry. The primary dressing should remain in place until new epidermis is formed but is typically no longer required after 6-8 days.



Re-apply new secondary and outer dressings, if applicable.

Subsequent Dressing Changes

At subsequent dressing changes leave the primary dressing in place until it begins to lift as new epidermis is formed (typically 6-8 days).

- Take care to keep the primary dressing dry while changing secondary and outer dressings.
- The primary dressing must not be forcibly removed from areas to which it is still adhered.
- Typically it can be separated (gently peeled back) as new epidermis is formed.
- If it is beyond post-operative day 6-8 and the primary dressing remains adherent, consider atraumatic removal of the primary dressing.
- To prevent trauma, any dressing not easily removed should be soaked with an aqueous or oil-based solution prior to removal. Once the primary dressing (such as Telfa™ Clear) has been atraumatically removed, an appropriate protective dressing should be applied to protect the wound surface (for example Xeroform™, Cuticerin™, Adaptic™, or Mepitel® One) then secured with dry gauze and elastic bandage.

Do not use dry dressings as protection over blisters or areas of punctate bleeding, as dried exudate could cause newly regenerated epidermis to adhere to the dressing, leading to potential injury upon dressing removal. Instead, use a sterile greasy or paraffin gauze dressing until any blistering or open areas resolve.

FOLLOWING WOUND HEALING¹

Protection of Newly Formed Skin

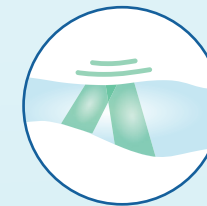


CLEANSING

As with autografts, protect the newly regenerated skin from maceration and shearing while it matures.

Avoid rigorous cleansing or rigorous application of topical creams or moisturizers for a minimum of two weeks subsequent to closure, as not to damage the newly formed skin.

Thereafter, post-operative care should be consistent with the standard of care for the specific injury and treatment provided.



PROTECTIVE GARMENTS AND/OR BANDAGING

The newly healed epidermis must be protected with a dressing for a minimum of two weeks (for example Xeroform™, Cuticerin™, Adaptic™, or Mepitel® One, and secured with dry gauze and elastic bandage).

Light compression bandages may be considered as epidermis matures. Thereafter, post-operative care should be consistent with the standard of care for the specific injury and treatment provided.



PATIENT EDUCATION

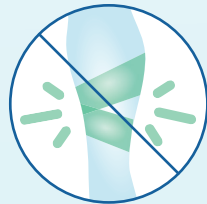
Discuss with Your Patient Prior to Discharge

Patients and caregivers should be provided with adequate information on how to care for their wounds during and after the healing process.



Keep Follow-up Appointments

Emphasize importance of return to clinic for wound assessments.



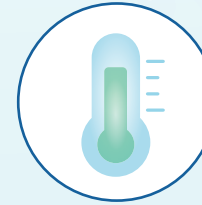
Shear and Friction Precautions

Instruct patient to avoid friction and shear by excessive rubbing or bumping of their bandages and to keep bandages in place, as directed.



Sun Protection

Provide the patient with sun precautions including avoiding direct sun exposure, wearing protective clothing and using a sunscreen with an SPF of 30+.



Signs and Symptoms of Infection

Provide instructions for strict return to clinic for signs or symptoms of infection including fever, redness around the bandage, increased drainage and swelling.



Activity Restrictions

Provide patient with any range of motion restrictions and/or splinting instructions. Refer to the standard of care related to elevation of treated areas.



Scar Management

Once the new skin has matured and become more robust, scar massage and compression may be considered. Encourage regular follow-up for scar management.

The patient should be advised that the wound area will change over the subsequent weeks and months. The pigmentation and skin texture will continue to mature and improve and the final result may take up to 12 months to be achieved.

Follow-up procedures should follow standard protocols for the specific injury and treatment given.

Please see back page for Important Safety Information.

To learn more, visit **RECELLsystem.com**
or call our customer service helpline at
833-GO-AVITA (833-462-8482)

IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous Regenerative Epidermal Suspension (RES™) for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.

CONTRAINDICATIONS: RECELL is contraindicated for: the treatment of wounds clinically diagnosed as infected or with necrotic tissue, the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate (Hartmann's) solution, patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

WARNINGS: Autologous use only. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL is provided sterile and is intended for single-use. Do not use if packaging is damaged or expired. Choose a donor site with no evidence of cellulitis or infection and process skin immediately. A skin sample should require between 15 and 30 minutes contact with Enzyme. Contact in excess of 60 minutes is not recommended. RECELL Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.

PRECAUTIONS: RECELL is not intended for use without meshed autograft for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints, >320 cm², in patients with wounds totaling >20% total body surface area (TBSA). The safety and effectiveness of RECELL with autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, in patients with wounds totaling >50% TBSA.

SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-thickness or full-thickness burn wounds in pediatric patients younger than 18 years of age.

For complete Important Safety Information, refer to Instructions for Use at RECELLsystem.com.

Reference: 1. Instructions for Use. RECELL® Autologous Cell Harvesting Device.



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