RECELL®
Autologous Cell Harvesting Device

# AFTERCARE GUIDANCE

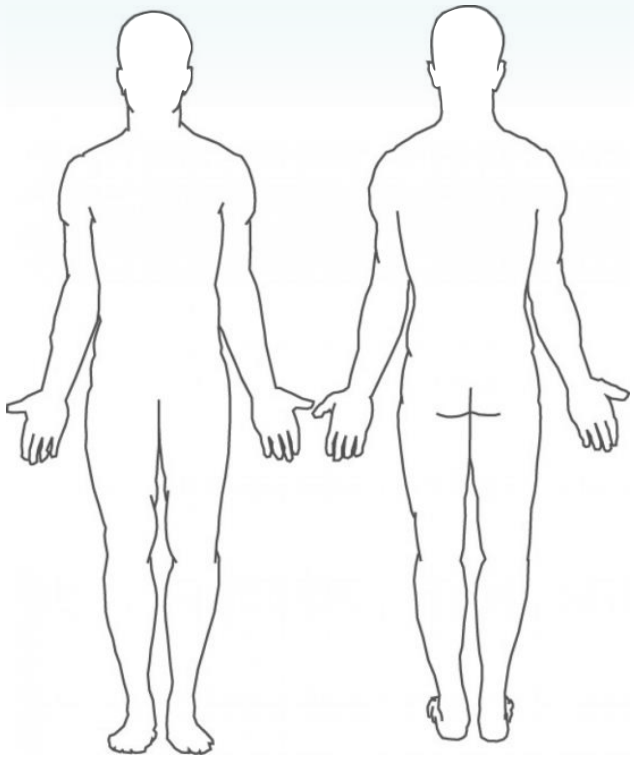
Your patient has been treated with autologous Spray-On Skin™ Cells.[1]

## Patient Information

*Name:*

*Room:*

*Surgery Date:*



Spray-On Skin Cells only

Wide meshed graft plus Spray-On Skin Cells

Other (*specify*)

Other (*specify*)

## Spray-On Skin Cells Aftercare Notes

*Initial Dressing Change Date:*

*Subsequent Dressing Change Date:*

*Subsequent Dressing Change Date:*

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## PT/OT comments

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## AFTERCARE GUIDANCE

Using the RECELL System, your patient has been treated with autologous Spray-On Skin Cells, a process that uses patients' own skin cells to heal at the cellular level.[1,2]
The following information, precautions, and notes provide dressing management guidance.

### Initial Dressing Change[1]

A. Frequency of dressing change should reflect your facility's standard of care

B. Should a dressing change be required, e.g., if exudate levels are high, remove outer dressings

C. Use counterpressure to remove secondary dressing (e.g., Xeroform™, Cuticerin™, or Adaptic™)

*If secondary dressing is adherent, leave in place or trim around adherent area*

D. Take care to protect the primary dressing (e.g., Telfa™ Clear) 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

E. Apply new secondary dressings if applicable

*Moderately absorbent, minimally adherent, low shear, and readily removable (Examples are above - Point C)*

F. Apply new outer dressing

*Additional absorbent gauze for padding as well as compression bandages may be used*

G. Cytotoxic medication is contraindicated for areas treated with Spray-On Skin Cells

### Subsequent Dressing Changes[1]

A. Frequency of dressing change should reflect your facility's standard of care

B. Remove all secondary and outer dressings

C. The primary dressing should remain in place and kept dry until new epidermis is formed, but is typically no longer required after 6-8 days

D. The primary dressing must not be forcibly removed from area(s) to which it is still adhered. Typically it can be separated (gently peeled back) as new epidermis is formed

E. 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*

F. Once the dressing is fully removed, gently cleanse with mild soap and water

G. Once the primary dressing has been removed, a protective dressing should be applied and secured to protect the wound surface (e.g., Cuticerin, Xeroform, Adaptic, or Mepitel® One)

### Post Healing[1]

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

B. The newly healed epidermis must be protected with a dressing for a minimum of 2 weeks

C. Dry dressings should NOT be applied directly to blistered areas or bleeding, this could lead to potential injury to the regenerated epidermis upon dressing removal

D. Change protective, non-adherent dressing as needed

E. Avoid rigorous cleaning or excessive topical creams to avoid damage to the newly forming skin

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

**Refer to the RECELL System Dressing Guidelines for full details.**

## MANAGING SUSPECTED INFECTION[1]

If infection is suspected, treat per standard of care

## PHYSICAL/OCCUPATIONAL THERAPY[1]

- Spray-On Skin Cell-treated areas should be clearly noted and a therapy treatment plan made to avoid disruption of re-epithelialization
- Range of motion should be resumed based on facility's standard of care for autografts
- Special care should be taken to avoid friction and shearing of treated areas
- PT/OT sessions can be performed when bulky dressings are removed in order to visualize the primary dressing and prevent shearing

## PREVENT FRICTION AND SHEARING

As with autografts, it's important to protect the newly forming epidermis during the healing process

**Please see the back for Important Safety Information.**

*For more information, please visit*
***RECELLsystem.com*** *or call* ***1-833-462-8482***

**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 $cm^2$, 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.

**REFERENCES: 1.** Instructions for Use. RECELL® Autologous Cell Harvesting Device. **2.** Wood FM, Giles N, Stevenson A, Rea S, Fear M. Characterisation of the cell suspension harvested from the dermal epidermal junction using a ReCell® kit. *Burns*. 2012;38(1):44-51.

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