RECELL®
Autologous Cell Harvesting Device

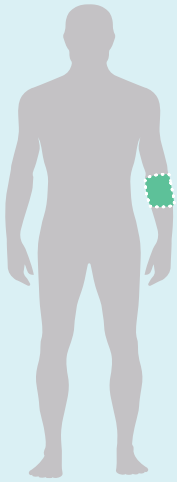
RECELL® SYSTEM TREATMENT REDUCED DONOR SKIN REQUIREMENTS FOR THE TREATMENT OF DEEP PARTIAL-THICKNESS BURN

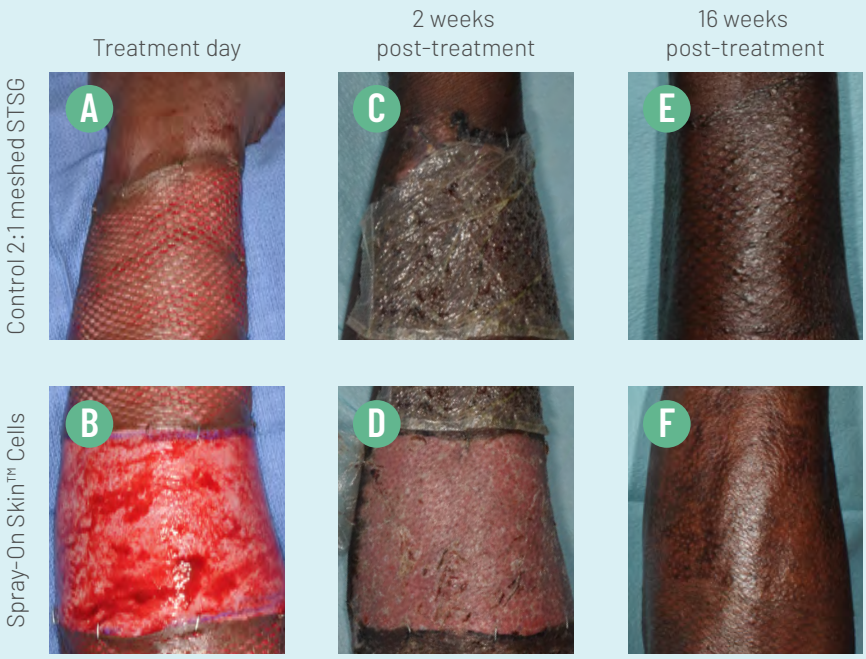
CASE STUDY / David Smith, MD / University of South Florida, Tampa, FL

PATIENT PRESENTATION

A 48-year-old male had a burn injury from fire/flames. This case focuses on the treatment of the left lower dorsal forearm with a 2:1 meshed split-thickness skin graft (STSG) compared to RECELL treatment.

RECELL TREATMENT AREA





TREATMENT REGIMEN

This patient was treated as part of a prospective, randomized controlled trial. Three days after injury, the burn wound was excised and divided into two comparable sections which were randomized to receive 2:1 meshed STSG (Figure A) or application of Spray-On Skin™ Cells prepared using the RECELL System (Figure B). Both treatment sites were dressed with Telfa™ Clear followed by Xeroform™ and bulky dressings for exudate and to provide protection to the regenerating epidermis.

CLINICAL OUTCOME

The use of RECELL in the treatment of the burn injury reduced donor site requirements by 98% compared to the 2:1 meshed STSG. Two weeks following treatment, the RECELL treatment site and 2:1 meshed STSG site were healed (Figures C and D). At week 16, the Vancouver Scar Scale had better scores in pigmentation and height for the RECELL site compared to the STSG site (Figures E and F).

CONCLUSION

This case study demonstrates treatment of deep partial-thickness burn injuries with RECELL reduced donor skin requirements compared to conventional autografting without compromise to healing times. At 16 weeks, scar outcomes related to pigmentation and height were closer to native skin for the RECELL treated site compared to the 2:1 meshed skin graft.

For Important Safety Information, refer to back page.

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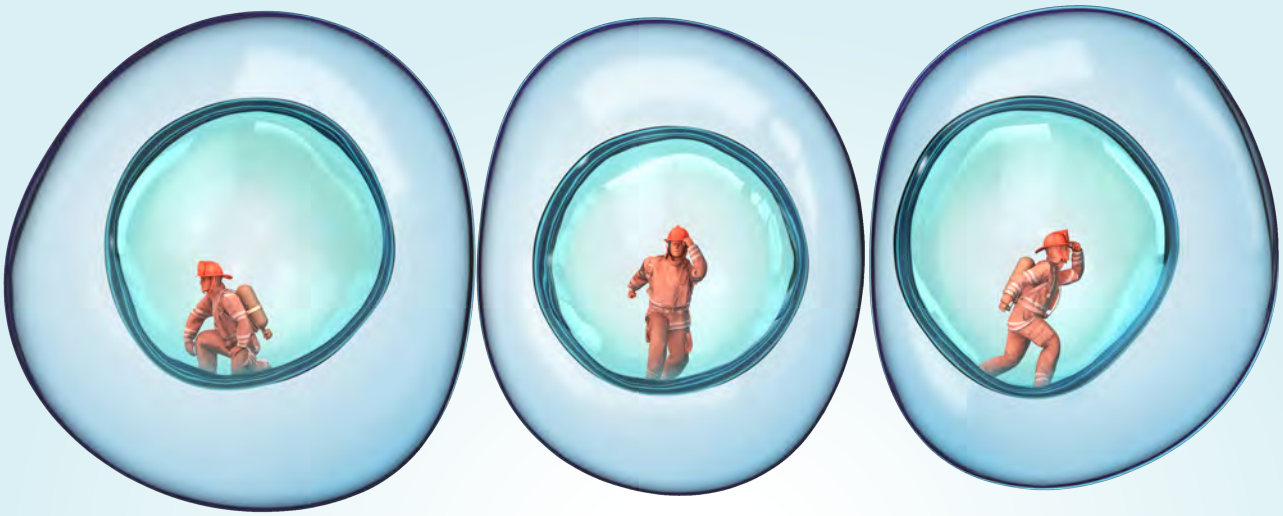
Inside burn patients' skin cells are regenerative forces at the ready.

GIVE THEM THE SIGNAL TO MOVE.



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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.

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