RECELL®
Autologous Cell Harvesting Device

RAPID RE-EPITHELIALIZATION OBTAINED USING RECELL® SYSTEM TREATMENT COMBINED WITH WIDELY MESHED AUTOGRAFT FOR ANATOMICALLY CHALLENGING AREA (BACK)

CASE STUDY

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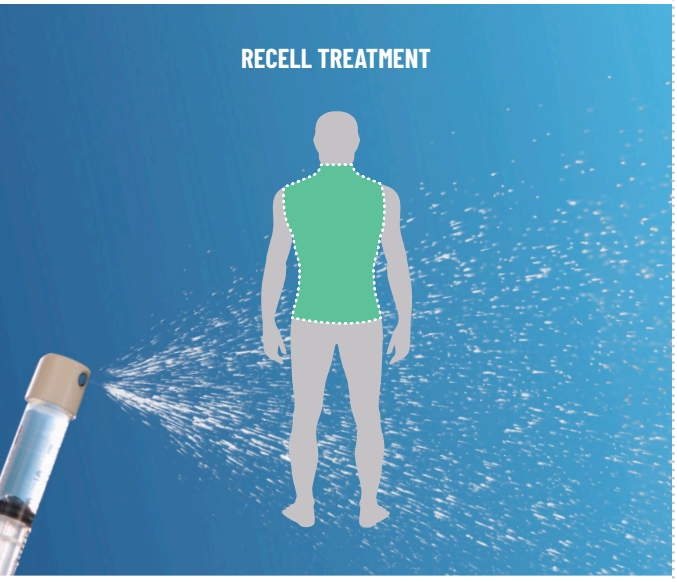
PATIENT PRESENTATION

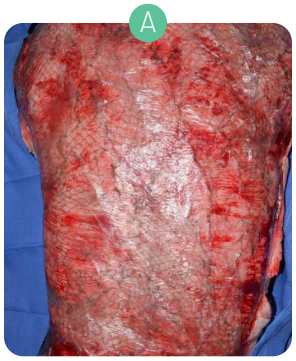
A 29-year-old male sustained a mixed-depth flame burn injury. Areas of injury included the buttocks, genitalia, head, anterior and posterior trunk, upper extremities, and lower extremities. This case study focuses on the treatment of the full-thickness injury to the posterior torso.



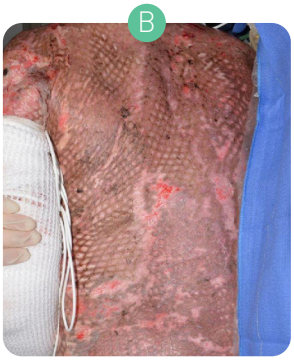
CONCLUSION

This case demonstrates that using RECELL in combination with a 4:1 meshed STSG to treat a full-thickness burn resulted in excellent outcomes with sparing use of donor skin. This case also highlights that RECELL achieved robust definitive closure on the back, an anatomically challenging area where pressure and shearing forces often cause issues when a meshed autograft is used.

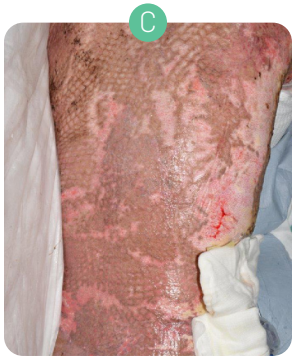
Treatment Day



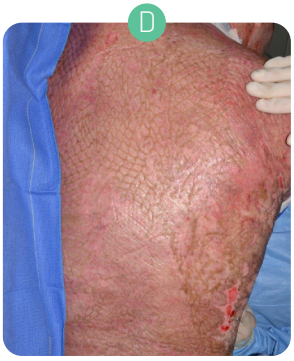
7 Days Post-treatment



28 Days Post-treatment



2 Months Post-treatment



TREATMENT REGIMEN

The back burn was initially excised and treated with allografts and 5% Sulfamylon® solution. After tangential excision, a 33 cm^2 split-thickness skin sample was harvested and the RECELL System was used to prepare Spray-On Skin™ Cells. The resulting suspension was applied over 4:1 meshed split-thickness skin graft (STSG) at an expansion ratio of 80:1 and Telfa™ Clear was immediately applied (Figure A). The treatment areas were then covered with Xeroform™ and bulky dressings.

CLINICAL OUTCOME

One week following RECELL treatment, the wound was 70% re-epithelialized (Figure B), and by 4 weeks, re-epithelialization was greater than 95% (Figure C). By 2 months, the color in terms of vascularity, as well as pigment, matched the surrounding non-injured areas, and the texture was only mildly mismatched (Figure D). No durability issues were reported over the 2-month follow-up.

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.

Visit RECELLsystem.com to learn more.

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 RES® Regenerative Epidermal Suspension 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 present in the wound bed. RECELL® is contraindicated for the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate solution (Hartmann's Solution). The skin sample collection procedure specified for use of RECELL® should not be used with 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 RECELL® or device components if packaging is damaged, there are signs of tampering or date of use is beyond the stated expiration date. Choose a skin sample donor site that shows no evidence of surrounding cellulitis or infection. The skin sample should be processed immediately after harvesting. If a skin sample is harvested and processed according to these instructions, it should require between 15 and 30 minutes of contact with the 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 to be used alone (i.e., without meshed autograft) for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL® used alone (i.e., without meshed autograft) have not been established for treatment of partial-thickness burn wounds: on the hands and articulated joints, >320 cm2, in patients with wounds totaling >20% Total Body Surface Area (TBSA). The safety and effectiveness of RECELL® plus autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, in patients with wounds totaling >50% Total Body Surface Area (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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