RECELL®
Autologous Cell Harvesting Device

HEALING OF A 9% DEEP PARTIAL-THICKNESS BURN USING RECELL®

CASE STUDY

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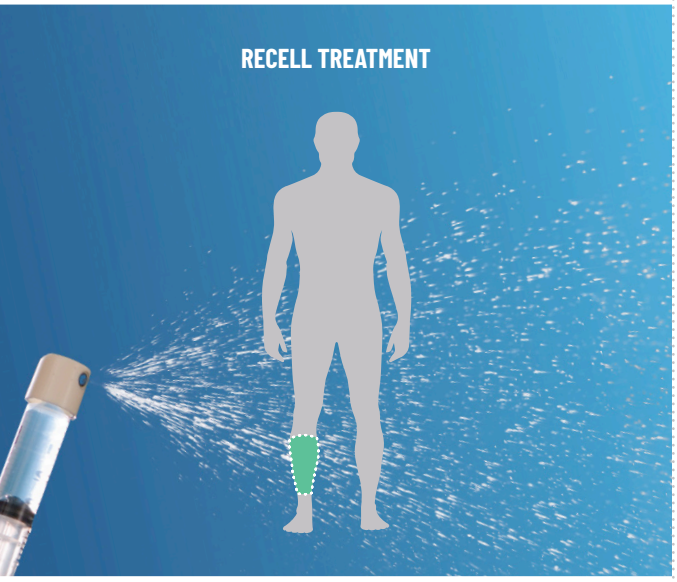
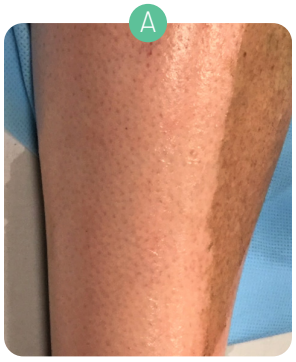
PATIENT PRESENTATION

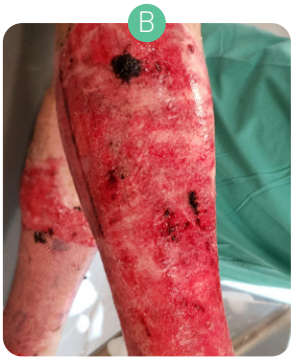
A 62-year-old male presented with a deep partial-thickness burn injury to the bilateral lower extremities secondary to using accelerant on a brush fire (Figure A). This case focuses on the RECELL treatment area of the right lower leg, representing ~ 9% body surface area (BSA).



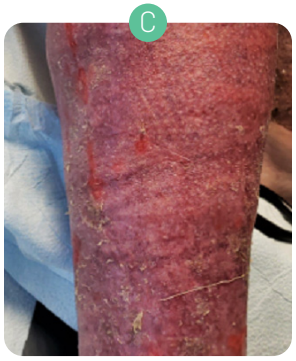
Day 1
A



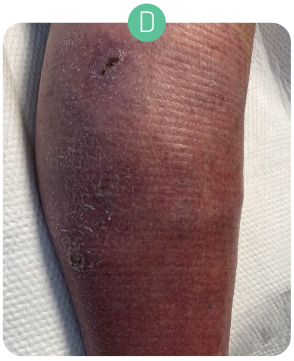
Day 2
B



8 Days Post-treatment
C



29 Days Post-treatment
D



TREATMENT REGIMEN

The patient was treated on Day 1 in hydrotherapy and was placed in Silvadene® dressings for his right lower leg. After 2 days of this wound care, the wound showed no optimal signs of healing and RECELL was used to treat the right lower leg. The wound was excised using Versajet® until a healthy wound bed was reached (Figure B). Using the RECELL System, Spray-On Skin™ Cells were prepared and applied to the wound bed. The treatment site was dressed with Telfa™ Clear, Xeroform™, Kerlix™ Gauze, and ACE™ Wrap.

CLINICAL OUTCOME

On RECELL post-op Day 8, the primary dressings were removed under conscious sedation. The affected extremity treated with Spray-On Skin yielded a satisfactory outcome with 100% re-epithelialization at post-op Day 8 (Figure C). Patient was discharged on post-op Day 13. Upon return to the burn clinic on 29 days post-op, the patient denied inflammation and itching (Figure D). The patient also reported that pain was controlled by non-opiate analgesia.

CONCLUSION

This case study demonstrates that the use of RECELL on a small deep partial-thickness burn resulted in 100% re-epethelialization by post-op Day 8. The treatment area shows re-pigmentation by post-op Day 29, with absence of inflammation and itching observed by the patient.

For Important Safety Information, refer to back page.

RECELL®
Autologous Cell Harvesting Device

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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