RECELL®
Autologous Cell Harvesting Device

RECELL® SYSTEM TREATMENT OF DEEP PARTIAL-THICKNESS BURNS IN A 10% TBSA FLAME BURN PATIENT

CASE STUDY

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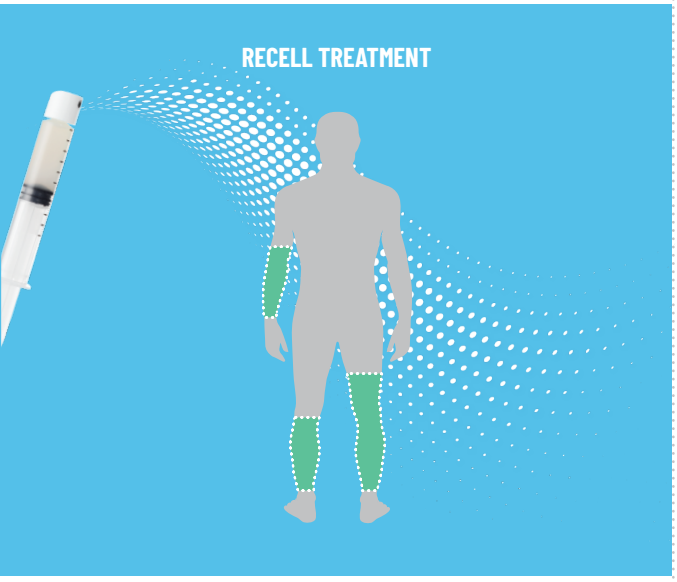
PATIENT PRESENTATION

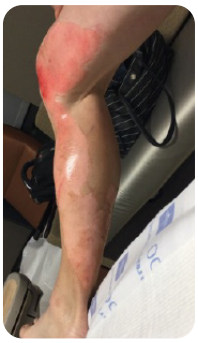
A 52-year-old, male, sustained a 10% TBSA deep partial-thickness flame burn to bilateral lower extremities and left upper extremity. The patient had no pertinent previous medical history or underlying comorbidities. This case focuses on healing outcomes and 7 month follow up.



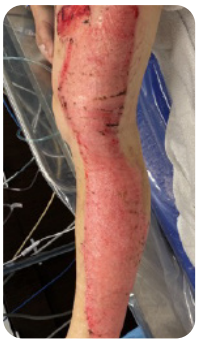
CONCLUSION

This case demonstrates the use of Spray-On Skin Cells in a deep partial-thickness wound and positive outcomes.

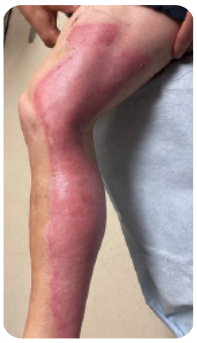
Admission



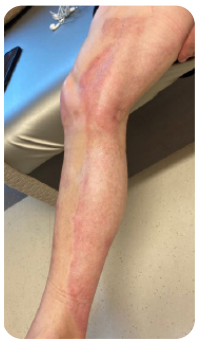
9 Days Post-treatment



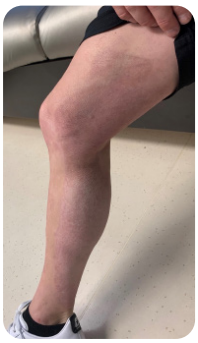
15 Days Post-treatment



2 Months Post-treatment



7 Months Post-treatment



TREATMENT REGIMEN

The wounds were prepared using tangential excision and VERSAJET™ and the RECELL System was used to prepare Spray-On Skin™ Cells. The donor site was taken from the medial right thigh, proximal to the burn wound. The treated areas were dressed with Telfa™ Clear, secured with staples, then ASSIST® Ag, Kerlix™ and ACE™ wraps. The patient was discharged the following day.

Secondary dressings were changed in clinic post-op day 4. The patient returned to the clinic post-op day 7, all dressings were removed from the upper extremity and the ASSIST Ag removed from the legs. The Telfa Clear was removed on post-op day 9 from the bilateral lower extremities.

The safety and effectiveness of RECELL has not been established for the treatment of burn wounds on the hands and articulated joints.

CLINICAL OUTCOME

On post-op day 7 there was > 95% re-epithelialization. Both the wounds and RECELL donor site healed without complication and the majority of erythema dissipated by 1 month post treatment. The patient returned to work two weeks post-surgery. Both the patient and surgeon were incredibly satisfied with the outcome.

For Important Safety Information, refer to back page.

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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. 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 in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients.

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, and in patients younger than 28 days of age (neonates).

SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-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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