RECELL®
Autologous Cell Harvesting Device

TREATMENT OF A DEEP-PARTIAL THICKNESS FACIAL BURN WITH RECELL® ALONE

CASE STUDY

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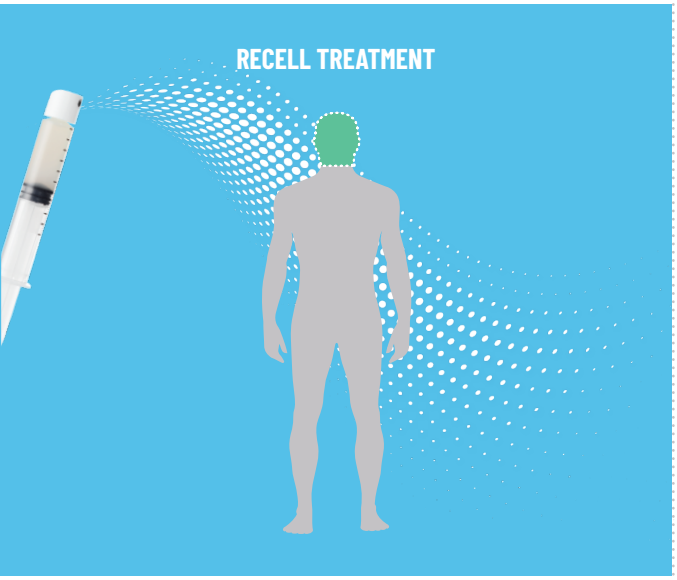
PATIENT PRESENTATION

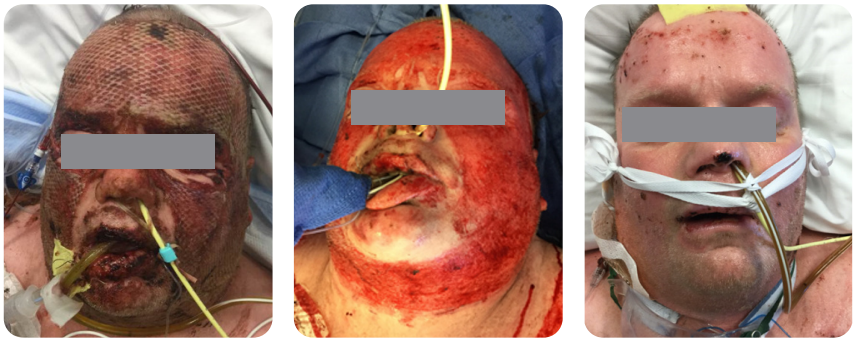
A 43-year-old male presented to the burn clinic with deep partial-thickness scald burns to the face (~7% total body surface area [TBSA]) and significant airway injury. No notable past medical history.



CONCLUSION

This case demonstrates the use of Spray-On Skin Cells to treat a 7% TBSA facial burn. Whereas traditional standard of care would have indicated autografting as first line treatment protocol, treatment with the RECELL System resulted in re-epithelialization and re-pigmentation at 2 weeks post-treatment.

7 Days Post-homograft | **RECELL Treatment Day** | **14 Days Post-treatment**



TREATMENT REGIMEN

The patient was taken to the operating room once he was stabilized and was resuscitated appropriately. After inital debridement, the facial burn was covered with a meshed homograft. The attending surgeon assessed the burn to be a papillary to almost reticular dermal burn, and noted that traditional standard of care would predicate autografting. However, upon taking the patient to the operating room on day 10 post-homograft, the homograft was removed and the surgeon noted, "excellent bed," and decided to proceed with Spray-On Skin™ Cells alone.

CLINICAL OUTCOME

Initial dressings were removed at 2 weeks post-RECELL application. The wound bed was almost completely healed except for the tip of the nose. The clinician noted re-epithelialization and re-pigmentation at 2 weeks post-application of Spray-On Skin Cells.

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 cm2, 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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