RECELL®
Autologous Cell Harvesting Device

RE-PIGMENTATION AFTER TREATMENT OF A FACIAL BURN WITH RECELL® ALONE

CASE STUDY

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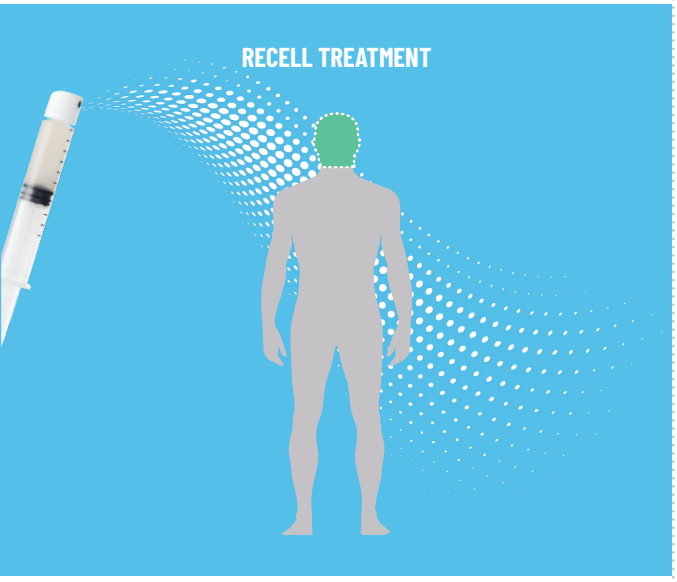
PATIENT PRESENTATION

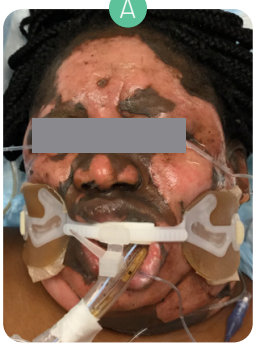
A 31-year-old female presented with an approximately 11% total burn surface area (TBSA) deep partial-thickness burn injury to the face from an unknown flammable liquid and flame (Figure A).



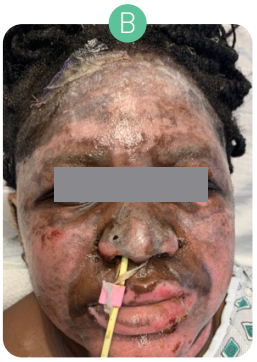
CONCLUSION

This case study demonstrates the effectiveness of using autologous Spray-On Skin Cells alone in treating an 11% TBSA deep partial-thickness burn to the face. The patient exhibited definitive wound closure at post-op day 9. With RECELL alone, the patient experienced re-pigmentation and a close match to surrounding skin.

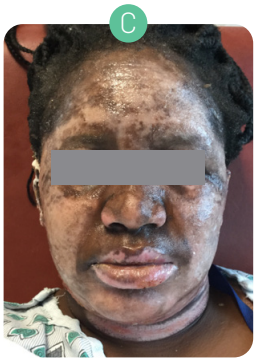
Treatment Day (A)



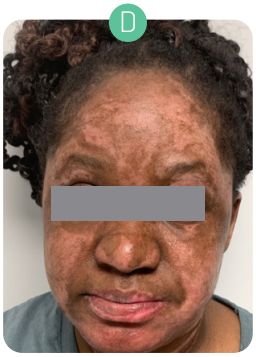
6 Days Post-treatment (B)



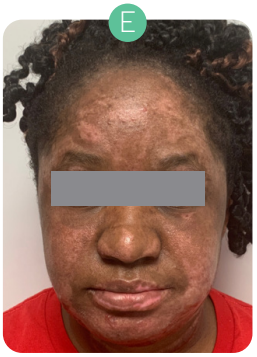
9 Days Post-treatment (C)



2 Months Post-treatment (D)



3 Months Post-treatment (E)



12 Months Post-treatment (F)

TREATMENT REGIMEN

This patient was treated on Day 1 with hydrotherapy debridement, placement of bacitracin and covered with Xeroform™. After 6 days of conservative treatment and wound care it was determined that the facial wounds would not heal on their own. The face was debrided intraoperatively with VERSAJET® until a healthy wound bed was confirmed. Allograft was placed to the face, and after 7 days it was decided to use RECELL for the patient's face due to improvement of edema and demarcation of injury. Using the RECELL System, Spray-On Skin™ Cells were prepared and applied to the wound bed. The treatment site was dressed with Telfa™ Clear and Xeroform.

CLINICAL OUTCOME

On post-op Day 6, dressings were removed (Figure B). At post-op Day 9, the patient presented with 100% re-epithelization and no signs of infection or inflammation (Figure C). The patient continued to show progressive re-pigmentation 2 months post-treatment (Figure D), 3 months post-treatment (Figure E) and 12 months post-treatment (Figure F).

For Important Safety Information, refer to back page.

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Visit RECELLsystem.com to learn more.

RECELL EASE OF USE—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 Spray-On Skin™ Cells 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.

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