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transforming lives

# RECELL® System

## Innovative treatment option for full-thickness pediatric thermal burns

**PEDIATRIC BURNS FACT SHEET**
Updated June 2021

With less donor skin requirements and fewer surgical procedures, the RECELL® System offers proven burn healing efficacy for all sizes of acute full-thickness thermal burns, in combination with meshed autografting, for patients 1-month of age and older.

The RECELL® System is approved by the U.S. Food and Drug Administration (FDA) for the treatment of acute thermal burns. Please see Important Safety Information and Instructions for Use on next page.

## HOW COMMON ARE PEDIATRIC BURNS?

Nearly a quarter of all burn cases in the United States occur in children under the age of 16 years old.[i] Thermal burns occur when external heat sources, such as hot metals, scalding liquids, steam, and flames, raise the temperature of the skin and tissues and cause tissue cell death or charring.

## HOW ARE PEDIATRIC BURNS CURRENTLY TREATED?

Treatment of pediatric acute, full-thickness burns typically includes autografting, commonly referred to as skin grafting. Conventional skin grafting results in scar formation in the area treated and involves the harvesting of substantial amounts of donor skin, resulting in an additional wound to the patient. Significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring are all associated with skin graft donor site wounds. For pediatric burn patients, additional complications may occur as they grow.

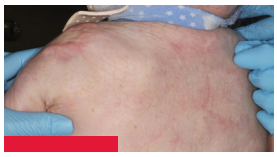
# HOW CAN RECELL® SYSTEM ADVANCE THE TREATMENT OF PEDIATRIC BURNS?

The RECELL® System offers a treatment option for pediatric burn patients that reduces the amount of donor skin needed for burn treatment, promotes healing, often with less pain and scarring at the donor site, and helps to decrease overall cost of care as patients are often able to recover with less operations and fewer dressing changes. Compared to the National Burn Repository, treatment with RECELL® reduced the mean number of pediatric grafting procedures required to achieve definitive wound closure by 56%.

**Case Study:** 15-month-old female who sustained 58% TBSA full-thickness flame burns to the patient's back

**Treatment Day:** RECELL® applied

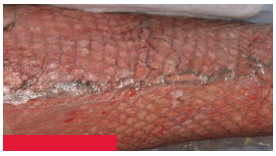
**Day 7:** Re-epithelialized post RECELL® treatment



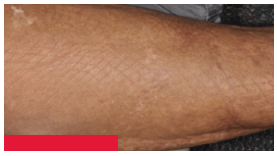
**12 Months:** Wound post RECELL® treatment

**Case Study:** 12-year-old female who sustained a 62% TBSA mixed depth flame burn wound to the patient's legs.

**Treatment Day:** Autografted and RECELL® applied to full-thickness leg burn injury



**Day 7:** 75% re-epithelialized post RECELL® treatment



**12 Months:** Wound post RECELL® treatment

RECELL® has not been studied for treatment of articulating joints.

## To learn more, visit avitamedical.com or Contact Us: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[i] National Burn Repository 2019 Update – Report of data from 2009-2018. 22.5% of burns occur between ages 1-15.



## 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.

Please review the RECELL® System Instructions for Use at www.RECELLSystem.com

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