RECELL® System
Product Fact Sheet

Overview

The RECELL System is approved by the FDA for the treatment of acute thermal burn injuries in patients 18 years of age and older. The RECELL System is used by a trained healthcare professional at the point of care to prepare Spray-On Skin™ Cells to be sprayed directly on second-degree burn injuries or applied in combination with meshed autografts for third-degree burn injuries.

Compelling data from randomized, controlled clinical trials conducted at leading U.S. burn centers and real-world use reinforce that the RECELL System is an advancement over the current standard of care for burn patients as it offers reduction in donor skin requirements and cost savings as demonstrated by reduction in length of stay.

The current standard of care for patients with severe burns is skin grafting, which is invasive and painful. The RECELL System addresses common skin grafting challenges, including availability and usability of donor skin, donor site pain, hospitalization costs, and need for multiple procedures.

The RECELL System heals burns using 97.5%[1] less donor skin when used alone to treat a second-degree burns, and 32% less donor skin when used with autograft to treat third-degree burns.[2]

The RECELL System was developed and is manufactured by AVITA Medical (ASX:AVH, NASDAQ:RCEL), a global regenerative medicine company that provides a novel approach to skin regeneration. Supported by a substantive body of international RECELL System clinical evidence treating patients for additional skin applications, such as chronic and traumatic wounds as well as vitiligo, AVITA Medical is seeking expanded labeling in the U.S. after completion of additional clinical trials.

RECELL Highlights[1, 2, 3]

Regenerative cell therapy for immediate use at the point of care

Reduced donor skin requirements up to 97.5%

Significantly less donor site pain

Significantly higher patient satisfaction with donor site appearance

Significantly better donor site scarring results

Significantly greater incidence of donor site healing at one and two weeks

Reduced total treatment costs

Reduced length of stay

Decreased number of operations a burn patient must undergo

How it Works

A small skin sample is enzymatically and mechanically processed in the RECELL System at the point of care to isolate the skin cells to produce a suspension of Spray-On Skin™ Cells. The regenerative cell suspension includes keratinocytes, fibroblasts, and melanocytes, which play a critical role in wound healing. The suspension can be sprayed directly on a second degree burn or with an expanded skin graft on a third-degree burn, allowing for broad and even distribution of live cells across the entire wound bed.

The RECELL System can be used to prepare enough Spray-On Skin Cells to treat a wound up to 80 times the size of the donor skin sample, so a skin sample about the size of a credit card can be used to treat a wound that covers a patient's entire back.

Typically, wound healing occurs from the outside edges of a wound inward. The RECELL System overcomes this limitation by delivering the patient's own skin cells across the entirety of the wound surface. By delivering single cells, the RECELL System facilitates healing across the whole wound, not just the edges.

Market Focus

AVITA Medical is focusing initially on the $900 million burn market in the United States, where significant unmet medical needs exist.[4] The burn sector in the U.S. is highly concentrated, with 132 major burn centers and roughly 300 burn surgeons, many of whom already have experience with the RECELL System. Established facility and physician reimbursement codes make the RECELL System accessible to treat burn patients in hospital and outpatient settings, as well as ambulatory surgery centers.

AVITA Medical is conducting clinical trials in additional applications, such as pediatric burns, trauma injuries, and vitiligo, which represent a potential $2 billion market opportunity inclusive of the current burns market.

Clinical Milestones

U.S. FDA PMA approval was received on Sept. 20, 2018. The results from the pivotal and other clinical studies of the RECELL System have been presented at multiple scientific conferences, and the pivotal trial results were published in the *Journal of Burn Care & Research* (JBCR)[1] and *Burns.*[2]

The company commenced two controlled pediatric clinical trials in the U.S., funded by the Biomedical Advanced Research and Development Authority

(BARDA) as part of its overarching goal of building burn care preparedness under USG Contract No. HHSO100201500028C.

Cost Benefit

IQVIA developed, with AVITA Medical and BARDA support, a Burn Care Pathway Health Economic Model to determine cost savings to burn centers as a result of using the RECELL System compared to the current standard of care to treat second and third degree burns of varying sizes. Utilizing this model, health economic data projects that use of the RECELL System to treat in-patient burns could save a major U.S. burn center treating 200 patients $13 million annually compared to treatment with the standard of care.

On average, burn centers utilizing the RECELL System can reduce overall costs associated with the care of patients with severe burn injuries:[3]

- 30% reduction in length of stay – fewer procedures gets patients home sooner
- 35% fewer procedures – reduced donor size and greater expansion ratio enables permanent closure with fewer invasive autograft procedures
- 35% cost savings – shorter and fewer procedures, decreased length of stay, and reduced resource use translates in burn center savings

RECELL saves money in all in-patient scenarios where the total burn surface area is >10%.[3]

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, 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, in

patients with wounds totaling >50% 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

To learn more, visit www.avitamedical.com

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[1] Holmes JH, Molnar JA, Carter JE, et al. A comparative study of the RECELL® device and autologous split-thickness meshed skin graft in the treatment of acute burn injuries. J Burn Care Res. 2018.
[2] Holmes JH, Molnar JA, Shupp JW, et al. Demonstration of the safety and effectiveness of the RECELL System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. Burns. 2019;45:772-782.
[3] Kowal, S., Kruger, E., Bilir, P. et al. Cost-Effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States. Advances in Therapy. (May 2019). https://doi.org/10.1007/s12325-019-00961-2.
[4] Market sizing and other data on this page is based on information and estimates on file at AVITA Medical Limited. In the U.S., RECELL is approved for acute thermal burns in patients >18 (("ATB") only (see www.avitamedical.com)). Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.