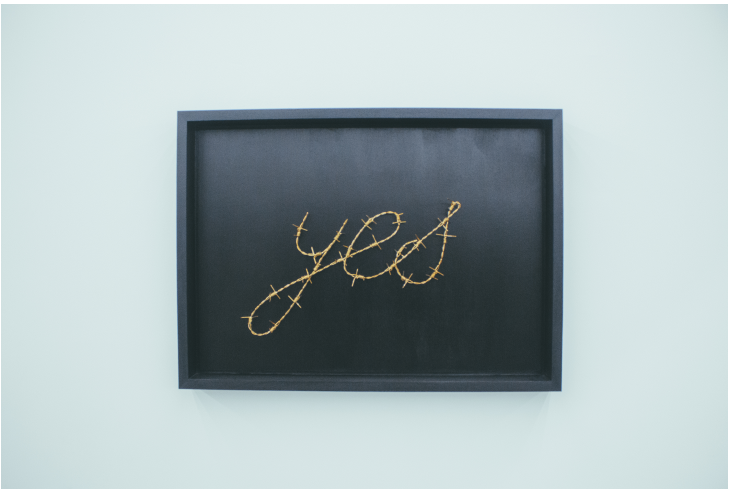
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

AVITA Medical Receives U.S. FDA Investigational Device Exemption Approval

17 September 2019 | News

AVITA Medical Receives U.S. FDA Investigational Device Exemption Approval of Pivotal Study Evaluating RECELL System for Soft Tissue Reconstruction



AVITA Medical, a regenerative medicine company focused on the development and commercialization of innovative therapies leveraging the healing properties of a patient's own skin, announced that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational Device Exemption (IDE) application to conduct a pivotal trial evaluating the safety and effectiveness of the RECELL® Autologous Cell Harvesting Device (RECELL® System) in combination with meshed autografting for the treatment of acute full-thickness skin defects, such as degloving (a type of injury where the skin is ripped from the underlying tissue), crush wounds (a break in the external surface of the body), abrasions, lacerations, and surgical wounds.

"FDA approval of our IDE for a soft tissue reconstruction pivotal clinical trial is an important next step in expanding the potential indications of our RECELL System technology platform. We are pleased with the strong interest expressed by the clinical community in participating in this study and we look forward to working with physicians and their patients upon study commencement," said Dr. Michael Perry, Chief Executive Officer of AVITA Medical. "Many burn specialists who have experience treating burn patients with the RECELL System also treat patients with trauma injuries in their clinics. The treatment protocols for burns and trauma are well-aligned and as such, we anticipate a positive transfer of clinical experience to benefit this patient population during the clinical trial."

Skin grafting is the standard of care for soft tissue reconstruction, including post-trauma and post-surgical skin reconstruction. Skin grafting requires the harvesting 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 associated with donor site wounds. While skin grafting is commonly associated with burn treatment, in 2017 approximately 80% of acute wounds that required skin grafting were non-burn related injuries accounting for more than 200,000 procedures in the U.S.

"Based on the compelling safety and effectiveness of the RECELL System in treating burn wounds, we believe our innovative technology is ideally positioned to be evaluated as a treatment to heal trauma- and surgery-related wounds," said Andy

Quick, Chief Technology Officer of AVITA Medical. “With a clear opportunity to improve the standard-of-care, we look forward to sharing results upon completion of this pivotal trial.”

AVITA Medical will initiate a prospective, multi-center, randomized controlled study to compare the clinical performance of conventional skin grafting with and without the use of the RECELL System on acute non-burn full-thickness skin defects. Each patient will have a control wound treated with conventional skin grafting and a wound treated with expanded skin grafting in combination with the RECELL System. The study’s two primary effectiveness endpoints are:

- Incidence of healing by eight weeks post treatment
- Donor skin sparing, evaluated by comparing the ratios of donor skin required to treat the wounds

Healing will be evaluated by a qualified clinician blinded to the treatment allocation. Additional long-term safety and effectiveness data collected over the course of the 52-week study will include blinded evaluation of scar outcomes and patient treatment preference.

The pivotal studies leading to the RECELL System’s FDA premarket approval (PMA) for the treatment of acute thermal burns demonstrated that the RECELL System treated burns using 97.5 percent less donor skin when used alone in second-degree burns, and 32 percent less donor skin when used with autograft for third-degree burns. Despite the statistically significant reduction in donor skin required to treat burn patients with the RECELL System, burn wounds treated with the RECELL System achieved healing comparable to the burn wounds treated with standard of care. Donor site outcomes from the clinical trial for second-degree burns also revealed a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved scar outcomes.