CONTINUED ACCESS PROTOCOL

A Prospective, Multicenter, Single-Arm, Observational Study of the Safety and Clinical Performance of RES (Regenerative Epithelial Suspension) Prepared with the ReCell® Device Combined with Meshed Skin Graft in the Treatment of Acute Burn Injuries

Investigational Plan

Study Number:	CTP001-8
Device:	ReCell Autologous Cell Harvesting Device
Study Type:	IDE Study (IDE 13053)
Date:	December 19, 2017
Sponsor:	Avita Medical Americas, LLC 28159 Avenue Stanford, Suite 220 Valencia, CA 91355

PRINCIPAL INVESTIGATOR'S STATEMENT

This statement is to certify that I have received the above-referenced investigational plan, which has been approved for initiation at my investigational site by the Institutional Review Board on the date of _____. As Principal Investigator, I will ensure that all personnel who have been delegated responsibilities for this study will be trained on the investigational plan and associated responsibilities prior to study participation. I agree to conduct this clinical study in compliance with the investigational plan and applicable requirements of the U.S. Code of Federal Regulations (21 CFR Parts, 50, 54, 56, 812 and 45 CFR Part 46).

Signature: _____ Date: _____

Principal Investigator

PROTOCOL SYNOPSIS

Title:	CONTINUED ACCESS PROTOCOL A Prospective, Multicenter, Single-Arm, Observational Study of the Safety and Clinical Performance of RES (Regenerative Epithelial Suspension) Prepared with the ReCell® Device Combined with Meshed Skin Graft in the Treatment of Acute Burn Injuries
Purpose:	This Continued Access Protocol has been written to allow ongoing treatment of subjects at selected investigational sites while the marketing application for the ReCell® Autologous Cell Harvesting Device is under FDA review. Data collected within this study will augment safety and effectiveness results from previous Investigational Device Exemption (IDE) studies using the ReCell® device, increasing the available clinical evidence for the application of RES (Regenerative Epithelial Suspension) prepared from the ReCell® device as an adjunct to meshed grafts in subjects with acute thermal burn injuries requiring skin grafting for closure.
Design:	This is a prospective, multicenter, single-arm observational study. Patients 5 years or older with a total body surface area (TBSA) thermal burn injury between 5 and 50% (inclusive) who require autografting will be considered for participation in this study. The regenerative epithelial suspension (RES) prepared using the ReCell® device will be applied over skin grafts meshed more widely than conventional autografting. RES may also be applied to donor areas. Healing, scar outcomes, pain and treatment-related adverse events will be evaluated at follow-up visits. Data concerning the clinical performance and safety of the ReCell device will be collected. Follow-up visits will be performed at 1, 2, 4, 8, 12, and 24 weeks post-treatment. Healing outcomes will be evaluated at all visits by direct visualization by the investigator. Scar outcomes will be evaluated at 12 and 24 weeks post-treatment using the Patient and Observer Scar Assessment Scale (POSAS) questionnaire. Treatment-related and serious adverse events will be captured throughout the study. At all visits, the study treatment area and RES-treated donor area will be documented photographically.
Safety Outcomes:	Safety will be assessed by evaluation of treatment-related and serious adverse events.
Clinical Performance Outcomes:	**<u>Healing</u>** Treatment and RES-treated donor area closure will be evaluated via direct visualization. Complete wound closure is defined as skin re-epithelialization without drainage, confirmed at two consecutive study visits at least 2 weeks apart by direct visualization by the investigator.

	Scar Scar outcomes will be measured using the Patient and Observer Scar Assessment Scale (POSAS) questionnaire which includes a component for both investigator and patient scar assessment. **Treatment-area Pain** Measured via a numeric scale (1-10) and then as a component of the POSAS beginning at Week 12.
Enrollment	Up to 60 patients may be enrolled at up to 15 investigational sites in the United States.
Statistical Consideration	A sample size of 60 subjects will allow for continued access of the ReCell device during PMA preparation and FDA review. Additionally, a sample size of 60 subjects will allow for the detection of an adverse event with true probability of occurrence among RES-treated subjects of ≥5% with 95% probability, allowing for additional characterization of safety profile of the ReCell device. Analyses of treatment area closure will be performed for the As Treated (AT) and Per Protocol (PP) populations. Data will be summarized using counts and percentages for healed/not healed, and an exact (Clopper-Pearson) two-sided 95% confidence interval for the true proportion will be presented. The AT population includes all those enrolled into the study and treated with RES. The AT population will be the primary analysis population for the healing, POSAS and pain assessments**.** The PP population includes all AT subjects who have no major protocol deviations. The PP population will serve as the secondary analysis population for the healing, POSAS and pain assessments. For evaluation of healing, scars, and pain, it is anticipated that there will be minimal missing data. No imputation of missing data is planned.