INSTRUCTIONS FOR USE

RECELL GO™ Autologous Cell Harvesting Device
AVRL0103, AVRL0104

The RECELL GO Autologous Cell Harvesting Device (RECELL GO Device) should be used only by licensed healthcare professionals trained in the use of the device.

Caution: Federal law restricts this device to sale by or on the order of a physician.

AW-IFU045, Rev 3
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A BACKGROUND

A1 DEVICE DESCRIPTION

RECELL GO™ Autologous Cell Harvesting Device comprises two separate units. The RECELL GO Processing Device is a durable, powered, reusable device that provides the control for the sterile single-use RECELL GO Cartridge. The sterile, single-use RECELL GO Cartridge is part of the RECELL GO Preparation Kit which consists of components used for preparing the RECELL Spray-On Skin™ Cells.

The clinician places split-thickness skin samples into the single-use cartridge along with RECELL Enzyme™ and delivery solutions. The RECELL GO Cartridge locates into the RECELL GO Processing Device which then performs both enzymatic and mechanical disaggregation. Sterile syringes and blunt needles are provided to draw up the RECELL Spray-On-Skin Cells from the cartridge once the processing has completed. Sterile nozzles are provided to then apply the RECELL Spray-On-Skin Cells to the patient's prepared treatment sites at the point-of-care.

The cell suspension contains a mixed population of cells, including keratinocytes, fibroblasts, and melanocytes, obtained from the disaggregation of the skin sample. Additionally, sub-populations of keratinocytes critical for re-epithelialization have been identified in the cell suspension including basal keratinocytes, suprabasal keratinocytes, and activated keratinocytes. The Enzyme used to process the cells is a biological agent and as such may have slight variations in color and texture.

A2 INDICATIONS FOR USE

The RECELL GO Autologous Cell Harvesting Device is indicated for the treatment of thermal burn wounds and full-thickness skin defects. The RECELL GO Device is used by an appropriately licensed and trained 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 and full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer) in patients 15 years of age and older.

A3 CONTRAINDICATIONS

- RECELL GO is contraindicated for the treatment of wounds clinically diagnosed as infected or with necrotic tissue present in the wound bed.
- RECELL GO is contraindicated for the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate solution (Hartmann's Solution).
- The skin sample collection procedure specified for use of RECELL GO should not be used with patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

A4 WARNINGS

- Autologous use only.
- Control infections on wounds prior to application of the cell suspension.
- Excise the necrotic tissues on wound bed prior to application of the cell suspension.
- Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of cell suspension.
- The RECELL GO Preparation Kit cartridge and components are provided to the healthcare professional sterile and are intended for single use.
- Do not reuse, freeze, or re-sterilize device components.
- Handle using aseptic technique.
- Do not use RECELL GO Preparation Kit or device components if packaging is damaged or there are signs of tampering.
- Choose a skin sample donor site that shows no evidence of surrounding cellulitis or infection.
- For optimum cell viability, the skin sample should be processed immediately after harvesting.
- The Enzyme is derived from animal tissue and, although strict controls have been implemented in the manufacturing process to minimize the risk of pathogen contamination, a small risk of contamination exists and absolute freedom from infectious agents cannot be guaranteed.
- Contaminated materials and waste must be disposed of using appropriate biohazard waste receptacles.
- This device is intended to produce heat as part of its normal operation. Avoid touching the heating plate directly.
- The device is not intended to be calibrated or inspected (as part of preventative maintenance) in the field. Unauthorized device modification may impact the safety of the user.
- The use of RECELL GO Processing Device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Although RECELL GO Processing Device is designed for electromagnetic immunity, use of cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Although RECELL GO Processing Device is designed to be unaffected by typical electrostatic discharge (ESD), very high levels of ESD can result in a temporary suspension of normal operation requiring the operator to recover the operations.

A5 PRECAUTIONS

- RECELL GO is not intended to be used alone (i.e., without meshed autograft) for treatment of acute full-thickness burn wounds or full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer).
- The safety and effectiveness of RECELL GO used alone (i.e., 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 GO plus autografting have not been established for treatment of full-thickness burn wounds:
    - In patients younger than 28 days of age (neonates)
- The safety and effectiveness of RECELL plus autografting have not been established for application in combination with meshed autografting on full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer):
    - On the hands and genitalia
- If the harvested skin sample is processed at ambient temperature above 43°C, it may affect the effectiveness of the enzyme.
- The RECELL GO Processing Device shall be connected to a grounded mains outlet with a supplied hospital-grade power cord.
- Using cleaning agents other than non-woven wipes could damage the equipment or pose an electrical hazard.

A6 CAUTION

- The device is intended for use only in a healthcare professional environment complying to electromagnetic limits for medical devices contained in IEC 60601-1-2.
- Follow standard precautions including use of appropriate Personal Protective Equipment (PPE) while cleaning and using the processing device.
- Do not use sterile RECELL GO Preparation Kit components beyond the stated expiration date indicated on the adhesive Lot # and Expiration Date labels on the outer box packaging.
- Do not operate the device while in transit.

A7 SPECIAL PATIENT POPULATIONS

- The safety and effectiveness of RECELL GO have not been established for treatment of acute thermal partial-thickness burn wounds in pediatric patients younger than 18 years of age.

A8 ADVERSE REACTIONS

- Any adverse reaction or suspected adverse reaction related to RECELL GO should immediately be reported to AVITA Medical® [+1 833 GO AVITA].

A9 MEANING OF SYMBOLS

The packaging system is labeled with various symbols. These symbols are internationally harmonized and define certain characteristics of the product and the manufacturing process:

Symbol	Description	Symbol	Description
	Refer to Instruction for Use		Lot Number
	Product is for single use only		Product or components within have been sterilized using ethylene oxide
	Manufacturer		Catalogue number
	Upper and lower limit of temperature (Storage/Operation)		Products or components within have been sterilized using steam
	Do Not Re-sterilize		Product is sterile
	Upper and lower limit of humidity range (Storage/Operation)		Product or components within have been sterilized using gamma irradiation
	Atmospheric pressure limitation		Waste Electrical and Electronic Equipment (WEEE)
	Expiration date		Do not use if package is damaged
	Date of manufacture		Sterile barrier system
	Serial Number	IP22	Protected against solid foreign objects and vertically falling water drops (at 15°)
	Medical Device		Nationally Recognized Test Laboratory (NRTL) Listing
	Contains biological tissue of animal origin		

A10 DOSAGE

The RECELL GO System consists of the reusable, powered RECELL GO Processing Device and the sterile single-use RECELL GO Preparation Kit consisting of the RECELL GO Cartridge and Disaggregation Head, RECELL Enzyme plus sterile RECELL GO Suspension Components.

The contents of each RECELL GO Preparation Kit are sufficient to prepare up to 24 ml of cell suspension which can be used to cover a wound area of up to and including 1,920 cm^2.

A11 HOW SUPPLIED

The RECELL GO Autologous Cell Harvesting System consists of:

RECELL GO Processing Device (AVRL0104)

- 1 x RECELL GO Processing Device
- 1 x Power Cord
- 1 x Procedure Guide

RECELL GO Preparation Kit (AVRL0103)

- 1 x RECELL Enzyme
- 2 x Telfa™ Clear Primary Dressings
- 1 x Procedure Guide
- **RECELL GO Cartridge Tray**
  - 1 x RECELL GO Cartridge
  - 1 x Disaggregation Head
- 1 x **RECELL GO Suspension Components Tray**
  - 1 x Tray Diagram
  - ABC TRAY

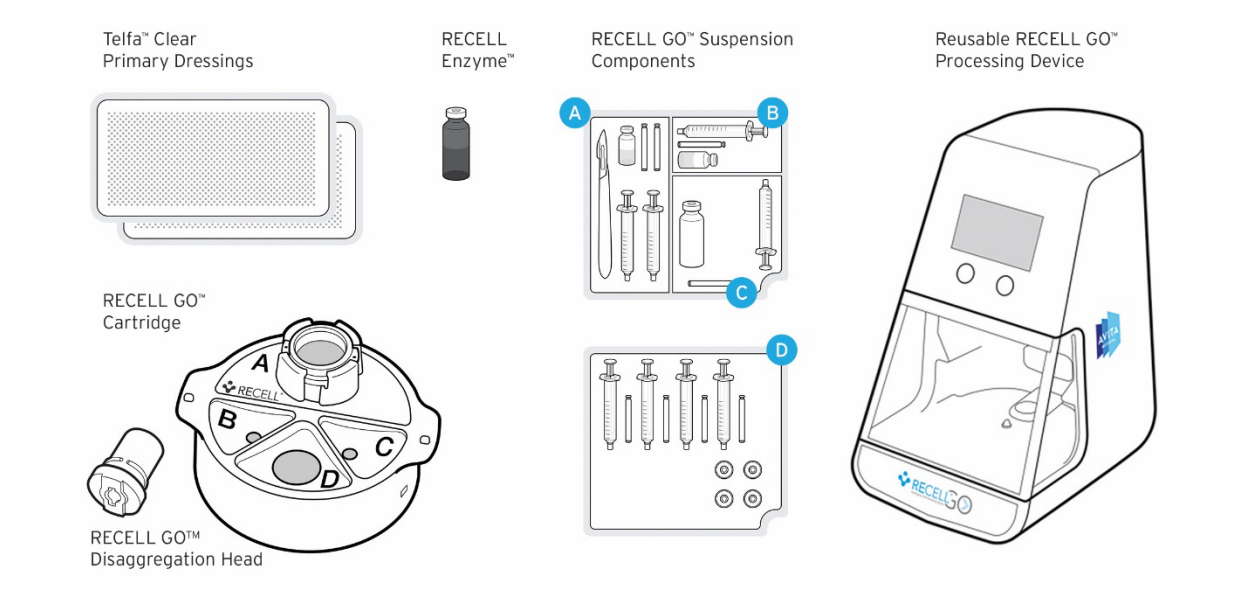
    Section A
    - 1 x 10 ml Sterile Water
    - 2 x 10 ml Syringe
    - 2 x Blunt Fill Needle
    - 1 x scalpel

    Section B
    - 1 x 10 ml Buffer
    - 1 x 10ml Syringe
    - 1 x Blunt Fill Needle

    Section C
    - 1 x 30 ml Buffer
    - 1 x 10 ml Syringe
    - 1 x Blunt Fill Needle

    D TRAY
    - 4 x 10 ml Syringes
    - 4 x Spray Nozzles
    - 4 x Blunt Fill Needles

RECELL GO System Components



Upon receiving RECELL GO, examine the packaging for external signs of damage. If the external packaging or the packaging for any of the individual components appears damaged, contact your AVITA representative immediately. Do not use any components of the device if the packaging appears damaged. If returning RECELL GO, ensure all original packaging and components are returned with the device.

A12 DISPOSAL

- The RECELL GO Cartridge and RECELL GO Suspension Components are intended for single use. The RECELL GO Cartridge and RECELL GO Suspension Components are not reusable and should be discarded after use. Reuse may lead to infection or disease transmission.
- Follow local regulations for proper disposal.
- Contaminated materials and waste must be disposed of using appropriate biohazard receptacles.
- The RECELL GO Processing Device shall be disposed of as per the electrical and electronic equipment disposal process established by the healthcare facility in order to avoid harm to the environment.

A13 REUSABLE PROCESSING DEVICE

It is highly recommended to clean the RECELL GO Processing Device after retrieving from storage and in between uses as part of regular maintenance. Refer to Section C8 for cleaning instructions.

B CLINICAL DATA SUMMARY

Two prospective randomized clinical studies were conducted to evaluate the safety and effectiveness of the RECELL Device in the treatment of acute thermal burn wounds in a total of 131 subjects. One prospective randomized clinical study was conducted to evaluate the safety and effectiveness of the RECELL Device in the treatment of acute non-thermal full-thickness skin defects in a total of 65 subjects. Further, retrospective analyses were conducted on data from 39 pediatric patients with acute full-thickness thermal burn wounds, who received the RECELL Device in Expanded Access and in Continued Access Protocols, 49 patients with >50% TBSA acute full-thickness thermal burn wounds, who received the RECELL Device in Expanded Access Protocols, and 61 patients with acute full-thickness wounds over a joint (including hands) treated in Expanded Access.

B1 RECELL Combined with Meshed Skin Graft for Treatment of Acute Burn Injuries (Full- thickness and Mixed-Depth Burns)

Demonstration of the Safety and Effectiveness of RECELL Combined with Meshed Skin Graft for Reduction of Donor Area in the Treatment of Acute Burn Injuries (Mixed-Depth Burns)

Study Design

In this randomized, multi-center, standard of care-controlled study, RECELL was used in combination with widely meshed autografts, allowing for the treatment of deep, extensive burn wounds. The study population included 30 subjects from 6 clinical sites. Subjects were eligible for enrollment if they were ≥ 5 years of age with 5-50% TBSA burn wounds requiring autografts for closure. Each subject served as their own control, using two comparable contiguous or non-contiguous areas of at least 300 cm^2 in size. The recipient sites were randomly assigned to receive autografting consistent with the investigator's pre- specified graft plan (Control) or application of Spray-On Skin Cells over an autograft meshed more widely (i.e., one ratio higher) than identified in the pre-specified graft plan. Acute healing and pain outcomes were evaluated through 12 weeks. Pain, healing, durability, and scar outcomes were evaluated in the longer-term follow-up visits conducted at 24, 36, and 52 weeks.

Endpoints. The co-primary endpoints were: 1) Non-inferiority of the incidence of complete wound closure for RECELL-treated burn wounds (treated with the combination of Spray-On Skin Cells and widely meshed autografts) compared to that observed in Control-treated burn wounds (conventional autograft) by 8 weeks after treatment, as assessed by a blinded evaluator. The pre-specified non-inferiority margin (Control minus RECELL) was 10%.

Complete wound closure was defined as complete skin re-epithelialization without drainage, confirmed at 2 consecutive study visits at least 2 weeks apart; and 2) Superiority in relative reduction in donor area requirements for RECELL versus Control treatment, as assessed by the Geometric Mean Ratio (GMR) of the RECELL: Control autograft expansion ratios. Safety assessment included evaluation of healing time based on the investigator's assessment, infection, allergic response to trypsin, wound durability, scarring outcomes, and device-related adverse events and serious adverse events.

Results

Demographics. Thirty subjects were enrolled in the study, and their wound sites were randomized to the control or treatment group. The majority of subjects were male (25/30, 83.3%); 66.7% were Caucasian (20/30). The mean age was 39.1 years (range 9-68 years). Nine subjects had risk factors (including smoking, drug and alcohol abuse, and inadequate nutrition) for impaired wound healing. All of the wounds were from acute thermal burn wounds, and the majority of the burn wounds were the result of fire or flames (22/30, 73.3%). The mean percent TBSA affected by burn wounds was 21.2% (±12.8%).

Effectiveness. Non-inferiority of RECELL relative to Control for recipient site healing was established using the pre-specified non-inferiority margin of 10%. Confirmed treatment area closure by Week 8 was 92.3% for RECELL vs. 84.6% for the Control treatment areas. The treatment difference (Control minus RECELL) was -7.7% (1-sided 97.5% CI upper bound of 6.40%). The progression of healing was similar between treatments, with both RECELL and Control treatments achieving 100% re-epithelialization for approximately 50% and 80% of treatment areas at Week 4 and Week 6, respectively.

Superiority of RECELL was established with respect to relative reduction in donor site harvesting ($p<0.001$). Treatment with RECELL required, on average, use of 32% less donor skin, compared to that required for autografting. Secondary effectiveness outcomes (patient satisfaction, Week 24 observer overall opinion on the Patient and Observer Scar Assessment Scale (POSAS), and Week 24 patient overall opinion on POSAS) were comparable between treatments. These outcomes were also comparable between treatments at Week 52.

Safety – Adverse Events. No unanticipated adverse device effects or device-related events were reported. The number of subjects with any treatment-emergent adverse event (TEAE) at the RECELL treatment site was the same as the number of subjects with any TEAE at the Control treatment area (17/30, 56.7%). Similar numbers of TEAEs were reported in areas that were not involved in the study treatments (63.3%). Most subjects experienced TEAEs that were mild (26.7%) or moderate (36.7%). The incidence of TEAEs (impaired healing, pain, graft loss, skin abrasion, and skin graft failure) was comparable between RECELL and Control treatment sites. The most common TEAE at both the RECELL and Control treatment areas was pruritus, experienced by 7 (23.3%) subjects. One or more severe TEAEs were experienced by 7 (23.3%) subjects; however, no TEAE was related to the RECELL Device.

Twelve subjects had serious adverse events (SAEs). There was no difference in the incidence and types of SAEs at the RECELL and Control treatment areas.

Table 1. Summary of Recipient and Donor Site TEAEs by System Organ Class and Preferred Term

Primary System Organ Class/Preferred Term N=30	RECELL n (%)	Control n (%)	Donor Site n (%)	Non-Study Area n (%)
Any Primary System Organ Class	17 (57%)	17 (57%)	5 (17%)	19 (63%)
General disorders and administration site conditions				
Disease Susceptibility	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Impaired Healing	1 (3%)	3 (10%)	0 (0%)	1 (3%)
Pain	2 (7%)	1 (3%)	0 (0%)	1 (3%)
Secretion Discharge	0 (0%)	1 (3%)	0 (0%)	0 (0%)
Infections and Infestations				
Cellulitis	0 (0%)	0 (0%)	0 (0%)	3 (10%)
Purulent Discharge	0 (0%)	0 (0%)	1 (3%)	0 (0%)
Skin Graft Infection	0 (0%)	2 (7%)	0 (0%)	0 (0%)
Injury, poisoning, and procedural complications				
Graft delamination	1 (3%)	0 (0%)	0 (0%)	0 (0%)
Graft loss	3 (10%)	3 (10%)	0 (0%)	4 (13%)
Scratch	1 (3%)	0 (0%)	0 (0%)	1 (3%)
Skin abrasion	1 (3%)	1 (3%)	0 (0%)	1 (3%)
Skin graft failure	1 (3%)	2 (7%)	0 (0%)	1 (3%)
Wound	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Musculoskeletal and connective tissue disorders				
Arthralgia	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Extra skeletal ossification	0 (0%)	1 (3%)	0 (0%)	1 (3%)
Extremity contracture	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Joint range of motion decreased	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Muscle contracture	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Pain in extremity	1 (3%)	0 (0%)	0 (0%)	2 (6%)
Nervous system disorders				
Burning sensation	1 (3%)	1 (3%)	0 (0%)	1 (3%)
Neuralgia	1 (3%)	1 (3%)	0 (0%)	1 (3%)
Skin and subcutaneous tissue disorders				
Blister	0 (0%)	0 (0%)	1 (3%)	1 (3%)
Dermatitis	1 (3%)	1 (3%)	0 (0%)	1 (3%)
Dermatitis, contact	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Diabetic dermopathy	1 (3%)	1 (3%)	0 (0%)	0 (0%)
Pruritus	7 (23%)	7 (23%)	3 (10%)	5 (16%)
Rash	1 (3%)	1 (3%)	0 (0%)	1 (3%)
Surgical and medical procedure				
Scar excision	1 (3%)	1 (3%)	0 (0%)	1 (3%)

Safety – Additional Endpoints. Pre-specified safety events – including delayed healing, scar necessitating surgical intervention, allergic response to trypsin, wound durability issue, infection, and pain – were evaluated during the study. There was no difference in the incidence of delayed healing and scar revision surgery at RECELL compared to Control treatment areas. No patient had either an allergic response to trypsin or an issue related to durability of wound healing. Infection was not observed at the RECELL treatment areas but was observed at two Control treatment sites; however, the numbers were too small to draw conclusions regarding incidence of infection at wound-treatment sites. There was no clinically meaningful difference in the degree of pain associated with the two treatments.

Retrospective Reviews of Data from Expanded Access & Continued Access Protocols for RECELL Combined with Meshed Skin Graft for the Treatment of Full-thickness Burns.

(1) In Patients ≥18 Years of Age with>50% TBSA Acute Thermal Injury and
(2) In Patients <18 Years of Age

Study Design
Two retrospective reviews were conducted to evaluate the safety and effectiveness of RECELL with meshed autograft for the treatment of full-thickness burns, utilizing data collected in patients who received RECELL combined with meshed autograft in Expanded Access and Continued Access protocols (RECELL Cohort). The RECELL Cohort data were compared with data from patients in the American Burn Association's National Burn Repository (NBR Control), who received standard of care (conventional autograft). Week 8 wound healing data (not available in the NBR) were reported for the RECELL Cohort. RECELL Cohort adverse events were compared with the adverse events in the randomized controlled trial (RCT Control). Propensity score (PS) stratification was used to reduce bias attributable to potential differences in key covariates such as age, gender, %TBSA and Baux Score, between RECELL and NBR Control datasets.

Endpoints. The primary endpoint was the number of autograft treatments required to achieve definitive closure per patient, comparing the RECELL Cohort to the NBR Control. Difference in length of hospital stay (LOS) between the RECELL Cohort and NBR Control was a secondary endpoint. LOS was measured as:

$$\textit{Days per \%TBSA} = \frac{\textit{Number of inpatients hospital days}}{\textit{Burn injury size (\%total body surface area)}}$$

Safety assessments included mortality in RECELL Cohort compared with NBR Control, specified adverse events (infections, skin graft failure, graft loss and/or impaired healing, compared to the RCT Control), and wound durability (no comparison).

Results

(1) In Patients ≥18 Years of Age with >50% TBSA Acute Full-thickness Thermal Injury:

Demographics and baseline characteristics. Data from 49 patients with 342 mixed-depth acute thermal burn wounds treated with RECELL combined with meshed autograft were included within the RECELL Cohort. Data from 277 patients were included in the NBR Control, and 28 patients were included in the RCT Control. The RECELL Cohort and NBR Control had comparable baseline characteristics regarding age, gender, %TBSA and Baux scores. Percent TBSA and Baux scores were greater for the RECELL Cohort compared with the RCT Control (Table 2).

Table 2. Demographic and Baseline Characteristics

	RECELL Cohort N=49	RCT Control N=28	NBR Control N=277
Age			
Mean ± SD	37.9 ± 11.9	41.1 ± 14.3	39.6 ± 13.0
Range (Min, Max)	(20.9, 64.1)	(18.0, 68.0)	(18.0, 74.9)
Sex			
Female	26.5% (13/49)	17.9% (5/28)	24.2% (67/277)
Male	73.5% (36/49)	82.1% (23/28)	75.8% (210/277)
Race/Ethnicity [1]			
White	77.6% (38/49)	67.9% (19/28)	N/A
Black or African American	8.2% (4/49)	21.4% (6/28)	N/A
Asian	0% (0/49)	3.6% (1/28)	N/A
Hispanic	10.2% (5/49)	N/A	N/A
Not Hispanic or Latino	2.0% (1/49)	N/A	N/A
Other	2.0% (1/49)	7.1% (2/28)	N/A
Cause of Burn Injury			
Fire/flames	93.9% (46/49)	75.0% (21/28)	N/A
Hot water/steam	0% (0/49)	10.7% (3/28)	N/A
Other	6.1% (3/49)	14.3% (4/28)	N/A
Total Estimated Injury Size (% TBSA)			
Mean ± SD (N) [2]	65.6 ± 11.2 (49)	20.3 ± 12.5 (28)	61.9 ± 10.1 (277)
Range (Min, Max)	(51.0, 91.0)	(5.0, 46.0)	(50.0, 96.0)
Baux Score [2]			
Mean ± SD (N)	110.1 ± 19.8 (49)	62.0 ± 19.5 (28)	107.6 ± 17.4 (277)
Range (Min, Max)	(80.9, 161.8)	(24.0, 95.0)	(70.2, 170.0)

[1] Race/ethnicity were collected as a combined variable for CTP004. Data being presented as collected.

[2] Percent TBSA and Baux scores were significantly greater (p=<0.0001) for the RECELL Cohort compared with the RCT Control.

Effectiveness. Median number of autograft treatments required for definitive closure in the RECELL Cohort (2.0 treatments, range 1.0-6.0) was lower than in the NBR Control (5.0 treatments, range 1.0-32.0).

Mean number of autograft treatments required for definitive closure in the RECELL Cohort was 2.4 treatments (SD 1.3) and in the NBR Control was 5.9 treatments (SD 4.6).

Median Length of Hospital Stay was 1.2 days per %TBSA (range 0.6-3.0) in the RECELL Cohort and 1.2 (range 0.5-6.3) within the NBR Control Cohort (p= 0.60). By Week 8 after treatment, 90.6% of the wounds treated in the RECELL Cohort achieved ≥95% re-epithelialization.

Safety. There were no unanticipated adverse device effects or adverse events attributed to RECELL use. Mortality rates were similar between the RECELL Cohort (18.4%) and the NBR Control (20.2%). The incidence of infection and graft failures was greater in the RECELL Cohort compared to the RCT Control, which was anticipated due to greater burn size in the RECELL Cohort. Beyond Week 8, there was no occurrence of spontaneous breakdown of the treated areas in either the RECELL Cohort or RCT Control. Table 3 summarizes the key safety events in patients ≥18 years of age with>50% TBSA acute thermal burn wounds in the RECELL Cohort and RCT Control.

Table 3. Key Safety Events in RECELL Cohort and RCT Control in Patients ≥18 Years of Age with>50% TBSA Acute Thermal Injury

Key safety Event	RECELL Cohort N= 49 Number of (%) Subjects with Event	RCT Control N=28 Number of (%) Subjects with Event
Graft Infection	7 (14.3%)	1 (3.6%)
Graft Failure	4 (8.2%)	1 (3.6%)
Graft Loss/Impaired Healing	9 (18.4%)	5 (17.9%)

(2) In Patients <18 Years of Age with Acute Full-thickness Thermal Injury:

Demographics and Baseline Characteristics. In the RECELL Cohort, 39 pediatric patients (mean age of 7.1 years) with 175 acute thermal burn wounds were treated with RECELL in combination with meshed autografts. In the NBR Control, 245 pediatric patients (mean age of 8.7 years) were treated with conventional autografts. Mean total estimated injury size (%TBSA) was greater in the pediatric RECELL Cohort (40.1%) compared with the NBR Control (28.1%). Other demographics including age, sex, and Baux scores were comparable between the two groups.

Table 4. Demographic and Baseline Characteristics

	RECELL Cohort N=39	NBR Control N=245
Age (years)		
Mean ± SD	7.1 ± 4.9	8.7 ± 5.0
Range (Min, Max)	(0.8, 17.0)	(0.2, 16.0)
Sex		
Female	53.8% (21/39)	26.9% (66/245)
Male	46.2% (18/39)	73.1% (179/245)
Race/Ethnicity [1]		
White	59.0% (23/39)	N/A
Black or African American	30.8% (12/39)	N/A
Asian	2.6% (1/39)	N/A
Hispanic	2.6% (1/39)	N/A
Not Hispanic or Latino	2.6% (1/39)	N/A
Other	59.0% (23/39)	N/A
Cause of Burn Injury		
Fire/flames	66.7% (26/39)	N/A
Hot water/steam	20.5% (8/39)	N/A
Other	12.8% (5/39)	N/A
Total Estimated Injury Size (% TBSA)		
Mean ± SD (N) [2]	40.1 ± 19.2 (39)	28.1 ± 15.5 (245)
Range (Min, Max)	(8.0, 90.0)	(8.5, 82.2)
Baux Score [2]		
Mean ± SD (N)	50.3 ± 24.4 (39)	39.3 ± 17.0 (245)
Range (Min, Max)	(16.0, 115.3)	(22.5, 95.2)

[1] Race/ethnicity were collected as a combined variable for CTP004. Data being presented as collected.

[2] Percent TBSA and Baux scores were significantly greater (p=<0.0001) for the RECELL Cohort compared with the NBR Control.

Effectiveness. Median number of autograft treatments required for definitive closure in the pediatric RECELL Cohort (1.0 treatment, range 1.0-5.0) was lower than in the NBR Control (2.0 treatments, range 1.0-20.0). Mean number of autograft treatments required for definitive closure was 1.6 treatments (SD 1.1) in the RECELL Cohort and was 3.6 treatments (SD 3.7) in the NBR Control.

Median Length of Hospital Stay was 1.7 days per %TBSA (range 0.6-3.3) in the RECELL Cohort and 1.2 (range 0.5-3.9) in the NBR Control. By Week 8 after treatment, 91.8% of wounds treated in the RECELL Cohort achieved ≥95% re-epithelialization.

Safety. No unanticipated adverse device effects or adverse events attributed to the use of RECELL were reported. Mortality rates were comparable between the RECELL Cohort (0%) and the NBR Control (0.4%). The incidence of treatment-related adverse events (graft infection, graft failure and graft loss/impaired healing) was greater in the pediatric RECELL Cohort compared with the adult RCT Control. This was anticipated due to greater burn size and increased number of treatment areas in the pediatric RECELL Cohort, providing a greater opportunity for treatment-area complications. The proportion of patients experiencing at least one key safety event was similar between two groups; i.e., 17.9% in the pediatric RECELL Cohort and 20.0% for the RCT Control. Table 5 summarizes the key safety events in subjects aged <18 years in the RECELL Cohort and RCT Control.

Table 5. Key Safety Events in Pediatric RECELL Cohort <18 Years of Age and RCT Control with Acute Full-thickness Thermal Injury

Key safety Event	RECELL Cohort (N= 39) Number of (%) Subjects with Event	RCT Control (N=30) Number of (%) Subjects with Event
Graft Infection	5 (12.8%)	2 (6.7%)
Graft Failure	3 (7.6%)	2 (6.7%)
Graft Loss/ Impaired Healing	6 (15.4%)	3 (10%)
Experienced at least 1 key safety event	7 (17.9%)	6 (20.0%)

Retrospective Review of Data from Expanded Access Protocol for RECELL Combined with Meshed Skin Graft for the Treatment of Full-thickness Burns on Joints (Including Hands)

A retrospective review and analysis of the available data from an expanded access protocol (CTP004) was conducted to evaluate the application of RECELL with meshed autograft for the treatment of full-thickness burns over joints and hands. The analysis included 61 patients who had 443 RECELL-treated areas (237 contained a joint including hands and 206 did not involve a joint or hand) with Week 8 wound closure. There were no appreciable differences with respect to safety or wound closure with the use of RECELL combined with meshed autograft for the treatment of wounds between areas involving joints (including hands) and the areas not involving joints (including hands).

B2 RECELL for Treatment of Acute Burn Injuries (Deep Partial-Thickness Burns)

A Comparative Study of RECELL Device and Autologous Split-thickness Meshed Skin Graft in the Treatment of Acute Burn Injuries (Deep Partial-Thickness Burns)

Study Design

The RECELL Device was studied as a primary intervention in the treatment of acute burn wounds in a randomized, multi-center, standard of care controlled (meshed split-thickness skin graft) study. The study population included consenting patients who were between the ages of 18 and 65 with 1-20%

TBSA thermal burn wounds. Each subject served as their own control, using two comparable contiguous or non-contiguous areas of deep partial- thickness thermal burns. One site was treated with RECELL (with Spray-On Skin Cells applied directly to the wound), and the other was treated with 2:1 meshed autograft. Subjects were evaluated at 1, 2, 3, 4, 8, 16, 24, and 52 weeks.

Endpoints. The co-primary effectiveness endpoints were: 1) Non-inferiority of the incidence of RECELL-treated recipient site (burn injury) wound closure (≥95% re-epithelialization) at 4 weeks compared to that observed in Control-treated recipient sites. The pre-specified non- inferiority margin (RECELL minus Control) was -10%; and 2) Superiority of donor site healing (100% re-epithelialization) at 1 week for RECELL versus Control. For both endpoints, healing was confirmed at two consecutive visits. Safety assessments included evaluation of delayed healing, infection, allergic response to trypsin, wound durability, scarring outcomes, device-related adverse events, and serious adverse events.

Results

Demographics and baseline characteristics. 101 subjects were enrolled in the study at 12 US Burn Centers. The mean age of the subjects was 39.5 (range: 18.2-63.5) with the majority being male (85/101, 84.2%) and Caucasian (59/101, 58.4%). Most of the burn wounds were the result of fire or flames (78/101, 77.2%). Mean percent TBSA affected by burn wounds was 10% (± 4.53%) with similarly sized recipient site areas for RECELL and Control (168.2 ± 68.0 cm^2 vs. 165.0 cm^2 ± 66.5 cm^2, respectively). On average, surgical intervention for definitive closure occurred 7 days following the burn injury, demonstrating that these partial-thickness burns failed to heal with conservative measures and confirming that autografting was indicated.

Effectiveness. At Week 4, using a Modified Per Protocol (MPP) population designed to exclude four subjects managed post-operatively with silver sulfadiazine, the incidence of complete wound healing was 97.6% in the RECELL-treated sites and 100% in the Control autografting sites. The difference in the incidence of complete wound healing (RECELL minus Control) was -2.4% (95% CI: -8.4 to 2.3%), establishing non-inferiority (by excluding the pre-specified NI margin of -10%) for RECELL compared to Control sites treated with meshed autograft.

Donor site healing was superior at Week 1 (the co-primary endpoint) for the RECELL donor sites versus the Control donor sites (21.8% vs. 10.0%, respectively p=0.0042).

At Week 4, mean percent re-epithelialization of the recipient site was 97.7 ± 12.0% and 100.0 ± 0.07%, for the RECELL and Control recipient sites, respectively. Subjects reported less pain at the RECELL donor site compared to the Control donor site within the 8 weeks following treatment.

Similarly, subjects expressed greater satisfaction with the visual appearance of the RECELL donor site compared with the Control donor site at all longer-term follow-up visits. The mean size of donor sites for burn wounds randomized to RECELL treatment was substantially less than that of the Control: 4.7 ± 3.19 cm^2 vs 194.1 ± 158.5 cm^2, representing a 97.5% reduction in donor skin requirements.

Safety – Adverse Events. Of the 101 subjects, 58.4% experienced an adverse event, with 35.6% having an adverse event at the RECELL sites and 22.8% at the Control sites. Overall, adverse experiences reported for RECELL-treated sites were typical for the type of injury sustained by subjects with burn wounds requiring skin grafting procedures. A numerically greater number of subjects had adverse events at the RECELL sites when compared with the Control sites; however, most of these events were

mild in nature, were not considered device-related, and were not serious. Additionally, the greater incidence of adverse events noted at RECELL recipient sites is primarily attributed to events contributing to primary endpoint failures, re-injury at the recipient site, and other primarily self-limited skin and subcutaneous tissue disorders such as blisters and excessive granulation tissue. There were no meaningful differences in the incidence of adverse events at the RECELL vs Control donor sites (4.0% vs. 6.9%, respectively). The observed systemic AEs are consistent with a study population undergoing grafting. In ancillary burn injury areas not included in the randomized treatment areas, 27.7% of subjects experienced AEs that were similar to those that occurred at the treatment sites; these AEs included hypertrophy, hypertrophic scarring, and additional injury (i.e., laceration, skin wound, and skin injury).

Safety – Additional Endpoints. There was no difference in the incidence of graft loss, and graft and donor site infections between the RECELL and Control treatments. Recipient site scarring was measured by mean total Vancouver Scar Scale (VSS) scores with comparable scores for RECELL and Control. The RECELL donor sites had improved appearance at all time points based on the VSS total score outcomes when compared with the Control. Long-term durable wound healing was achieved for both the RECELL-treated and control wounds, as no events of late wound breakdown were reported.

Table 6. Summary of Recipient and Donor Site AEs by System Organ Class and Preferred Term

Primary System Organ Class/Preferred Term N=101	**Recipient Site RECELL n (%)**	**Recipient Site Control n (%)**	**Donor Site RECELL n (%)**	**Donor Site Control n (%)**	**Non-Study Area n (%)**
Any Primary System Organ Class	**36 (**36%)	**22 (**22%)	**4 (**4%)	**7 (**7%)	**28 (**28%)
General disorders and administration site conditions					
Total	8 (8%)	5 (5%)	0 (0%)	0 (0%)	5 (5%)
Edema	1 (1%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)
Hypertrophy	6 (6%)	3 (3%)	0 (0%)	0 (0%)	5 (5%)
Pain	2 (2%)	2(2%)	0 (0%)	0 (0%)	0 (0%)
Infections and Infestations					
Cellulitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)
Folliculitis	0 (0%)	2 (2%)	0 (0%)	0 (0%)	0 (0%)
Infection	2 (2%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)
Rash, pustular	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Suspected wound infection	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Injury, poisoning, and procedural complications					
Laceration	2 (2%)	1 (1%)	0 (0%)	0 (0%)	3 (3%)
Scar	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Seroma	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Skin graft contracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Skin graft failure	4[a] (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Skin injury	1 (1%)	0 (0%)	0 (0%)	1 (1%)	1 (1%)
Skin scar contracture	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Skin wound	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Thermal burn	1 (1%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)
Wound decomposition	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Nervous system disorders					
Neuralgia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Neuropathy, peripheral	1 (1%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)
Paresthesia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Skin and subcutaneous tissue disorders					
Blister	5 (5%)	0 (0%)	0 (0%)	1 (1%)	1 (1%)
Dermal cyst	0 (0%)	1 (1%)	0 (0%)	0 (0%)	3 (3%)
Dermatitis, contact	1 (1%)	1 (1%)	0 (0%)	1 (1%)	0 (0%)
Erythema	1 (1%)	1 (1%)	0 (0%)	0 (0%)	2 (2%)
Excessive granulation tissue	7 (7%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)
Hypertrophic scar	10[b] (10%)	6 (6%)	0 (0%)	0 (0%)	8 (8%)
Pruritus	5 (5%)	5 (5%)	2 (2%)	2 (2%)	4 (4%)
Rash	3 (3%)	1 (1%)	1 (1%)	1 (1%)	0 (0%)

[a]2 events of graft loss were classified as device-related

[b]3 events of hypertrophic scar were classified as device-related although for 2 of the 3 events, hypertrophic scarring was also noted at the Control Sites.

B3 RECELL for Non-thermal Full Thickness Skin Defects

A Prospective Multicenter Randomized Controlled Clinical Study to Investigate the Safety and Effectiveness of the RECELL System Combined with Meshed Autograft for Wound Closure and Reduction of Donor Skin Requirements.

Study Design

The efficacy and safety of the Spray-On Skin Cells prepared using the RECELL Device were evaluated in a prospective, multicenter, intra-subject randomized and controlled, evaluator blinded study. Two comparable wounds in each subject were selected and randomized at 1:1 ratio to receive either the prespecified meshed autografting (i.e., 2:1 meshed ratio) alone in control-treated area or more widely meshed autografting (i.e., 3:1 meshed ratio) plus RECELL in RECELL-treated area.

Endpoints. The co-primary effectiveness endpoints were: 1) Non-inferiority of the proportion of complete wound closure for RECELL-treated areas (treated with the combination of RECELL and more widely meshed autografts) compared to that observed in Control-treated areas (prespecified conventional autograft) by Week 8 after treatment, as assessed by a blinded evaluator in per protocol (PP) population. The pre-specified non-inferiority margin (Control minus RECELL) was 10%. Complete wound closure was defined as complete skin re-epithelialization without drainage, confirmed at 2 consecutive study visits at least 2 weeks apart; and 2) Superiority in relative reduction in donor area requirements for RECELL versus Control treatment, as assessed by the ratio of actual expansion ratios (RECELL to Control) of the treatment area (size) to the required donor skin area (e.g., RECELL treatment area/corresponding donor area to Control treatment area/corresponding donor area) in the intent-to-treat (ITT) population. Safety assessment included reporting treatment emergent adverse events (TEAEs).

Results

Demographics. Sixty-five patients with a mean age of 45.7 years (range 15-85 years) from 18 clinical sites were enrolled in the study. Majority of subjects were male (44/65, 67.7%). Seventy one percent of subjects were White, 22% were African American and the remainder were American Indian or Alaska Native or other. The types of wounds included acute and chronic wounds of necrotizing (35.4%) and other (9.2%) infections, open (16.9%) and closed (6.2%) degloving injuries, fasciotomy/compartment Syndrome (7.7%), surgical (7.7%), crush injury (4.6%), traumatic hematoma (3.1%), flap donor (3.1%), road rash (3.1%), gunshot wound (1.5%) and laceration wound (1.5%). The median size of RECELL-treated and the control-treated areas are 160 cm^2 (ranged 80 to 1155 cm^2) and 156 cm^2 (ranged 80 to 1155 cm^2), respectively, and the wounds are located at arms, legs, back, buttocks, and anterior-torso. The mean affected area was 5.0% (±3.9%) of total body surface area (TBSA).

Effectiveness. Non-inferiority of RECELL-treated areas compared to Control-treated areas in promoting wound closure was established based on the pre-specified non-inferiority margin of 10%. Among the 52 subjects in PP population, 34 (65%) subjects in RECELL group achieved complete wound closure by Week 8. Thirty (58%) subjects in control group achieved complete wound closure by Week 8. The treatment difference (Control minus RECELL) was -7%, with a one-sided 97.5% CI upper bound of 6.2%.

Superiority of RECELL compared to control was established on reduction in donor area requirement for harvesting ($p<0.001$), in ITT population. Treatment with RECELL required, on average, 27% less donor skin, compared to that required for autografting.

Safety – Adverse Events. The safety population includes the ITT population that consists of all 65 subjects who were randomized and received treatment. Each subject received one time treatment of the prespecified meshed autografting (i.e., 2:1 meshed ratio) in control-treated area and a more widely meshed autografting (i.e., 3:1 meshed ratio) plus RECELL in RECELL-treated area. The adverse reactions observed on RECELL, control, RECELL-treated donor site and non-RECELL treated donor site are summarized in Table 7.

Table 7. Summary of Subjects with Event by Location, System Organ Class, and Preferred Term

Primary System Organ Class/Preferred Term	**RECELL n (%) N=65**	**Control n (%) N=65**	**RECELL-treated Donor Site n (%) N=43**	**Non RECELL-treated Donor Site n (%) N=29**
Any Primary System Organ Class	36 (55%)	37 (57%)	9 (21%)	9 (31%)
General disorders and administration site conditions				
Impaired Healing	14 (22%)	16 (25%)	1 (2%)	4 (14%)
Oedema	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Pain	0 (0%)	0 (0%)	2 (5%)	0 (0%)
Infections and Infestations				
Local Soft Tissue Infection	6 (9%)	5 (8%)	1 (2%)	2 (7%)
Other Infection	2 (3%)	2 (3%)	0 (0%)	0 (0%)
Injury, poisoning, and procedural complications				
Fall	1 (2%)	1 (2%)	0 (0%)	0 (0%)
Graft Loss	7 (11%)	9 (14%)	0 (0%)	0 (0%)
Skin Graft Failure	1 (2%)	2 (3%)	0 (0%)	0 (0%)
Skin Graft Scar Contracture	0 (0%)	1 (2%)	0 (0%)	0 (0%)
Skin Laceration	0 (0%)	0 (0%)	0 (0%)	2 (7%)
Soft Tissue Foreign Body	1 (2%)	1 (2%)	0 (0%)	0 (0%)
Suture Related Complication	1 (2%)	0 (0%)	0 (0%)	0 (0%)
Wound Decomposition	4 (6%)	6 (9%)	2 (5%)	0 (0%)
Wound Necrosis	0 (0%)	1 (2%)	0 (0%)	0 (0%)
Wound Secretion	1 (2%)	1 (2%)	0 (0%)	0 (0%)
Product Issues[a]				
Device Malfunction	1 (2%)	1 (2%)	0 (0%)	0 (0%)
Skin and subcutaneous tissue disorders				
Blister	1 (2%)	1 (2%)	0 (0%)	0 (0%)
Blister Rupture	0 (0%)	0 (0%)	1 (2%)	0 (0%)
Excessive Granulation Tissue	12 (19%)	8 (12%)	0 (0%)	2 (7%)
Pruritus	3 (5%)	3 (5%)	3 (7%)	0 (0%)
Rash	2 (3%)	1 (2%)	1 (2%)	1 (3%)
Skin Exfoliation	5 (8%)	4 (6%)	2 (5%)	4 (14%)

[a] Site-reported term is wound vac malfunction.

C TREATMENT

C1 WOUND BED PREPARATION

Clean, vascularized wound bed – To optimize the treatment, the cell suspension should only be applied to a clean, vascularized wound bed with no remaining necrotic tissue. This can be achieved with either dermabrasion using a rotating diamond-head burr, laser ablation, sharp dissection, or other alternative techniques, depending on the nature of the wound.

Infection free – The cell suspension must not be used in the presence of any contamination or infection, as initial re-epithelialization and long-term viability are highly dependent on the absence of infection. Prophylactic antibiotics may be prescribed if the patient is at risk of contamination or infection. Wound swabs for up to-date microbiology are recommended 48 hours prior to the planned surgery.

Pinpoint bleeding – The wound bed should be prepared so that pinpoint bleeding is observed. Accurate debridement to the level of viable tissue is essential; all necrotic tissue must be removed.

When RECELL GO is used for treatment of acute thermal burn wounds, RECELL Spray-On Skin Cells can be directly applied to partial-thickness wounds or applied in combination with meshed autografts for full-thickness wounds.

C2 REQUIREMENTS

The following materials and instruments will be needed during the procedure:

- Clean work area
- Procedure table
- Personal Protective Equipment
- Skin preparation solution
- Local anesthetic with adrenaline where not contraindicated
- Wound bed preparation tool of choice
- Skin harvesting instrument, e.g., dermatome
- Sterile drape
- Sterile gloves
- Sterile gauze
- Sterile saline
- Sterile blunt forceps
- Sterile ruler, marker
- Appropriate wound dressings - see “Aftercare” section for details.

C3 RECELL GO DEVICE SET-UP

Perform the following set-up steps in the order shown to avoid setup errors. A procedure guide describing the set-up process is included with the System for reference during a procedure.

Note: Follow software prompts to load RECELL GO Cartridge with the appropriate components.

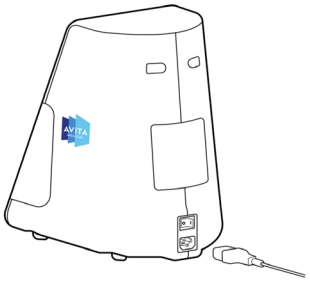
C3A REUSABLE PROCESSING DEVICE

The RECELL GO Processing Device may be used for (up to) 200 uses with separate single-use RECELL GO Cartridges. The device screen will indicate the number of RECELL GO preparations. Once the count reaches 180 of 200, the RECELL GO Processing Device is within 10% of reaching its limit. It is recommended that you contact your AVITA Medical representative to discuss the appropriate time to replace your RECELL GO Processing Device in order to ensure uninterrupted patient care. It is important to remember that your RECELL GO Processing Device will not prepare any RECELL GO Cartridges beyond the 200-use limit. Once 200 uses have been reached, the RECELL GO Processing Device **MUST** be replaced to maintain effective cell harvesting.

MAXIMUM REACHED! Contact AVITA Medical Customer Service for a New RECELL Processing Device

FIRST TIME USE: Remove the RECELL GO Processing Device from the packaging along with the power cable.

Ensure the RECELL GO Processing Device is placed into a clean and flat area and plugged in to a power socket.



CAUTION: The device is intended for use only in a healthcare professional environment complying to electromagnetic limits for medical devices contained in IEC 60601-1-2.

Switch the device ON at the back. Upon a successful test, the screen will now display:

Total RECELL Cartridges Used XX of 200

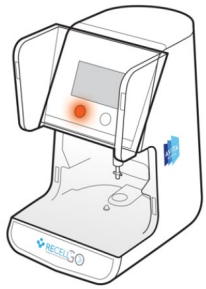
The system will then ready itself. Please wait and don't interact with the system at this time.

Preparing RECELL Processing Device
Please Wait

The screen will now display:

PLEASE CLEAN

To clean the RECELL GO Processing Device, select the flashing orange CLEAN button.



The screen will now display:

WIPE CLEAN

The shaft will lower and the device is ready for cleaning.

Refer to Section C8 for cleaning instructions.

The screen will display:

Select DONE When Complete

Press the flashing green Done button after the cleaning is completed and the shaft will retract back up.

The screen will now display:

GO PREPARE
RECELL Cartridge With Enzyme, Buffer, and Skin for Processing

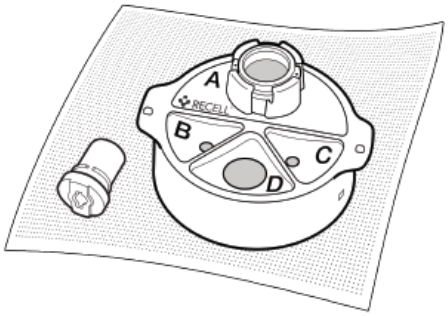
Move to the next step to start preparation of the sterile RECELL GO Cartridge.

C3B PREPARE SINGLE USE CARTRIDGE AND COMPONENTS

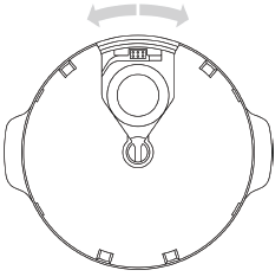
Open the RECELL GO Preparation Kit and place the Procedure Guide, RECELL GO Cartridge Tray, RECELL GO Suspension Components Tray and Telfa Clear in a clean area.

Remove the pouched RECELL Enzyme vial from the cardboard tray and aseptically open and transfer the RECELL Enzyme vial on a sterile draped procedure table. The outer shelf box may be discarded.

Remove the lid from the RECELL GO Cartridge Tray and aseptically transfer the RECELL GO Cartridge and Disaggregation Head onto a sterile draped procedure table.



Check the underside of the RECELL GO Cartridge to ensure proper alignment and the pins are centered.



Remove the lid of the RECELL GO Suspension Component Tray and aseptically transfer the two trays and the tray diagram onto a sterile draped procedure table. Remove the retainer lids from both trays and discard.

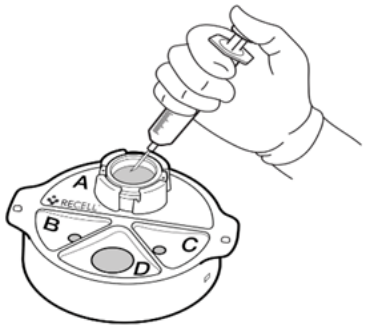
Prepare Well A.

Caution: Do not use sterile RECELL GO components beyond the stated expiration date indicated on the adhesive Lot # and Expiration Date labels on the outer shelf box.

From Suspension Components Tray Section A, use a 10 ml syringe and needle to add 10 ml of sterile water to the RECELL Enzyme.

Mix gently until dissolved (do not shake).

From Section A, use a clean 10 ml syringe and needle, draw up the reconstituted RECELL Enzyme into the 10 ml syringe and dispense entire volume of RECELL Enzyme into Well A of the Cartridge. Dispose of syringe and needle.



Remove the scalpel from the tray and place onto the sterile draped procedure table.

Prepare Wells B and C.

From Suspension Components Tray Section B, use the clean 10 ml syringe and needle to draw up all 10 ml of Buffer. Add to Well B of the RECELL GO Cartridge.

From Suspension Components Tray Section C, use the 10 ml syringe and needle to draw up the relevant volume of BUFFER from the 30 ml vial (Refer to Table 8) and add to Well C of the Cartridge. Discard the ABC Tray.

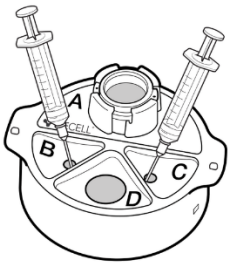
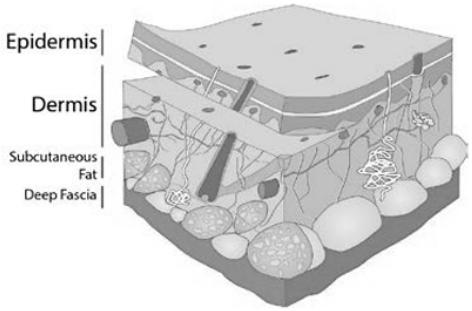


Table 8

Treatment Area	Skin Sample Size	Starting Volume of Buffer	Approximate Resultant Spray-On Skin Cells Volume
up to 320 cm^2	2 cm x 2 cm (4 cm^2)	4.5 ml	4 ml
up to 480 cm^2	3 cm x 2 cm (6 cm^2)	6.5 ml	6 ml
up to 960 cm^2	2 ea. 3 cm x 2 cm (12 cm^2)	12.5 ml	12 ml
up to 1440 cm^2	3 ea. 3 cm x 2 cm (18 cm^2)	18.5 ml	18 ml
up to 1920 cm^2	4 ea. 3 cm x 2 cm (24 cm^2)	24.5 ml	24 ml

C4 HARVEST SKIN



Skin Sample Type

It is essential that the skin sample harvested is a thin, split-thickness skin sample that leaves pinpoint bleeding at the donor site. The thickness of the skin sample will vary with the body site and patient age and should be in the range of 0.006 – 0.008 in (0.15 – 0.20 mm). The use of a dermatome, or similar device is recommended.

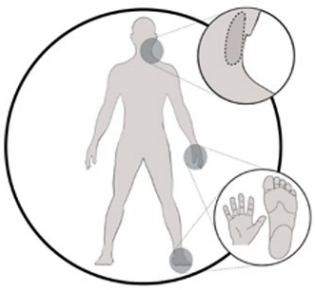
Size of Skin Sample

Choose the appropriate skin sample size for the application. Each square centimeter skin sample can create 1 ml of cell suspension for treatment of an area of up to 80 cm^2. Each 6 cm^2 (3 cm x 2 cm) skin sample can yield approximately 6 ml of cell suspension; each RECELL GO Device can process up to four 6 cm^2 skin samples for a maximum of 24 ml of cell suspension. This can be used to treat an area of approximately up to 1,920 cm^2.

Table 8 provides guidance for skin sample needed for several treatment area sizes.

Choice of Donor Site

It is essential the donor site is clean, of appropriate depth, and shows no evidence of surrounding inflammation or infection. Choose a donor site of glabrous tissue when creating suspension for glabrous tissue regeneration.



Using the preferred instrument such as a dermatome, take a split-thickness skin sample from the donor site of thickness 0.006 – 0.008 in (or 0.15 – 0.20 mm).

The skin sample may be trimmed from skin harvested for split-thickness skin grafting. Use Table 8 to estimate the skin sample size needed or calculate by taking 1/80 of the total treatment area.

Clean the donor site with antiseptic solution such as povidone-iodine or chlorhexidine. Allow the antiseptic to dry before removing with sterile saline (antiseptic solutions may be cytotoxic and as such, may affect cell viability if left on the skin sample site).

If desired, infiltrate the subcutaneous tissue with a tumescent solution of choice, to provide a firmer surface and anesthesia for taking the skin sample. Ensure that anesthetic is not injected intradermally.

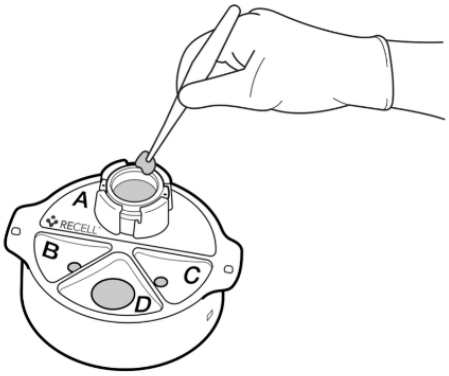
The donor site area may be lubricated (e.g., with sterile mineral oil) to ease travel of the dermatome.

Due to the thick keratin layer found on glabrous skin, it is necessary to take two shaves over the same site in these areas. Discard the first sample and process the second skin sample to create the cell suspension.

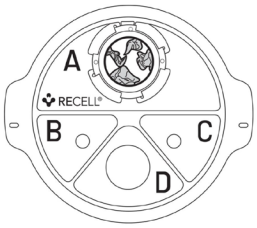
Use the scalpel to cut skin samples into pieces no larger than 3 cm x 2 cm prior to placing in the RECELL GO Cartridge. A maximum of 24 cm^2 can be placed in Well A. Keep the skin samples moist in sterile gauze moistened with sterile saline prior to use.

C5 ADD DONOR SKIN TO THE CARTRIDGE

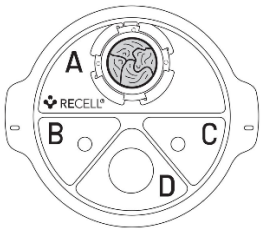
Place donor skin sample(s) into Well A.



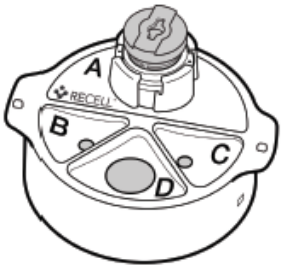
Place donor skin sample(s) separately from each other in Well A. It does not matter which side of the skin is placed up in Well A.



Use **blunt** forceps to spread out the skin along the base of Well A. Do not use pointed forceps so as to not pierce the filter in Well A.



Place the Disaggregation Head on top of the skin sample.
Gently push the Disaggregation Head down until it meets with resistance at the stopping point.

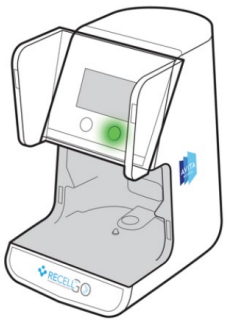


Once the RECELL GO Cartridge is prepared, press the flashing green CONTINUE button.

Next the RECELL GO Processing Device screen will display:

VERIFY
RECELL Cartridge Includes Enzyme, Buffer, Skin and Disaggregation Head

Once you have verified the contents of the RECELL GO Cartridge, press the flashing green CONTINUE button.



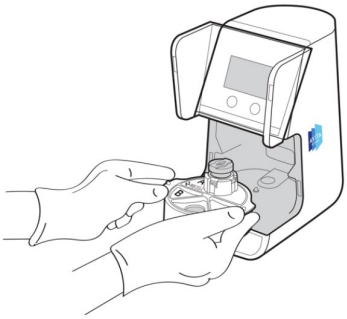
C6 PREPARE CELL SUSPENSION

The screen will now display:

INSERT
RECELL Cartridge and Press START

A non-sterile assistant should open the door of the RECELL GO Processing Device.

While maintaining aseptic technique, keep the RECELL GO Cartridge level and with Well A containing the Disaggregation Head at the back of the RECELL GO Cartridge, slide it into the RECELL GO Processing Device until the side tabs on the Cartridge meet the Device.



A non-sterile assistant should close the door and press the flashing green START button to start the skin processing sequence. The screen will display:

RECELL Spray-On Skin Cells Processing
XX Minutes Remaining

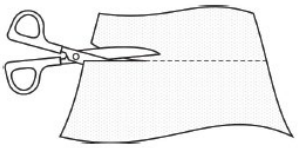
The buttons will cease flashing and screen will count down until the RECELL Spray-On Skin Cells are ready for collection.

This will take around 35 minutes. Do not open the door while the RECELL Spray-On Skin Cells are processing.

C7 DELIVER CELL SUSPENSION

Prepare the Dressings

Prior to applying the cell suspension, ensure the dressings are cut and prepared for immediate application. The primary dressing may be fixed using surgical glue, sutures, or staples, or held at the lower aspect of the wound prior to applying the cell suspension to reduce runoff.



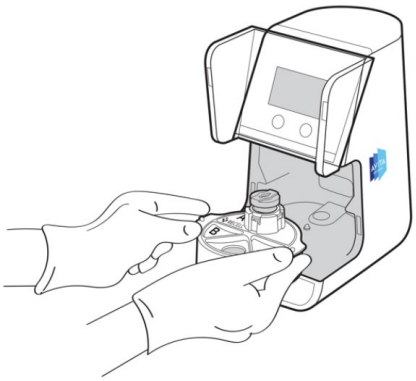
Draw up the Prepared Cell Suspension

An audible alert will sound, and the screen will display:

> Process Complete
> Aseptically Draw Up RECELL Spray-On Skin Cells from Well D

The RECELL Spray-On Skin Cells are ready to be drawn aseptically from Well D.

Locate the D Tray in the sterile draped procedure field. Attach a blunt tip needle to the 10 ml syringe. Return to the RECELL GO Processing Device noting the device is not sterile. A non-sterile assistant should open the door of the device and move the RECELL GO Cartridge forward on the base of the device so that Well D is accessible using aseptic technique. The RECELL GO Cartridge can also be placed in a clean area next to the RECELL GO Processing Device, if desired.



Using aseptic technique, seat the needle in the dimple at the base of Well D. Mix the cell suspension by drawing up and returning back to Well D. Draw up the required volume to apply to the treatment area using the additional syringes and needles provided in the D Tray as required.

Apply Cell Suspension to the Wound Bed

The cell suspension can be sprayed or dripped onto the wound bed, with the technique (i.e., spraying vs. dripping) dependent on the volume of cell suspension to be applied and size of wound bed.

Prior to application, invert the syringe several times to ensure an even suspension.

Spray Application - Application of greater than or equal to 2 ml of cell suspension

The spray application technique should only be used when there is greater than or equal to 2 ml of cell suspension in the syringe.

Remove the needle from the syringe containing the cell suspension. Locate the nozzle in the D Tray. Using firm pressure, attach the supplied spray nozzle to the syringe. Be careful not to press the plunger.

Check that the aperture of the attached spray nozzle faces the wound. Hold the spray applicator approximately 10 cm from the most elevated point of the wound and in a position, such that the first drop of suspension falls onto the wound surface. Apply moderate pressure to the plunger of the syringe. Start spraying at the most elevated part of the wound so that any run-off helps to cover the more dependent areas of the wound. A fine mist of cell suspension should be delivered to the wound surface. To cover a larger area, carefully move the spray applicator in one continuous motion from one side of the wound to the other as you spray.

Drip Application - Application of less than 2 ml of cell suspension

The drip application should be used any time that the remaining volume of cell suspension in the syringe is less than 2 ml. Please note that if the remaining volume of cell suspension is less than 2 ml, there is an insufficient amount of cell suspension to cover a wound that is ≥160 cm^2.

Do not remove the needle from the syringe containing the cell suspension.

Starting at the most elevated point of the wound, carefully drip the cells onto the wound surface so that any run-off helps to cover the more dependent areas of the wound.

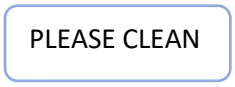
Note: Following application, it is typical to observe run-off of the suspension from the treated wound; results from prospective randomized clinical studies indicate sufficient cellular attachment is obtained post-application of the cellular suspension as epidermal regeneration for definitive closure is achieved.

Apply Dressings
After applying the cell suspension, cover the wound with a non-adherent, non-absorbent, small pore dressing. Always follow the instructions as set by the dressing manufacturer. Dry dressings may be applied moist at the direction of the healthcare professional by lightly soaking the dressing in sterile saline before dressing the wound. The dressing may be fixed to the wound with surgical glue, sutures, or staples, as necessary.

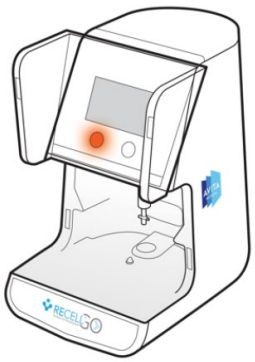
Secondary dressings that are moderately absorbent, minimally adherent, low shear, and readily removable should be placed over the primary dressing followed by absorbent gauze. Use of known cytotoxic medication (for instance, silver sulfadiazine) is contraindicated for areas treated using RECELL GO. Additional absorbent gauze for padding, as well as a crepe or compression bandages, may be used.

C8 CLEANING OF THE PROCESSING DEVICE
Once the procedure is complete, remove the RECELL GO Cartridge and dispose of it per the facility protocol. It is highly recommended to clean the equipment after retrieving and using the device from storage and in between treatment use as part of regular maintenance.

After pressing the flashing green CONTINUE button, the screen will display:



To clean the RECELL GO Processing Device, select the flashing orange CLEAN button.



The screen will now display:

WIPE CLEAN

The shaft will lower and the device is ready for cleaning.

Wipe the equipment with non-woven towelettes containing surface agents (e.g., disinfecting wipes) that are non-abrasive, non-corrosive and safe for all non-porous surfaces.

Wipe the entire device (interior and exterior) until all gross soil is visually eliminated including, but not limited to, the following areas:

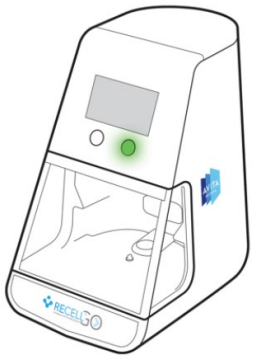
- Inner chamber where the cartridge is inserted
- Shaft which extends from the top of the inner chamber
- LCD screen and buttons
- Door & door hinges

Utilize as many towelettes as required to perform the wipe down and attention shall be paid to areas such as crevices, seams, fluid spillage and stained areas. Ensure all gross soil has been eliminated before proceeding.

Use a dry lint-free cloth to dry the interior and exterior of the device.

The screen will display the following message with flashing green DONE button:

Select DONE When Complete



Press the green Done button after the cleaning is completed and the shaft will retract back up and the screen will return to display status of RECELL GO Cartridges used. The system is now ready to be stored or used with the next patient.

CAUTION: Follow standard precautions including use of appropriate Personal Protective Equipment (PPE) while cleaning and using the processing device.

C9 STORAGE OF THE PROCESSING DEVICE

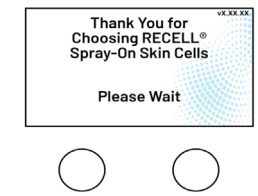
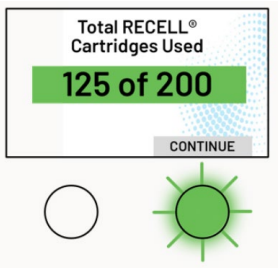
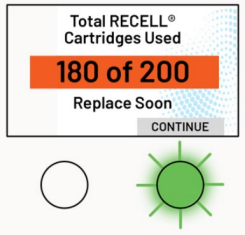
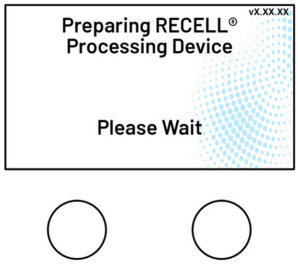
To store the Processing Device:

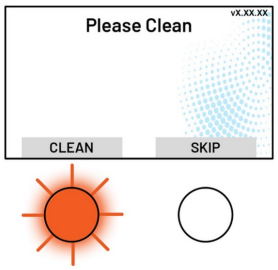
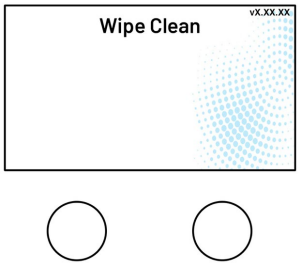
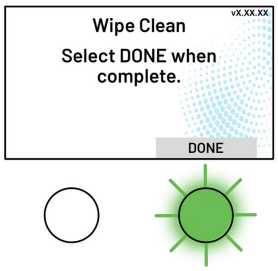
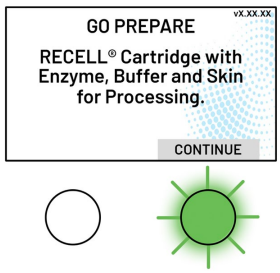
1. Turn ON/OFF switch to the OFF position.
2. Remove the power cord from the supply mains and detach the power cord from the device.
3. Store the Processing Device within ambient storage conditions.

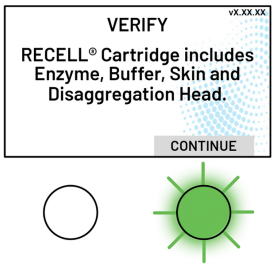
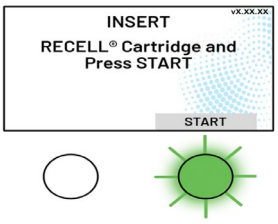
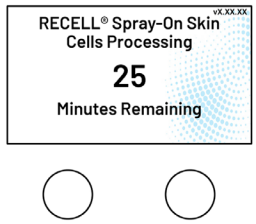
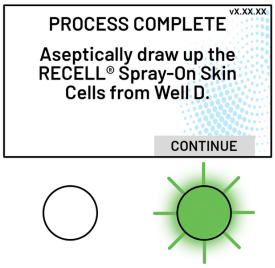
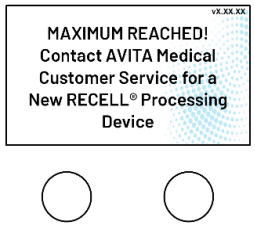
CAUTION: Do not operate the device while in transit.

C10 USER INTERFACE

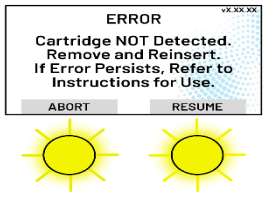
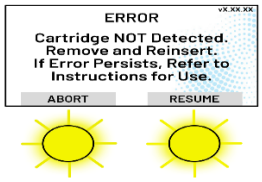
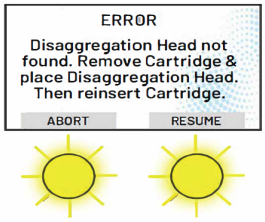
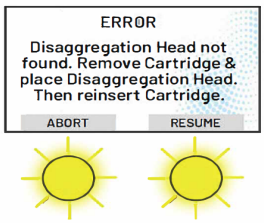
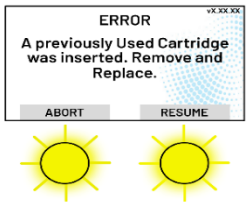
Operating Mode Screen Language

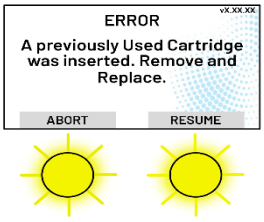
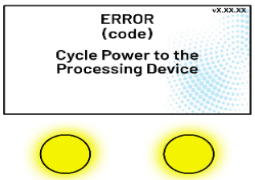
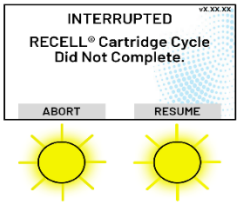
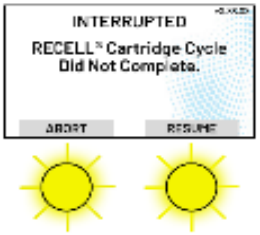
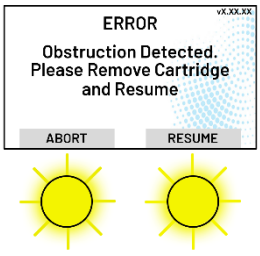
Screen Message	Button Function	Purpose	Response
	None	The system is powered on and running a self-test before proceeding.	None required
	CONTINUE Button flashes GREEN	Displays total number of RECELL GO Cartridges used to date. Numbers will be highlighted in GREEN if count is less than 180.	Select CONTINUE to proceed to next step.
	CONTINUE Button flashes GREEN	Displays total number of RECELL GO Cartridges used to date. Numbers will be highlighted in ORANGE if count is 180 or greater.	Contact your AVITA Medical representative to discuss when to replace your RECELL GO Processing Device. Select CONTINUE to proceed to next step.
	None	The RECELL GO Processing Device is undergoing a homing process to prepare for the next step. Note: This message will appear after pressing “CONTINUE” at Total RECELL Cartridge Used screen or if the device is recovering from an error state.	None required

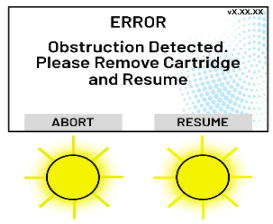
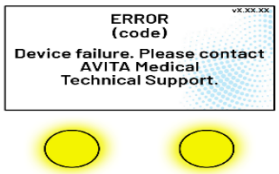
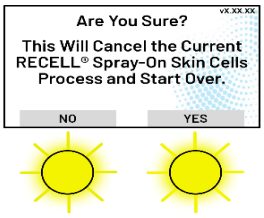
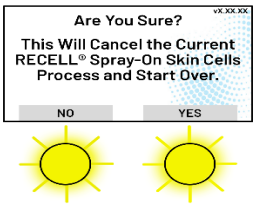
Screen Message	Button Function	Purpose	Response
	CLEAN Button flashes ORANGE and SKIP Button flashes WHITE.	Reminder to CLEAN the RECELL GO Processing Device before proceeding.	Select CLEAN to proceed with cleaning the RECELL GO Processing Device. Select SKIP if cleaning not necessary.
	None	The RECELL GO Processing Device prepares for you to wipe it clean by lowering the shaft.	Wipe down the RECELL GO Processing Device as instructed in the IFU and Procedure Guide.
	DONE Button flashes GREEN	When cleaning is complete, retracts the shaft before proceeding.	Select DONE once you have completed cleaning the RECELL GO Processing Device as instructed.
	CONTINUE button flashes GREEN	Reminder to step away from RECELL GO Processing Device and prepare RECELL GO Cartridge using the RECELL GO Preparation Kit components and skin.	Select CONTINE once the contents of the RECELL GO Cartridge have been prepared and included.

Screen Message	Button Function	Purpose	Response
	CONTINUE button flashes GREEN	Reminder to pause and verify the contents of the RECELL GO Cartridge before placing it in the RECELL GO Processing Device.	Only select CONTINUE once all contents are confirmed to be in the Cartridge.
	START Button flashes GREEN	Notification that the RECELL GO Processing Device is ready to accept the placement of the RECELL GO Cartridge.	Select START once RECELL GO Cartridge is successfully inserted within the RECELL GO Processing Device chamber.
	None	Notification of the time remaining for Processing of the RECELL Spray-On Skin Cells.	Do not interact with the Device during this process.
	CONTINUE button flashes GREEN	Notification that the process is complete and the RECELL Spray-On Skin Cells are ready to be aseptically drawn from Well D of the RECELL GO Cartridge.	Follow the instructions in the IFU or Procedure Guide for drawing the suspension from Well D and preparing the syringes for application of the RECELL Spray-On Skin Cells. Select CONTINUE once Cartridge is removed from the Device.
	None	Notification that the RECELL GO Processing Device is not able to process any additional Cartridges and must be replaced.	Contact AVITA Medical Customer Service as soon as possible to arrange for a replacement RECELL GO Processing Device.

Error Mode Screen Language

Screen Message	Button Function	Purpose	Response
	ABORT flashes Yellow	Alert that the cartridge is not properly situated or detected by the Device.	Select ABORT if no cartridge or not ready to proceed with processing.
	RESUME flashes Yellow	Alert that the cartridge is not properly situated or detected by the Device.	Select RESUME if the cartridge is repositioned and detected.
	ABORT flashes Yellow	Alert that the disaggregation head has not been properly placed in Well A.	Select ABORT if disaggregation head not available.
	RESUME flashes Yellow	Alert that the disaggregation head has not been properly placed in Well A.	Select RESUME once disaggregation head is placed in Well A.
	ABORT flashes Yellow	Alert when a previously used cartridge is detected. Using a cartridge more than once is not permitted.	Select ABORT if no new cartridge is available.

Screen Message	Button Function	Purpose	Response
	RESUME flashes Yellow	Alert when a previously used cartridge is detected. Using a cartridge more than once is not permitted.	Select RESUME if a new cartridge is available and can be used for RECELL Spray-On Skin Cell Processing.
	None	Alert that there is a motor jam or another disruption to the cycle that has halted Processing.	Unplug and turn off the Power to the RECELL GO Processing Device to continue recovery process.
	ABORT flashes Yellow	Alert that the Processing cycle had been interrupted and did not complete.	Select ABORT if Not continuing RECELL GO process.
	RESUME flashes Yellow	Alert that the Processing cycle had been interrupted and did not complete.	Select RESUME to continue RECELL Spray-On Skin Cell Processing.
	ABORT flashes Yellow	Alert if the cartridge was left in the Device chamber when selecting CLEAN.	Select ABORT if the shaft is jammed on the well housing plate and the cartridge is stuck in place.

Screen Message	Button Function	Purpose	Response
	RESUME flashes Yellow	Alert if the cartridge was left in the Device chamber when selecting CLEAN.	Select RESUME after removing the cartridge from the Device chamber.
	Buttons are solid Yellow. Button presses are ignored. Continuous audible tone.	Alert that RECELL GO Processing Device is inoperable.	Contact AVITA Technical Support.
	NO button returns system to previous screen.	Confirmation before aborting the process.	Select NO to go back to ABORT/RESUME prompt.
	YES button proceeds with the ABORT request.	Confirmation before aborting the process.	Select YES to ABORT the RECELL GO process.

D AFTERCARE

The following information, precautions, and notes provide guidelines for care after RECELL GO treatment. Discuss appropriate aftercare with your AVITA representative and provide the patient with aftercare instructions.

D1 SUBSEQUENT DRESSINGS

The outer dressings and compression bandages may need to be changed if exudate levels are high; however, the primary dressing should remain in place for 6-8 days, or as clinically indicated. Protect the primary dressing during secondary dressing changes.

The primary dressing must not be forcibly removed from area(s) to which it is still adhered. Typically, it can be separated (gently peeled back) as new epidermis is formed.

To prevent trauma, any dressing not easily removed should be soaked with an aqueous or oil-based solution prior to removal.

Once the primary dressing has been removed, an appropriate protective dressing should be applied to protect the wound surface.

Do not use dry dressings as protection over blisters or areas of punctate bleeding, as dried exudate could cause newly regenerated epidermis to adhere to the dressing, leading to potential injury upon dressing removal. Instead, use a sterile greasy or paraffin gauze dressing until any blistering or open areas resolve.

Any signs or symptoms of infection or impaired healing at this stage should be recorded and addressed.

D2 AFTERCARE PRECAUTIONS

- Patients should take necessary precautions to prevent the treated area from getting wet while the wound is still open.
- The primary dressing should remain in place as clinically indicated but is typically no longer required after 6-8 days.
- Up to two additional weeks may be needed after initial closure of the treated area for the newly regenerated epidermis to mature and become robust. During this time protective dressings must be worn, particularly on extremities.
- Use of known cytotoxic medication (for instance, silver sulfadiazine) is contraindicated for areas treated using RECELL GO.
- Patients and caregivers should be provided with adequate information and materials for appropriate protection against re-injury during healing and maturation of the treated area.
- Patients should be advised to refrain from strenuous activity.
- Patients should avoid direct sun exposure. A minimum of SPF30 and protective clothing should be worn.

- Patients should be counseled about increased risks of skin cancers after thermal burn wounds, and to notify their treating physician of their prior treatment with RECELL GO if they develop skin cancers.

D3 SCAR MANAGEMENT

When the wound has healed, the patient should be advised to continue to protect the area from any surface trauma and to avoid direct sun. Regular use of sunscreen (SPF30) and twice-daily massage with a non-oily skin moisturizer is recommended.

The patient should be advised that the wound area will change over the subsequent weeks and months. The pigmentation and skin texture will continue to mature and improve during this time and the final result may take up to 12 months to be achieved.

Follow-up procedures should follow standard protocols for the specific injury and treatment given.

E SYSTEM SPECIFICATIONS

This device meets the following standard - IEC 60601-1 edition 3.2 Medical electrical

E1 TECHNICAL SPECIFICATIONS

Mechanical

Dimensions	32.7 cm X 21.5 cm X 34.5 cm (DXWXH)
Weight	7.6 Kg
Case Material	ABS Lustran 348
IP Rating:	IP22

Electrical

Protection	Class I
Rated Power	230 – 264 VA
Supply Frequency	50/60 Hz
Fuse Specification	250 VAC, 2A Slow blow, 100A breaking capacity, 5.2mmX20mm

E2 OPERATION AND STORAGE CONDITIONS

RECELL GO Processing Device

	Operation	Storage
Temperature	15-35°C	Ambient condition
Relative humidity	30 - 60 % (RH)	Ambient condition
Atmospheric pressure	Ambient condition	Ambient condition

Transportation

To move the RECELL GO Processing Device:

1. Turn off the equipment.
2. Disconnect the power cord from the Mains outlet.
3. Lift the equipment from top and bottom to avoid any damage.
4. Use transit cart compliant to healthcare facility regulations for transporting the device.

RECELL GO Preparation Kit

Upon receiving the RECELL GO Preparation Kit, examine the packaging for external signs of damage. If the external packaging or the packaging for the Cartridge appears damaged, contact your AVITA representative immediately. Do not use any components of the sterile Cartridge if the packaging appears damaged. If returning RECELL GO, ensure all original packaging and components are returned with the device.

	Storage
Temperature	20-25°C
Relative humidity	Ambient condition
Atmospheric pressure	Ambient condition

The single-use RECELL GO Cartridge and System Components, including the Enzyme, may be stored in a safe and dry environment.

Note: Do not open or use RECELL GO beyond the expiration date listed on the packaging.

E3 INTENDED USE ENVIRONMENT

RECELL GO is intended for use in an operating room of a hospital, surgical center or surgical suite. However, do not use RECELL GO near active high-frequency surgical equipment, and do not use RECELL GO near RF shielded room of a magnetic resonance imaging equipment where electromagnetic disturbances are high.

E4 ESSENTIAL PERFORMANCE

The degradation of performance or failure of the RECELL GO Processing Device does NOT cause an unacceptable risk to the patient as per the product risk management. The worst-case harm to the patient is limited to reversible skin tissue damage due to the harvesting of skin from a donor site on the patient. Therefore, the device does not support any essential performance functions.

E5 COMPONENT STERILIZATION AND TESTING

- The RECELL GO Preparation Kit components in the trays have been sterilized by ethylene oxide.
- The RECELL Enzyme has undergone filtration and terminal sterilization by gamma irradiation.
- The Buffer and Sterile Water have been sterilized using steam.

F ELECTROMAGNETIC COMPATIBILITY

The RECELL GO Processing Device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device complies with the requirements of the EMC international standard IEC 60601-1-2 when used in accordance with the electromagnetic environment specified in the following tables.

Guidance and manufacturer's declaration – electromagnetic emissions

Emission Test	Compliance	Electromagnetic environment – guidance
Radiofrequency (RF) emissions CISPR 11	Group 1	The RECELL GO Processing Device does not generate any RF energy for their internal functioning. Therefore, the RF emissions produced by the device shall be very low.
RF emissions CISPR 11	Class A	The RECELL GO Processing Device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	The RECELL GO Processing Device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	N/A

Guidance and manufacturer's declaration – electromagnetic Immunity

Immunity Test Standard	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electromagnetic compatibility (EMC) IEC 61000-4-3	3 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device. Otherwise, degradation of the performance of this equipment could result.
Power Frequency (50/60 Hz) Magnetic Field, IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	± 1 kV for input/output lines ± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, shorts, interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT [>95% dip in UT] for 0.5 cycle (<5% UT [>95% dip in UT] for 0.5 cycle) 40% UT [60% dip in UT] for 5 cycles (40% UT [60% dip in UT] for 5 cycles) 70% UT [30% dip in UT] for 25 cycles (70% UT [30% dip in UT] for 25 cycles) <5% UT [>95% dip in UT] for 5 s (<5% UT [>95% dip in UT] for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	RF shielded environment including filtering of all cable passing through the shielding, with a minimum shielding effectiveness and filter attenuation of 20 dB.

WARNINGS:

Use of RECELL GO Processing Device adjacent to or stacked with other equipment.

Use of RECELL GO Processing Device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers, or cables not specified.

Although RECELL GO Processing Device is designed for electromagnetic immunity, use of cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Electrostatic Discharge Warning

Although RECELL GO Processing Device is designed to be unaffected by typical electrostatic discharge (ESD), very high levels of ESD can result in a temporary suspension of normal operation requiring the operator to recover the operations.

G TROUBLESHOOTING

Cartridge not detected
In the event of the RECELL GO Cartridge not making electrical connection to the RECELL GO Processing Device after multiple attempts the following error message shows up on the LCD screen – 'Cartridge Not Detected. Remove and reinsert. If Error Persists, Refer to Instructions for Use'. In this scenario, clean the electrical pads with non-woven towelettes before the next attempt. If the issue persists, use a new RECELL GO Preparation Kit, and set up the RECELL GO Cartridge according to the instructions in section C3B. Using aseptic technique, retrieve the skin sample from Well A of the existing RECELL GO Cartridge and transfer to the replacement cartridge.

Enzyme powder does not dissolve completely
Make sure that the Enzyme is mixed well with the sterile water by gently inverting the vial several times. Often a small amount of particulate matter remains undissolved in the reconstituted solution. This does not reduce the activity of the Enzyme.

Do not use Buffer to dissolve the Enzyme as it may interfere with the Enzyme action.

Skin sample is too large, or too thin
Take particular care when harvesting the skin sample. It should be a thin (0.006 – 0.008 in, 0.15 – 0.20 mm) split-thickness graft with just a very thin section of dermis. The skin sample of the appropriate thickness will ensure successful disaggregation of cells. The maximum size of each skin sample recommended for use with the RECELL GO Device is 3 cm by 2 cm.

If the skin sample is too large (greater than the maximum recommended), cut it into a smaller size and discard the excess.

If the skin sample is too thin, you should take another skin sample from a DIFFERENT donor site.

Buffer added to Enzyme vial
If Buffer, instead of sterile water, is mistakenly added to the Enzyme vial, the Enzyme activity may be inhibited. If Buffer is mixed with the Enzyme powder, the Enzyme should be discarded and a new RECELL GO Preparation Kit used.

Nozzle blocked
If the cell suspension is not easily sprayed, the cell suspension may be dripped onto the wound bed. If the cell suspension does not come out at all, the nozzle attached to the syringe may be blocked by unfiltered particles. Filter the suspension and place in a new 10- ml syringe prior to attaching a new spray nozzle.

Insufficient treatment area coverage
If cell suspension is lost in the application process and sufficient coverage of the treatment area was not achieved, take another skin sample and repeat the process with a new RECELL GO Preparation Kit to create additional cell suspension and complete the treatment.

For further information regarding the RECELL GO Autologous Cell Harvesting Device, contact:

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