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# INSTRUCTIONS FOR USE

## RECELL® Autologous Cell Harvesting Device

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

**Warning:**

The RECELL Autologous Cell Harvesting Device is internally powered by four non-replaceable AA batteries (1.5V). The device should not be used in the presence of flammable anesthetic mixtures. Do not incinerate batteries on disposal. The performance of the device may be affected by sources of electromagnetic radiation and if any malfunctions are noted, all possible sources of electromagnetic radiation must be removed before further use.

**Caution:**

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

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# A BACKGROUND

## A1 DEVICE DESCRIPTION

RECELL® is a single-use, stand-alone, battery-operated, autologous cell harvesting device containing enzymatic and delivery solutions, sterile surgical instruments, and actuators. The RECELL Device enables a thin split-thickness skin sample to be processed to produce a Regenerative Epidermal Suspension (RES™) for immediate delivery onto a prepared wound bed.

The cell suspension contains a mixed population of cells, including keratinocytes, fibroblasts, and melanocytes, obtained from the disaggregation of the skin sample. The preservation of melanocytes is important for restoring natural pigmentation to the recipient area.

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® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL Device is used by an appropriately-licensed healthcare professional at the patient's point-of-care to prepare autologous Regenerative Epidermal Suspension (RES™) for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.

## A3 CONTRAINDICATIONS

- RECELL is contraindicated for the treatment of wounds clinically diagnosed as infected or with necrotic tissue present in the wound bed.
- RECELL 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 should not be used with patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

## A4 WARNINGS

- Autologous use only.
- Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension.
- RECELL is provided to the healthcare professional sterile and is intended for single-use.
- Do not reuse, freeze, or re-sterilize device components.
- Handle using aseptic technique.
- Do not use RECELL or device components if packaging is damaged or there are signs of tampering.
- Do not use RECELL or device components if the date of use is beyond the stated expiration date on the packaging.
- 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.
- If a skin sample is harvested and processed according to these instructions, it should require between 15 and 30 minutes of contact with the Enzyme. Contact in excess of 60 minutes is not recommended.
- 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.

## A5 PRECAUTIONS

- RECELL is not intended to be used alone (i.e., without meshed autograft) for treatment of full-thickness burn wounds.
- The safety and effectiveness of RECELL 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 plus autografting have not been established for treatment of full-thickness burn wounds:
  - On the hands and articulating joints
  - In patients with wounds totaling >50% Total Body Surface Area (TBSA)

## A6 SPECIAL PATIENT POPULATIONS

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

## A7 ADVERSE REACTIONS

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

## A8 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:

User must read instructions for use

User should refer to the accompanying instructions for use

Product is for single use only

Do not use if package is damaged

Caution

Expiration date

Manufacturer

Date of manufacture

Specifies the storage temperature range

Specifies the upper limit of storage temperature


Catalogue number


Lot number


Sterile components in package


Product or components within have been sterilized using ethylene oxide


Product or components within have been sterilized using gamma irradiation


Product or components within have been sterilized using steam

## A9 DOSAGE

RECELL is supplied as a single-use device. The contents of each package are sufficient to prepare up to 24 ml of cell suspension which can be used to cover an acute wound area of up to and including 1,920 $cm^2$.

## A10 HOW SUPPLIED

The RECELL Device consists of:

- 1 x Processing Unit with built-in heating mechanism
- 1 x removable sterile tray
- 1 x removable cell strainer
- 1 x sealed vial of Enzyme
- 1 x 10-ml vial of sterile water
- 4 x 10-ml vials of Buffer
- 7 x 10-ml syringes
- 6 x 18G blunt fill needles
- 2 x disposable surgical scalpels
- 4 x spray nozzles

## A11 STORAGE

Upon receiving RECELL, 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, ensure all original packaging and components are returned with the device.

RECELL, including the Enzyme, may be stored at controlled room temperature, 20-25 °C. See Section E1 for storage conditions of RECELL.

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

## A12 DISPOSAL

- RECELL and all individual components are intended for single use. RECELL components are not reusable and should be discarded after single 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.

⚠ CAUTION: RECELL contains batteries and electrical components. Do not incinerate until removal of batteries and electrical components.

- If required, a procedure for removal of Processing Unit Battery/electronics is as follows:
  - Take proper Biohazard precautions when handling the used Processing Unit.
  - Remove the Processing Unit top cover. Set top cover aside.
  - Remove Processing Unit inner tray and set aside.
  - Open inner main tray by pressing both sides of the outer housing simultaneously.
  - Verify that the parts are separated (inner main tray and outer housing). If the parts of the inner tray and outer housing are not separated, a small, flat-blade screwdriver may be used to assist in releasing the inner and outer parts.
  - Lift the battery inner tray to expose battery compartment.
  - Remove the batteries and the electronics and dispose of them in the appropriate waste streams.
  - Dispose of the remaining components in accordance with the appropriate methods.

# 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.

**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 Regenerative Epidermal Suspension (RES™) 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 RES™ 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 s (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 | | Control | | Donor Site | | Non-Study Area | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Any primary system organ class** | 17 | (58%) | 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%) |
| **Extraskeletal 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 procedures** | | | | | | | | |
| **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.

**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 RES™ 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 2. Summary of Recipient and Donor Site AEs by System Organ Class and Preferred Term**

| Primary System Organ Class/Preferred Term N=101 | Recipient Sites | | | | Donor Sites | | | | Non-Study Area | |
|---|---|---|---|---|---|---|---|---|---|---|
| | RECELL | | Control | | RECELL | | Control | | | |
| | n | (%) | n | (%) | n | (%) | n | (%) | 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.*

# C TREATMENT

## C1 REQUIREMENTS

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

- Sterile field
- Non-sterile preparation area
- Personal protective equipment
- Skin preparation solution
- Local anesthetic with adrenaline where not contraindicated
- Sterile ruler and marker pen
- Appropriate wound dressings - see “Aftercare” section for details
- 1 or 2 x fine-point (long nosed) forceps of choice
- Skin harvesting instrument of choice
- Wound bed preparation tool of choice
- Clock or timer to monitor incubation time

## C2 RECELL® DEVICE SET-UP

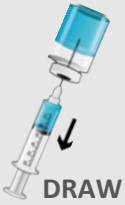
⚠ CAUTION: Ensure that use of the RECELL Device is within the expiration date stated on the packaging.

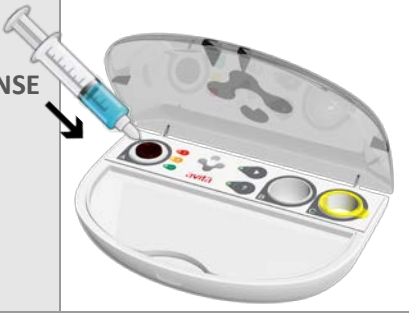
Perform the following set-up steps in the order shown to avoid setup errors. A procedure guide describing the set-up process is included with the device for reference during a procedure.

The RECELL Device contains both sterile and non-sterile components. Select and prepare sterile and non-sterile work areas. Using standard aseptic technique set up a sterile surgical field. Complete the steps based on the assigned roles in the following table.

| NON-STERILE PREPARATION AREA | STERILE AREA |
|---|---|
| **TRANSFER PROCESSING UNIT TO STERILE FIELD** | |
| Using aseptic technique, remove the Processing Unit from the sterile packaging and transfer it to the sterile field.  | Open the Processing Unit lid and note the removable inner white plastic insert. This insert acts as a sterile tray for use in preparing and scraping the skin sample. |
| **PERFORM SELF-TEST** | |
| | Perform the self-test to verify the device is functioning correctly.<br><br>  Test the device to ensure functionality by pressing the button marked (?). All lights should illuminate during the self-test.<br><br>  When the unit has completed the self-test (this takes approximately 30 seconds), it will beep once and the green 'ready' light (✓) will illuminate to indicate that the Processing Unit is functioning correctly.<br><br>  **<u>DO NOT</u>** press the flashing run button (▶) at this time.<br><br>  If lights do not illuminate, or the red light (!) illuminates, this indicates device failure. Do not use the device. Use another device.<br><br>• The unit will automatically turn off after 1 minute if Enzyme heating is not initiated.<br>• If the device turns off after self-test, additional self-tests may be run. |

| NON-STERILE PREPARATION AREA | STERILE AREA |
|---|---|
| ***SET A – PREPARE ENZYME*** | |
| • In the non-sterile work area, remove the cover from the vial marked Enzyme to expose the injection diaphragm. The diaphragm of the Enzyme vial may be wiped with a sterile alcohol wipe and allow to dry; however, this step is optional.<br>• Connect a sterile needle to a sterile 10-ml syringe and draw up the entire volume of sterile water.<br>• Inject the entire volume of sterile water into the Enzyme vial. DO NOT USE Buffer at this stage as this may inhibit the Enzyme action.<br>• Mix gently until dissolved. Do not shake; use care to avoid foaming. Draw the Enzyme back into the syringe.<br>• Using aseptic technique, dispense the entire volume of Enzyme into the left-hand well of the Processing Unit (Well A). Discard syringe and needle. | |



| NON-STERILE PREPARATION AREA | STERILE AREA |
|---|---|
| ***SET B – PREPARE BUFFER*** | |
| The four (4) Buffer vials are to remain in the non-sterile preparation area.<br><br>Using aseptic technique introduce the following items into the sterile field.<br><br>• 2 x 10-ml syringes<br>• 1 x blunt fill needle<br>• 2 x disposable surgical scalpels | |
| | • Mark one of the new 10-ml syringes "BUFFER". The "BUFFER" syringe will be used several times to draw Buffer from the vials. Set aside within the sterile field.<br>• Mark the other 10-ml syringe "UNFILTERED SUSPENSION". The "UNFILTERED SUSPENSION" syringe will be used several times to collect cell suspension from the tray and dispense into the cell strainer. Set aside within the sterile field.<br>• It is important that these syringes are used only for their intended purpose and that they remain sterile. |
| • Remove the cover from one of the Buffer vials. The diaphragm of the Buffer vial may be wiped with a sterile alcohol wipe and allow to dry; however, this step is optional. | • Attach the sterile needle to "BUFFER" syringe. |
| • Hold the Buffer vial to allow for the volume to be drawn up by person in the sterile field.<br><br>  <br> | • Draw up the entire volume of Buffer (approximately 10 ml) from the vial being held by the person in the non-sterile area.<br><br>**DRAW UP** |

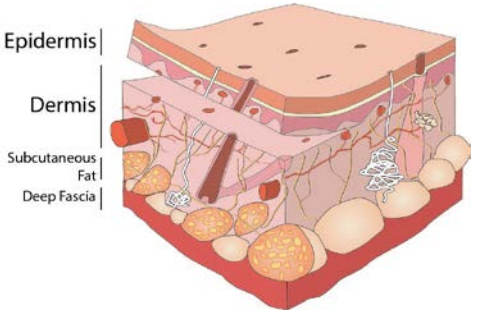
| | |
|---|---|
| | • Dispense the entire volume of Buffer into Well B of the Processing Unit. The entire 10 ml of Buffer will be used to rinse skin samples.<br>  <br><br>• Set the "BUFFER" syringe and needle aside within the sterile field for later use. |
| **NON-STERILE PREPARATION AREA** | **STERILE AREA** |
| ***SET C – PREPARE DELIVERY ITEMS*** | |
| Introduce all Delivery Set items into the sterile field.<br><br>• 4 x 10-ml syringes<br>• 4 x blunt fill needles<br>• 4 x spray nozzles | **RECELL Device Set-Up Complete** |

## C3 BURN 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 is used for treatment of acute thermal burn wounds, RES™ can be directly applied to partial-thickness wounds or applied in combination with meshed autografts for full-thickness wounds.

## C4 SKIN SAMPLE HARVESTING




### 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.

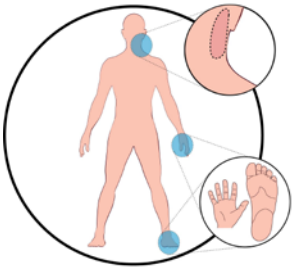
### Size of Skin Sample

Choose the appropriate skin sample size for the application. Each square centimeter of 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 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 $cm^2$.

The following table provides guidance for skin sample needed for several treatment area sizes.

| Treatment Area | Skin Sample Size |
|---|---|
| up to 80 $cm^2$ | 1 cm x 1 cm (1 $cm^2$) |
| up to 160 $cm^2$ | 2 cm x 1 cm (2 $cm^2$) |
| up to 320 $cm^2$ | 2 cm x 2 cm (4 $cm^2$) |
| up to 480 $cm^2$ | 3 cm x 2 cm (6 $cm^2$) |
| up to 960 $cm^2$ | 2 ea. 3 cm x 2 cm (12 $cm^2$) |
| up to 1440 $cm^2$ | 3 ea. 3 cm x 2 cm (18 $cm^2$) |
| up to 1920 $cm^2$ | 4 ea. 3 cm x 2 cm (24 $cm^2$) |

**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 the table above 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 povidine-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.

Large pieces of harvested skin should be cut into skin samples appropriately sized for use in the device. Keep the skin samples moist in sterile gauze moistened with sterile saline prior to use.

## C5 PREPARING CELL SUSPENSION USING THE RECELL DEVICE

### Heat Enzyme

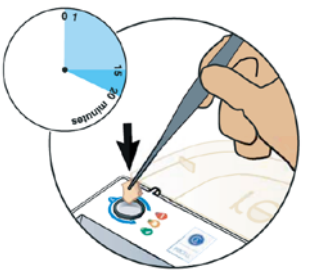
Verify that the Enzyme has been transferred to Well A. The Processing Unit will quickly overheat if the run button (⏵) is pressed before the Enzyme has been placed in the well. Any malfunctioning of the unit, including overheating, will be indicated by the red light (!) illuminating. Should this occur, use another RECELL Device and contact your local representative to arrange the return or replacement of the unit.

Press the run button (⏵) to heat the Enzyme in Well A. If the device is ready, (✓) then heating will commence. If more than one minute has passed since the last self-test, a self-test will automatically run, followed immediately by heating of the Well A. The orange light will illuminate when warming begins and the Enzyme will be heated and maintained at approximately 37 °C.

### STAGE A- ENZYMATIC PROCESSING

#### 1. Incubate the Skin Samples

When the orange warming light turns off and the green (✓) illuminates the Enzyme has reached its target temperature. This will take approximately 3 minutes. The orange light will flash from time to time, indicating that the heating element has been activated to maintain temperature.



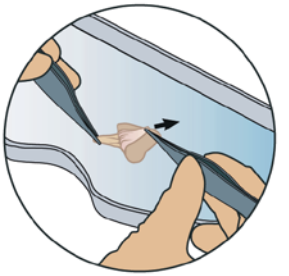

Place 1 or 2 skin samples into the heated Enzyme for 15 to 20

minutes to allow the breakdown of protein-protein interactions. DO NOT incubate more than two 6 $cm^2$ skin samples at a time. Up to 4 samples may be processed using a single device, 2 initially, then 2 following those. If the skin samples are thick, they may require longer incubation. Each sample may be incubated for up to 60 minutes.

After approximately 60 minutes, an alarm will sound and will sound each minute for 15 minutes. At 75 minutes, the Processing Unit will turn off and stop heating the enzyme. Incubation of a skin sample for more than 60 minutes is not recommended.

*May complete Step 4. Prepare Buffer while skin is incubating.*

**2. Test Scrape for Cell Disaggregation**



After 15 to 20 minutes, remove the skin sample from the heated Enzyme with sterile forceps and place the skin sample dermal side down on the sterile tray. Gently scrape the epidermis edge with the scalpel to test if cells disaggregate, i.e., epidermal cells easily come off. Once the test is complete STOP scraping. If the cells do not come off freely, return the skin sample to the heated Enzyme for a further 5 to 10 minutes and then repeat the test scrape. When the cells scrape off freely, proceed to the next step- Rinse Skin Sample.

**3. Rinse Skin Sample**

Upon a successful test scrape, rinse the skin sample in the middle well (Well B) containing the Buffer to rinse off the residual Enzyme. When applicable, place the 2nd incubated sample in Well B. Proceed to *Stage B-Mechanical Processing.*

***Multiple Skin Samples?***

For 3 or 4 skin sample(s) initiate *Stage A - Enzymatic Processing* by placing them into Well A prior to proceeding with *Stage B - Mechanical Processing* for the 1st and 2nd skin samples.

**STAGE B- MECHANICAL PROCESSING**

**4. Prepare Buffer**

*This step may be performed while the skin sample is incubating in Step 1.*

An assistant in the non-sterile area removes the cover from a vial marked Buffer. Wipe the diaphragm of the vial with a sterile alcohol wipe and allow it to dry (optional). The assistant in the non-sterile area then holds the Buffer vial while the healthcare professional (HCP) in the sterile area uses the sterile "BUFFER" syringe with needle to draw up the required volume of Buffer from the vial. Use 1 ml of Buffer per square centimeter of the first skin sample and add 0.5 ml Buffer to allow for loss during processing.

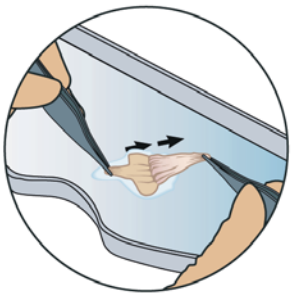
The following table provides example surface areas to be treated, skin sample sizes needed, volumes of Buffer to use, and approximate resultant suspension volumes. Place the syringe with Buffer back into the sterile field for later use.

Each 1 ml of suspension may be used to treat up to 80 $cm^2$; however, a suspension volume of greater than or equal to 2 ml is required to spray the suspension on the wound. Volumes less than 2 ml may be applied using the drip method.

| Surface Area to be Treated per Syringe | Skin Sample Size | Starting Volume of Buffer, per Sample | Approximate Resultant Suspension Volume |
|---|---|---|---|
| Up to 80 $cm^2$ | 1 $cm^2$ (1 cm x 1 cm) | 1.5 ml | 1.0 ml |
| Up to 160 $cm^2$ | 2 $cm^2$ (2 cm x 1 cm) | 2.5 ml | 2.0 ml |
| Up to 320 $cm^2$ | 4 $cm^2$ (2 cm x 2 cm) | 4.5 ml | 4.0 ml |
| Up to 480 $cm^2$ | 6 $cm^2$ (3 cm x 2 cm) | 6.5 ml | 6.0 ml |

**5. Scrape Cells from the Skin Sample**

Place the skin sample on the sterile tray with dermal side down. Apply a few drops of Buffer from the previously filled "BUFFER" syringe onto the skin sample. Using the forceps to anchor the skin sample, gently scrape the epidermal surface with the blade of the scalpel. Once the epidermis has been scraped away into suspension, scrape the remaining dermis more vigorously. Continue scraping until the dermis has nearly disintegrated.



**6. Rinse and Aspirate; Draw up Cell Suspension**

Use the remaining Buffer in the "BUFFER" syringe to rinse the scalpel and tray, collecting the cells into one corner of the tray. Hold and tilt the tray to pool the suspension in the corner as necessary. Set the "BUFFER" syringe aside for later use. Using the "UNFILTERED SUSPENSION" syringe, collect and draw up the cell suspension. Using the drawn-up suspension, rinse the tray. Draw up and rinse several times to maximize cell collection. Finally, draw up all of the cell suspension into the syringe.

**7. Filter Suspension**

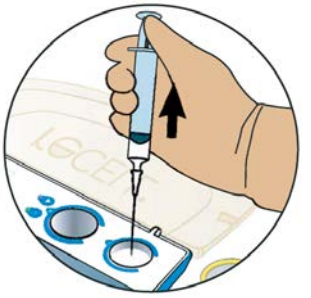
Dispense the cell suspension into the cell strainer in Well C. The strainer removes particulates >100 µm and is critical in preventing nozzle blockage when spraying the cellular suspension. Set the "UNFILTERED SUSPENSION" syringe aside, within the sterile field, for use with subsequent suspensions from the remaining skin samples.

After the cell suspension has passed through the cell strainer, carefully remove the cell strainer and tap it over the well to release any drops of cell suspension into Well C.

If the cell suspension does not easily pass through the cell strainer when processing multiple skin samples, the cell strainer may be clogged. If this occurs, leave the cell strainer in Well C and carefully draw up all the cell suspension from the cell strainer back into the "UNFILTERED SUSPENSION" syringe and utilize a new cell strainer from a new RECELL Device.

**8. Draw Up Cell Suspension**

Attach a needle to a new 10-ml syringe. Draw up the filtered cell suspension using the new 10-ml syringe (Do not use "UNFILTERED SUSPENSION" syringe) from Well C. There is a conical point in the center of the bottom of Well C to aid in drawing up all of the cell suspension. Set the new 10-ml syringe



containing the cell suspension (RES™ syringe) aside for later application.

Return the cell strainer to Well C. RES™ syringe is ready for *Stage C - Deliver RES™*.

Complete *Stage B - Mechanical Processing* to create a syringe of RES™ for each skin sample; then proceed to *Stage C - Deliver RES™.*

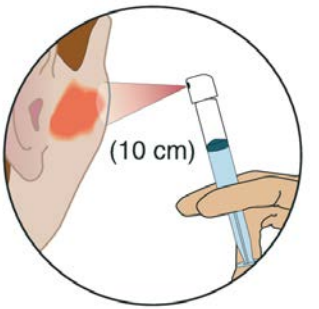
**Stage C- DELIVER CELL SUSPENSION**

**9. Prepare Dressing**

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. Section C- Aftercare, provides information on dressing selection and use.

**10. Apply Cell Suspension to Wound Bed**

The cell suspension can be applied directly to partial-thickness wounds or in combination with meshed autografts for full-thickness wounds.




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. Using firm pressure, attach the supplied spray nozzle to the syringe.

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 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.

**11. Place Initial Dressing**

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. Additional absorbent gauze for padding, as well as a crepe or compression bandages, may be used.

# D AFTERCARE

The following information, precautions, and notes provide guidelines for care after RECELL® 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. Take care to protect the primary dressing during secondary dressing changes. The primary dressing will loosen and lift as new epidermis is formed and should not be removed from areas to which it is still adhered.

IT IS ESSENTIAL THAT PRIMARY DRESSING REMOVAL IS ATRAUMATIC. 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.
- Do not disrupt the primary dressing for a minimum of 5 days. Ensure that primary dressing removal is atraumatic. Do not forcibly remove the primary dressing.
- 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.
- 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 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 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 sun screen (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 3.1 Medical electrical

## E1 OPERATION AND STORAGE CONDITIONS

| | Operation | Storage |
|---|---|---|
| Temperature | 15-35°C | 20-25°C |
| Relative humidity | 10-90% | 10-60% |
| Atmospheric pressure | 65-106 kPa | 65-106 kPa |

**Transportation**

The RECELL® Device is shipped under controlled conditions (e.g., 20-25°C).

## E2 INTENDED USE ENVIRONMENT

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

RECELL is internally powered by four non-replaceable AA batteries. The device should not be used in the presence of flammable materials and must not be incinerated on disposal.

## E3 ESSENTIAL PERFORMANCE

RECELL maintains target temperature (34-39°C) of Enzyme in Well A for 60 minutes in the specified environmental conditions.

## E4 COMPONENT STERILIZATION AND TESTING

- The Processing Unit and needles have been sterilized by ethylene oxide.
- The Enzyme has undergone filtration and terminal sterilization by gamma irradiation.
- The scalpels and spray nozzles have been sterilized by gamma irradiation.
- The syringes have been sterilized by either ethylene oxide or gamma irradiation.
- The Buffer and sterile water have been sterilized using steam.

# F ELECTROMAGNETIC COMPATIBILITY

RECELL® is intended for use in the electromagnetic environment specified below. The customer or the user of RECELL should assure that it is used in such an environment.

| Emission Test | Compliance | Electromagnetic environment – guidance |
|---|---|---|
| Radiofrequency (RF) emissions CISPR 11 | Group 1 | RECELL uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | RECELL is suitable for use in all establishments, other than domestic establishments. |

**Emissions Guidance and manufacturer's declaration – electromagnetic emissions**

| Immunity Test Standard | Compliance Level | Electromagnetic environment – guidance |
|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact<br>± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 10%. |
| Electromagnetic compatibility (EMC) 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 RECELL. Otherwise, degradation of the performance of this equipment could result. |
| 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. |

**Immunity**

**Use of RECELL adjacent to or stacked with other equipment Warning**

Use of this RECELL 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 Warning**
Although RECELL is designed for electromagnetic immunity, use of accessories, transducers and 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 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 press the run button (⏵) to resume normal operations.

# G TROUBLESHOOTING

**Clogging of cell strainer**
If the cell suspension does not easily pass through the cell strainer, the cell strainer may be clogged. If this occurs, leave the cell strainer in Well C and carefully draw up all the cell suspension from the cell strainer back into the "UNFILTERED SUSPENSION" syringe and utilize a new cell strainer from a new RECELL® Device.

**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, too thick, 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 skin sample recommended for use with the RECELL 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 thick, cut the skin sample into 1 cm by 1 cm pieces before placing in the heated Enzyme. If the cells cannot be disaggregated, repeatedly return the skin sample to the heated Enzyme for a further 5 to 10 minutes, up to a maximum of 60 minutes of total time. If the cells still do not scrape off freely it may be necessary to take another thin, split-thickness skin sample (0.006 – 0.008 in, 0.15 – 0.20 mm) from a DIFFERENT donor site and repeat the process using a new RECELL Device.

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

**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 Device used.

**Difficult Cell Disaggregation**

Ensure that the heating element is switched on. The green light (✓) will illuminate when the RECELL Device is switched on and ready for use. The orange light will illuminate when the device is warming. Disaggregation of the cells will take longer if the skin sample is too large or thick. See above for advice.

**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 Device to create additional cell suspension and complete the treatment.

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

AVITA Medical Americas LLC
28159 Avenue Stanford
Suite #220
Valencia, CA 91355
UNITED STATES OF AMERICA
Tel: +1 833 GO AVITA
Fax: +1 661-367-9180
Email: cs.am@avitamedical.com



The RECELL® Autologous Cell Harvesting Device is subject to pending patent and design applications of AVITA Medical.

RELEVANT PATENTS AND PATENTS PENDING
US patent no 9,029,140 & 9,078,741