

INSTRUCTIONS FOR USE

RECELL[®] Autologous Cell Harvesting Device AVRL0102

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 suspension of Spray-On Skin™ Cells for immediate delivery onto a prepared treatment area, up to 20 times the area of the donor skin sample.

The regenerative epidermal 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. Additionally, sub-populations of keratinocytes critical for re-epithelialization have been identified in Spray-On Skin Cells 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 INDICATION FOR USE

The RECELL Autologous Cell Harvesting Device is indicated for repigmentation of stable depigmented vitiligo lesions in patients 18 years of age and older. The RECELL Device is intended for use by an appropriately licensed and trained healthcare professional at the patient's point-of-care for the safe and rapid preparation of Spray-On Skin Cells from a small sample of a patient's own skin. The suspension of Spray-On Skin Cells is suitable for application to skin resurfaced by an ablative laser. A portion of the suspension of Spray-On Skin Cells may also be applied to the donor site.

A3 CONTRAINDICATIONS

- 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.
- 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 beyond the stated expiration date indicated on the adhesive Lot # and Expiration Date labels on the outer box packaging.
- Choose a healthy skin sample donor site that shows no evidence of lack of pigmentation or surrounding cellulitis or infection.
- For optimum cell viability, the skin sample should be processed immediately after harvesting.
- Do not use silver sulfadiazine or other cytotoxic agents on the ablative laser prepared RECELL treatment areas.
- 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

- The safety and effectiveness of RECELL has not been established for repigmentation of:
 - Vitiligo lesions appearing on lips, eyelids, plantar surface of feet, or palmar surface of hands.
 - Vitiligo lesions with recent history (within 12 months) of Koebnerization, confetti-like or trichrome appearance.
 - Patients with a history of keloid formation.

A6 ADVERSE REACTIONS

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

A7 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



Contains biological tissue of animal origin

A8 DOSAGE

RECELL is supplied as a single-use device. The contents of each device are sufficient to prepare up to 6 mL of cell suspension which can be used to cover prepared area(s) areas up to and including 480 cm².

A9 HOW SUPPLIED

The RECELL Device consists of:

- 1 x Processing Unit with built-in heating mechanism, a removable sterile tray, and a removable cell strainer
- 1x Telfa™ Clear

Set A

- 1 x sealed vial of RECELL Enzyme
- 1 x 10 mL vial of sterile water
- 2 x 10 mL syringe
- 2 x 18 G blunt needle

Set B

- 2 x 10 mL vials of Buffer
- 2 x 10 mL syringes
- 1 x 5 mL syringe
- 1 X 3 mL syringe
- 2 x 18 G blunt fill needles
- 2 x disposable surgical scalpels

Set C

- 2 x spray nozzles
- 1 x 5 mL syringe
- 1 x 3 mL syringe

- 2 x 1 mL syringes
- 2 x 18 G blunt fill needles

A10 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 Medical 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 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.

A11 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

A Prospective, Multicenter, Intra-subject randomized, Standard of care (SOC)-controlled, Central evaluator-blinded Clinical Study to Investigate the Safety and Effectiveness of RECELL for Repigmentation of Stable Vitiligo Lesions

Study Design

The safety and effectiveness of the RECELL Device were evaluated in a prospective, multicenter, intra-subject randomized, SOC-controlled, central evaluator-blinded study. Each subject served as their own control by contributing a matched pair of stable depigmented areas that were randomized 1:1 to the RECELL area (received ablative laser treatment, RECELL treatment, and UVB phototherapy) or the control area (received UVB phototherapy only). On the treatment day, the RECELL area skin was resurfaced using an FDA cleared ablative laser device (i.e., Er:YAG or CO₂) prior to application of Spray-On Skin Cells prepared from the RECELL Device. The control area did not receive any treatment (neither ablative laser treatment nor the RECELL treatment). Once the RECELL area healed and was ready, both the RECELL and control areas received UVB phototherapy.

Endpoints. The effectiveness was evaluated based on the proportion of responders for RECELL areas versus control areas at Week 24. Responders were defined as treatment areas achieving $\geq 80\%$ repigmentation as determined by an expert Central Review Committee (CRC) who were blinded to treatment assignment of the areas. Repigmentation was categorized based on review of standardized digital photographs.

The effectiveness was further evaluated based on the CRC categorization of percentage of repigmentation at Week 24.

Safety assessment included reporting treatment emergent adverse events (TEAEs).

Results

Demographics. Twenty-five subjects from ten clinical sites were enrolled in the study. Approximately half of the subjects were female (13/25); 80% of subjects were Caucasian, 12% were Asian, and 8% were African American. The mean age was 41 years (range 22-71 years). The mean disease duration was 11 years (range 1-32 years). The

mean duration of stabilized lesions was 6.2 years (range 1-25 years). Most subjects (76%) had non-segmental vitiligo, including 48% of generalized vitiligo and 28% of focal vitiligo. Twenty-four percent (24%) of subjects had segmental vitiligo. The median size of RECELL and the control areas were 22 cm² (ranged 2 to 360 cm²) and 24 cm²(ranged 2 to 375 cm²), respectively, and the depigmented areas were located at head, neck, dorsal hand, dorsal foot, arm, leg, trunk and other. The mean affected area was 5.3% of total body surface area (TBSA) (range 0.3-28.8% TBSA).

Effectiveness. Effectiveness was established based on the proportion of responders for repigmentation. Nine of the 25 (36%) RECELL areas had $\geq 80\%$ repigmentation and none of the 25 control areas had $\geq 80\%$ repigmentation. The treatment difference was 36% [95% CI: 13.0%, 55.0%; p=0.012], where the lower bound exceeded the superiority margin of 10%. None of the RECELL or control areas achieved 100% repigmentation. The percentage of repigmentation assessment indicated that 56% of RECELL areas achieved >50% repigmentation versus 12% of control areas.

Safety – Adverse Events. The safety population consists of all 25 subjects. Each subject contributed a matched pair of stable depigmented areas that received one-time RECELL treatment and serve as a control area, respectively. The adverse reactions occurred on RECELL area (RECELL), control area (Control), donor site and non-Study area are summarized in **Table 1**.

Table 1. Adverse Reactions by System Organ Class, Preferred Term and Location, ITT Population

Primary System Organ Class/Preferred Term N=25	RECELL n (%)	Control n (%)	Donor Site n (%)	Non-Study Area n (%)
Any Primary System Organ Class	3 (12%)	1 (4%)	1 (4%)	2 (8%)
Injury, poisoning and procedural complications				
Scar ^a	1 (4%)	0 (0%)	0 (0%)	0 (0%)
Skin and subcutaneous tissue disorders				
Erythema	1 (4%)	0 (0%)	0 (0%)	0 (0%)
Hypertrophic scar	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Koebner phenomenon	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pruritus	2 (8%)	0 (0%)	0 (0%)	0 (0%)
Vitiligo ^b	1 (4%)	1 (4%)	0 (0%)	1 (4%)

a. The scar was reported ongoing at 166 days post-treatment.

b. One subject experienced a moderate AE of worsening of vitiligo and was reported for multiple locations.

C TREATMENT

C1 REQUIREMENTS

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

- Sterile procedure table
- Clean preparation area
- Personal protective equipment
- Skin preparation solution
- Topical or local anesthetic
- Sterile ruler, labels, and marker pen
- Appropriate wound dressings - see “Aftercare” section for details
- Fine-point (long nosed) forceps
- Skin harvesting instrument
- Treatment area resurfacing preparation tool (i.e., FDA-cleared ablative laser)
- Clock or timer to monitor incubation time

C2 RECELL® DEVICE SET-UP










CAUTION: Do not use RECELL or device components beyond the stated expiration date indicated on the adhesive Lot # and Expiration Date labels on the outer box 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 clean work areas. Using standard aseptic technique set up a sterile procedure table.

Open the outer box. Remove the Telfa Clear Dressings and Procedure Guide and place in clean work area. Complete the steps based on the assigned roles in the following table, refer to the Procedure Guide.

CLEAN WORK AREA	STERILE PREPARATION TABLE
TRANSFER PROCESSING UNIT TO STERILE TABLE	
<p>Using aseptic technique, remove the Processing Unit from the sterile packaging and transfer it to the sterile table.</p> 	<p>Open the Processing Unit lid and note the removable inner white plastic tray. This acts as a sterile tray for use in preparing and scraping the skin sample.</p>
PERFORM SELF-TEST	
	<p>Perform the self-test to verify the device is functioning correctly.</p> <ul style="list-style-type: none"> <li data-bbox="638 581 1162 711">  Test the device to ensure functionality by pressing the button marked (?). All lights should illuminate during the self-test. <li data-bbox="638 735 1182 938">  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. <li data-bbox="638 963 1189 1198">  DO NOT press the flashing run button (▶) at this time. Doing so will cause a red warning light and the device will be unusable. Enzyme is required in Well A prior to pressing run. Device will turn off after 1 minute of non-use. <li data-bbox="638 1222 1189 1360">  If lights do not illuminate, or the red light (!) illuminates, this indicates device failure. Do not use the device. Use another device. <ul style="list-style-type: none"> <li data-bbox="638 1385 1095 1440"> • If the device turns off after self-test, additional self-tests may be run.

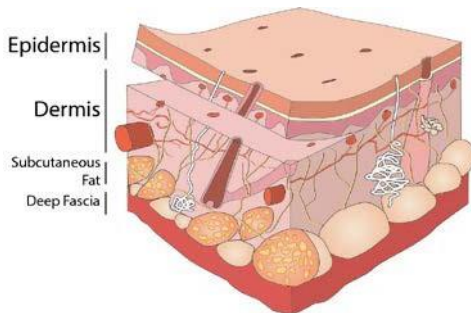
CLEAN WORK AREA	STERILE PREPARATION TABLE
SET A – PREPARE WELL A	
<ul style="list-style-type: none"> • Remove the cover from the Enzyme vial to expose the injection diaphragm. • Connect a sterile needle to a sterile 10 mL syringe and draw up the entire volume of sterile water. • Use syringe to add 10 mL of sterile water to Enzyme. DO NOT USE Buffer at this stage as this may inhibit the Enzyme action. Discard syringe and needle. • Mix gently (DO NOT SHAKE) until dissolved. • Using another 10 mL syringe and needle, draw up the Enzyme solution. • Dispense entire volume of Enzyme into Well A. • Discard the syringe and needle. 	
SET B – PREPARE WELL B	
<ul style="list-style-type: none"> • Remove the cover from one of the Buffer vials. • Connect a sterile needle to a sterile 10 mL syringe and draw up the entire volume of the Buffer from the Buffer vial. • Dispense the entire volume of Buffer into Well B. Discard the syringe and needle. • Place the second 10 mL Buffer Vial in clean area. • Transfer the following items to the sterile draped table. <ul style="list-style-type: none"> - Scalpels - 5 mL syringe - 3 mL or 10 mL syringe - Blunt Needle Refer to Look-up Table 1 to determine the syringe size for use with the second vial of buffer. 	 <ul style="list-style-type: none"> • Label 5 mL syringe UNFILTERED • Label 3 mL or 10 mL syringe BUFFER • Attach blunt needle to BUFFER syringe

CLEAN WORK AREA	STERILE PREPARATION TABLE
SET C – PREPARE DELIVERY ITEMS	
<ul style="list-style-type: none"> • Refer to Look-up Table 2 and Table 3 to determine syringe size of treatment area(s). Choose 1 mL, 3 mL, or 5 mL syringe(s) and transfer to the sterile table. • Transfer a 1 mL syringe (to be used for the donor site) to the sterile table. • Transfer blunt needles and nozzles as required to the sterile table. A spray nozzle may be used when applying at least 2 mL of suspension continuously. 	<ul style="list-style-type: none"> • Label 1 mL syringe as DONOR and attach a blunt needle • Label remaining syringe(s) as TREATMENT and attach either blunt needle or nozzle. <p style="text-align: center;">RECELL Device Set-Up Complete</p>

C3 VITILIGO TREATMENT AREA PREPARATION

- Clean the treatment area with an antiseptic
- Administer local or topical anesthetic without epinephrine per the manufacturers' instructions to the required treatment area(s).
- Using the FDA-cleared ablative laser resurfacing tool (i.e., ablative laser Er:YAG or CO₂), follow the manufacturers' instructions, and ablate the lesion down to the papillary dermis. Use clean sterile gauze to wipe away ablated epidermis completely.
- 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.

C4 DONOR SKIN SAMPLE HARVESTING



Donor Skin Sample Type

It is essential that the donor skin harvested is a thin, split-thickness skin sample that leaves behind pinpoint bleeding. The thickness of the donor 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 dermablade, guarded knife e.g., silvers knife, or similar device is recommended.

Size of Donor Skin Sample – Refer to LOOK UP TABLE 1

Choose the appropriate skin sample size for the application. Each 4 cm² of donor skin can prepare 1mL of cell suspension for treatment of an area up to 20 cm². Use **LOOK-UP TABLE 1** to estimate the donor skin sample size needed to treat the depigmented area(s).

Each RECELL Device can process up to 24 cm² donor skin for a maximum of 6 mL of cell suspension. This can be used to treat an area of approximately up to 456 cm² plus the 24 cm² donor site for a total of 480 cm². Multiple donor skin samples may be taken to make up the total area required. Each skin sample may be as small as 2 cm x 0.5 cm or up to 2 cm x 3 cm. Keep the skin samples moist in sterile gauze moistened with sterile saline prior to use.

Harvesting the donor skin

Take the donor skin from a clean, normally pigmented area that shows no evidence of surrounding cellulitis or infection.

Clean the donor site with antiseptic solution. 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).

Administer local or topical anesthetic per manufacturers' instructions to the donor skin area.

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



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

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.

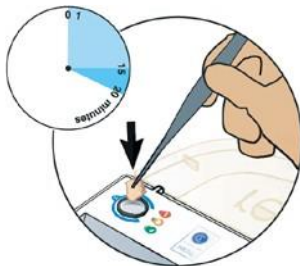
Press the run button (▶) to heat the Enzyme in Well A. If the device is ready, (✓) then heating will commence. If more than one minute has passed since the last self-test, a self-test will automatically run, followed immediately by the heating of Well A. The orange light will illuminate when warming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



C6 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.



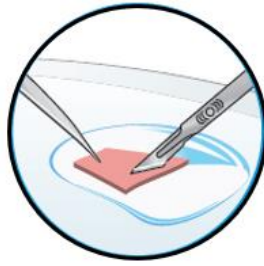
Place skin samples into the heated Enzyme for 15 to 20 minutes to allow the breakdown of protein-protein interactions. DO NOT incubate more than a total of 12 cm² skin at a time. If the skin samples are thick, they may require longer incubation. Each sample may be incubated for up to 60 minutes.

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 remaining incubated sample(s) in Well B. Proceed to *Stage B-Mechanical Processing*.



Skin Sample Requirements greater than 12 cm²?

Following a successful test scrape for the initial 12 cm² donor skin, initiate *Stage A - Enzymatic Processing* by placing the remaining donor skin into Well A, prior to proceeding with *Stage B - Mechanical Processing* for the initial 12 cm² donor skin.

C7 STAGE B- MECHANICAL PROCESSING

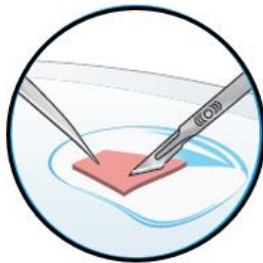
4. Prepare Buffer

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

Refer to LOOK-UP Table 1 (section D4) to determine the volume of buffer required for the size of the donor skin. Ask an assistant in the clean area to hold the buffer vial. Use the “BUFFER” syringe with needle to draw up the required volume of Buffer from the vial. Place the syringe with Buffer back into the sterile preparation table for later use.

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. Replace scalpel as needed.



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 with any remaining skin samples. Using the “UNFILTERED” syringe (an attached needle is not required), 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 $>100\ \mu\text{m}$ and is critical in preventing nozzle blockage when spraying the cellular suspension. Set the “UNFILTERED” syringe aside, on the sterile procedure table, for use with subsequent suspensions from any remaining skin samples.

Complete *Stage B - Mechanical Processing* for any remaining skin samples such that Well C contains the cell suspension resulting from all sample strips.

After all 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. Set the filter on clean portion of the preparation tray.

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” syringe and utilize a new cell strainer from a new RECELL Device.

8. Draw Up Cell Suspension

Refer to **LOOK-UP TABLE 2** and **LOOK-UP Table 3** for treatment site and donor site application volumes. Attach a needle to the TREATMENT syringe. Use the TREATMENT syringe and needle to mix cell suspension in Well C by drawing up the suspension and returning back into Well C. Using the same syringe, draw up the required filtered cell suspension (Do not use “UNFILTERED” syringe) from Well C. There is a conical point in

the center of the bottom of Well C to aid in drawing up the cell suspension. Set the TREATMENT syringe containing the cell suspension aside on the sterile procedure table for later application. Attach a needle to the labeled DONOR syringe, draw up the required volume for the donor site and set the syringe aside on the sterile procedure table for later application.



C8 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 held at the lower aspect of the treatment site(s) prior to applying the cell suspension to reduce runoff. Section D- Aftercare, provides information on dressing selection and use.

10. Apply Cell Suspension to Treatment site(s)

The cell suspension can be applied directly to the Treatment site.

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

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

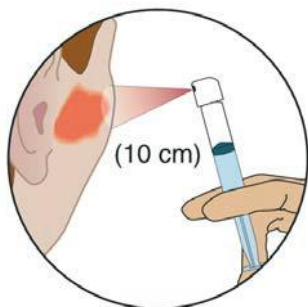
Spray Application – Application of greater than or equal to 2 mL of cell suspension

The spray application technique should only be used when there is greater than or equal to 2 mL of cell suspension in the syringe and will be applied continuously to one lesion.

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 prepared area(s) 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 prepared 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 volume of cell suspension in the syringe is less than 2 mL.

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 treatment site surface so that any run-off helps to cover the more dependent areas.

Note: Following application, it is typical to observe some run-off of the suspension.

11. Place Initial Dressing

After applying the cell suspension, cover the treatment area with a non-adherent, non-absorbent, small pore dressing. Always follow the instructions as set by the dressing manufacturer.

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 is contraindicated for areas treated using RECELL. Additional absorbent gauze for padding, as well as a crepe or compression bandages, may be used. Allow the patient to remain stationary for a minimum of 10 minutes.

C9 Look-up Tables

Look-up Table 1: Total Donor Skin and Buffer Required

VITILIGO TREATMENT AREA MEASUREMENT (cm ²)	TOTAL DONOR SKIN REQUIRED (cm ²)	DONOR SKIN TO PLACE IN WELL A AND REQUIRED BUFFER
4-70	4	4 cm ² requires 1.25 mL
71-104	6	6 cm ² requires 1.75 mL
105-144	8	8 cm ² requires 2.5 mL
145-176	10	10 cm ² requires 3 mL
177-208	12	12 cm ² requires 3.5 mL
*209-256	14	8 cm ² requires 2.5 mL 6 cm ² requires 1.75 mL
*257-288	16	12 cm ² requires 3.5 mL 4 cm ² requires 1.25 mL
*289-336	18	12 cm ² requires 3.5 mL 6 cm ² requires 1.75 mL
*337-368	20	12 cm ² requires 3.5 mL 8 cm ² requires 2.5 mL
*369-416	22	12 cm ² requires 3.5 mL 10 cm ² requires 3 mL
*417-456	24	12 cm ² requires 3.5 mL 12 cm ² requires 3.5 mL

*Do not incubate more than 12 cm² of skin in Well A at a time

Look-Up Table 2: Cell Suspension Volumes for Drip Application to Treatment Area(s) and Donor Site

TREATMENT AREA MEASUREMENT (cm²)	VOLUME TO APPLY TO TREATMENT AREA (mL)	VOLUME TO APPLY TO DONOR SITE (mL)
4	0.06	0.06
5	0.07	0.06
6	0.08	0.06
7-8	0.10	0.06
9-11	0.14	0.06
12-14	0.18	0.06
15-17	0.22	0.06
18-20	0.26	0.06
21-24	0.30	0.06
25-27	0.34	0.06
28-32	0.40	0.06
33-36	0.46	0.06
37-41	0.52	0.06
42-48	0.60	0.06
49-54	0.68	0.06
55-62	0.78	0.06
63-70	0.88	0.06
71-80	1.00	0.08
81-96	1.20	0.08
97-104	1.40	0.08
105-128	1.60	0.10
129-144	1.80	0.10

Look-Up Table 3: Cell Suspension Volumes for Spray or Drip Application to Treatment Area(s) and Drip Application to the Donor Site

TREATMENT AREA MEASUREMENT (cm ²)	VOLUME TO APPLY TO TREATMENT AREA (mL)	VOLUME TO APPLY TO DONOR SITE (mL)
145-176	2.2	0.14
177-190	2.4	0.16
191-208	2.6	0.16
209-240	3.0	0.18
241-256	3.2	0.18
257-288	3.6	0.20
289-304	3.8	0.24
305-336	4.2	0.24
337-368	4.6	0.26
369-384	4.8	0.28
385-416	5.2	0.28
417-456	5.6	0.30

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

After RECELL treatment, areas are to be covered with a non-adherent, low-absorbent, small pore dressing (e.g., Telfa™ Clear wound dressing by Covidien). Secondary dressings of petrolatum gauze, or similar, are placed over the primary dressing. Additional padding of dry gauze and a crepe bandage may be used.

D2 AFTERCARE PRECAUTIONS

- Take necessary precautions to prevent the dressing from getting wet.
- Do not disrupt the primary dressing for a minimum of 5 days. Ensure that primary dressing removal is atraumatic.
- Ensure any dressing that is not easily removed be soaked in aqueous or oil-based solutions to prevent trauma upon removal. Do not forcibly remove the primary dressing.
- Protect the RECELL areas as appropriate for a minimum of one week after healing, using dry gauze and/or elastic bandaging (e.g., ACE™).
- Educate that treatment sites may be relatively fragile and require approximately one week (following healing) to mature. During this time protective dressings must be worn.
- Manage infection or impaired healing.
- Protect the RECELL areas from trauma and avoid vigorous cleaning or excessive application of topical creams after healing.
- Practice scar precautions.

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

E2 INTENDED USE ENVIRONMENT

RECELL is intended for use in a healthcare facility. 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 ± 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 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 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 the 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: customerservice@avitamedical.com

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