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.

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.

ADVERSE REACTIONS

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

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

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 cm^2.

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

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.

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.

- 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 CO_2) 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 [redacted] 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); [redacted] of subjects were Caucasian, [redacted] were Asian, and [redacted] 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 had non-segmental vitiligo, including generalized vitiligo and focal vitiligo. Twenty-four percent of subjects had segmental vitiligo. The median size of RECELL and the control areas were 22 cm^2 (ranged 2 to 360 cm^2) and 24 cm^2(ranged 2 to 375 cm^2), respectively, and the depigmented areas were located at head, neck, dorsal hand, dorsal foot, arm, leg, trunk and other. The mean affected area of total body surface area (TBSA) (range 0.3- TBSA).

Effectiveness. Effectiveness was established based on the proportion of responders for repigmentation. N and none of the 25 control areas had . The treatment difference was , where the lower bound exceeded the superiority . E
The percentage of repigmentation assessment indicated that of RECELL areas achieved > n versus 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**.