INSTRUCTIONS FOR USE

RECELL® 320 cm^2
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.

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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 wound bed.

The cell suspension contains a mixed population of cells, including epidermal stem cells (progenitor cells), keratinocytes, fibroblasts, Langerhans cells, 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, proliferating keratinocytes, and activated keratinocytes.

The Enzyme, derived from animal tissue, used to process the cells is a biological agent and as such may have slight variations in color and texture.

A2 INTENDED PURPOSE

RECELL is intended to be used to disaggregate cells from a patient's split-thickness skin sample and to collect these cells for autologous application to a prepared wound bed.

A3 INDICATIONS FOR USE

The cells can be used for autologous application to the prepared wound bed as determined by the physician for a variety of indications such as:

- Burns, or other acute wounds
- Scars
- Chronic wounds or other dermal defects.

A4 INTENDED USERS

Healthcare Professionals

A5 PATIENT TARGET GROUP

Patients of any age group weighing 3.5kg and above with need for autologous skin cell suspension application for Burns, or other acute wounds; Scars; Chronic wounds or other dermal defects.

A6 CONTRAINDICATIONS

- RECELL is contraindicated for patients with wounds that are clinically infected or necrotic.
- RECELL should not be used to prepare Spray-On Skin Cells for application to patients with a known hypersensitivity to trypsin or compound sodium lactate 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.

A7 WARNINGS

- The Spray-On Skin Cells produced with RECELL should only be applied to the patient from whom the original skin sample was taken (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.
- 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.
- RECELL components should be handled using aseptic technique.
- If a skin sample is harvested and processed according to these instructions, it should only require between 15 and 30 minutes of contact with the Enzyme. Contact in excess of 60 minutes is not recommended.
- Contaminated materials and waste must be disposed of using appropriate biohazard waste receptacles.
- The separation 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.
- RECELL 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.

A8 PRECAUTIONS

- Protective eyewear and other protective clothing should be worn.
- For optimum cell viability, the skin sample should be processed immediately after harvesting.
- The RECELL device is for single use only. Do not reuse, freeze, or re-sterilize any items within the device.
- Do not use the device if there is evidence of container tampering or damage.

A9 ADVERSE REACTIONS AND SERIOUS INCIDENTS

Any adverse reaction or suspected adverse reaction related to RECELL should immediately be reported to AVITA Medical, and any serious incident that has occurred in relation to the device should be reported to AVITA Medical and the competent authority of the Member State in which the user and/or patient is established.

A10 CLINICAL BENEFITS

RECELL is used at a patient's point-of-care to prepare an autologous Spray-On Skin Cells suspension using minimal donor skin. Application of the cellular suspension promotes definitive closure and restoration of natural pigmentation in cutaneous wounds and defects.

A11 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The summary of safety and clinical performance will be available in the European database on medical devices (EUDAMED) public website: https://ec.europa.eu/tools/eudamed

A12 DOSAGE

RECELL is supplied as a single use device. The contents of each device are sufficient to prepare up to 4 ml of Spray-On Skin Cells which can be used to cover an acute wound area of up to and including 320 cm^2.

A13 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
- 1 x 10-ml vial of Buffer
- 2 x sharp needles
- 2 x blunt drawing-up needles
- 3 x 5-ml syringes
- 2 x 10-ml syringes
- 1 x disposable surgical scalpel
- 2 x spray nozzles

A14 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 scalpel 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.

A15 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 local 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 RECELL Enzyme, must be stored at a temperature range between 20°C – 25°C.

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

A16 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.
- RECELL contains batteries and electrical components – DO NOT INCINERATE
- The 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 RECELL TREATMENT

B1 REQUIREMENTS

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

- 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

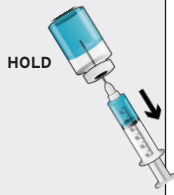
B2 RECELL DEVICE SET-UP

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 self-test to verify the processing unit is functioning correctly. 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.  Test the device to ensure functionality by pressing the button marked (?). All lights should illuminate during the self-test.  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.  DO NOT press the flashing run button (►) at this time.  If lights do not illuminate, or the red light (!) illuminates, this indicates device failure. Do not use the device. Use another device. • The unit will automatically turn off after 1 minute if Enzyme heating is not initiated. • 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. • Connect a sharp sterile needle to a sterile 10-ml syringe and draw up the entire volume of sterile water. • 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. • Mix gently until dissolved. Do not shake; use care to avoid foaming. Draw the Enzyme back into the syringe. • Using aseptic technique, dispense the entire volume of Enzyme into the left-hand well of the processing unit (Well A). Discard syringe and needle.  **DRAW UP**	 **DISPENSE**

NON-STERILE PREPARATION AREA	STERILE AREA
SET B – PREPARE BUFFER	
The one (1) Buffer vial is to remain in the non-sterile preparation area. Using aseptic technique introduce the following items into the sterile field. • 1 x 10-ml syringes • 1 x sharp needle	
	• Mark the new 10-ml syringe "BUFFER". Set aside within the sterile field.
• Remove the cover from the Buffer vial. 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. **HOLD** 	• Draw up the entire volume of Buffer (approximately 10 ml) from the vial being held by the person in the non-sterile area. **DRAW UP** • Dispense the entire volume of Buffer into Well B of the processing unit . **DISPENSE** 

NON-STERILE PREPARATION AREA	STERILE AREA
SET C – PREPARE DELIVERY ITEMS	
Introduce all Delivery Set items into the sterile field. • 3 x 5-ml syringes • 2 x blunt drawing-up needles • 2 x spray nozzles • 1 x disposable surgical scalpel	RECELL Device Set-Up Complete

B3 WOUND BED PREPARATION

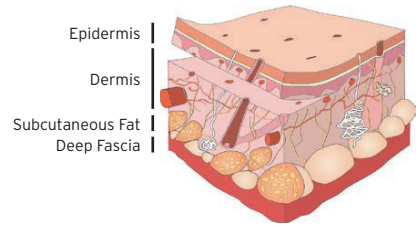
- Clean, vascularized wound bed – To optimise the treatment, the Spray-On Skin Cells should only be applied to a clean, vascularised wound bed with no remaining necrotic tissue. This can be achieved with either dermabrasion using a rotating diamond-head burr, laser ablation, sharp dissection, or other alternative techniques depending on the nature of the wound.
- Infection free – The Spray-On Skin Cells 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. This may be accomplished via several methods, e.g., ablative laser, fractional laser, or mechanical abrasion. As much viable dermis as possible should be preserved. If tissue damage is present (e.g., burns) accurate debridement to the level of viable tissue is essential; all necrotic tissue must be removed.
- When RECELL is used for treatment of acute, full-thickness wounds, combination with split-thickness skin graft and/or dermal replacement technology is recommended.

B4 STEP-BY-STEP INSTRUCTIONS FOR PREPARING THE SPRAY-ON SKIN CELLS

1. Take Skin Sample

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 0.15 – 0.20 mm (0.006 – 0.008 in). The use of a dermatome, or similar device is recommended



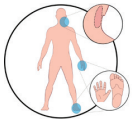
Size of Skin Sample

Choose the appropriate skin sample size for the application. Each square centimeter of skin sample area can create up to 1 ml of Spray-On Skin Cells for treatment of an area of up to 80 cm^2. Each RECELL device can process a maximum skin sample of 2 cm by 2 cm and yield a maximum of 4 ml of Spray-On Skin Cells. This will treat an area of approximately 320 cm^2. Sample guidance for skin sample size is shown in the table below.

Treatment Area (including donor site)	Skin Sample Size
Up to 80 cm^2	1 cm x 1 cm (1 cm^2)
Up to 320 cm^2	2 cm x 2 cm (4 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.



Harvesting the Skin Sample

Using the preferred instrument such as a dermatome, take a maximum 2 cm by 2 cm, 0.15 to 0.20 mm (0.006 to 0.008 in) split-thickness shave biopsy of the donor site.

The following settings are recommended for obtaining a skin sample of the proper thickness using a Zimmer dermatome.

	Children	Adult
Blade guard (width)	2.5 cm	4.5 cm
Dermatome Setting	6	8

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

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

The donor site area may be lubricated, for instance with sterile mineral oil, to ease travel of the dermatome.

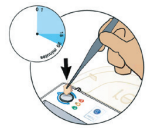
Due to the thick keratin layer found on glabrous skin, it is necessary to take two shaves over the same site in these areas. Discard the first sample and process the second skin sample to create the cell suspension.

2. 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.

3. 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 the skin sample into the heated Enzyme for 15 to 20 minutes to allow extra-cellular matrix breakdown. If the skin sample is thick, it may require longer incubation. Each sample may be incubated for up to 60 minutes.

4. Draw up Buffer

This step may be performed whilst the skin sample is incubating.

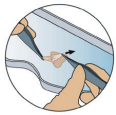
Determine the final Spray-On Skin Cells volume required for the wound to be treated. Use one milliliter of Buffer per square centimeter of the skin sample and add 0.5 ml Buffer to allow for loss during processing. Draw up the required volume of Buffer from Well B into a new 5-ml syringe with drawing-up needle. The following table provides the surface areas that can be treated with RECELL when used alone on acute partial-thickness wounds and the volumes of Buffer to use.

Place the syringe in the sterile field for use in steps 7 and 8, below.

Surface Area to be Treated per Syringe	Skin Sample Size Needed	Starting Volume of Buffer	Approximate Resultant Spray-On Skin Cells 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 (1 cm x 2 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

RECELL Spray-On Skin Cells may be used alone or in combination with meshed, split-thickness grafts, or dermal substitutes. Each 1 ml of Spray-On Skin Cells may be used to treat of up to 80 square centimeters when used on acute partial-thickness wounds.

5. Test Scrape for Cell Disaggregation



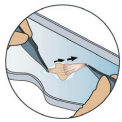
After 15 to 20 minutes, remove the skin sample from the heated Enzyme with sterile forceps and place the skin sample dermal side down on the sterile tray. Gently scrape the epidermis edge with the scalpel to test if cells disaggregate, i.e., epidermal cells easily come off. Once the test is complete 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.

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.

6. 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. Return the skin sample to the sterile tray.

7. Scrape Cells from the Skin Sample



With the skin sample dermal side down on the sterile tray, apply a few drops of buffer from the previously filled 5-ml syringe onto the skin sample. Using the forceps to anchor the skin sample, gently scrape the epidermal surface with the blade of the scalpel and collect in the pool of buffer. Once the epidermis has been scraped away, scrape the remaining dermis more rigorously. Continue scraping until the dermis has nearly disintegrated.

8. Rinse and Aspirate; Draw up cell unfiltered suspension

Use the remaining Buffer in the 5-ml syringe to rinse the scalpel and tray, collecting the unfiltered suspension into one corner of the tray. Tilt the tray as necessary. Using the same 5-ml syringe and blunt needle, draw the unfiltered suspension into the syringe. Using the drawn-up suspension, rinse the tray. Draw up and rinse several times to maximize cell collection. Finally, draw the unfiltered suspension into the syringe.

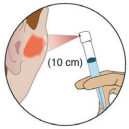
9. Filter Cells

Dispense the unfiltered suspension into the cell strainer in Well C.

10. Draw up Spray-On Skin Cells

Prepare a new sterile 5-ml syringe and blunt drawing-up needle. Carefully remove the cell strainer, tapping the cell strainer over the well to release any residual drops of Spray-On Skin Cells. Draw up the filtered Spray-On Skin Cells 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 Spray-On Skin Cells.

11. Apply Spray-On Skin Cells to Wound Bed



Prior to applying the Spray-On Skin Cells, ensure the dressings are cut and prepared for immediate application. The primary dressing should be fixed or held at the lower aspect of the wound prior to applying the Spray-On Skin Cells. Section C, Aftercare, provides information on dressing selection and use.

The Spray-On Skin Cells can be sprayed using the spray nozzles provided, dripped onto the wound, or introduced under the primary dressing using a blunt drawing-up needle, the details are as follow:

Spray Application

Remove the needle from the syringe containing the Spray-On Skin Cells. Attach the spray nozzle supplied to the syringe using firm pressure. Invert the syringe several times prior to the application to ensure an even suspension. 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 Spray-On Skin Cells 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 Spray-On Skin Cells 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

Do not remove the blunt needle from the syringe containing the Spray-On Skin Cells. Invert the syringe several times prior to application to ensure an even suspension. Starting at the most elevated point of the wound, carefully drip the Spray-On Skin Cells onto the wound surface.

Application under Primary Dressing

If introducing the Spray-On Skin Cells under a dressing do not remove the blunt needle from the syringe containing the Spray-On Skin Cells. Invert the syringe several times prior to application to ensure an even suspension. Place the cut dressing over the wound and gently introduce the needle under the dressing and introduce the Spray-On Skin Cells. Larger wounds may require introducing the needle and Spray-On Skin Cells at several points to ensure complete coverage.

Note: The fibrin in the prepared wound bed provides an ideal environment to cell adhesion. Many, but not all, of the delivered cells will adhere to the wound. It is normal for some of the Spray-On Skin Cells to run off the wound. A well-prepared suspension has enough cells to treat the wound, allowing for run off.

The choice of application method depends on the volume of Spray-On Skin Cells and the size and location of the wound(s) (refer to table below). Some Spray-On Skin Cells may be reserved for application to the donor site.

Spray-On Skin Cells Volume	Surface Area to be Treated	Example Wound Site	Recommended Application Method
1.0 ml	Up to 80 cm^2	Palms	Drip or beneath dressing
2.0 ml	Up to 160 cm^2	Face, Neck	Spray or Drip
4.0 ml	Up to 320 cm^2	Trunk, Extremities	Spray

The minimum volume of Spray-On Skin Cells required for spray application is approximately 2 ml.

Note: A spare 5-ml syringe and nozzle are provided.

12. Place Initial Dressing

After applying the cell suspension, cover the wound with a primary dressing (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.

C AFTERCARE

The following information, precautions, and notes provide guidelines for care after RECELL. Discuss appropriate aftercare with your AVITA representative and provide patient with the "After RECELL" guidance brochure.

C1 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 TO PREVENT TRAUMA.

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 (for instance) a 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.

C2 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 6-8 days. Ensure that primary dressing removal is atraumatic - Do not forcibly remove the primary dressing.
- Patients should be advised to avoid trauma to the wound and dressing, including off-loading as appropriate. Up to two additional weeks may be needed after initial closure of the treated area for the newly regenerated skin 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 for at least four weeks following treatment

C3 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 block 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.

D SYSTEM SPECIFICATIONS

D1 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

D2 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.

D3 ESSENTIAL PERFORMANCE

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

E TROUBLESHOOTING

Enzyme powder does not dissolve completely

Make sure that the Enzyme is mixed well with the sterile water by 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 (0.15 to 0.20 mm) split-thickness shave biopsy with just a very thin section of dermis (see previous instructions for dermatome settings). 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 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 is mistakenly added to the Enzyme vial, instead of sterile water, 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 warming 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 Spray-On Skin Cells is not easily sprayed or does not come out at all, the nozzle attached to the syringe may be blocked. Use one of the other nozzles provided or consider dripping the suspension on to the wound.

Insufficient treatment area coverage

If Spray-On Skin Cells 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 Spray-On Skin Cells and complete the treatment.

F APPLICABLE SYMBOLS

The symbols below and harmonized symbols may be found on the product or product label:

Symbol	Description	Symbol	Description
	Consult instructions for use or consult electronic instructions for use		Refer to instruction manual/ booklet
	Manufacturer		Do not use if package is damaged and consult the instructions for use
	Date of manufacture		Use-by Date (i.e., Expiration Date)
	Do not re-sterilize		Do not re-use
	Sterile		Sterilized using irradiation
	Sterilized using ethylene oxide		Sterilized using steam or dry heat
	Single sterile barrier system with protective packaging outside		Caution
	Temperature limit (Operating/ Storage/ Transport)		Contains biological material of animal origin
	Serial Number		Unique device identifier
	Batch Code/ Lot Number		Catalogue number
	Medical device		Importer
	Authorized representative in the European Union		Authorized representative in Switzerland
	European Mark of Conformity		Prescription only

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For further information regarding RECELL Autologous Cell Harvesting Device, contact your local sales representative:

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