Instructions For Use

RECELL® Autologous Cell Harvesting Device

RECELL should be used only by licensed health care professionals trained in the use of RECELL

CE 1639

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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 anaesthetic mixtures. Do not incinerate 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.

A BACKGROUND

A1 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 thin split-thickness skin samples to be processed to produce a cell population for immediate delivery onto a prepared wound surface.

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

The RECELL Enzyme used to process the cells is a biological agent and as such may have slight variations in colour and texture.

A2 INTENDED USE / INDICATIONS

RECELL is intended to be used to disaggregate cells from split-thickness skin samples and to collect these cells for reintroduction to the patient. These cells can be used as determined by a physician for:

- Treatment of partial-thickness tissue defects, including burns
- Reconstruction of scars to improve surface colour and texture
- Reconstructive surgery for epidermal defect (e.g., hypo-pigmentation, stable vitiligo)

A3 CONTRAINDICATIONS

- RECELL is contraindicated for patients with wounds that are clinically infected or necrotic.
- RECELL should not be used to prepare cell suspensions 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 anaesthetics, adrenaline/epinephrine, povidine-iodine, or chlorhexidine solutions.
- RECELL is contraindicated for any patient who has unstable vitiligo.

A4 WARNINGS

- Cell suspension 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-sterilise 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 RECELL 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 RECELL 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. The device should not be used in the presence of flammable materials and must not be incinerated on disposal.

A5 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-sterilise any items within the device.
- Do not use the device if there is evidence of container tampering or damage.
- To optimize treatment, the suspension should be applied to a clean, dry, haemostatic, vascularized wound bed.

A6 ADVERSE REACTIONS

Any adverse reaction or suspected adverse reaction related to RECELL should immediately be reported to Avita Medical.

A7 MEANING OF SYMBOLS

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

This symbol states that the product is for single use only

This symbol states that the user should refer to the accompanying instructions for use

This symbol states that the date adjacent is the date of manufacture

This symbol states that the date adjacent is the expiry date of the product

This symbol states the manufacturer of the product

This symbol states that the temperature adjacent specifies the upper limit of storage temperature

This symbol states that the product or components within have been sterilised using ethylene oxide

This symbol states that the product or components within have been sterilised using gamma irradiation

This symbol states that the product or components within have been sterilised using steam

A8 DOSAGE

RECELL is supplied as a single use device. The contents of each kit are sufficient to prepare a cell suspension to cover a wound area up to and including 320 cm^2.

A9 HOW SUPPLIED

The RECELL Device consists of:

- 1 x RECELL processing unit (RPU) with built-in heating mechanism.
  - 1 x removable sterile tray
  - 1 x removable cell strainer
- 2 x spray nozzles
- 1 x sealed vial of RECELL 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

Component sterilisation and testing

- The RECELL processing unit and needles have been sterilised by ethylene oxide.
- The RECELL Enzyme has undergone filtration and terminal sterilisation by gamma irradiation.
- The scalpel and spray nozzles have been sterilised by gamma irradiation.
- The syringes have been sterilised by either ethylene oxide or gamma irradiation.
- The Buffer and sterile water have been sterilised using steam.

A10 STORAGE

Upon receiving RECELL, examine the packaging for external signs of damage. If the external kit packaging or the packaging for any of the individual components appears damaged, contact your local sales 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. Testing indicates that the RECELL Enzyme remains active for at least 21 months at this temperature. The RECELL Enzyme is labelled with an expiry date of 21 months after sterilisation.

Do not open or use RECELL or components if outside of 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.
- RECELL contains batteries and electrical components – DO NOT INCINERATE
- A procedure for removal of RECELL processing unit Battery/ Electronics is as follows:
  - Take proper Biohazard precautions when handling the used RECELL 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 MATERIALS

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

- Surgical gloves and a suitable sterile drape
- Protective eyewear and garments
- Skin preparation solution
- Local anaesthetic with adrenaline where not contraindicated
- Appropriate wound dressings. See "Aftercare" below for details
- 1 or 2 x fine-point (long nosed) forceps of choice
- Skin harvesting instrument of choice, e.g., Zimmer® Dermatome (Zimmer Orthopedic Surgical Products, Inc., USA), Silver's knife, Humby knife, Dermablade® (Personna® American Safety Razor Co, USA)
- Wound bed preparation tool of choice

B2 RECELL KIT SET UP

Select and prepare sterile and non-sterile work areas. Note that the RECELL kit contains both sterile and non-sterile components.

Ensure that the batch number of the RECELL Enzyme used matches the RECELL Enzyme batch number listed on the RECELL kit outer packaging and is within the expiration date.

Using standard aseptic technique, set up a sterile surgical field.

- Remove the RECELL processing unit from the sterile packaging and place it in the sterile field.
- Open the processing unit 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. If lights do not illuminate, or the red light (!) illuminates, do not use the device. The unit will automatically turn off after 1 minute if RECELL Enzyme heating is not initiated.
- If the device turns off after self-test, additional self-tests may be run.
- Do not press the run button (▶) at this time.

A – PREPARE RECELL ENZYME (COMPONENT SET A)

- In the non-sterile work area, remove the cover from the vial marked RECELL Enzyme to expose the injection diaphragm. Wipe the diaphragm with a sterile alcohol wipe and allow to dry (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 RECELL Enzyme vial. DO NOT USE Buffer at this stage as this may inhibit the RECELL Enzyme action.
- Mix gently until dissolved. Do not shake and use care to avoid foaming. Draw the RECELL Enzyme back into the syringe.
- Using aseptic technique, dispense the entire volume of RECELL Enzyme into the left-hand well of the processing unit (Well A).

B – PREPARE BUFFER (COMPONENT SET B)

- Remove the cover from the vial marked Buffer. Wipe the diaphragm of the vial with a sterile alcohol wipe and allow it to dry (optional).
- Attach a sharp, sterile needle to a new sterile 10-ml syringe and draw up the entire volume of Buffer (approximately 10 ml).
- Dispense the entire volume of Buffer into the empty centre well of the processing unit (Well B).

C – OPEN REMAINING ITEMS (COMPONENT SET C)

Introduce the remaining items into the sterile field.

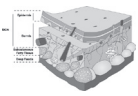
- 2 x spray nozzles
- 2 x blunt drawing-up needles
- 3 x 5-ml syringes
- 1 x disposable surgical scalpel

B3 WOUND BED PREPARATION

- Clean, vascularized wound bed – To optimise the treatment, the RECELL cell suspension 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 RECELL-derived cell suspension must not be used in the presence of any contamination or infection, as initial re-epithelialisation 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 dermis is exposed and 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.

B4 STEP-BY-STEP INSTRUCTIONS FOR PREPARING THE RECELL CELL SUSPENSION

1. Take Skin Sample



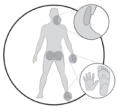
Skin Sample Type

It is essential that the skin sample harvested is a thin, split-thickness skin sample that penetrates to the dermis and 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 to 0.20 mm (0.006 to 0.008 in). The use of a dermatome, Silver's knife, Humby knife or DermaBlade® is recommended.

Size of Skin Sample

Choose the appropriate skin sample size for the application. Each RECELL kit can process a maximum skin sample of 2 cm by 2 cm and yield a maximum of 4 ml of cell suspension. This will treat an area of approximately 320 cm^2 for an acute partial-thickness wound bed. Guidance for skin sample size is as follows:

Treatment Area	Skin Sample Size
up to 80 cm^2	1 cm x 1 cm
up to 320 cm^2	2 cm x 2 cm



Choice of Donor Site

The selection of the donor site is important for promotion of the same functional and cosmetic characteristics as the surrounding tissue. Site-specific characteristics may include keratinocyte layers in glabrous tissues (soles of the feet and palms of the hands), and melanocyte distribution.

It is essential the donor site is clean, of appropriate depth, and shows no evidence of surrounding cellulitis or infection.

Harvesting the Skin Sample

Using the preferred instrument such as a dermatome, Silver's knife, or Humby knife, 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. Please note the following recommended settings for obtaining a skin sample using a Zimmer dermatome.

	Children	Adult
Blade	2.5 cm	4.5 cm
Dermatome Setting	6	8

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 anaesthesia for taking the skin sample. Ensure that anaesthetic is not injected intradermally.

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

The donor site may be treated similarly to the primary wound. Once haemostasis has been achieved, a small amount of cell suspension may be applied to the donor site wound, and dressed as described in the Aftercare section below.

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

2. Heat RECELL Enzyme

Verify that the RECELL Enzyme has been transferred to Well A. The device will quickly overheat if the run button (▶) is pressed before the RECELL 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 kit and contact your local representative to arrange the return or replacement of the unit.

Press the run button (▶) to heat the RECELL 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 RECELL Enzyme will be heated and maintained at the optimum temperature (approximately 37 °C).

3. Incubate the Skin Sample

When the orange warming light turns off and the green (✔) illuminates, after approximately three minutes, the RECELL Enzyme has reached optimum temperature. Place the skin sample into the heated RECELL Enzyme for 15 to 20 minutes to allow cell disaggregation. If the skin sample is thick, it may be incubated for up to 60 minutes. The orange light will flash from time to time, indicating that the heating element has been activated to maintain temperature.

4. Draw up Buffer

This step may be performed whilst the skin sample is incubating. Determine the final suspension volume required for the wound to be treated. RECELL may be used alone or in combination with meshed, split-thickness grafts. 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.

Surface Area to be Treated	Required Volume of Buffer	Approximate Resultant Suspension Volume
Up to 80 cm^2	1.5 ml	1.0 ml
Up to 160 cm^2	2.5 ml	2.0 ml
Up to 320 cm^2	4.5 ml	4.0 ml

Draw up the required volume of Buffer from Well B into a new 5-ml syringe with drawing-up needle and place the syringe in the sterile field for use in steps 7 and 8, below.

5. Test for Cell Disaggregation

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

After approximately 60 minutes, an alarm will sound. Incubation of the skin sample for more than 60 minutes is not recommended.

6. Rinse Skin Sample

Upon a successful test scrape, briefly rinse the skin sample in the middle well (Well B) containing the Buffer to rinse off and deactivate the residual RECELL 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. Once the epidermis has been scraped away into suspension, scrape the remaining dermis more rigorously. Continue scraping until the dermis has nearly disintegrated.

8. Rinse and Aspirate; Draw up cell suspension

Use the remaining Buffer in the 5-ml syringe to rinse the scalpel and tray, collecting the cells into one corner of the tray. Using the same 5-ml syringe and blunt needle, draw the cell 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 cell suspension into the syringe.

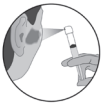
9. Filter Cells

Dispense the cell suspension through the cell strainer in Well C.

10. Draw up Cell Suspension

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 cell suspension. Draw up the filtered cell suspension from Well C. There is a conical point in the centre of the bottom of Well C to aid in drawing up all of the cell suspension.

11. Apply ReCell Suspension to Wound Bed



Prior to applying the cell suspension, 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 cell suspension.

The cell suspension can be sprayed using the spray nozzles provided, or dripped onto the wound or introduced under the primary dressing using a blunt drawing-up needle. Before proceeding to the cell application step, ensure that the prepared primary dressing is ready for immediate application.

The choice of application method depends on the volume of cell suspension and the size and location of the wound (refer to table below). Some cell suspension may be reserved for application to the donor site.

Suspension 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 cell suspension required for spray application is approximately 2 ml.

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

Spray Application

Remove the needle from the 5-ml syringe containing the cell suspension. 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 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

Do not remove the blunt needle from the 5-ml syringe of cell suspension. 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 cells onto the wound surface.

Application under Primary Dressing

If introducing the cell suspension under a dressing do not remove the blunt needle from the 5-ml syringe. 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 cell suspension. Larger wounds may require introducing the needle and suspension 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 cell suspension to run off the wound with Buffer. A well-prepared suspension has enough cells to treat the wound, allowing for run off.

C AFTERCARE

The following information, precautions, and notes provide guidelines for care after RECELL. Discuss appropriate aftercare with your Avita representative.

C1 INITIAL DRESSING

After applying the RECELL cell suspension, cover the wound with a non-adherent, non-absorbent, small pore dressing such as Surfasoft® (Mediprof, Holland) wound dressing or similar. Always follow the instructions as set by the dressing manufacturer. The dressing may be fixed to the wound with surgical glue, sutures, or staples, as necessary.

Place a secondary dressing (moderately absorbent, minimal adherence, low shear, readily removable) over the primary dressing. An example is Jelonet® paraffin gauze dressing (Smith & Nephew, UK), placed over the primary dressing with a moist saline or Povidine-Iodine compress, and followed by Webril™ (Covidien, USA) and a crepe bandage. An alternative is to place a haemostatic calcium alginate dressing such as Algisite M® (Smith & Nephew, UK) over the primary dressing and secure with an adhesive retention dressing such as Fixomull® (Smith & Nephew, UK) or gauze and crepe bandage.

C2 SUBSEQUENT DRESSINGS

Dressings may be debulked after 48 hours to facilitate review of the wound. The primary dressing should remain in place for 5 days, or as clinically indicated. IT IS ESSENTIAL THAT PRIMARY DRESSING REMOVAL IS ATRAUMATIC. 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 such as Jelonet® (Smith & Nephew, UK) or Mepitel® (Mölnlycke, Sweden) should be applied to protect the wound surface.

Do not use dry dressings as protection over an area of punctate blistering, as dried exudate could cause newly regenerated skin 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.

C3 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.
- 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 RECELL-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.

C4 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 for at least four weeks. 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 TROUBLESHOOTING

RECELL Enzyme Powder Does Not Dissolve Completely

Make sure that the RECELL 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 RECELL Enzyme.

Do not use Buffer to dissolve the RECELL Enzyme as it may interfere with the RECELL 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 MUST be of the appropriate thickness to ensure successful disaggregation of cells. The maximum size of skin sample recommended for use with the ReCell device is 2 cm by 2 cm.

If the skin sample is too large (greater that 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 RECELL Enzyme. If the cells cannot be disaggregated, repeatedly return the skin sample to the heated RECELL 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 kit.

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 RECELL Enzyme vial, instead of sterile water, the RECELL Enzyme activity may be inhibited. If Buffer is mixed with the RECELL Enzyme powder, the RECELL 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 or does not come out at all, the nozzle attached to the syringe may be blocked. Use the spare nozzle provided.

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 your local sales representative at:

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