RECELL® Autologous Cell Harvesting Device

Procedure Guide

RECELL® By AVITA Medical

CONSIDERATIONS

Requirements

- Sterile field
- Surgical gloves and suitable sterile drape
- Non-sterile preparation area
- Personal protective equipment
- Skin preparation solution
- Skin harvesting instrument e.g. dermatome or guarded knife
- Wound bed preparation instrument
- Fine-point (long nosed) forceps
- Appropriate anesthesia
- A clock or timer
- Sterile ruler and marker pen
- Suitable dressings

Patient selection

- Stable condition
- No history of hypersensitivity to trypsin or compound sodium lactate solution

Wound bed characteristics

- Clean wound
- No necrotic tissue
- No wound infection
- Pinpoint bleeding
- Well-vascularized

DEVICE SET-UP

NON-STERILE PREPARATION AREA

Transfer Processing Unit to Sterile Field

STERILE PREPARATION AREA

Perform Self Test

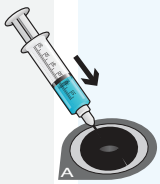
- Press (?) button. Wait 30 seconds. All lights will illuminate
- Ready (√) light = Self-test successful
- (!) or no lights = Device failure. Use another device

DO NOT press the flashing run button at this stage.
Device will turn off after 1 minute of non-use

Set A–Prepare Enzyme

- Use syringe to add 10 ml of sterile water to Enzyme (DO NOT USE Buffer)
- Mix gently (DO NOT SHAKE)
- Dispense entire volume of Enzyme into Well A
- Discard syringe and needle

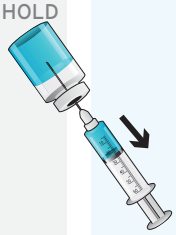
Dispense



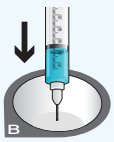
Set B–Prepare Buffer

- Place Buffer vials in non-sterie preparation area
- Open remaining Buffer Solution Set components and introduce into sterile field:
  - 10-ml syringes (x2)
  - Scalpel
  - Blunt fill needle

HOLD



DRAW UP



- Make one of the syringes "BUFFER" and the other syringe "UNFILTERED SUSPENSION" (Use only for intended purpose and keep sterile)
  Note: labeled syringes will be used multiple times during the process
- Attach needle to "BUFFER" syringe
- Draw up entire volume (10 ml) of Buffer from vial
- Dispense solution into Well B

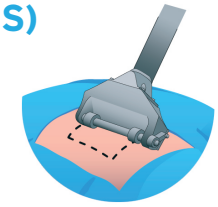
Set C–Prepare Delivery Items

- Open Delivery Set items into sterile field:
  - Spray nozzle (x4)
  - Blunt fill needles (x4)
  - 10-ml syringes (x4)

RECELL Device Set-Up Complete

HARVEST SKIN SAMPLE(S)

- Harvest thin, split-thickness donor skin sample(s)
- Depth 0.006-0.008 in (0.15-0.20 mm)



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

Step-By-Step Instructions

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HEAT ENZYME

Check Enzyme is in Well A

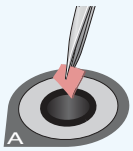
Press run button to heat Enzyme

A self-test will be automatically run when more than one minute has passed since the last self-test

= Warming (approx. 3 min.)

= Target temperature reached

STAGE A– ENZYMATIC PROCESSING



1. Incubate Skin Sample(s)

- When target temperature is reached, place 1 or 2 skin samples in Well A for 15-20 minutes
- DO NOT incubate more than 2 6 cm^2 of skin sample at a time

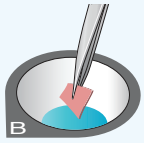
May complete Step 4. Prepare Buffer while skin is incubating

2. Test Scrape

- Remove one skin sample from Well A and place on tray dermal side down
- Use scalpel to gently scrape edge of skin sample to test if cells separate easily
- Once test is complete STOP scraping

Unsuccessful? Cells do not separate easily	Successful? Cells separate freely and easily
Incubate for another 5-10 minutes and repeat	Proceed to **3. Rinse Skin Sample**

2. Test Scrape



3. Rinse

Tested skin sample
- Rinse the skin sample in Well B

2nd incubate sample (when applicable)
- Place in Well B

3rd and 4th sample (when applicable)
- Repeat from Stage A

Proceed with **Stage B – Mechanical Processing**

STAGE B– MECHANICAL PROCESSING

4. Prepare Buffer*

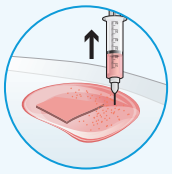
- Ask an assistant in the non-sterile area to hold the Buffer vial
- Using the "BUFFER" syringe and needle, draw up the required volume from a Buffer vial
- Set aside in sterile field

Skin Sample Size	Buffer Volume	Spray-On Skin™ Cells
1 cm^2 (1 cm x 1 cm)	1.5 ml	1.0 ml
2 cm^2 (2 cm x 1 cm)	2.5 ml	2.0 ml
4 cm^2 (2 cm x 2 cm)	4.5 ml	4.0 ml
6 cm^2 (3 cm x 2 cm)	6.5 ml	6.0 ml

***May complete this step while waiting for skin to incubate in Step 1**

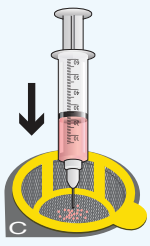
5. Scrape Skin Sample

- Place all skin samples on tray with dermal side down
- Place a few drops of Buffer fro mthe BUFFER syringe on the skin sample
- Using forceps, anchor the skin sample
- Using the scalpel, gently scrape the epidermis until the cells are separated into suspension
- Scrape the remaining dermis more vigorously, until the dermis has nearly desintegrated



6. Rinse and Aspirate

- Using all of the remaining Buffer in the BUFFER syringe, rinse the scalpel and the tray
- Hold and tilt the tray to pool the suspension into the corner
- Using the UNFILTERED SUSPENSION syringe, draw up the suspension and rinse tray several times with cell suspension to collect all of the cells scraped from skin sample (An attached needle is not required)
- Draw up ALL of the suspension on tray into the UNFILTERED SUSPENSION syringe



7. Filter Suspension

- Dispense the unfiltered suspension through the cell strainer in Well C
- Set aside the UNFILTERED SUSPENSION syringe in the sterile field for later use
- Remove cell strainer and tap over Well C

Stage B Continues on Next Page

Step-By-Step Instructions
(continued)

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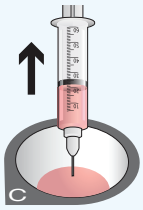
STAGE B–CONTINUED



8. DRAW UP Spray-On Skin Cells

- Prepare a new 10-ml syringe and needle
- Draw up the filtered suspension from Well C
- Set aside for later application
- Spray-On Skin Cells syringe is ready for Stage C – **Deliver** Spray-On Skin Cells
- Complete **Stage B – Mechanical Processing** to create a syringe of Spray-On Skin Cells for each skin sample, then proceed to **Stage C – Deliver Spray-On Skin Cells**

Multiple Skin Samples?

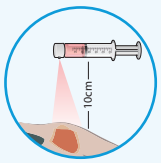
- If cell strainer becomes clogged, replace with a new cell strainer from a new RECELL device
- Replace scalpel as needed

STAGE C– DELIVER SPRAY-ON SKIN CELLS

Position a dressing below wound

9. Prepare Dressing

- Ensure dressings are cut and prepared for immediate application once Spray-on Skin Cells is applied
- Dressings may be positioned below the wound to reduce runoff



10. Apply Spray-On Skin Cells to Wound Bed

- Application technique is dependent on volume of Spray-On Skin Cells to be applied and size of wound bed
- Prior to application invert syringe several times to ensure even suspension
- For both techniques, begin application at the most elevated aspet of the treatment area

Spray Application

- Must have ≥ 2ml of Spray-On Skin Cells in syringe to use spray technique
- Connect nozzle to syringe

Drip Application

- Application of < 2 ml of Spray-On Skin Cells or when treatment area is smaller than 160 cm^2
- Do not remove needle from syringe

11. Place Dressing

- Immediately apply a primary dressing to the treated areas
- Follow with a secondary dressing and secure

DRESSING AND AFTER CARE GUIDELINES

- Primary dressing - small pore, non-adherent, non-absorbent and non-toxic to cells
- Secondary dressing - moderately absorbent, minimally adherent, low shear and readily removable
- Carefully change secondary dressings as needed i.e. high exudate levels
- Prevent treated area from getting wet while the wound is open
- **IMPORTANT:**
  Do not disrupt the primary dressing for a minimum of 5 days
- Ensure primary dressing removal is atraumatic
- Do not use dry dressings on areas of blistering to avoid adhesion to newly regenerated skin
- Do not use known cytotoxic medications on areas treated with RECELL
- Protective dressings must be worn for up to 2 weeks after initial closure of the treated area, particularly on extremities
- Patient/caregiver education:
  - Refrain from strenuous activity
  - Use measures to protect area from trauma or re-injury during healing
  - Avoid direct sun exposure for at least 4 weeks after treatment
- Once the area has healed:
  - Massage using a moisturizer at least twice daily
  - Regular use of sun block
  - Protect area from trauma

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The RECELL Device Technical Specifications

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Indications	RECELL is intended to be used to disaggregate cells from a patient's split-thickness skin sample and to collect these cells for reintroduction to the patient. The cells can be used for autologous application to the prepared wound bed as determined by the physician such as for the treatment of burns, or other acute wounds.
Instructions for Use	Consult the Instructions for Use before using RECELL.
Maximum coverage per kit	Up to 1920 cm^2 Adults: approximately 10% TBSA
Processing time	Spray-On Skin Cells are ready for application in approximately 30 minutes. Four skin samples can be processed in approximately 60 minutes. (Treatment area up to 1920 cm^2 and skin sample size up to 4 ea. 3 cm x 2 cm)
Contraindications	The device is contraindicated for the treatment of: patients with wounds clinically infected or with necrotic tissue present in the wound bed, patients with a known hypersensitivity to trypsin or compound sodium lactate solution, and patients with a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.
Skin sample specifications	Thin, split-thickness skin sample of 0.006-0.008 in (0.15-0.20 mm) delivers up to a 1:80 expansion

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