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RECELL® Autologous Cell Harvesting Device Procedure Guide

Considerations

Requirements

- Sterile field
- 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

STERILE PREPARATION AREA

Transfer Processing Unit to Sterile Field

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

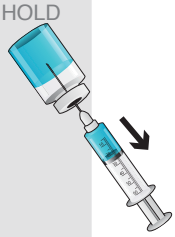
- Use syringe to add 10 ml of sterile water to Enzyme
- Mix gently (DO NOT SHAKE)
- Dispense entire volume of Enzyme into Well A
- Discard syringe and needle

DISPENSE

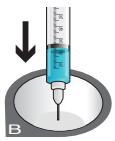
SET B - PREPARE BUFFER

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

HOLD



DRAW UP



- Mark one of the syringes "BUFFER" and the other syringe "UNFILTERED SUSPENSION"
  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 nozzles (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

Heat Enzyme

- Check Enzyme is in Well A

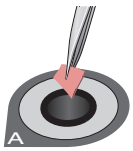
Press run button to heat Enzyme

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

= Warming (approx. 3 min.)

= Target temperature reached

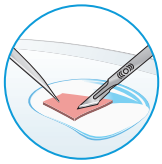
Stage A - Enzymatic Processing



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 skin samples at a time

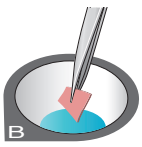
May complete Step 4. Prepare Buffer while skin is incubating.



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 *2. Test Scrape*	Proceed to *3. Rinse Skin Sample*



3. RINSE SKIN SAMPLE

Tested skin sample
- Rinse the skin sample in Well B

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

3rd and 4th sample (when applicable)
- Place in Well A

Proceed with *Stage B - Mechanical Processing*

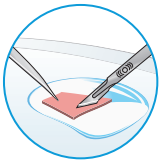
Stage B - Mechanical Processing

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

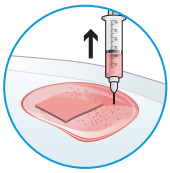
Skin Sample Size	Buffer Volume	Total RES™
1 cm^2 (1 cm x 1 cm)	1.5 ml	1.0 ml
2 cm^2 (2 cm x 1 cm)	2.5 ml	2.0 ml
4 cm^2 (2 cm x 2 cm)	4.5 ml	4.0 ml
6 cm^2 (3 cm x 2 cm)	6.5 ml	6.0 ml

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



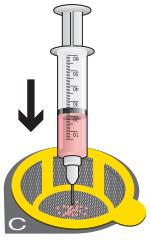
5. SCRAPE SKIN SAMPLE

- Place skin sample on tray with dermal side down
- Place a few drops of Buffer from the 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 disintegrated



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
- Draw up ALL of the suspension on tray into the UNFILTERED SUSPENSION syringe

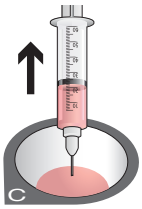


7. FILTER SUSPENSION

- 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 →

Stage B - Continued



8. DRAW UP Regenerative Epidermal Suspension (RES™)

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

Multiple Skin Samples?

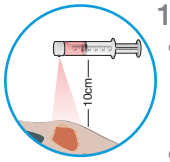
- If cell strainer becomes clogged, replace with a new cell strainer from a new RECELL device
- Replace scalpel as needed

Stage C - Deliver Regenerative Epidermal Suspension (RES™)

Position a dressing below wound

9. PREPARE DRESSING

- Ensure dressings are cut and prepared for immediate application once RES™ is applied
- Dressings may be positioned below the wound to reduce runoff



10. APPLY RES™ TO WOUND BED

- Application technique is dependent on volume of RES™ 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 aspect of the treatment area

Spray Application

- Must have ≥2 ml of RES™ in syringe to use spray technique
- Connect nozzle to syringe

Drip Application

- Application of <2 ml of RES™ 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 Aftercare 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

For clinical support, please contact an Avita Medical regional office below:

EUROPE:
Tel: +44 (0) 2089 479 804
Email: cs.eu@avitamedical.com

AMERICA:
Tel: +1 661 367 9170
Email: cs.am@avitamedical.com

ASIA-PACIFIC:
Tel: +61 (0) 8 9474 7738
Email: cs.ap@avitamedical.com

The RECELL® Device Technical Specifications

Indications:	The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL device is used by an appropriately-licensed healthcare professional at the patient's point-of-care to prepare autologous Regenerative Epidermal Suspension (RES™) for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.
Instructions for Use:	Consult the Instructions for Use before using RECELL. The Instructions for Use can be located at www.avitamedical.com.
Maximum coverage per kit:	Up to 1920 cm^2 Adults: approximately 10% TBSA
Processing time:	RES™ is 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:	RECELL is contraindicated for use on a wound clinically diagnosed as infected or with necrotic tissue present in wound bed. RECELL should not be used to prepare cell suspensions for application to 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, povidine-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 ratio

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