

# RECELL® Autologous Cell Harvesting Device

## Procedure Guide

### Considerations

Requirements	Patient Selection	Wound Bed Characteristics
<ul style="list-style-type: none"><li>Sterile field</li><li>Non-sterile preparation area</li><li>Personal protective equipment</li><li>Skin preparation solution</li><li>Skin harvesting instrument e.g. dermatome or guarded knife</li><li>Wound bed preparation instrument</li></ul>	<ul style="list-style-type: none"><li>Stable condition</li><li>No history of hypersensitivity to trypsin or compound sodium lactate solution</li></ul>	<ul style="list-style-type: none"><li>Clean wound</li><li>No necrotic tissue</li><li>No wound infection</li><li>Pinpoint bleeding</li><li>Well-vascularized</li></ul>
<ul style="list-style-type: none"><li>Fine-point (long nosed) forceps</li><li>Appropriate anesthesia</li><li>A clock or timer</li><li>Sterile ruler and marker pen</li><li>Suitable dressings</li></ul>		

### 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

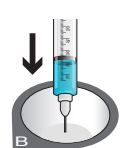
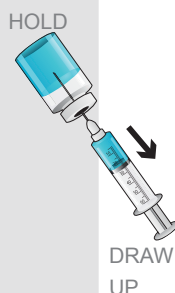
#### SET A - PREPARE ENZYME

- 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



#### 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



- Mark 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 nozzles (x4)
  - 10-ml syringes (x4)
  - Blunt fill needles (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 <sup>2</sup>	1 cm x 1 cm (1 cm <sup>2</sup> )
Up to 160 cm <sup>2</sup>	2 cm x 1 cm (2 cm <sup>2</sup> )
Up to 320 cm <sup>2</sup>	2 cm x 2 cm (4 cm <sup>2</sup> )
Up to 480 cm <sup>2</sup>	3 cm x 2 cm (6 cm <sup>2</sup> )
Up to 960 cm <sup>2</sup>	2 ea. 3 cm x 2 cm (12 cm <sup>2</sup> )
Up to 1440 cm <sup>2</sup>	3 ea. 3 cm x 2 cm (18 cm <sup>2</sup> )
Up to 1920 cm <sup>2</sup>	4 ea. 3 cm x 2 cm (24 cm <sup>2</sup> )


# Step-By-Step Instructions

## Heat Enzyme

- Check Enzyme is in Well A

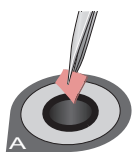
 Press run button to heat Enzyme

*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

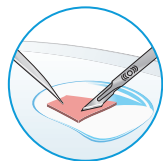
## Stage A - Enzymatic Processing



### 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 6cm<sup>2</sup> 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?

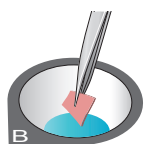
Cells do not separate easily

Incubate for another 5-10 minutes and repeat 2. Test Scrape

#### SUCCESSFUL?

Cells separate freely and easily

Proceed to 3. Rinse Skin Sample



### 3. RINSE SKIN SAMPLE

Tested skin sample

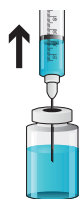
- Rinse the skin sample in Well B
- 2nd incubated sample (when applicable)
- Place in Well B

3rd and 4th sample (when applicable)

- Repeat from Stage A

Proceed with Stage B - Mechanical Processing

## Stage B - Mechanical Processing

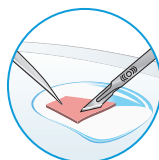


### 4. PREPARE BUFFER\*

- 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

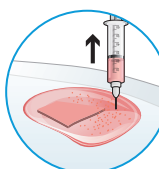
Skin Sample Size	Buffer Volume	Spray-On Skin™ Cells
1 cm <sup>2</sup> (1 cm x 1 cm)	1.5 ml	1.0 ml
2 cm <sup>2</sup> (2 cm x 1 cm)	2.5 ml	2.0 ml
4 cm <sup>2</sup> (2 cm x 2 cm)	4.5 ml	4.0 ml
6 cm <sup>2</sup> (3 cm x 2 cm)	6.5 ml	6.0 ml

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



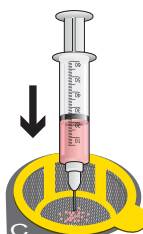
### 5. SCRAPE SKIN SAMPLE

- 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 (An attached needle is not required)
- Draw up ALL of the suspension on tray into the UNFILTERED SUSPENSION syringe

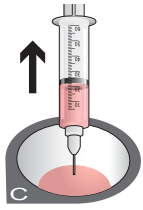


### 7. FILTER SUSPENSION

- 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 →

## 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?

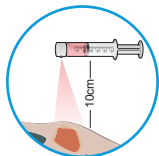
- If cell strainer becomes clogged, replace with a new cell strainer from a new RECELL device
- Replace scalpel as needed

## 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 aspect of the treatment area

#### Spray Application

- Must have  $\geq 2$  ml 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  $160 \text{ cm}^2$
- 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:

AMERICA:

Tel: +1 661 367 9170

Email: [customerservice@avitamedical.com](mailto:customerservice@avitamedical.com)

# The RECELL Device Technical Specifications

Indications:	The RECELL Autologous Cell Harvesting Device is indicated for the treatment of thermal burn wounds and full-thickness skin defects. The RECELL Device is used by an appropriately licensed healthcare professional at the patient's point of care to prepare autologous Spray-On Skin Cells for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds, in pediatric and adult patients and full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing soft tissue infection) or resection (e.g., skin cancer), in patients 15 years of age and older.
Instructions for Use:	Consult the Instructions for Use before using RECELL. The Instructions for Use can be located at <a href="http://www.RECELLsystem.com">www.RECELLsystem.com</a> .
Maximum coverage per kit:	Up to 1920 cm <sup>2</sup> Adults: approximately 10% TBSA
Processing time:	Spray-On Skin Cells is ready for application in approximately 30 minutes. Four skin samples can be processed in approximately 60 minutes. (Treatment area up to 1920 cm <sup>2</sup> and skin sample size up to 4 ea. 3 cm x 2 cm)
Contraindications:	RECELL is contraindicated for the treatment of wounds clinically diagnosed as infected or with necrotic tissue present in the 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

