Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.
**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

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**Device Set-Up**

**NON-STERILE PREPARATION AREA**

**Transfer Processing Unit to Sterile Field**

**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

**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"
  - 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)

**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

**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)

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**Treatment Area**

<table>
<thead>
<tr>
<th>Skin Sample Size</th>
<th>Skin Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 80 cm²</td>
<td>1 cm x 1 cm (1 cm²)</td>
</tr>
<tr>
<td>Up to 160 cm²</td>
<td>2 cm x 1 cm (2 cm²)</td>
</tr>
<tr>
<td>Up to 320 cm²</td>
<td>2 cm x 2 cm (4 cm²)</td>
</tr>
<tr>
<td>Up to 480 cm²</td>
<td>3 cm x 2 cm (6 cm²)</td>
</tr>
<tr>
<td>Up to 960 cm²</td>
<td>2 ea. 3 cm x 2 cm (12 cm²)</td>
</tr>
<tr>
<td>Up to 1440 cm²</td>
<td>3 ea. 3 cm x 2 cm (18 cm²)</td>
</tr>
<tr>
<td>Up to 1920 cm²</td>
<td>4 ea. 3 cm x 2 cm (24 cm²)</td>
</tr>
</tbody>
</table>
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

Step-By-Step Instructions

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

   SUCCESSFUL?
   Proceed to 3. Rinse Skin Sample

3. RINSE SKIN SAMPLE
   Tested skin sample
   - Rinse the skin sample in Well B
   - Place in Well B
   - 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

<table>
<thead>
<tr>
<th>Skin Sample Size</th>
<th>Buffer Volume</th>
<th>Total RES™</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 cm² (1 cm x 1 cm)</td>
<td>1.5 ml</td>
<td>1.0 ml</td>
</tr>
<tr>
<td>2 cm² (2 cm x 1 cm)</td>
<td>2.5 ml</td>
<td>2.0 ml</td>
</tr>
<tr>
<td>4 cm² (2 cm x 2 cm)</td>
<td>4.5 ml</td>
<td>4.0 ml</td>
</tr>
<tr>
<td>6 cm² (3 cm x 2 cm)</td>
<td>6.5 ml</td>
<td>6.0 ml</td>
</tr>
</tbody>
</table>

*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™)

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™ when treatment area is smaller than 160 cm²
      • 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:

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# 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 (REST™) 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 cm² | Adults: approximately 10% TBSA |

## Processing time:
REST™ is ready for application in approximately 30 minutes. Four skin samples can be processed in approximately 60 minutes. (Treatment area up to 1920 cm² 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