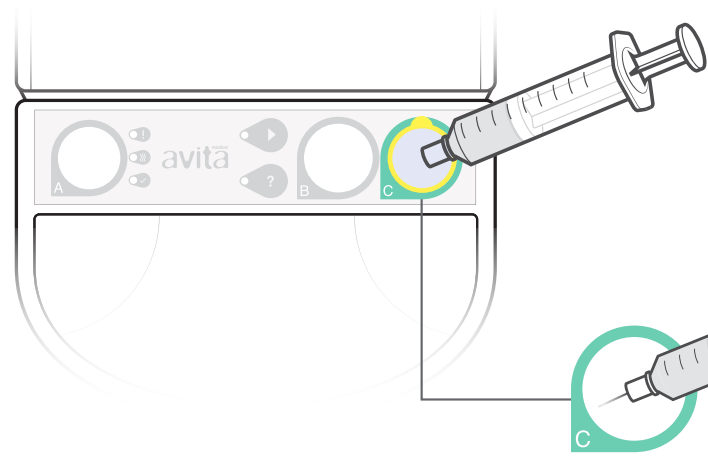


..... *mechanical processing* .....



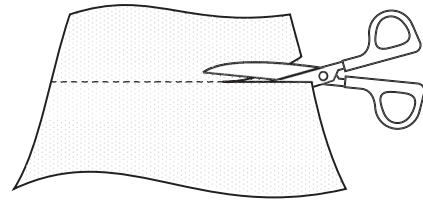
**16 FILTER SUSPENSION**

Dispense the unfiltered suspension through the cell strainer in Well C  
Set aside the UNFILTERED SUSPENSION syringe in sterile field for later use  
If processing 3 or 4 samples, replace filter



**17 DRAW UP SPRAY-ON SKIN™ CELLS**

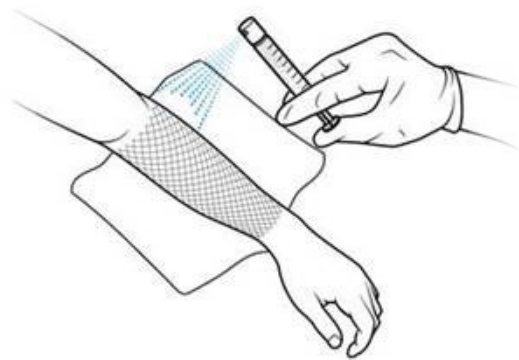
Locate a clean syringe from C Tray labeled SPRAY-ON SKIN CELLS  
Apply needle to syringe  
Remove cell strainer and tap over Well C  
Draw up the Spray-On Skin Cells from the conical bottom of Well C  
Set aside until ready for application  
Follow steps 14 - 17 to prepare additional Spray-On Skin Cells from remaining skin samples



**18 PREPARE DRESSINGS**

Cut primary dressings  
Affix to lower aspect of the wound

..... *deliver Spray-On Skin Cells* .....



**19 APPLY SPRAY-ON SKIN CELLS**

Invert syringe several times  
**Spray Application:** Must have at least 2 ml of cells in the syringe  
Connect nozzle (located in C Tray) to syringe, check that spray nozzle faces the wound. Hold approximately 10 cm from the most elevated point of the wound and spray  
**Drip Application:** When applying less than 2 ml of cells, do not remove syringe from the needle. Starting from the most elevated aspect of wound, drip cells onto the wound

**20 APPLY DRESSINGS**

Apply primary dressing (e.g., Telfa™ Clear) and secondary dressings  
Secure dressings with outer bandages

For Aftercare Instructions refer to SPRAY-ON SKIN CELLS: Dressing Guidelines for the Healthcare Professional

**IMPORTANT SAFETY INFORMATION**

**INDICATIONS FOR USE:** The RECELL® Autologous Cell Harvesting Processing Unit is indicated for the treatment of acute thermal burn wounds. The RECELL device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension 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

**CONTRAINDICATIONS:** RECELL is contraindicated for: the treatment of wounds clinically diagnosed as infected or with necrotic tissue, the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate (Hartmann's) solution, patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.

**WARNINGS:** Autologous use only. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL is provided sterile and is intended for single-use. Do not use if packaging is damaged or expired. Choose a donor site with no evidence of cellulitis or infection and process skin immediately. A skin sample should require between 15 and 30 minutes contact with Enzyme. Contact in excess of 60 minutes is not recommended. RECELL Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.

**PRECAUTIONS:** RECELL is not intended for use without meshed autograft for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints, > 320 cm2, in patients with wounds totaling > 20% total body surface area (TBSA). The safety and effectiveness of RECELL with autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, and in patients younger than 28 days of age (neonates).

**SPECIAL PATIENT POPULATIONS:** The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-thickness burn wounds in pediatric patients younger than 18 years of age.

For complete Important Safety Information, refer to Instructions for Use.

**INSTRUCTIONS FOR USE:** Consult the Instructions for Use prior to using RECELL. The Instructions for Use can be located at [www.RECELLsystem.com](http://www.RECELLsystem.com).

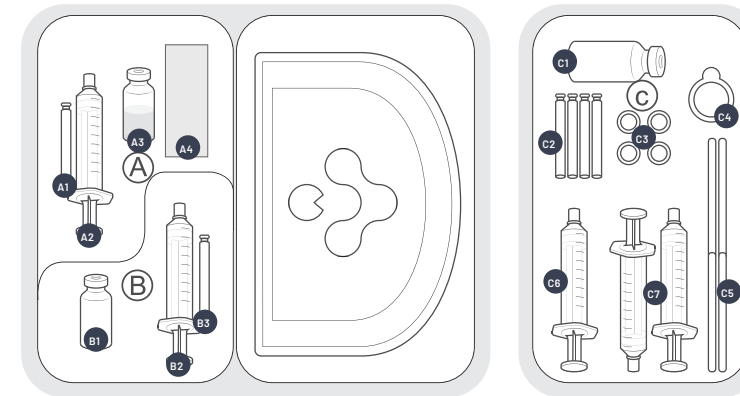
REFERENCE: 1. Instructions for Use. RECELL Autologous Cell Harvesting Processing Unit.

RECELL is a registered trademark of AVITA Medical. Spray-On Skin is a trademark of AVITA Medical. Telfa is a trademark of Covidien.

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RECELL® AUTOLOGOUS CELL HARVESTING DEVICE  
PROCEDURE GUIDE¹



- A1 Blunt needle
- A2 10 ml syringe
- A3 10 ml sterile water
- A4 Enzyme housing
- B1 10 ml buffer vial
- B2 Buffer syringe
- B3 Blunt needle
- Syringe labels (not shown)
- Processing Unit
- C1 30 ml buffer vial
- C2 Blunt needles x4
- C3 Spray nozzles x4
- C4 2nd cell strainer
- C5 Scalpels x2
- C6 Unfiltered suspension syringe
- C7 Spray-On Skin™ Cells syringe x4

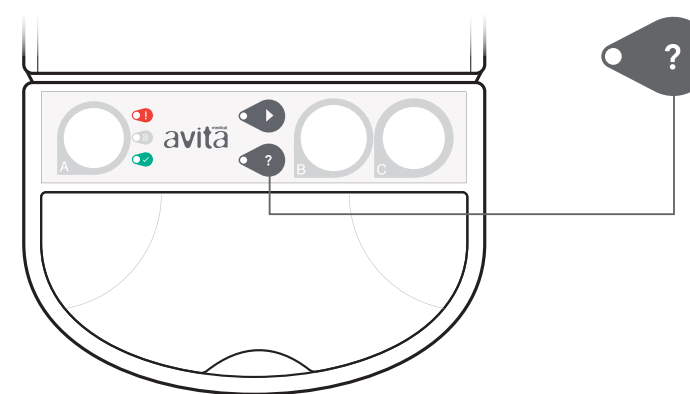
**1 PREPARE STERILE FIELD**

Remove Telfa™ Clear Dressings and Procedure Guide from the box and place in non-sterile area  
A/B/Processing Unit Tray and C Tray: Peel off lid from the outer non-sterile tray  
Starting with C Tray, transfer both sterile trays to the sterile field  
Once in the sterile field, remove tear off lid from A/B/Processing Unit Tray  
Remove clear retainer from the A/B/Processing Unit Tray starting from the upper left corner

**Enzyme:** Remove pouch from outer box  
Transfer Enzyme to sterile field  
Place Enzyme Vial within housing in A/B Tray

**Additional sterile items needed:** Forceps, Marker and Ruler

..... *set up Processing Unit* .....



**2 PERFORM A SELF-TEST**

Remove Processing Unit from the tray, open lid, place labels in sterile field. Press (?) button. All lights by Well A will illuminate

- (!) or no light = Processing Unit failure, use another unit
- Ready (✓) light = Self-test successful
- Do not press the flashing run button at this time
- Processing Unit will turn off after 1 minute without use

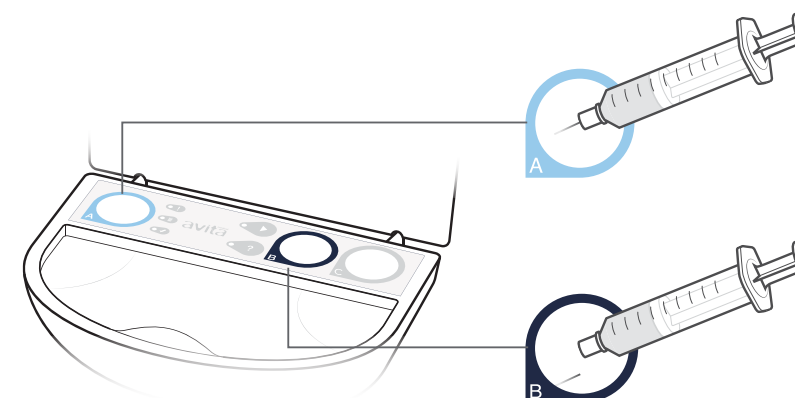
**3 PREPARE WELL A**

Use syringe and needle in A Tray to add 10 ml of sterile water to Enzyme  
Mix gently until dissolved (do not shake)  
Dispense entire volume of Enzyme into Well A  
Discard syringe and needle

**4 PREPARE WELL B**

Label syringe in B Tray with BUFFER label  
Use syringe and needle in B Tray to draw up 10 ml buffer  
Dispense 10 ml of buffer into Well B

**Set aside BUFFER syringe and needle in sterile field. This will be used multiple times to prepare Spray-On Skin Cells later in procedure. Discard A/B/Processing Unit Tray.**



..... harvest skin sample(s) .....

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> )

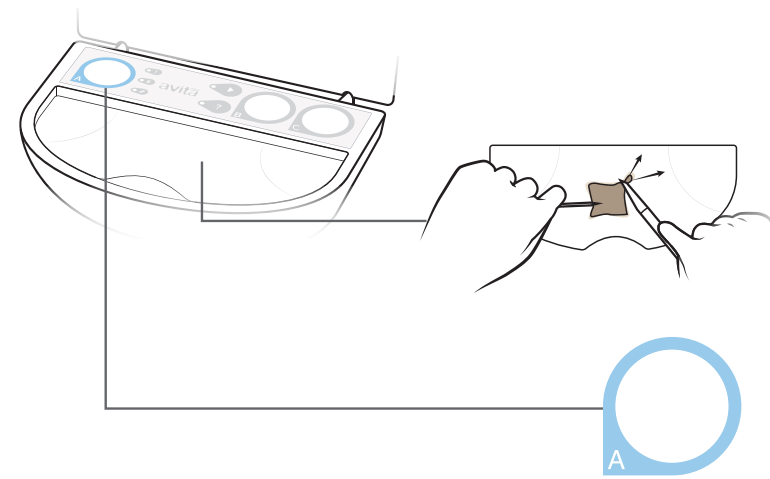
**5 HARVEST SKIN**

The donor site should be clean, of appropriate depth, and show no evidence of surrounding inflammation or infection

If desired, infiltrate the subcutaneous tissue with a tumescent solution of choice

The donor site area may be lubricated (e.g., sterile mineral oil) to ease travel of the dermatome

Harvest thin skin graft at 0.006-0.008 inch (or 0.15-0.20 mm)



**11 TEST SCRAPE**

Remove one skin sample from Well A and place on tray dermal side down

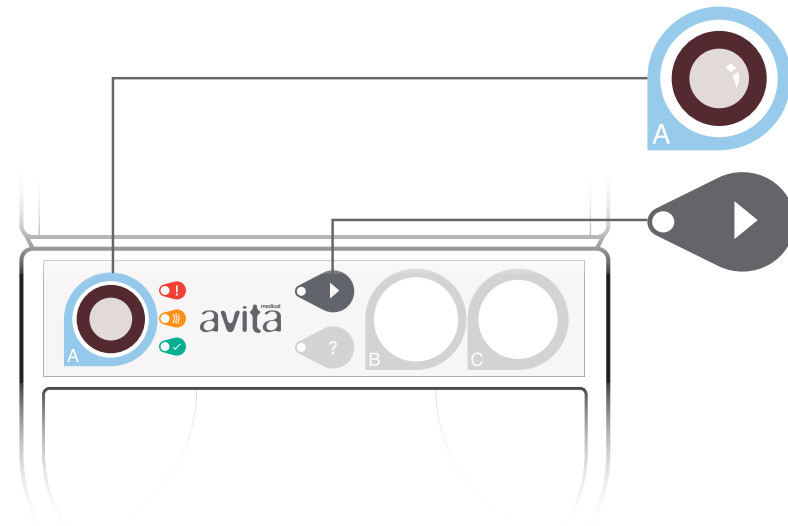
Use scalpel from C Tray to scrape and forceps to anchor. Scrape edge of skin sample to test if cells separate easily. If cells separate freely, proceed to step 12

If cells don't separate, return sample back to Well A



Incubate for 5-10 minutes. Repeat test scrape

..... enzymatic processing .....

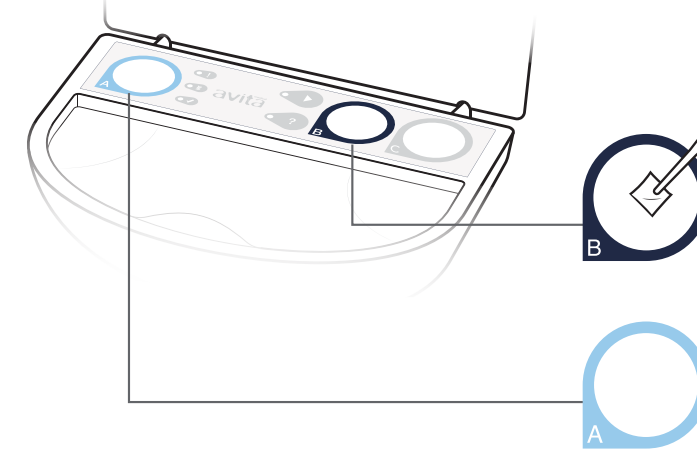


**6 CONFIRM ENZYME IS IN WELL A**

**7 ENSURE SKIN SAMPLE IS AVAILABLE PRESS RUN BUTTON TO HEAT ENZYME**

A self-test will automatically run if >1 minute has passed since the last self-test

- Processing Unit failure, use another unit
- Warming (~3 minutes)
- Target temperature reached



**12 RINSE SKIN SAMPLE(S)**

Place enzymatically processed skin sample(s) into Well B

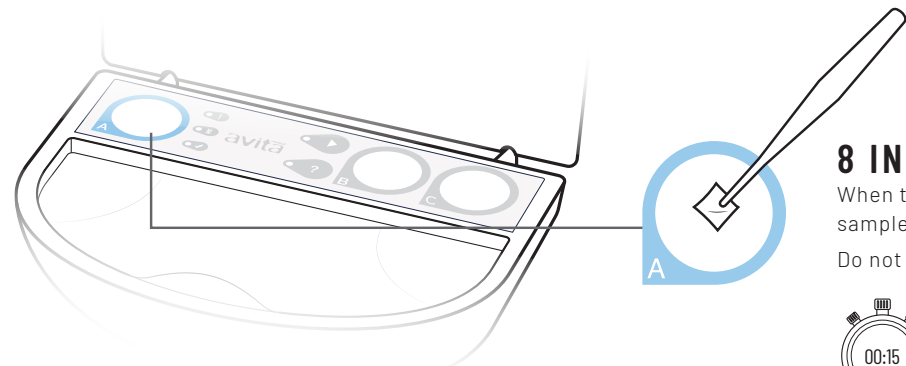
**13 INCUBATE ADDITIONAL SAMPLE(S)**

Place 3rd and 4th skin samples in Well A (when applicable)



Incubate for 15 minutes

Return to step 10 for 3rd and 4th skin samples



**8 INCUBATE SKIN SAMPLE(S)**

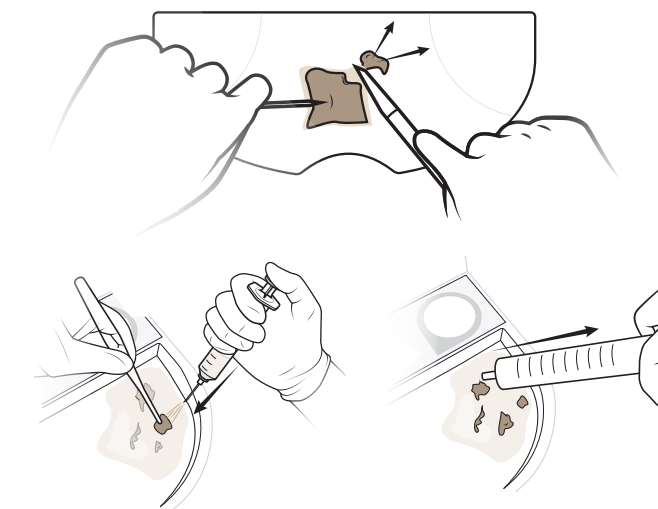
When target temperature is reached, place 1 or 2 skin samples into Well A

Do not incubate more than 2 skin samples at a time



Incubate for 15 minutes

..... mechanical processing .....



**14 SCRAPE SKIN SAMPLE**

Remove one skin sample from Well B and place on the tray dermal side down

Apply 2-3 drops of buffer from prepared syringe labeled BUFFER. Using forceps, anchor the skin sample

Using the scalpel, scrape the epidermis away from the dermis, starting from the edge

Once the epidermis has been removed, scrape the remaining dermis vigorously until nearly disintegrated

**15 RINSE TRAY AND DRAW UP CELL SUSPENSION**

Using the remaining buffer in the BUFFER syringe, rinse the scalpel and forceps into the tray and collect entire suspension into one dipped corner

Locate a clean syringe from C Tray labeled UNFILTERED SUSPENSION

Using the UNFILTERED SUSPENSION syringe, collect and draw up the cell suspension. Using this suspension, rinse the tray and repeat as required to maximize cell collection. Once the tray is rinsed several times, draw up all the cell suspension into the syringe.

Rinsing the tray *several times* is essential for maximizing cell collection.

**9 PREPARE C TRAY**

Peel off lid and remove clear retainer

Apply UNFILTERED SUSPENSION label to the single placed 10 ml syringe

Apply SPRAY-ON SKIN CELLS labels to the 4 remaining 10 ml syringes

**10 PREPARE BUFFER**

Using the syringe labeled BUFFER, located in the sterile field, draw up the required volume from the 30 ml buffer vial in C Tray

Set aside in the sterile field

SKIN SAMPLE SIZE	STARTING VOLUME OF BUFFER	APPROXIMATE RESULTANT SPRAY-ON SKIN™ CELLS VOLUME
1 cm x 1 cm (1 cm <sup>2</sup> )	1.5 ml	1.0 ml
2 cm x 1 cm (2 cm <sup>2</sup> )	2.5 ml	2.0 ml
2 cm x 2 cm (4 cm <sup>2</sup> )	4.5 ml	4.0 ml
3 cm x 2 cm (6 cm <sup>2</sup> )	6.5 ml	6.0 ml