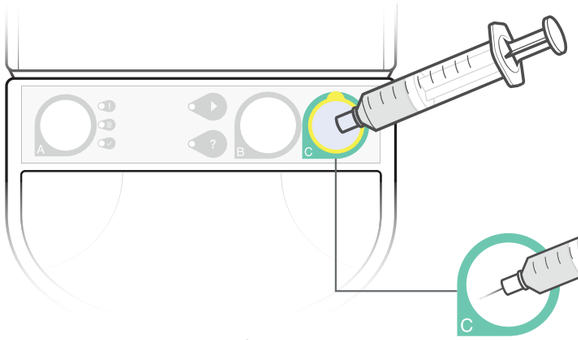
mechanical processing



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

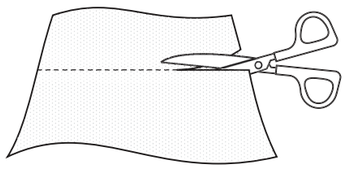
Apply needle to syringe

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

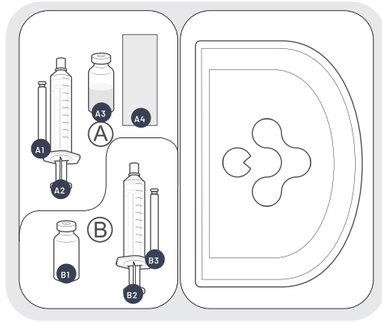
Secure dressings with outer bandages

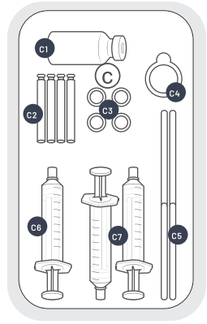
For Aftercare Instructions refer to SPRAY-ON SKIN CELLS: Dressing Guidelines for the Healthcare Professional

RECELL® Autologous Cell Harvesting Device

Procedure Guide

RECELL® By AVITA Medical





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

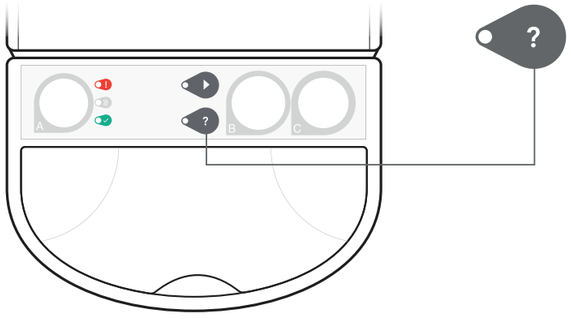
Enzyme: Remove pouch from outer box

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

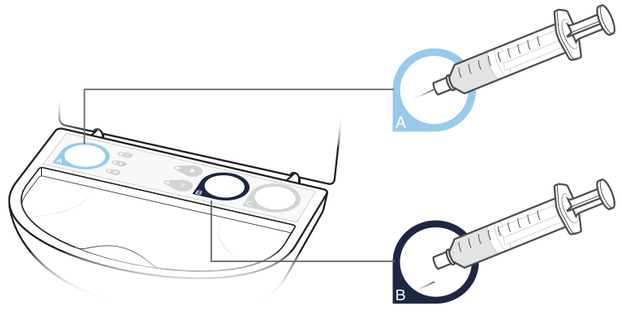
Remove Processing Unit from the tray, open lid, place labels in sterile field. Press (?) button.
All lights by Well A will illuminate.

(!) or no light = Processing Unit failure, use another unit

Ready (✓) light = Self-test successful

Do not press the flashing run button at this time

00:01 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 (DO NOT USE Buffer)

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 (Use only for intended purpose and keep sterile)

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^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)

5 HARVEST SKIN

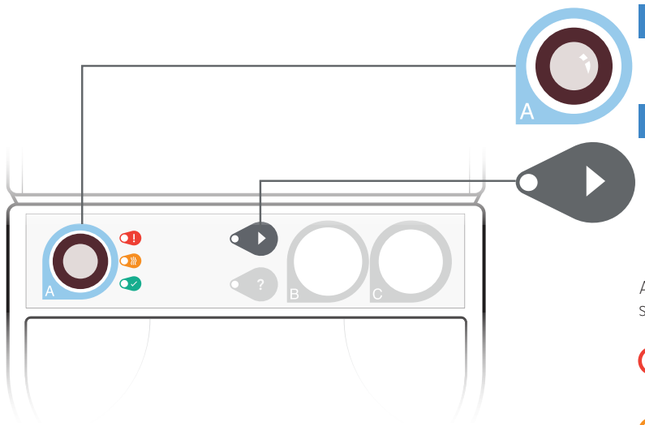
The donor site should be clean, of appropriate depth, and show no evidence of surrounding inflammation or infection

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 dermatome

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

enzymatic processing



6 CONFIRM ENZYME IS IN WELL A

7 ENSURE SKIN SAMPLE IS AVAILABLE

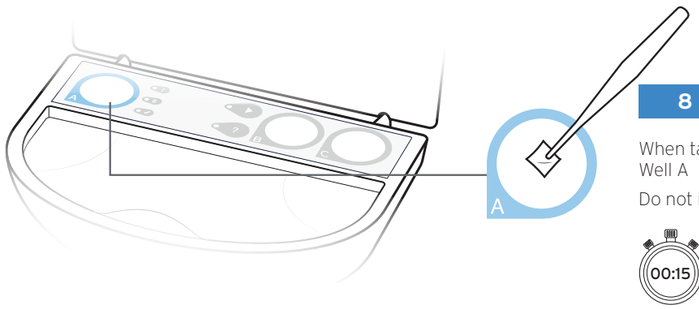
PRESS RUN BUTTON TO HEAT ENZYME

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



8 INCUBATE SKIN SAMPLE(S)

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

Do not incubate more than 2 6 cm^2 skin samples at a time

00:15

Incubate for 15 minutes

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

9 PREPARE C TRAY

Peel off lid and remove clear retainer

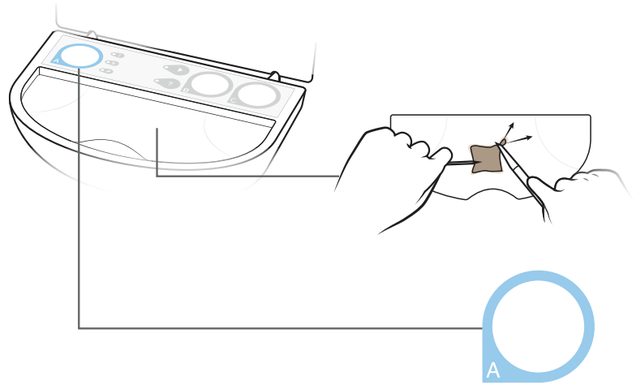
Apply UNFILTERED SUSPENSION label to the single placed 10 ml syringe

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



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

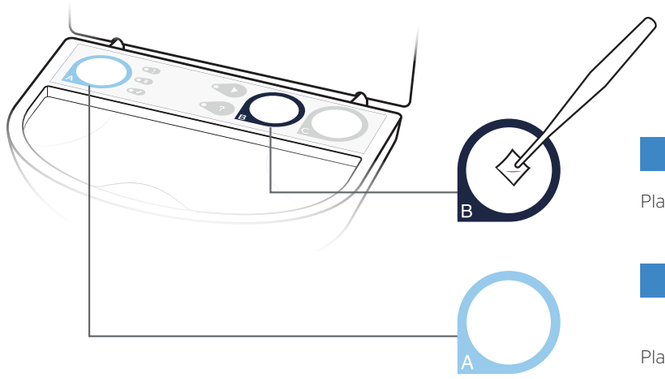
Scrape edge of skin sample to test if cells separate easily

If cells separate freely, proceed to step 12

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

00:05-00:10

Incubate for 5-10 minutes. Repeat test scrape



12 RINSE SKIN SAMPLE(S)

Place enzymatically processed skin sample(s) into Well B

13 INCUBATE ADDITIONAL SAMPLE(S)

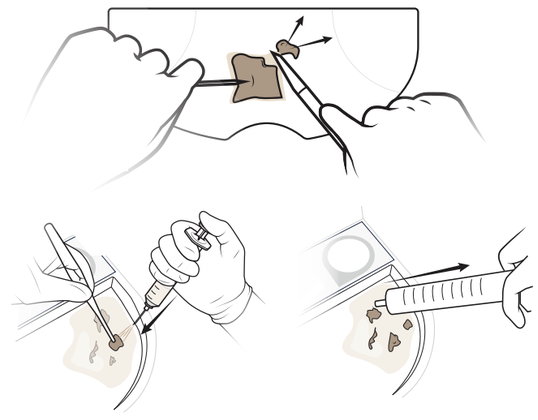
Place enzymatically processed skin sample(s) into Well B

00:15

Incubate for 5-10 minutes. Repeat test scrape

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

mechanical processing



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

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 (An attached needle is not required)

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.