

Procedure Guide

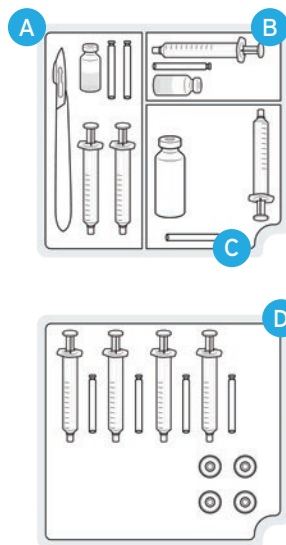
Telfa™ Clear Primary Dressings



RECELL® Enzyme



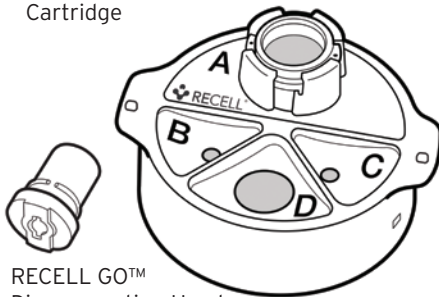
RECELL GO™ Suspension Components



Reusable RECELL GO™ Processing Device



RECELL GO™ Cartridge



RECELL GO™ Disaggregation Head

RECELL GO Processing Device (AVRL0104)

1 x RECELL GO Processing Device 1 x Power Cord

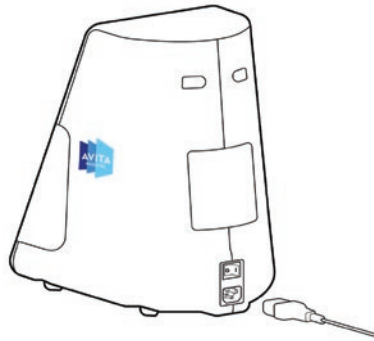
RECELL GO Preparation Kit (AVRL0103)

RECELL GO Cartridge Tray	RECELL GO Suspension Components				RECELL Enzyme	
	ABC Tray			D Tray		Telfa Clear Primary Dressings
	Section A	Section B	Section C			
1 x RECELL GO Cartridge	1 x 10ml Sterile Water	1 x 10ml Buffer	1 x 30ml Buffer	4 x 10ml Syringes		
1 x Disaggregation Head	2 x 10ml Syringe	1 x 10ml Syringe	1 x 10ml Syringe	4 x Spray Nozzles		
	2 x Blunt Fill Needle	1 x Blunt Fill Needle	1 x Blunt Fill Needle	4 x Blunt Fill Needles		
	1 x scalpel					

Additional items required: Clean work area, Procedure Table

The following sterile items: Drape, gauze, saline, blunt forceps, ruler, marker

1 PREPARE RECELL GO™ SYSTEM



The RECELL GO™ System is used to prepare Spray-On Skin™ Cells from a small sample of the patient's own skin. Ensure that the wound bed is clean, free of necrotic tissue or infection and well vascularized with pinpoint bleeding before proceeding.

Ensure the RECELL GO Processing Device is placed into a clean and flat area and plugged in to a power socket. Switch the device ON at the back. Upon a successful test, the screen will now display:

Total RECELL Cartridges Used XX of 200

The system will then ready itself. Please wait and don't interact with the system at this time.

**Preparing RECELL Processing Device
Please wait**



The screen will now display:

Please CLEAN

To clean the RECELL GO Processing Device, select the flashing orange CLEAN button.

The screen will now display:

WIPE CLEAN

The shaft will lower and the device is ready for cleaning.

Wipe the equipment with non-woven towelettes containing surface agents that are non-abrasive, non-corrosive and safe for all non-porous surfaces.

Refer to the Instructions for Use for more detailed cleaning instructions.

The screen will display:

Select DONE When Complete

Press the flashing green Done button after the cleaning is completed and the shaft will retract back up.

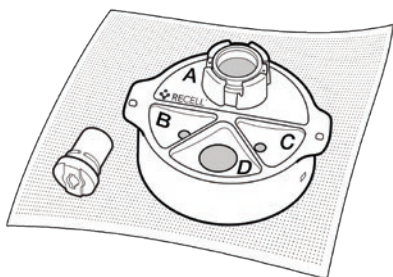
The screen will now display:

**GO PREPARE
RECELL Cartridge With Enzyme, Buffer And Skin For Processing**

Move to step 2 to start preparation of the sterile RECELL GO Cartridge.

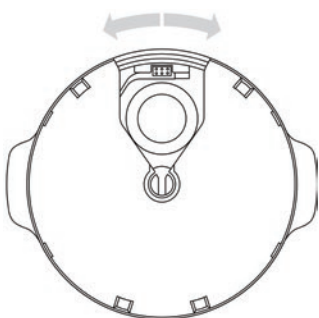


2 PREPARE WELL A



Caution: Do not use sterile RECELL® components beyond the stated expiration date indicated on the adhesive Lot # and Expiration Date labels on the outer shelf box.

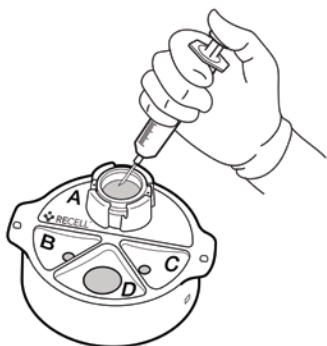
Open the RECELL GO Preparation Kit and place this Procedure Guide, RECELL GO Cartridge Tray, RECELL GO Suspension Components Tray and Telfa Clear in a clean area. Remove the pouched RECELL Enzyme vial from the cardboard tray and aseptically open and transfer the RECELL Enzyme vial onto a sterile draped procedure table. The outer shelf box may be discarded.



Remove the lid from the RECELL GO Cartridge Tray and aseptically transfer the RECELL GO Cartridge and Disaggregation Head onto a sterile draped procedure table.

Check the underside of the RECELL GO Cartridge to ensure proper alignment and the pins are centered.

Remove the lid of the RECELL GO Suspension Component Tray and aseptically transfer the two trays and the tray diagram onto a sterile draped procedure table. Remove the retainer lids from both trays and discard.



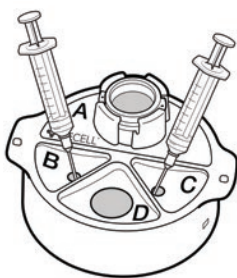
From Suspension Components Tray Section A, use a 10ml syringe and needle to add 10ml of sterile water to the RECELL Enzyme.

Mix gently until dissolved (do not shake).

From Section A, use a clean 10ml syringe and needle, draw up the reconstituted RECELL Enzyme into the 10ml syringe and dispense entire volume of RECELL Enzyme into Well A of the Cartridge. Dispose of syringe and needle.

Remove the scapel from the tray and place onto the sterile draped procedure table.

3 PREPARE WELLS B & C



From Suspension Components Tray Section B, use the clean 10ml syringe and needle to draw up all 10ml of Buffer. Add to Well B of the RECELL GO Cartridge.

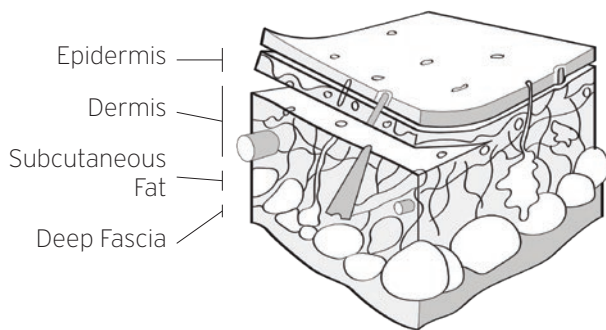
From Suspension Components Tray Section C, use the 10ml syringe and needle to draw up the relevant volume of BUFFER from the vial (Refer to TABLE 1) and add to Well C of the RECELL GO Cartridge.

3 PREPARE WELLS B & C (continued)

Table 1:

Treatment Area	Skin Sample Size	Starting Volume of Buffer	Approximate Resultant Spray-on Skin Cells Volume
up to 320 cm ²	2 cm x 2 cm (4 cm ²)	4.5 ml	4 ml
Up to 480 cm ²	3 cm x 2 cm (6 cm ²)	6.5 ml	6 ml
Up to 960 cm ²	2 ea 3 cm x 2 cm (12 cm ²)	12.5 ml	12 ml
Up to 1440 cm ²	3 ea 3 cm x 2 cm (18 cm ²)	18.5 ml	18 ml
Up to 1920 cm ²	4 ea 3 cm x 2 cm (24 cm ²)	24.5 ml	24 ml

4 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).

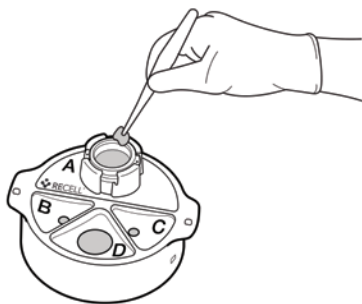
Harvest thin skin graft at 0.006-0.008 inch (or 0.15-0.20mm).

Refer to TABLE 1 for the appropriate sizes.

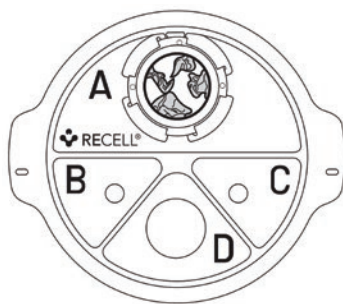
Use the scalpel provided in Section A to cut skin samples into pieces no larger than 3 cm x 2 cm prior to placing in Well A.

A maximum of 24 cm² can be placed in Well A.

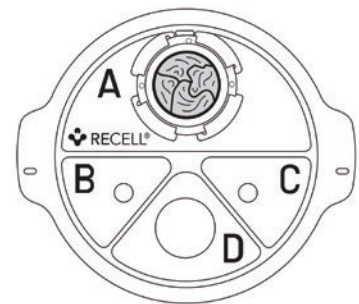
5 ADD DONOR SKIN TO RECELL GO CARTRIDGE



Place donor skin sample(s) into Well A.

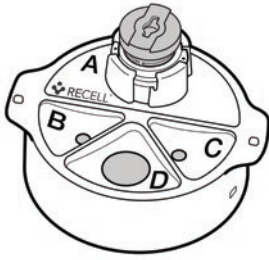


Place donor skin sample(s) separately from each other in Well A. It does not matter which side of the skin is placed up in Well A.



Use blunt forceps to spread out the skin along the base of Well A. Do not use pointed forceps so as not to pierce the filter in Well A.

ADD DONOR SKIN TO RECELL GO CARTRIDGE (continued)



Place the Disaggregation Head on top of the skin sample.

Gently push the Disaggregation Head down until it meets with resistance at the stopping point.

Once the RECELL GO Cartridge is prepared, press the flashing green CONTINUE button.



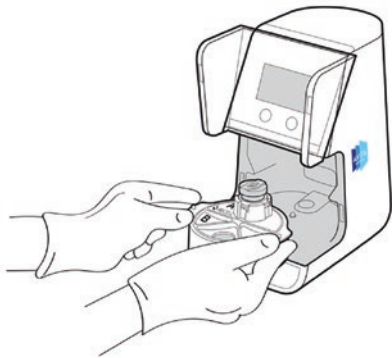
Next the RECELL GO Processing Device screen will display:

VERIFY

Cartridge Includes Enzyme, Buffer, Skin and Disaggregation Head

Once you have verified the contents of the RECELL GO Cartridge, press the flashing green CONTINUE button.

PREPARE THE CELL SUSPENSION



The screen will now display:

INSERT

RECELL Cartridge and Press START

A non-sterile assistant should open the door of the RECELL GO Processing Device.

While maintaining aseptic technique, keep the RECELL GO Cartridge level and with Well A containing the Disaggregation Head at the back of the RECELL GO Cartridge, slide it into the RECELL GO Processing Device until the side tabs on the Cartridge meet the Device.

A non-sterile assistant should close the door and press the flashing green START button to start the skin processing sequence. The screen will display:

RECELL Spray-On Skin Cells Processing
XX Minutes Remaining

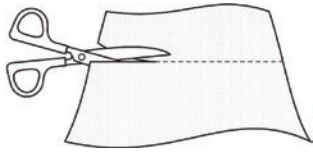


Note: If the RECELL GO Cartridge is not properly detected, refer to the troubleshooting section in the Instructions For Use.

The buttons will cease flashing and the screen will count down until the RECELL Spray-On Skin Cells are ready for collection.

This will take approximately 35 minutes. Do not open the door while the RECELL Spray-On Skin Cells are processing.

7 PREPARE THE DRESSINGS



Cut the primary dressing as required to cover the size of the aftercare wound.

Affix to lower aspect of the wound to help reduce run off.

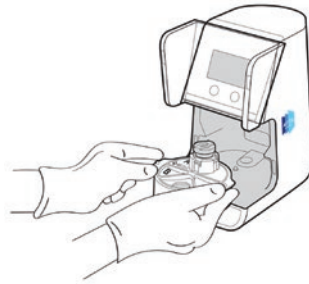
8 DRAW UP THE PREPARED CELL SUSPENSION



An audible alert will sound and the screen will display:

**Process Complete
Aseptically Draw Up The RECELL
Spray-On Skin Cells From Well D**

The RECELL Spray-On Skin Cells are ready to be drawn aseptically from Well D.



Locate the D Tray in the sterile draped procedure field. Attach a blunt tip needle to the 10 ml syringe. Return to the RECELL GO Processing Device noting the device is not sterile. A non-sterile assistant should open the door of the device and move the RECELL GO Cartridge forward on the base of the device so that Well D is accessible using aseptic technique. The RECELL GO Cartridge can also be placed in a clean area next to the RECELL GO Processing Device, if desired.



Using aseptic technique, seat the needle in the dimple at the base of Well D. Mix the cell suspension by drawing up and returning back to Well D. Draw up the required volume to apply to the treatment area using the additional syringes and needles provided in the D Tray as required.

9 APPLY RECELL SPRAY-ON SKIN™ CELLS



Spray Application: Must have at least 2 ml of cell suspension in the syringe. Connect nozzle (located in the D Tray) to syringe, and 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 cell suspension, do not remove the syringe from the needle. Starting from the most elevated aspect of the wound, drip cells onto the wound.

10 APPLY DRESSINGS

Apply primary dressings (e.g. Telfa Clear) and secondary dressings. Secure dressings with outer bandages. For Aftercare instructions refer to the RECELL System: Aftercare Instructions for the Healthcare Professional.

11 CLEAN THE RECELL GO PROCESSING DEVICE



Once the procedure is complete, remove the RECELL GO Cartridge and dispose of per facility protocol. It is highly recommended to clean the RECELL GO Processing Device after retrieving from storage and in between uses as part of regular maintenance.

After pressing the flashing green CONTINUE button, the screen will display:

Please CLEAN

To clean the RECELL GO Processing Device, select the flashing orange CLEAN button.

The screen will now display:

WIPE CLEAN

The shaft will lower and the device is ready for cleaning.

Wipe the equipment with non-woven towelettes containing surface agents that are non-abrasive, non-corrosive and safe for all non-porous surfaces.

Refer to the Instructions for Use for more detailed cleaning instructions.

The screen will display:

Select DONE When Complete



Press the green Done button after the cleaning is completed and the shaft will retract back up and the screen will return to display status of RECELL GO Cartridges used. The system is now ready to be stored or used with the next patient.

Caution: Follow standard precautions including use of appropriate Personal Protective Equipment (PPE) while cleaning and using the processing device.

12 REUSABLE RECELL GO PROCESSING DEVICE

The RECELL GO Processing Device may be used for (up to) 200 uses with separate single-use RECELL GO Cartridges. The device screen will indicate the number of RECELL GO Cartridges used. Once the count reaches 180 of 200, the RECELL GO Processing Device is within 10% of reaching its limit. It is recommended that you contact your AVITA Medical representative at that point to discuss the appropriate time to replace your RECELL GO Processing Device to ensure uninterrupted patient care. It is important to remember that your RECELL GO Processing Device will not prepare any RECELL GO Cartridges beyond the 200 use limit. Once 200 uses have been reached, the RECELL GO Processing Device MUST be replaced to maintain effective cell harvesting.

MAXIMUM REACHED! Contact AVITA Medical Customer Service for a New RECELL Processing Device

IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The RECELL GO Autologous Cell Harvesting Device is indicated for the treatment of thermal burn wounds and full-thickness skin defects. The RECELL GO Device is used by an appropriately licensed and trained 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.

CONTRAINDICATIONS: RECELL GO is contraindicated for the treatment of wounds clinically diagnosed as infected or with necrotic tissue present in the wound bed. RECELL GO is contraindicated for: 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. Control infections on wounds prior to application of the cell suspension. Excise the necrotic tissues on wound bed prior to application of the cell suspension. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL GO Preparation Kit cartridge and components are provided sterile and are 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. RECELL Enzyme is animal derived and freedom from infectious agents cannot be guaranteed. Avoid touching the heating plate directly. Unauthorized device modification may impact the safety of the user.

PRECAUTIONS: RECELL GO is not intended for use without meshed autograft for treatment of acute full-thickness burn wounds or 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). The safety and effectiveness of RECELL GO without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints >320cm², in patients with wounds totaling >20% total body surface area (TBSA). The safety and effectiveness of RECELL GO with autografting have not been established for treatment of full-thickness burn wounds: in patients younger than 28 days of age (neonates). The safety and effectiveness of RECELL GO plus autografting have not been established for application in combination with meshed autografting on 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): on the hands and genitalia. If the harvested skin sample is processed at ambient temperature above 43°C, it may affect the effectiveness of the enzyme. The RECELL GO Processing Device shall be connected to a grounded mains outlet and shall not be operated while in transit. Using cleaning agents other than non-woven wipes could damage the equipment or pose an electrical hazard.

SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL GO 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 GO. The Instructions for Use can be located at avitamedical.com.