The ReGenerCell™ Device

Technical Specifications

Maximum coverage per kit: 320 cm²
- Adults: approximately 2% TBSA
- Children: approximately 4% TBSA

Processing time: Autologous suspension is ready for use in approximately 30 minutes.
- (Treatment area up to 80 cm² Skin sample size 1 ea. 1 cm x 1 cm)

Clinical applications: Treatment of chronic wounds including Venous Leg Ulcers & Diabetic Foot Ulcers

Contraindications: Infected or necrotic wounds

Skin sample specifications: Thin, split-thickness shave biopsy of 0.15 mm – 0.2 mm
Delivers an expansion ratio of up to 1:80

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www.avitamedical.com
www.regenercell.info

Wound healing, not wound management
The ReCell® device is used to create a Regenerative Epithelial Suspension - RES™ - which can be used in conjunction with other treatments to initiate and promote healing in unresponsive chronic wounds. ReCell® has been safely used in thousands of procedures worldwide and offers distinct advantages.

Promotes healing in unresponsive wounds

• RES™ introduces healthy multi-phenotype skin cells and wound healing factors directly to an unresponsive wound to restart and promote normal wound healing.1-6
• Significantly improves the healing rate and time to complete wound closure.1
• Good quality skin with similar elasticity, texture, pigmentation to surrounding skin, with limited scarring.1,5

Health Economic Benefits

• Fewer complications and a reduced tendency for wound recurrence.1
• Reduction in exudate levels, reducing the need for dressing changes and nursing time.7
• Healing chronic wounds versus exorbitant long-term wound management represents significant cost savings.5,8

Improved Patient Quality of Life

• A reduction in pain has been observed following the application of RES™.1-3,5,7
• These early changes in pain and exudate levels allow patients to resume their usual activities and regain their independence.1,2,3,5,7
• Wound healing and decreased wound recurrence results in positive quality of life changes.1,7

The regenerative mechanism is within the suspension...

ReCell’s® unique proprietary technology enables a clinician to rapidly create RES™ - Regenerative Epithelial Suspension - using just a small sample of the patient’s skin.

• Activated, containing disaggregated cells that are no longer contact-inhibited, behaving like those at an acute wound’s edge. RES™ introduces the cell signalling associated with wound healing across the surface area of the wound.
• Available immediately within minutes and is non-cultured, meaning it can be produced and applied at the point of care.
• Autologous, the patient is the donor, effectively eliminating rejection risks.
• Complete, containing the multiple skin cell phenotypes and normal wound healing factors that are necessary for the restoration of normal skin functionality and appearance.

EXAMPLE CASE: VENOUS LEG ULCER (VLU)

This 67-year-old female patient presented with peripheral arterial disease, controlled type II diabetes and a 10 cm² VLU above her right ankle that had been open for 46 weeks.

Treatment with RES™ introduced healthy skin cells, representing all normal phenotypes and wound healing factors to overcome the dysfunctional cell processes and cellular signalling that had impaired the healing of her wound.

At 13 weeks post-treatment, the patient’s wound had decreased to less than 1 cm² and her pain had been reduced significantly.

“At [it’s] just a miracle. Got my life back, can go out and socialise”

Case Study Patient

EXAMPLE CASE: DIABETIC FOOT ULCER (DFU)

A 48-year-old female patient with diabetic foot ulcer of approximately 80 cm²

The wound was debrided to pinpoint bleeding and immediately treated with RES™ together with a split thickness skin graft. At 10 days epithelialisation of the wound was observed, with the wound fully healed at 26 weeks.

This case is representative of 44 cases from the Randomized Clinical Trial of autologous skin cell suspension (RES™) combined with skin grafting for chronic wounds.

“The outcome was excellent given the ulcer had not healed with standard care for over a year”

Prof. Zhu
## Clinical Summary

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<tr>
<th>TITLE</th>
<th>SUMMARY</th>
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<tr>
<td>Randomized clinical trial of autologous skin cell suspension combined with skin grafting for chronic wounds.(^1)</td>
<td>STSG + RES™ v STSG RCT (n=88). Combination of RES™ + STSG grafting demonstrated significantly improved healing rates over STSG alone (41 versus 34; P=0.035). Time to healing in RES™ patients was significantly shorter (14 days versus 20 days) with a decrease in wound recurrence and complications.</td>
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<td>Preliminary results with the use of a non-cultured autologous cell suspension to repair non-healing vascular leg ulcers.(^2)</td>
<td>Treatment of 12 ulcers (11 venous and 1 vasculitic) with RES™ resulted in a 55% mean reduction of the surface area of 10 ulcers and a complete healing of the remaining 2, four weeks after treatment. These preliminary results demonstrate RES™ was effective in restarting the repair process of non-healing ulcers and in reducing pain.</td>
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<td>Autologous skin cells: a new technique for skin regeneration in diabetic and vascular ulcers.(^5)</td>
<td>Four patients (diabetic, n=3; non-diabetic, n=1) were treated using RES™. Effective epithelialization with no signs of infection was observed by 4, 6 or 8 months. No further clinical intervention of these ulcers was required.</td>
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### How to Order

ReCell® product number:

ReCell®: C3RL01

To order please contact the appropriate regional sales office as indicated below.

### References

6. Using ReCell® to Treat Difficult to Heal Chronic Wounds Case Study Jeremy Rawlins, FRCS(Plast), Consultant Plastic Surgeon.
7. Personal communication with Paul Hayes, lead principal investigator, ongoing Pilot Randomized Controlled Trial of the Use of ReCell® Autologous Cell Harvesting Device for Venous Leg Ulcers.
8. Company data, Avita Medical VLU chronic wounds health economic analysis v5, available on request.

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**ReCell®**