**Q&A Document**

**Treating acute burns using the ReCell® medical device:**

**New results from the latest multi-centre RCT involving ReCell®**

**ABOUT THE PRODUCT**

**1. What is ReCell®?**

ReCell® is a CE-approved medical device that is used to create a personalised, ‘spray on skin’. It enables medical professionals to collect cells from a small sample of a patient’s healthy skin to create a suspension that can be applied to regenerate skin following a burn. The ReCell® device is a battery-powered, lunchbox-sized device that contains all that is needed to generate normal, healthy skin for a patient, via a 4 step procedure that takes from as little as 30 minutes to complete. It is clinically proven to be safe and effective in treating wounds, including serious burns, and works by generating RES™ (Regenerative Epithelial Suspension) for spraying onto the wound site, to promote healing. RES™ is produced in 4 steps:

1. **Skin sample** - Removal of a small ‘shave’ of healthy skin around the size and thickness of a postage stamp (though it may be larger, for larger treatment areas) is taken from a healthy ‘donor’ site
2. **Cells prepared** – Placement of the healthy skin into an enzyme to enable the harvesting of skin cells, which are suspended in a liquid
3. **Liquid sprayed on** - Damaged skin is then removed, and the liquid sprayed onto both the wound and the donor site
4. **Cells multiply to form new skin** - The cells from the spray facilitate development of new skin within a week that matures over time to match closely the surrounding tissue in terms of texture and colour

**2. How does the spray (RES**™**) work?**

The body’s natural response to burns is to generate new skin cells which migrate across the wound from the periphery. However, cells in the RES™ behave like those on the edge of the wound because they are in liquid suspension, and are therefore no longer ‘contact-inhibited’. RES™ works by introducing cell signaling associated with wound healing - across the entire surface area of the wound, and contains the multiple skin cell phenotypes and normal wound healing factors that are necessary for the restoration of normal skin functionality and appearance.

**3. What size of wounds can be treated with ReCell®?**

From a small area of healthy skin, ReCell® can generate enough spray to cover an area of 1,920cm2 – roughly the area of an average adult torso. In order to spray an A5 sized wound, only 4cm2 of healthy skin would be needed.

**4. How long has ReCell® been available in the UK?**

ReCell® is a CE-approved medical device that has been used in the UK for over ten years, and it has been used on thousands of patients around the world. Clinical evidence, such as the data from this latest trial, is being submitted for review to the Food and Drug Administration, FDA. Avita Medical Limited, manufacturer of the ReCell® device, anticipates FDA approval in mid 2018.

**5. What type of patients / wounds are suitable for use of ReCell®?**

ReCell® can be used in children as well as adults. It is currently used to treat burns, as well as reconstructive procedures. RES™ can also be used to restart healing in unresponsive wounds, to restore pigmentation and to improve cosmesis (visual appearance) of damaged skin.

**6.** **Who performs the procedure involving the ReCell® device?**

As a surgical intervention, ReCell can be used by personnel qualified for theater procedures: surgeons and nursing support staff are typical users.

**7. What benefits does ReCell® have over conventional care of severe burns, namely meshed autografts?**

When carrying out a meshed autograft for treatment of a full-thickness burn injury, there is a trade-off between expanding the graft as far as possible so that less healthy skin needs harvesting, with the risk of the graft not taking or leaving a mesh-pattern scar. What this clinical trial has shown is that use of RES™ when sprayed onto the autograft means the autograft can be expanded more widely without compromising healing or long-term outcomes. On average, just over 30% less healthy donor skin was required.

An earlier trial involving 101 patients and 12 US centres between 2010-2014 compared outcomes from using ReCell alone for treatment 2nd degree burn injuries with outcomes from using 2:1 meshed autografting. ReCell achieved comparable definitive wound closure when appropriate follow-on care was provided, but importantly, its use led to smaller, less painful donor sites which healed faster, and had better scar outcomes for both donor site and wound site.

**8. Are there any risks of using ReCell®?**

As with all surgery, there are risks associated, such as reacting to the general anaesthesia, or developing an infection requiring antibiotics, developing scars, and/or undergoing further surgery. However, as the cells are autologous (patient’s own), there is no risk of rejection.

**9. How could wider use of ReCell® benefit the UK’s health services, e.g. The NHS?**

Patients with extensive burn injuries must often undergo autografting surgery several times to ensure wound closure. There may also be further additional surgery to address scarring. As such, a device which enables less healthy skin to be removed could translate to a patient enduring fewer operations, meaning less time is spent in hospital, along with the related savings in terms of time, resources and costs.

**DETAIL ABOUT THIS LATEST TRIAL and RESULTS**

**1. What was involved in this latest RCT (randomized controlled trial) involving ReCell®?**

The trial involved 30 patients aged over 5 years and took place at 7 major burns centres in the USA (listed below) between 2015 – 2017. The trial followed a ‘within-subject’ control design, under which two comparable areas requiring autografting were identified. A grafting plan was then made according to the centre’s standard of care. The control area was treated as per this plan, e.g. a meshed autograft with a thickness ratio of 2:1. The other area received an autograft which was expanded more widely (3:1 instead of 2:1) and was over-sprayed with RES™. Treated sites were assessed for closure at or before 8 weeks, and scar outcomes were evaluated at weeks 24, 36 and 52. Outcomes were then compared between the wound sites.

**2. Why is this latest RCT involving ReCell® so significant?**

This latest trial was designed to show that ReCell® is safe and effective when used in combination with meshed autografting (a standard burns procedure) for treatment of 3rd degree burn injuries. When using ReCell® in addition to meshed autografting, there was just over 30% reduction in the amount of donor skin required. This is significant because not only are larger skin grafts more painful, but healthy skin is a ‘precious commodity’ especially when patients have had a large percentage of their skin burned. Furthermore, grafts can sometimes fail and need to be repeated, meaning yet more healthy skin must be harvested.

As such, data from this trial adds to a growing body of evidence pointing to ReCell® as a ‘skin saving’ solution for patients, with wider clinical, social and economic benefits, such as less pain, faster healing, shorter lengths of stay in hospital, and better cosmetic results, compared to the conventional standard of care.

An earlier trial from 2010-2014 involved 101 patients at 12 UK centres and concluded that when compared to conventional meshed autografting alone for treatment of 2nd degree burn injuries, ReCell® achieved comparable, definitive wound closure, as well as smaller, less painful donor sites that healed faster, and achieved better scar outcomes for both donor and wound site.

**2. Are any RCTs involving ReCell® taking place in the UK**

NICE has commissioned a study looking at the clinical and health economic benefits, which could start later this year in the UK.

**3. Why is ReCell® being stock-piled in the USA to treat burns, in the event of a mass casualty event?**

The potential for autograft-sparing achieved with ReCell® addresses a bottleneck in the burn care pathway for treatment of a large number of patients in a mass casualty event. The ReCell® device contains all that is required to generate healthy new skin in a portable, battery-powered device. In May 2017, Avita Medical announced it had received notification of the initial FDA review of a Pre-EUA (Emergency Use Authorisation) submission by BARDA (The Biomedical Advanced Research and Development Authority) to allow FDA to consider emergency authorization for use of ReCell® for a mass casualty event involving burn injuries.

**CENTRES INVOLVED IN THE TRIAL**

Wake Forest Baptist Medical Centre, Winston-Salem, NC

University of North Carolina, Chapel Hill, HC

Maricopa Health System, Phoenix, AZ

University of Tennessee, Memphis, TN

US Army Institute for Surgical Research, Fort Sam Houston, TX

MedStar Washington Hospital Center, Washington DC

University of South Florida, Tampa, FL

**ABOUT AVITA MEDICAL LIMITED**
Avita’s patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient’s own skin. Our medical devices work by preparing a Regenerative Epithelial Suspension (RES™), an autologous suspension comprised of the patient’s own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This is then applied to the area to be treated. In all countries outside of Europe, our portfolio is marketed under the ReCell® brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics.
ReCell® is TGA-registered in Australia, and CFDA-cleared in China. In the United States, ReCell® is an investigational device limited by federal law to investigational and compassionate use. In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. ReCell® is designed for the treatment of burns and plastic reconstructive procedures; ReGenerCell™ has been formulated for chronic wounds including leg and foot ulcers; and ReNovaCellT™ is tailored for aesthetic applications including the restoration of pigmentation.

To learn more, visit [www.avitamedical.com](http://www.avitamedical.com)

**Expert user videos:**

Miss Alex Murray, Stoke Mandeville Hospital: <https://www.youtube.com/watch?v=YLGpbLac7zU>

Dr Jimmy Holmes, Wake Forest University, USA: https://www.youtube.com/watch?v=PfPgx3OduDc
Facebook: [@AvitaMedical](https://www.facebook.com/AvitaMedical) Twitter: [@AvitaMedical](https://twitter.com/AvitaMedical) LinkedIn: [Avita Medical](https://www.linkedin.com/company/avita-medical-limited)

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**  *This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “intend,” “could,” “may,” “will,” “believe,” “estimate,” “look forward,” “forecast,” “goal,” “target,” “project,” “continue,” “outlook,” “guidance,” “future,” other words of similar meaning and the use of future dates. Forward-looking statements in this letter include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company’s control. Investors should not place considerable reliance on the forward-looking statements contained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.*

**MEDIA ENQUIRIES**

For all enquiries,including interview requests, hi-res images, video content, or any other aspects, please contact Hannah Kapff or Siena Clarke at Curious PR Hannah@CuriousPR.com or Siena@CuriousPR.com

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