



Newsletter - March 2016

Hello from the Reapplix Team!

Welcome to this, our first ever Newsletter! We intend to use this format to collect together topics of interest, news and other items relating to Reapplix and provide a periodic update direct to you in one place. However, we will be continually updating our website too with ongoing news, so the website will always be a go-to place for the latest developments between the Newsletters.

In this edition of our Newsletter we have exciting news regarding our recent 510(k) clearance in USA. Just to clarify some points on product names and branding - for the US market we will use '3C Patch™' to describe our product; our process is 3CP™ and this is carried through to the product name. In Europe we have product in clinical trials and in market tests under our brand name 'LeucoPatch®'. We will continue with this, whilst evaluating feedback and branding options going forward.

These are exciting times and we hope that you enjoy reading about our continuing journey in this Newsletter.

US FDA 510(k) clearance

Reapplix has received US FDA 510(k) clearance for its 3C Patch™ System. Reapplix's proprietary simple-to-use device technology has been cleared as a "system intended to be used at the point of care for the safe and rapid preparation of platelet rich plasma (PRP) gel from a small sample of the patient's own peripheral blood". The resultant PRP gel patch is topically applied for the management of wounds and is cleared for indications covering diabetic ulcers, leg ulcers, pressure ulcers and mechanically or surgically-debrided wounds.

Reapplix is currently conducting a large scale Randomized Controlled Trial of its technology in ~250 Diabetic Foot Ulcer patients in up to 35 centres in UK, Sweden and Denmark and expects to report the data from this in 2017. Additionally, given that

the technology already has CE Mark approval, Reapplix is undertaking market tests in selected European markets to assess the pre-reimbursement commercial potential.

This 510(k) clearance opens the way for Reapplix to introduce its unique device technology to the US market, where it will be known as the 3C Patch System™.

Founders Niels Erik Holm (COO) and Rasmus Lundquist (CSO) jointly commented on the news: *“We are delighted to have achieved this milestone that will allow US patients to use their own blood to assist in the management of their wounds in US wound care clinics. Our ongoing CMS approved CED/IDE study is expected to further support our access to the world’s largest advanced wound care market.”*

Graeme Brookes, Chief Executive Officer at Reapplix, added: *“Achieving this clearance enables us to build out our plans to bring our technology to the key US market. Given our supportive investor base we are well positioned to continue to create value whilst achieving our goal of providing effective solutions to healthcare providers to help patients achieve better outcomes.”*

Innovations in Wound Healing Florida, December 2015

We attended this small but very science focused meeting for the first time in December in the beautiful Florida Keys. We found it to be very informative with open but in depth discussion on the science behind the complexities of wound etiology and the options available to address wound healing challenges. Our Chief Scientific Officer, Rasmus Lundquist, had the opportunity to present a poster on LeucoPatch entitled 'An adaptive triple layered autologous platelet and leucocyte rich fibrin patch and its clinical use in the treatment of hard-to-heal diabetic foot ulcers'.

We were very encouraged by the interest levels and the questions and discussion after the poster presentation, which was well attended as you can see below.



Patent News

Over the past months our patent position has continued to be strengthened by patents being granted in multiple territories. The granted patents cover both our device technology (used when producing a LeucoPatch, using our unique 3CP™ technology) and the unique triple layered structure of LeucoPatch.

Recent grants cover territories as diverse as USA, Japan, China, Europe and Eurasia

New paper published studying the impact of LeucoPatch on chronic wounds

A new paper has been published in Clinical & Experimental Immunology.

As each LeucoPatch contains a substantial number of leucocytes, the aim of the study was to investigate the activity of the polymorphonuclear neutrophils (PMNs) within the LeucoPatch. The researchers describe how they used a burst assay, phagocytosis assay, migration assay, biofilm killing assay and fluorescent in situ hybridization (FISH) assay to show significant respiratory burst in PMNs and active phagocytosis and killing of *Pseudomonas aeruginosa* by the LeucoPatch. In addition, it was shown that PMNs from LeucoPatch migrate toward, as well as phagocytise, *Pseudomonas aeruginosa*. The study substantiated that the beneficial clinical effect in chronic wounds by LeucoPatches is in part attributed to the activity of the polymorphonuclear neutrophils (PMNs) in the LeucoPatch.

Details of the paper are:

Thomsen, K., Trøstrup, H., Christophersen, L., Lundquist, R., Høiby, N., & Moser, C. (2016). The Phagocytic fitness of LeucoPatches may impact the healing of chronic wounds. *Clin Exp Immunol.* 2016 Feb 2. doi: 10.1111/cei.12773.

The paper abstract can be found at [pubmed](#) and the full paper accessed directly via [Clinical and Experimental Immunology](#).

Please do contact us with any questions you have or just to find out more!

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