



## ConvaTec Receives U.S. FDA 510(k) Clearance for its most advanced and innovative antimicrobial dressing: AQUACEL™ Ag Advantage dressing

- *Developed to help clinicians reduce the significant burden of chronic, non-healing wounds*
- *Unique Advantage formulation provides enhanced antimicrobial performance<sup>[1]</sup> in combination with Hydrofiber™ Technology*

**Reading, United Kingdom (24 July 2018)** - ConvaTec Group Plc ("ConvaTec"), a leading global medical products and technologies company, today announced it received U.S. Food and Drug Administration (FDA) 510(k) clearance for its AQUACEL™ Ag Advantage\* dressing for wound management.

In clinical studies and global practice, ConvaTec's proven, advanced antimicrobial dressing has demonstrated substantial wound improvements even in the most hard-to-heal wounds<sup>[2],[3]</sup>, and in 2016 was recognized by international wound care experts for its innovative and breakthrough technology with the ability to change patient lives.

Chronic non-healing wounds have a significant impact on quality of life for patients, many of whom are elderly, have diabetes or other underlying conditions, which often lead to serious events such as limb amputations or premature death.<sup>[4]</sup> In the U.S. Medicare recently published data showed that 8.2 million seniors had at least one type of wound or wound-related infection, with an estimated annual cost of up to \$96.8 billion.<sup>[5]</sup>

"Delayed wound healing presents multiple challenges for clinicians, and places a heavy burden on patients, society and our healthcare systems. Moving these types of recalcitrant wounds from a deteriorating or stagnant state toward improvement requires novel, non-antibiotic strategies," said Randall Wolcott, MD, Medical Director, Southwest Regional Wound Care Center, Lubbock, Texas. "I'm very excited about this new innovative dressing, which has shown significant potential to address this burden while not driving antibiotic resistance."

"AQUACEL Ag Advantage dressing is the culmination of many years of research and collaboration with clinicians to more effectively address their most difficult and persistent challenges in wound management," added Fiona Adam, Interim President, Advanced Wound Care, ConvaTec. "Customer feedback in markets outside the U.S. has been very positive, and we look forward to introducing U.S. clinicians to the latest addition to our AQUACEL family, and continuing to help wound specialists around the world promote better healing outcomes, address further unmet needs in wound care, and help more patients resume their daily lives."

"In clinical evaluation studies, we have seen excellent results in chronic non-healing wounds, some of which have not healed in years despite the use of topical antimicrobials and systemic antibiotics. We've also heard from many clinicians who have said the use of the new dressing has helped them save patients' limbs and lives."

AQUACEL Ag Advantage dressing is currently available in markets across Europe and Asia Pacific, where it is marketed as AQUACEL Ag+ Extra dressing. Commercial availability in the U.S. is expected to commence alongside product evaluations in October.

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## About AQUACEL™ Ag Advantage dressing

AQUACEL Ag Advantage dressing is ConvaTec's most advanced antimicrobial dressing, and builds on the company's 22-year history of innovation and customer collaboration with its AQUACEL dressings and the science of wound healing. At the 5th World Union of Wound Healing Societies Conference, an independent panel of Journal of Wound Care/WUWHS board members and other wound care experts named it the "Most Innovative Dressing," an award recognizing industry achievement in developing "breakthrough technologies that have revolutionized wound care over the last four years and genuine game-changing dressings which have changed patient lives through their outcomes."

AQUACEL Ag Advantage dressing is an enhanced Hydrofiber™ dressing with silver and strengthening fiber. AQUACEL Ag Advantage dressings combine two powerful technologies: ConvaTec's proprietary Hydrofiber Technology and its new Advantage Technology.

As demonstrated *in vitro*, Hydrofiber Technology absorbs and retains excess exudate to maintain a moist wound environment to support the healing process.<sup>[6],[7],[8],[9],[10],[11]</sup> AQUACEL Ag Advantage dressings have been developed to maximize the antimicrobial action of ionic silver, which has been shown *in vitro* to kill a broad spectrum of bacteria within the dressing, including antibiotic resistant superbugs.<sup>1</sup> The unique Advantage formulation contains ethylenediaminetetraacetic acid (EDTA) and benzethonium chloride (BeCl), two agents that enhance performance by providing more rapid and sustained antimicrobial activity within the dressing, as compared with AQUACEL Ag Extra dressing (without the Advantage Technology) and demonstrated *in vitro*.<sup>1</sup>

In an international clinical evaluation study of over 100 patients, the Advantage Technology in combination with Hydrofiber Technology showed positive results in hard-to-heal wounds.<sup>2</sup> In the

study, supported by ConvaTec and published in the *Journal of Wound Care*, a single wound in each of 113 patients was observed over an average treatment period of 4.1 weeks. By the end of the study,

- 95% of wounds improved or healed completely
- 73% showed an average reduction in wound size

Most of the wounds studied presented as venous leg ulcers (52%) or diabetic foot ulcers (12%). The majority displayed clinical signs of infection and 74% had suspected wound biofilm, a known precursor to infection<sup>[12]</sup> and a key cause of delayed healing<sup>[13],[14]</sup>, as clinically determined by the evaluator. During the clinical evaluations, the only stipulated change in the protocol of care was the replacement of the previous primary dressing.

### **About ConvaTec**

ConvaTec is a global medical products and technologies company focused on therapies for the management of chronic conditions. The Company is listed on the London Stock Exchange (stock symbol: CTEC) and has leading market positions in advanced wound care, ostomy care, continence and critical care, and infusion devices. ConvaTec's products provide a range of clinical and economic benefits, including infection prevention, protection of at-risk skin, improved patient outcomes and reduced total cost of care. [www.convatecgroup.com](http://www.convatecgroup.com)

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\*AQUACEL Ag Advantage dressing is marketed as AQUACEL Ag+ Extra dressing outside of the U.S.

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<sup>[1]</sup> WHRI5446 MA304: The antimicrobial activity of AQUACEL Ag+ Extra wound dressing using an *in vitro* direct inoculation simulated wound fluid model.

<sup>[2]</sup> Walker M.; Metcalf D.; Parsons, D.; Bowler P. A real-life clinical evaluation of a next-generation antimicrobial dressing on acute and chronic wounds. *Journal of Wound Care* 2015; 24:1, 11-22

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