

## RCT testing the efficacy of gas plasma treatment on biofilm in diabetic foot ulcers welcomes NHS hospital to join trial

LONDON, UNITED KINGDOM, July 10, 2018 /EINPresswire.com/ -- Adtec Healthcare is excited to announce that Leeds Teaching Hospitals NHS Trust will be joining as a trial centre for our randomised controlled trial to evaluate the efficacy of non-thermal gas plasma on sub-clinical wound infection (biofilm) in patients with diabetic foot ulcers compared to those treated with standard care of dressings. The clinical team will be led by our clinical partners, Mr David Russell, the Podiatry and Vascular Research Teams in the Diabetes Limb Salvage Service at Leeds Teaching Hospitals. The Chief Investigator for the trial is Professor Steven Jeffery from HM Forces, Queen Elizabeth Hospital.

Biofilms in wounds are considered to be one of the major challenges in infection management. They are associated with 65-80% of all non-healing wounds leading to chronic inflammation and delayed healing. 1

Bacteria produced within biofilm are up to 1000 times more resistant to antibiotics which severely complicates treatment options. 2

Debridement is one of the most important treatment strategies against biofilm but does not remove all biofilm and cannot be used alone. Biofilms can reform rapidly. Appropriate topical antiseptic applications within this time-dependent window can suppress biofilm reformation. 3



Adtec SteriPlas



Adtec SteriPlas

The hypothesis to be tested is that the healing of chronic diabetic foot ulcers that are stalled by biofilm

can be accelerated following intervention with the Adtec SteriPlas.

The secondary objective is to correlate clinical presentation of long standing wounds as recorded through digital photographs in terms of wound volume/wound dimensions with wound microbiology (number of bacterial species present), biochemistry and histology in a series of diabetic foot ulcers.

Recruited patients will be randomly selected to either receive standard care of dressings or two sessions of gas plasma treatment each week for a total of 4 weeks.

The Adtec SteriPlas is a CE marked medical device with proven efficacy in infection management of ulcers/surgical site infections and treatment of some skin diseases. It operates with a physical mode of action, meaning that bacteria developing a primary or secondary resistance to plasma is unlikely. 4

Previous clinical trials that we have conducted and patient treatments in hospitals have shown that the Adtec SteriPlas:

- · Is 50% more effective than antibiotics. 5
- Offers a 73% reduction in bacterial load despite the type of bacteria or its resistance to antibiotics.
- · Is proven to kill a wide range of microorganisms including fungal, viral, yeast and bacterial superinfections in both Gram-negative and Gram-positive.

For more information about the Adtec SteriPlas, visit our website <a href="www.adtecplasma.com">www.adtecplasma.com</a> or email us at info@adtec.eu.com

- 1. James et al, 2008; Percival and Bowler, 2008
- 2. Environ Health Perspect. 2010 Jul; 118 (7): A 228
- 3. Consensus guidelines for the identification and treatment of biofilms in chronic non-healing wounds, G. Shultz, T. Bjarnsholt, G. A. James, D. J. Leaper, A. McBain, M. Malone, P. Stoodley, T. Swanson, M. Tachi, R. Wolcott; for the Global Wound Biofilm Expert Panel
- 4. Plasma applications in medicine with a special focus on Dermatology, J. Heinlin, G. Isbary, W, Stolz, JEADV 2010.
- 5. Isbary et al, BJD Online 2012

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