



## **Preliminary trial results suggest Sterilox Tx solution as a powerful new treatment for chronic venous leg ulcers**

Radnor, PA, September 8, 2004 -- Sterilox Technologies Inc., and the Department of Dermatology, Churchill Hospital, Oxford, UK today announced positive, preliminary human clinical trial results of a new antiseptic wound irrigation fluid for the treatment of chronic venous leg ulcers. Thirteen of the seventeen patients admitted to the study (i.e., 76%), all of whom had previously failed at least two courses of standard treatment, benefited from a twelve-week course of Sterilox Tx ulcer treatment. The ulcers of seven patients healed completely; for six others the size of their ulcerated areas was reduced by more than 50%. All patients reported a marked reduction or total elimination of pain when Sterilox Tx treatments were started, a result which continued throughout the remainder of the study.

"These early results suggest that treatment with Sterilox Tx wound irrigant solution (CE marked) could provide clinicians with an effective way of treating wounds and alleviating the pain of chronic leg ulcers especially for patients who have failed an initial course of standard therapy," said David W. Anderson, President of Sterilox Technologies Inc. "In addition, the Sterilox Tx solution may also accelerate healing for patients with less chronic disease, particularly where heavy bacterial colonization is present in the wound."

Typically venous leg ulcers affect older people where the most common symptoms are chronic inflammation of the ulcerated leg, debility, pain (often so severe that patients need to take sleeping tablets at night), and social stigma from infection. According to the National Institutes of Health, chronic wounds such as venous leg ulcers, pressure sores, ischemic ulcers and diabetic foot ulcers, affect more than 4 million Americans each year and cost about \$9 billion to treat. (NIH, <http://www.clinicaltrials.gov/ct/gui/show/NCT00006437>).

The standard treatment for leg ulcers consists of compression bandaging combined with anti-bacterial dressings over a period of 12 to 24 weeks. However around 30% of patients fail to respond to this treatment and become long-term sufferers needing to undergo multiple and costly alternative therapies in an attempt to alleviate their symptoms.

Sterilox Tx is a novel antiseptic solution comprising mainly hypochlorous acid (>95%) as its active ingredient at pH 5.4 to 5.8. The solution has demonstrated extremely rapid bactericidal, virucidal and fungicidal action against many organisms. Sterilox Tx solutions have also shown lack of toxicity in the wound care setting and are prepared at the point of use in the clinically appropriate concentration for clinic or homecare therapy.

Patients admitted to this clinical trial, which is still on-going, continued with their standard course of treatment but also received a 20 minute Sterilox Tx treatment. Initially this was twice weekly for three weeks and then once per week for nine weeks.

Bacterial cell count studies showed that after one single treatment with Sterilox Tx the microbial count in the patient's ulcer fluid was typically reduced 10,000 fold.

*In vitro* cell culture studies have also shown that Sterilox Tx at the concentration used within this trial (140 to 160ppm of free chlorine) demonstrated no adverse effects on fibroblasts and keratinocytes. Therefore, the ability of Sterilox Tx solution to improve the outcome and markedly reduce or eliminate pain for patients suffering chronic venous leg ulcers is due to the solution's combined activities: as a potent microbiocide and its ability to aid the healing process by not inhibiting normal cell growth.

These early trial results were presented to the wound care community at the 2<sup>nd</sup> World Union of Wound Healing Societies Congress in Paris (8–13 July 2004). Sterilox Technologies Inc. is now in active discussion with a number of commercial partners to help introduce this novel approach more widely.

### **About Sterilox:**

Sterilox solutions are a group of non-toxic, non-hazardous, fast-acting broad-spectrum biocides. The disinfectants were developed for both rapid, cold sterilisation of heat-sensitive surgical instruments such as endoscopes, as well as for general disinfectant use in hospitals.

The solutions are produced only by Sterilox's patented generators which offer single-use application - for each patient as well as for each disinfecting cycle. They produce the powerful disinfectant, as required, from water and common salt (sodium chloride) - the main active component of the mixture is hypochlorous acid (>95%).

Sterilox solutions have multiple clearances from the US Food and Drug Administration (FDA) and have been cleared for use as surface disinfectants by the US Environmental Protection

Agency (EPA). In addition, the solutions have full clearance for disinfection and sterilization and as a wound irrigant in the UK and Europe, These clearances are supported by one of the largest libraries of disinfectant microbiology available in the world today.

The company supplies its customers a complete range of generators and associated equipment, as well as Sterilox-Ultradent, a disinfectant system developed specifically for the dental market.

The company's international subsidiary is one of the UK's leading disinfectant suppliers with an approximate 20% share of the endoscope disinfection market.

For further press information please refer to [www.sterilox.com](http://www.sterilox.com) or call:

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