

Potential of Steralythes in wound management in settings with limited resources

Symposium: Surgery in low resource settings
14-16 November 2014, Amsterdam

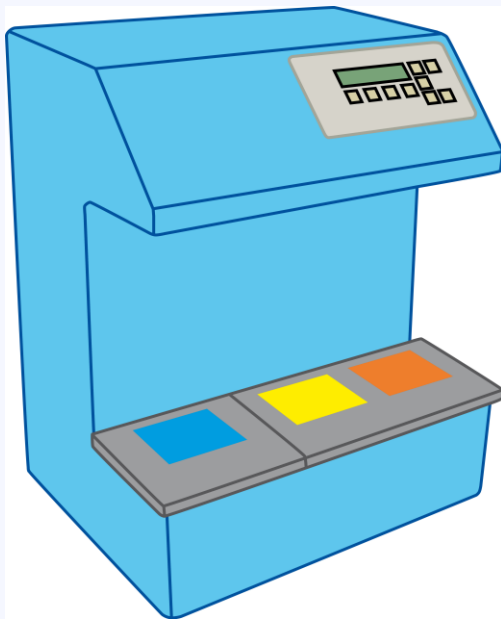
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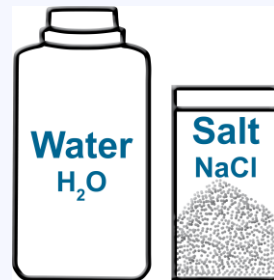
Electrodiaphragmalysis and Steralythes

- Developed from water purification technology, produces „Electro-Chemical-Activated“ (ECA) Water
- Further developed and certified for medical application within wound management (Germany and EC Certification) by AQUIS
- Steralythe[®] Wound Rinsing Solutions and Wound Gels marketed in Germany since November 2007



The technology can be used to produce:

- 2 solutions for wound cleansing
- a surface disinfectant
- drinking water / water purification

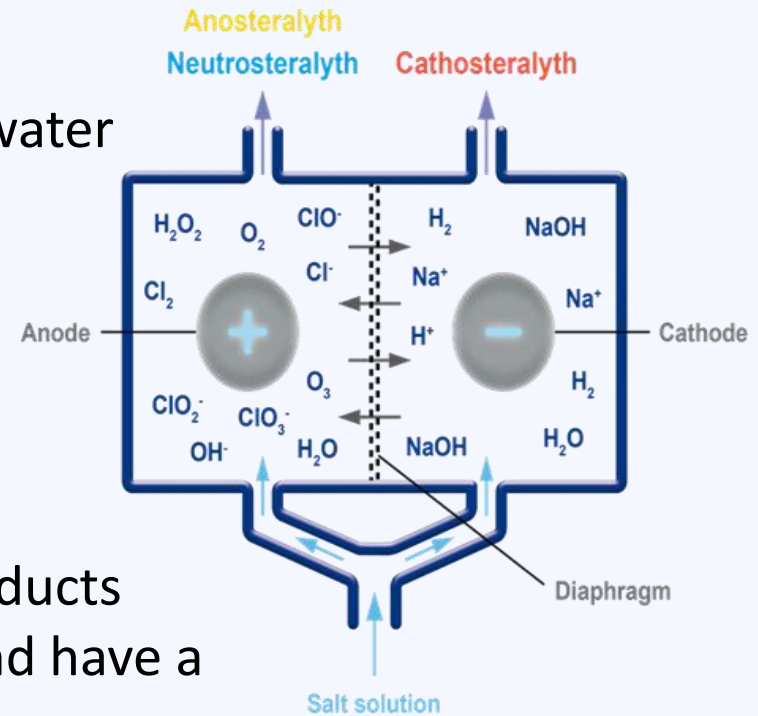


Requirements:

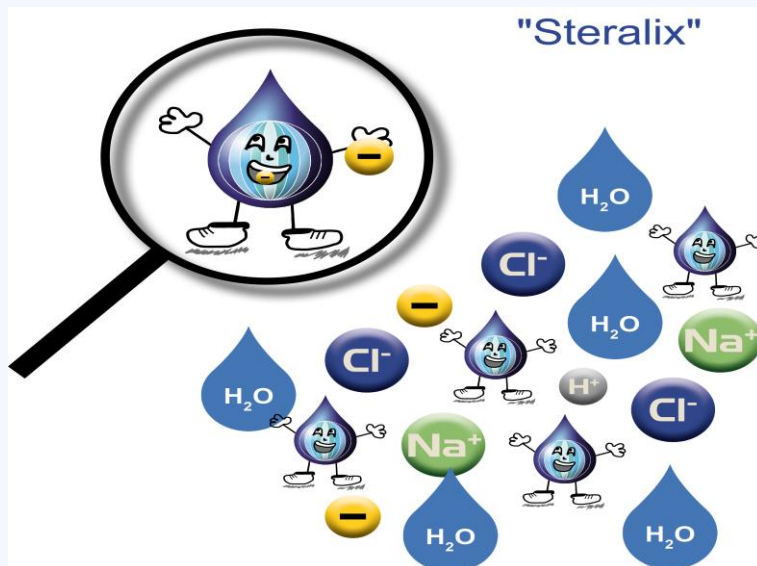
- demineralised / distilled H₂O
- salt (up to 7 g/ltr.)
- electricity

What are Steralythes?

- Steralythes are produced from distilled water with a mild concentration of NaCl via **electro-diaphragmalysis**.
- This leads to a temporary (6 – 12 weeks) electro chemical activation.
- Besides reactive oxygen species, the products contain different chlorine compounds and have a high oxidation-reduction potential.
- Steralythes
 - have very good **cell and tissue tolerability**,
 - are **biocompatible**,
 - **toxicologically safe** with **very low cytotoxicity**



STERALYTHER - ingredients



H ₂ O	water (aqua dest.)
NaCl	salt (pharm. salt)
O ₂	molecular oxygen
O ⁻ / O ²⁻	oxygen ions
O ₃	ozone
Cl ⁻	chloride ions
ClO ⁻	hypochlorite
ClO ₂ ⁻	chlorite
ClO ₂	chlorine dioxide
ClO ₃ ⁻	chlorate

	ANOSTERALYTH-Solution 30%	NEUTROSTERALYTH-Solution 30%
pH value	2,5 - 3,5	7,0 - 8,5
ORP	+1000 to +1300 mV	+600 to +900 mV
Hypochlorite and hypochlorous acid	57 mg/L	111 mg/L
Chlorine	29,4 mg/L	< 3 mg/L
Chlorine dioxide	7,8 mg/L	15,9 mg/L
Oxygen	5,25 mg/L	3,21 mg/L
Chlorate	7,2 mg/L	5,1 mg/L
Hydrogen peroxide	< 0,3 mg/L	< 0,3 mg/L
Max. content "active chlorine-oxygen compounds"	< 0,014% (±100 mg/l))	< 0,018% (±150 mg/l)

Effects of Steralythes

Wound cleansing

- Effective reduction of germs (Bacteria, Virus, Fungus, incl. MRSA, MRGN)
- Reduction of wound layers, biofilms and necrotic tissues through selective autolytic debridement
- Low pH supporting germ reduction and wound healing (e.g. by enhanced oxygen supply)*
- Active conditioning of wound ground
- Reduction of IL-1 β resulting in interruption of infection cascade

Physico - chemical effects on wounds

- Enhances physiological healing in compromised wounds and tissues (diabetes, poor circulation, burns)

* Steven L. Percival et al.; The effects of pH on wound healing, biofilms, and antimicrobial efficacy; Wound Rep Reg (2014) 22 174–186

Application of Steralythes

- Steralythe Solutions are wound irrigation solutions for **cleansing and moistening of acute and chronic wounds** and wound dressings.
- Even in problematic cases, such as **MRSA or Pseudomonas** populated wounds or skin, Steralythes contribute to wound cleansing and decontamination.
- The solutions can be applied for **irrigation of natural orifices and mucous membranes**.
- Beside the decontamination and cleaning there is a **marked effect on the wound healing process even of poorly circulated tissues and wounds**.
- Therefore patients with burn wounds, decubital defects, chronically contaminated wounds and ulcers, tropical ulcers or complicated diabetic foot problems benefit from the application of Steralythes .

Training on Steralythe production in Swaziland

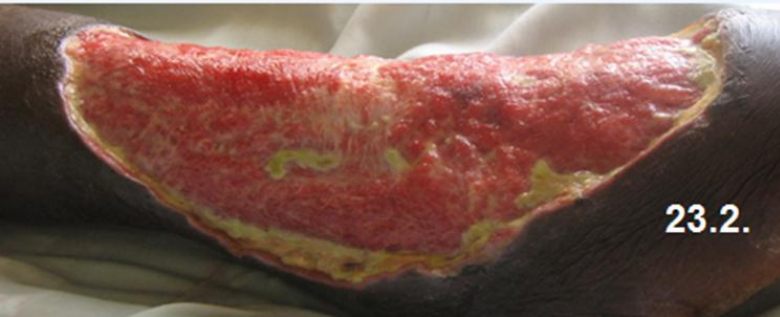


Case report Swaziland

- 30 y old female, insect bite, on 19.2. since 2 months treatment, including surgical debridement.
- Bandage sticking to wound, typical pseudomonas colouring.
- Following treatment from then onwards: daily dressing with initial cleaning with moistened gauze compress, followed by application of soaked Anosteralythe 30% for 10 min., cleaning of the wound and dressing with Anosteralythe 30% moistened gauze compresses, covered with dry compresses and fixed by bandage.
(It would have been recommended to have the dressing twice daily but in this case it was done only once (constraints b/c workload, lack of nursing staff)).
- On day 2 the pain was reduced substantially. The treatment was continued for 6 weeks, then skin grafted. See photos in the report.



**Ulcerating wound treated with
Anosteralyte 30%**

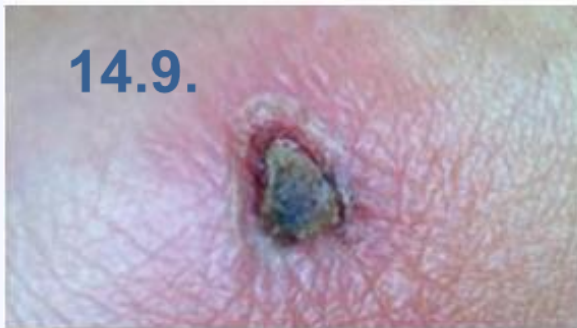


**Once daily cleaning,
application of soaked
compresses and dressing
with moistened
compresses.**

Skin grafted on 8.4.



Case Report fresh wound – accident left ankle, 57 y, m



- Necrotic ulceration due to pressure following luxation of left ankle (climbing accident, 5.9.)
- Treatment with Anosteralythe 30% twice daily
- Wound closed and clean after 3 weeks

Wound Management

- In general poor evidence!
- Few randomised clinical trials (RCT)
- RCTs only compulsory for products registered as pharmaceuticals, not for medical products applied in patient care
- Risk of „eminence driven“ and „industry driven“ concepts instead of evidence based procedures
- Need to further investigate effectiveness and efficiency of wound management (dressing + antimicrobial + healing)

- Burckhardt M, Nink-Grebe B: Wundbehandlung - Wertvolles vermehren, Überflüssiges reduzieren. Dt. Äbtl.; Heft 27–28; 7.7.2014
- Madden M: Alienating evidence based medicine vs. innovative medical device marketing: a report on the evidence debate at a Wounds conference. Soc Sci Med 2012; 74: 2046–52
- Ioannidis JP, Greenland S, et al.: Increasing value and reducing waste in research design, conduct, and analysis. Lancet 2014; 383:166–75.
- Vermeulen H, Ubbink DT, Goossens A, et al.: Dressings and topical agents for surgical wounds healing by secondary intention. Cochrane Database of Systematic Reviews 2004, Issue 2. Art. No.: CD003554

Innovative Technology

In 2010 AQUIS has participated in the call and Steralythe production has been selected as one of the innovative technologies.





INNOVATIVE TECHNOLOGIES THAT ADDRESS GLOBAL HEALTH CONCERNS

OUTCOME OF THE CALL
GLOBAL INITIATIVE ON HEALTH TECHNOLOGIES
2010



System for On-Site Production of Wound Irrigation Solution

Martina Janßen
Hermann Kranzl
Immanuel Jacobs

MEDICAL ISSUE	IMPLEMENTATION	HEALTH IMPACT
On-site Production of Wound Irrigation Solutions The Technology and the specifically designed equipment allow for need-based and cost effective on-site manufacturing of high quality wound irrigation solutions for decontamination, control of infection and stimulation of wound healing in accordance with modern standards for moist wound treatment.	Equipment The production devices are designed for decentralized and on demand manufacture of the solutions from basic source material (deminerallized water and sodium chloride) using advanced diaphragm-electrolysis-technology.  <p>Operational requirements:</p> <ul style="list-style-type: none"> Water demineralized (or distilled, if available) Salt max. 2.0 g per liter Electro power supply: 100-240 V AC or 24 VDC; max. 300 W <p>Device Specifications:</p> <ul style="list-style-type: none"> Total weight: 18 kg Dimensions: 41.5 x 33.0 x 51.5 cm Automatic controls 	Cleansing and Decontamination of Wounds The interaction of different, highly reactive oxidants in the fluids leaves no chance for microorganisms. Tests have confirmed that the solutions are effective in decontamination against a wide spectrum of microorganisms. <p>Decontamination Properties of Anode solution / Anode Neutral Solution</p> <ul style="list-style-type: none"> Staphylococcus aureus Multiresistant Staphylococcus aureus (MRSA) Escherichia coli Pseudomonas aeruginosa Legionella pneumophila Candida albicans
Wound Irrigation Solutions for Modern Treatment Standards The Technology provides means for topical treatment of wounds and infections meeting modern standards of wound management, such as wound irrigation, moistening and moisture of wounds. Users are provided with the possibility to manufacture their own solution for wound irrigation and wound moisture in a basic and cost effective way. Due to the specific properties of the solutions moist wound treatment on non-heals can be implemented in combination with simple and cost-effective wound dressing material (e.g. cotton swabs and cotton compresses).	Production Technology The basic technical process of the Technology is based on diaphragm-electrolysis (a special form of electrolysis). The technical procedure is called electro-chemical activation.  <p>In the diaphragm-electrolysis process, a source solution - demineralized water and a small quantity of highly pure salt - is conducted through the electrolysis cell and exposed to the effect of electric current.</p> <p>Thereby different processes of chemical and electro-chemical nature are running parallel and generate products, which in comparison to the source solutions show modified physical and chemical properties (electrical conductivity, pH value, ORP, structural composition). Besides different chlorine compounds the solutions contain a high number of ROS (reactive oxygen species) such as oxygen ions, ozone, hydroxide ions and hypochlorous acid and have a high oxidation-reduction potential. Due to the specific production process the shelf-life is limited.</p>	Stimulation of Wound Healing / Bioelectrical Effects Electrical processes are playing a central part in and on wounds (around electrolysis). In fact, vital skin has endogenous bioelectrical properties. Deeper skin layers are positively, the skin surface is negatively charged. The charge balancing (short circuit), that occurs in injury, generates a measurable wound current. Defensive cells, fibroblasts and epithelial cells (Calcium-Electrolysis) are attracted and activated. The physiological processes of wound healing - provision and release of mediators and stimulation of blood circulation - in the wound perimeter can be favourably affected and stabilized. However the electrical potential is a shadowed in complicated resp. large wounds or extended healing processes. In chronic wounds the wound current ceases almost entirely. The Anode and Anode Neutral Solutions contain a high density of negative charges. Irrigation, moist pads or moist dressings contribute to the stabilization resp. renewal of the electrical potential in the wound area, re-activation of the wound current, and optimization around healing. 
Health Issues Addressed <ul style="list-style-type: none"> Wounds Burns Skin Diseases Diabetic Foot Syndrome Neuropathic Infections 	Features of the Technology <ul style="list-style-type: none"> Covers a wide range of applications in a neglected sector of primary health care; Can prevent enormous secondary health complications with basic means; Shows immediate positive effects on the health situation; Requires no programs in preparation; Facilitates autonomy in supplies; Can be applied by using existing structures; Is safe and environmentally compatible. 	Case Study Wound Healing Patient: 70 years old, Diabetic Foot Syndrome, severe wound healing disorder following amputation of the toe. Treatment with moist swabs and moist dressings using Anode Solution 30% concentration.  <p>Creditline at the origin of the text.</p>

www.who.int/medical_devices/initiatives/en/

WHO

"Call for innovative technologies that address global health concerns"

Perspectives & Objectives

- Clinical case studies (270) have been documented within the registration and certification process
- To make steralythes available in hospitals of developing countries
 1. To identify possible partner – hospitals or pharmacies
 2. To supply steralyths for testing and further investigate effectiveness and efficiency of wound management (dressing + antimicrobial + healing)
- To start local production (equipment, material, training)
- To follow up opportunities to use the technology for the production of disinfectants (surfaces and instruments), registration process currently on the way

Research

- „The influence of Steralythes on cells of the musculoskeletal system and their activity on germ reduction and biofilms“
- was researched at the University of Marburg, Department of Medicine, Centre for Orthopedics.
- The data will be published in 2015.
- Preliminary Information: Biocompatibility of Steralythes in lower concentration has been shown in vitro in cell cultures of osteoblasts and chondrocytes.

What Aquis can offer

- Committed to further research in collaboration with partners in Europe and in developing countries
- Supply Steralythes for testing
- Thank you

