



SERENAGROUP NEWSLETTER

BUILDING THE NATION'S LEADING WOUND CARE TEAM

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THE RESULTS ARE IN FROM BIAKŌS – LOWER EXTREMITY ULCERS CLINICAL TRIAL

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SerenaGroup Monroeville



54 patients were enrolled in a double-blind controlled proof-of-concept clinical trial with the interest of reducing bioburden and promoting healing in chronic diabetic foot ulcers and venous leg ulcers. Patients who met inclusion and exclusion criteria were consented and randomized 1:1 to receive either the standard-of-care – normal saline wash and an amorphous gel or the treatment of interest – PHMB-1 (BIAKOS®, Sanara MedTech Fort Worth, TX) synergistic antimicrobial cleanser and antimicrobial gel. The BIAKOS® antibiofilm agent is formulated to disrupt the biofilm, kill bacteria, and prevent the reformation of biofilm. Patients received their randomized treatment for five weekly (+/-3 days) visits over 28 days of the study, which included the screening visit. At each visit, photography and digital surface measurement of the wound would be collected using the MolecuLight Procedure (MiX). Which was completed using the MolecuLight i:X Imaging Device, a handheld point-of-care medical device comprised of a high-resolution color LCD display and touch-sensitive screen with integrated optical and microelectronic components. Wound cleansing would occur with the randomly assigned treatment, and additional debridement and wound dressing would occur at the indication of the principal investigator.

27 patients were randomized to each treatment arm, with 19 patients (70%) receiving PHMB-1 and 16 patients (59%) receiving standard-of-care reaching >40% PAR in four weeks. A chi squared test of independence determined the relationship between the treatment and patient reaching 40% PAR in four weeks was not significant, $(1, N = 54) = 0.73$ and $p = .39$ at a significance level of .05; however, there was a strong trend favoring the antibiofilm cleanser and gel.

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MONTHLY NEWSLETTER

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CLINICAL TRIAL RESULTS CONTINUED

A significant reduction ($p < 0.05$) in bacterial load was observed in the antibiofilm group. This randomized controlled double-blind proof of concept study suggests that the performance of antibiofilm agents in vivo is comparable to in vitro studies.

Both the results of this clinical trial and the trial design are currently submitted to Diagnostics and Life journals, respectively.

Figure 1: A diabetic foot ulcer before (a) and after (b) debridement and cleansing with the PHMB-1 active agent. There is complete resolution of bacterial fluorescence indicating a reduction in bacterial load below 104 CFU/g.

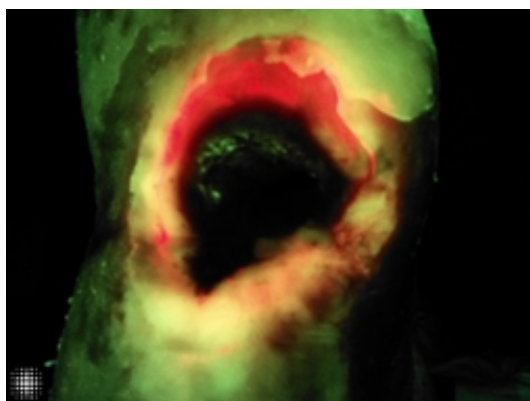


Image A- Before

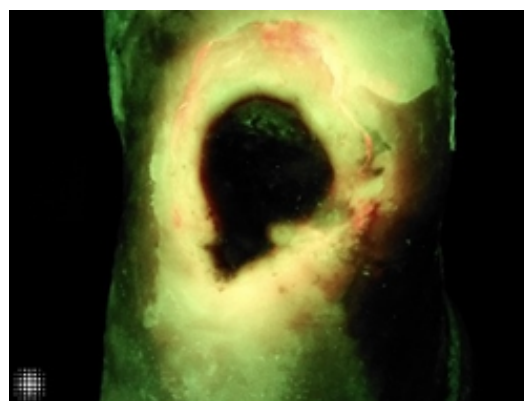


Image B- After

SKIN SUBSTITUTE LCD CHANGE UPDATE

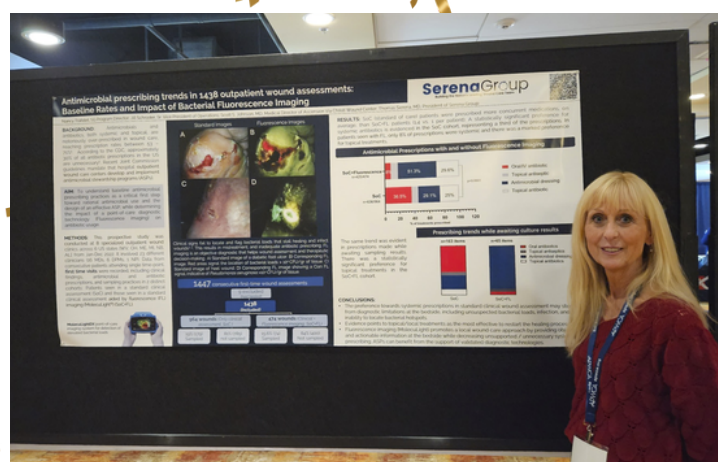
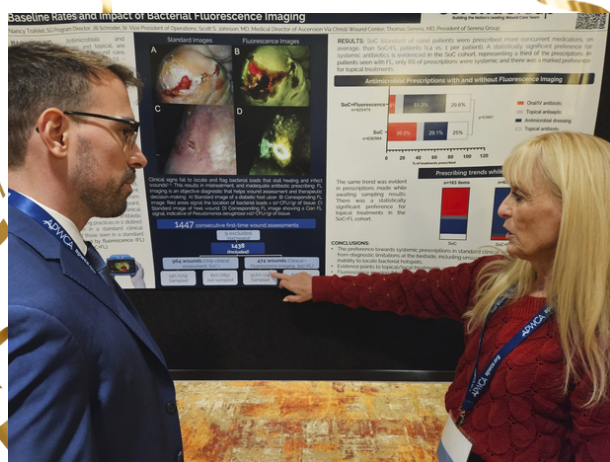
The proposed change to the LCD for Skin Substitute Grafts/Cellular and/or Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers **will not** become effective on 10/01/2023.

A new Proposed LCD will be published for comment and presented at an Open Meeting in the near future. In the meantime, current coverage has not changed, and you are viewing the existing policy in effect. For those in Novitas, CGS and First Coast, it is business as usual!

APWCA POSTER PRESENTATION

SerenaGroups very own Nancy Trafelet recently presented her findings from her American Professional Wound Care Association poster, "Antimicrobial prescribing trends in 1438 outpatient wound assessments: Baseline Rates and Impact of Bacterial Fluorescence Imaging".

Nancys consistent data collecting and persistence on ensuring best practices are in place is just one way SerenaGroup is making a difference to ensure chronic wound patients receive the best possible care through ASP.



HBO TECHS RECEIVE HOSPITALS PETAL AWARD

Brandi and Jess, HBO Techs at Inspira Health Elmer, were awarded the Hospitals Petal Award.

The hospital Leadership Team surprised them both in Early September with recognition.
Congrats to you both; well deserved!



The PETAL Award is a recognition program that honors the performance, dedication and diligence of Inspira’s nursing support partners.

The PETAL Award is administered by the Nursing Department to thank those who partner with nurses to care for patients and their families. The PETAL Award celebrates those who provide the “wow” experience in all aspects of care.

Monthly Education Topic

Think HBO!

HBO Safety Topic

Physiology of HBOT for Each Indication and When to Consider Continuation

Community Education Area of Focus

Orthopedics

Breast Cancer Awareness Month

Gynecological Cancer Awareness Month

Healthcare Quality Week

October 15-21

World Trauma Day

October 17

THIS MONTHS EDUCATION TOPICS & IMPORTANT DATES



SerenaGroup Blue Star Winner



Jackie Csora

Medical Assistant

Cleveland Clinic Akron General

Jackie is a true team player. She is a huge reason why our clinic runs so smoothly. She is constantly helping out wherever she can. Patients love her and her coworkers all express how lucky they are to work with her. Thank you Jackie for all your hard work!



UPCOMING

40hr Intro to HBO Courses

Nov 9-12, 2023 | West Palm Beach FL

To register for an upcoming course please go to serenagroupinc.com and click on courses.

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Building the Nation's Leading Wound Care Team

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