

# SERENAGROUP NEWSLETTER

Building the Nation's Leading Wound Care Team

## SERENAGROUP® LEADERSHIP CONFERENCE



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**THOMAS SERENA, MD, CEO**

SerenaGroup® is excited to announce SerenaGroup® Leadership Conference in October 2021 in St. Petersburg, FL. The purpose of this conference is to continue to invest in our strong leaders.

*"SerenaGroup® strength lies in its connectivity. Our Leadership conference celebrates the network of pioneers that drive the business of wound care."*

The agenda for the upcoming 2-day SerenaGroup® Leadership Conference consists of presentations on:

- Antimicrobial stewardship program
- Community education
- HBO workflow & best practices
- Internal compliance survey
- SerenaGroup formulary
- SerenaGroup quality metrics
- SerenaGroup research
- SerenaGroup vision
- SerenaGroup development
- Understanding billing/charges

What does it take to become a SerenaGroup Leader? A specialized skill set that consists of teamwork, networking, operations, and culture.

**Teamwork:** Teamwork is the collaborative effort of our group to complete a task in the most effective and efficient way. Our SerenaGroup leaders work together toward a common goal: healing patients.

**Networking:** Networking between SerenaGroup medical professionals across the health-care spectrum has enabled our team to deliver consistent and uniform care to our patients. The free exchange of ideas as they are developing and shared within our company provides an advanced and consistent body of methods, treatments and outcomes that has resulted in an exemplary level of medical care, of which we are justly proud.

**Operations:** Through education, training and mentorship SerenaGroup management assures that our Wound Care Centers deliver high quality medical care.

**Culture:** From our newest employee to our CEO, SerenaGroup strives toward an inclusive company culture with a shared goal of excellence in medicine, compassion and understanding in interpersonal relationships, universal respect for the rights of our fellow employees and a commitment for ALL of us to realize our potential.

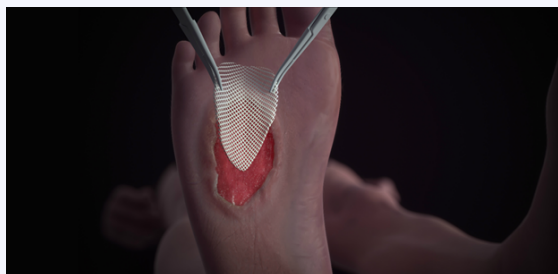


## Cellular and Tissue Products (CTP)

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### What is Cellular and Tissue Based Products?

Cellular and Tissue Based Products – Any human or nonhuman cellular-based transplantable or implantable products, whether classified by the US Food and Drug Administration (FDA) as a tissue or a medical device. Collagen and tissue products derived from plastics and polymers are not considered cellular-based products and are not subject to these policies.



### When and where do we use CTPs?

- Ulcers that have a granulated tissue bed
- Have been treated for infection, if necessary
- Meet all medical necessity requirements per the LCD, including vascular and glucose assessments
- CTPs can be used in the wound center or in the Operating Room

### Examples:

Apligraf, Theraskin, PriMatrix, Stravix, Dermagraft, PuraPly, Grafix, Epifix, Oasis

(not limited to these products)

### Will insurance cover CTPs?

Before a patient receives a CTP, the LCD should be consulted to review the conditions of medical necessity. Please review the LCD for those cellular or tissue products that are considered investigational.

### Will SerenaGroup help monitor the compliance regulations?

Annually, the Corporate Reimbursement Director will confirm that a supplier is registered with the FDA. Documentation of this verification will be maintained in the wound care center.

If the state in which the wound care center is located, requires a state license, permit, registration, or authorization, this will also be verified. Documentation of this verification will be maintained in the wound care center.

### What should be documented when using CPTs?

Product identification information (tissue/product type and unique identifier), including expiration date, as applicable, will be placed in the patient's medical record. Normal saline lot number and expiration date used in application of tissue product, where applicable, will be documented in the patient's medical record.



## SerenaGroup Research

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### Kristy Breisinger Research Analyst



The search for interventions that promote healing, reduce pain and enhance the quality of life continues. While many chronic ulcers will heal with standard of care treatment, the process can take several months. SerenaGroup Research Foundation is actively conducting several clinical research studies into adjunctive treatments that can speed the healing process and will result in lower treatment costs as well as lowering the risk of complications. The study treatments range from fluorescent light energy antimicrobial wound cleansers, dual layer amniotic membranes, and resorbable porcine peritoneum-derived matrix.



Our newest study, LumiHeal®, evaluates the preliminary efficacy of fluorescent light energy (FLE) as an adjunctive treatment to standard of care (SOC) on reduction of wound area in patients with diabetic foot ulcers (DFU) and venous leg ulcers (VLU) after 4 weeks of dosing and up to 12 weeks of dosing in responders compared to SOC alone as reflected in historical controls. LumiHeal® is a biophotonic system composed of two parts: a photo converter gel containing chromophores and a multi-LED Light source. The use of the gel and the fluorescent light energy as a combination treatment is considered investigational (i.e. not yet approved by the U.S. Food and Drug Administration “Investigational” means it has not been approved by the U.S. Food and Drug Administration.)

After positive results with subjects using Anaseptic, we are expanding our clinical trial to include additional subjects. Across the United States, many advanced wound care centers have adopted the practice of cleansing nonhealing wounds with antimicrobials; however, some centers continue to use normal saline to clean wounds, citing a lack of clinical trial evidence for antimicrobials. Commercially available antimicrobials promote products based on laboratory or preclinical evidence rather than on clinical trials. This clinical trial is designed to provide efficacy data for a commonly used antimicrobial, AnaSept® (Anacapa, San Dimes, CA).

Our largest active trial is a randomized controlled multicentre clinical trial, evaluating the efficacy of dual layer amniotic membrane (Artacent®) and standard of care versus standard of care alone in the healing of chronic diabetic foot ulcers. Artacent® is a double layer of dehydrated amniotic membrane that was released to the market with indications as wound covering in 2016. This HCT/P is regulated solely as a “361 Product” and meets all criteria in 21 CFR 1271.10(a). The amnion is harvested from human placenta obtained during planned caesarean sections. Tides Medical uses a proprietary process to clean and decellularize the amniotic membrane. The amnion is then folded into a bi-layer with the stromal sides facing outward. The dual layer is dried and cut into various sizes. In the final step the DLAM is terminally sterilized. All processing steps meets the requirement of minimal manipulation and the HCT/P is not dependent upon the metabolic activity of living cells for its primary function as a wound covering.

Lastly, we are actively enrolling the last few subjects in a post market study of Meso Wound Matrix. The study is a multi-center, prospective, clinical trial designed to evaluate the use of Meso Wound Matrix in Wagner grade 1 and 2 DFUs. Meso Wound Matrix is a resorbable porcine peritoneum-derived matrix intended for the management of topical wounds.



## SerenaGroup Education

SerenaGroup recognizes that the key to continued success with positive clinical outcomes is education. Education is provided through different platforms to ensure the tools are available to our centers. Topics for September Education included (but not limited to):

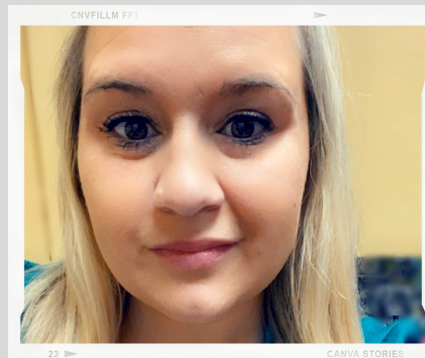
- Journal Club: TBA
- HBO Safety: Confinement Anxiety Claustrophobia
- Monthly Education: Cellular Tissue Products
- Roundtable Compliance Meeting
- Roundtable PD Meeting

Education is one of many key benefits to partnering with SerenaGroup.

### Educational Courses

HBOT 40hr Course  
November 11-14, 2021, West Palm Beach, FL

## SerenaGroup Blue Star Winner



**Niki Kirven**

Cleveland Clinic | Akron General

"Niki has brought a wealth of knowledge as a Wound Certified Nurse to our center; she is dedicated to the patients and is focused on healing."

# SerenaGroup

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