SERENAGROUP NEWSLETTER

Building the Nation's Leading Wound Care Team

FACTS ABOUT CELLULAR AND/OR TISSUE-BASED PRODUCTS



THOMAS SERENA, MD, CEO

What are cellular and/or tissue-based products?

A cellular and/or tissue product (CTP) is defined as a product containing or consisting of human or animal cells that is used to encourage tissue and cell growth in a wound bed. The goal is to promote skin coverage and closure in chronic wounds. CTP was designed to replace skin grafting, which is tissue taken from one part of the body and attached to the wound area. Skin grafting can be a serious procedure that is much more invasive and painful, whereas, a CTP comes in a package and is simply attached to the wound bed.

What you can expect?

Your provider may determine that you are a candidate for cellular tissue products if you have a chronic wound that has a clean wound bed with adequate blood flow and the wound has not had significant improvement with

standard wound care. CTP can be a single application or a series. It can be applied in the office or in the operating room, depending on your wound bed. Once a CTP has been applied to your wound, you will need to adhere to your provider's plan for you, which may be to keep the wound dressing intact until your next appointment, as well as keeping the dressing dry, and not bearing weight on the area.

Accelerating new tissue growth in a healthy wound bed!

How CTP works?

CTP can stimulate the body's healing process to rebuild tissues. CTP have epidermal cells that are embedded in a collagen dressing that works to create and stimulate the outermost layer of skin to grow over the wound.



Pictured: Ascension
Via Christi St. Francis
Wound Healing &
HBO Center using
CTPs to capture
chronic wound
healing with their
patients.



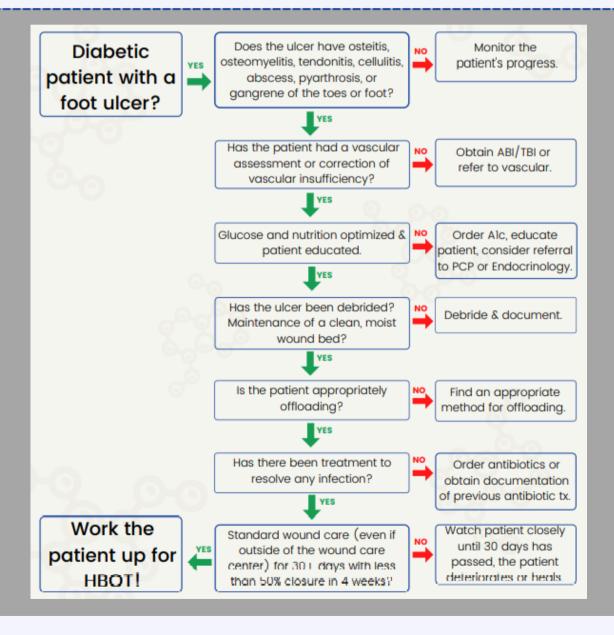
The Importance of Healthcare Workflow Management

Effective workflow management can streamline workflows and has been shown to reduce the potential for medical efforts, help to ensure compliance with industry regulations such as HIPAA, and improve quality of care provided to patients.

SerenaGroup continues to develop effective workflows to educate

providers and staff to ensure quality of life to the chronic wound care patient while they are with us on the path to healing chronic wounds. Below is ONE example of a workflow that is put in place in our centers. Those partnered with SerenaGroup can be assured the chronic wound care patient is appropriately taken care of without missing appropriate modalities along with way.

Qualifying a Diabetic Ulcer for Hyperbaric Oxygen Therapy





Sixty Seconds of Safety

Matt Schweyer Chief Compliance Officer



Sixty Seconds! What can happen in that short time span? Your heart will beat sixty to one hundred times, blood will flow through your vascular system approximately three times, you will blink fifteen to twenty times. In Hyperbaric Medicine, a missed opportunity for safety could be catastrophic in sixty seconds. And that is this month's topic of discussion.

In recent years, we have a had a relatively good safety record in the hyperbaric medicine field, but because of horrific incidents that have occurred in the past, NFPA now includes a chapter for Hypo/Hyperbaric Chambers. However, our recent past is indicative of failures that, in my opinion, could have been prevented (another topic of discussion for a future monthly call). As our National Safety Director, I would like to spend a few minutes to hardwire <u>Sixty Seconds of Safety</u>!

What exactly am I getting at: what does this mean and why is it important?

In days gone by, items had two pathways of clearance into the Hyperbaric Oxygen environment. The first, approval by the device manufacturer was included in the Food and Drug Administrations (FDA) 510k submission packet. Guess how many items had that clearance? Here is a hint, you can count them on one hand; Today, on all your fingers and toes. So, a few more! Also, in today's era, HBOT has seen some items pulled by manufactures, the Hospira Infusion pump being the latest. Why? Simple economics to the manufacturer. If they do not see a Return on Investment (ROI), they do not conduct the Research and

Development to clear it for our modality in medicine; but we are not alone. Imaging and, specifically, Magnetic Resonance Imaging is saddled with similar issues.

The second pathway, OOP's! Sadly, I am in the era, that OOPS happened; Gladly I am in the era that Sixty Seconds of Safety became reality and hardwired. The OOP's pathway was a biproduct of missed opportunity and coincided with the proliferation of hyperbaric oxygen as a modality. Despite face-to-face consultation with the Provider, education for the Nurses, and vigilant screening by the chamber techs, items made it into the hyperbaric chamber and, amazingly, the patient made it back to sea level safely! Thus, in the early days when we would contact a manufacturer about device A going into the chamber, they would say, it is not cleared by the FDA, HOWEVER, it has been reported it was safe at 33,45,60 or 66 feet of sea water! Why? Oops it made it to pressure and back. Talk about human clinical trials! Thus, we would document the information, clear it with the Safety Director and the physician would agree and, occasionally, we would run it through Risk Management at the hospital.

Within the Undersea and Hyperbaric Society (UHMS), we tracked, OOP's, created the Safety Committee technical symposiums. And checklists became reality in the mid 1980's (no judgement on age)! Since then, they are the Gold Standard, and Best Practice of HBOT today. So, the next time, you hear me ask, "Have you performed Sixty Seconds of Safety," you will know, it is not rapid fire (pardon the pun) movement to get the patient to pressure. I get the schedule thing! However, SIXTY SECONDS of SAFETY every day, every treatment, reviewing the checklist with every patient and engagement with two-way communication-I believe those SIXTY SECONDS are the most important of that daily treatment for the patient, yourself, and the lives of other staff! Do not Delay, Do Sixty Today!

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 May Education included (but not limited to):

- Journal Club: TBA
- HBO Safety: Choosing a Safe Dressing for Patients Receiving HBOT
- Monthly Education: Vendor Access
- Roundtable Compliance Meeting
- Roundtable PD Meeting

Education is one of many key benefits to partnering with SerenaGroup. We are Building the Nation's Leading Wound Care Team.

Educational Courses

HBOT 40hr Course = Atlanta GA August 2021 *More details to come*





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