

The SerenaGroup® Difference

I founded SerenaGroup® to bring a clinical focus to the operation of wound and hyperbaric centers. At the time, management companies offered business only solutions: Their unrealistic proforma-driven proposals lacked a clinician-led, patient-centered approach. Staffing the center with a panel of part-time, semi-retired physicians failed to advance the specialty of wound healing. If wound care is to gain acceptance and fully integrate into mainstream medicine, full-time woundologists must staff the wound center. The goal of SerenaGroup® is to advance the specialty of wound care and redirect attention to clinical excellence. We continue to adhere to our core principles:

SerenaGroup® Core Principles

- C** – Clinical excellence
- O** – Outreach (Community/Physicians
- R** – Research and quality improvement.
- E** – Education (on-site & ongoing)

Clinical excellence defines a SerenaGroup® center. We measure performance through validated quality metrics benchmarked against our other advanced wound care centers. Quality measures do not include easily manipulated healing rates, but well-defined evidence-based practices, such as off-loading for diabetic foot ulcers and compression for venous leg ulcers. An additional quality measure, the screening of all patients with lower extremity skin breakdown, fits into the role of the wound clinic as a partner in limb preservation. Quality scores direct future educational activities. SerenaGroup® policies and procedures and algorithms do not gather dust on shelves or hide deep within the electronic health record (EMR). We believe that achieving clinical distinction begins with adherence to the fundamental principles outlined in these documents.

The popular adage, “if you build it, they will come,” does not apply to wound care centers. The SerenaGroup® **Community Outreach** program, in cooperation with the hospital’s marketing team, will identify potential referral sources for wound care and hyperbaric patients. SerenaGroup® provides tried and tested collateral (see examples below) branded with the hospital’s logo and color scheme for distribution. Dr. Serena personally works directly with program directors and community educators on techniques. In a weekly community outreach call he reviews the latest advances and techniques for communicating effectively with physicians.



Hyperbaric Oxygen Therapy in the Treatment of COVID-19 Patients

Hyperbaric Oxygen Therapy (HBOT), involves breathing 100% Oxygen in a pressurized chamber. The treatment is cleared by the FDA, however, treating respiratory distress in COVID-19 patients is not an approved indication. Initial studies show COVID-19 triggers an intense immune response leading to pulmonary inflammation and hypoxia. HBOT has the potential to increase oxygen delivery, alleviate symptoms and reduce inflammation. Ongoing research aims to determine if HBOT can help COVID-19 patients recover more rapidly and decrease the need for mechanical ventilation.

SerenaGroup® is working with its hospital partners to evaluate the safety and efficacy of the compassionate use of HBOT to reduce the need for mechanical ventilation in COVID-19 patients. SerenaGroup® has developed IRB-approved protocols, and policies and procedures to safeguard patients and clinicians.

On April 29, 2020 – Dr. Serena and other professional colleagues partnered with AAWOC and presented a case study webinar on HBOT for the treatment of COVID-19. To view the webinar including 3 case studies, go to the AAWOC website to view – or use the link below:
<https://www.aawoc.com/members/docs/04/2020/HBOT-for-the-treatment-of-COVID-19>

Hyperbaric Oxygen and COVID-19: Clinical trials registered on clinicaltrials.gov
<http://www.aawoc.com/covid-19/>
<https://www.serengroup.com/covid-19/>

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UTILIZING HYPERBARIC OXYGEN THERAPY FOR DIABETIC FOOT ULCERS



Healing a diabetic foot ulcer challenges the most experienced clinician. The high levels of bacteria and infection in the ulcer, poor glucose control, underlying vascular disease and neuropathy, difficulties with offloading and patient compliance combine to frustrate the healing effort. Patients that fail to respond to standard wound care benefit from advanced therapy. Clinical trials demonstrate that HBOT accelerates healing in recalcitrant ulcers reducing the risk of amputation.

Who is a candidate for Hyperbaric Oxygen Therapy?

- Patients with nonhealing diabetic foot ulcers that have failed to progress in 30 days.
- Patients who have had previous infection in their DFU benefit from HBOT.
- Wagner 3 or greater DFUs

How does hyperbaric oxygen therapy help?

HBOT induces the growth of new blood vessels, angiogenesis, through local and systemic means. The poorly perfused DFU benefits from the increased oxygenation that comes from angiogenesis. In addition, HBOT enhances the immune system reducing the negative influence of bacteria on healing. Finally, HBOT stimulates the production of growth factors that promote healing.

Wagner Grade Classification System

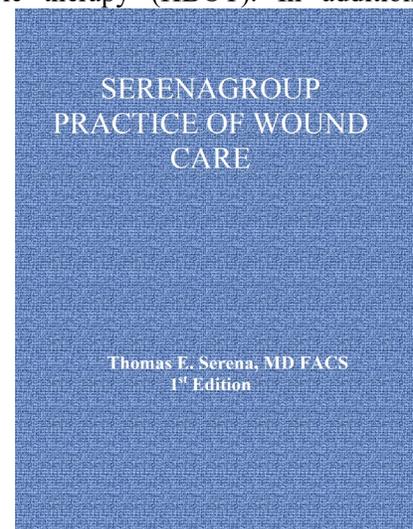
Grade 0 – intact skin
 Grade 1 – superficial ulcer of skin or subcutaneous tissue
 Grade 2 – ulcer extend into tendon, bone, or deep
 Grade 3 – ulcer deep with osteomyelitis or abscess
 Grade 4 – partial foot gangrene
 Grade 5 – whole foot gangrene

CLINICAL INVESTIGATION
 HBOT

Senior Vice-President of operations, Jill Schroder and her education committee create a strong presence on social media both nationally and locally.

A glance at the wound care literature confirms SerenaGroup's® hegemony in **quality improvement** initiatives and **clinical research**. Although it is not required, we encourage clinicians in our centers to participate in clinical research. The SerenaGroup® research staff will assist in the development of Medicare mandated quality improvement projects (QIPs). Wound care centers treat the uninsured and under-insured. A clinical research program allows these patients to receive the latest technology at no cost, while the hospital and physician receive remuneration from the trial sponsor. During the COVID-19 crisis, the SerenaGroup® research team quickly adapted technology from virtual clinical trials to create telehealth apps. SerenaGroup®, in collaboration with its affiliates, published the world's first case series on the use of HBOT to reduce the need for mechanical ventilation in patients with COVID-19.

The burgeoning specialty of “woundology” lacks formal residency or fellowship training programs and receives minimal attention in nursing schools; Therefore, **education** is crucial to success. SerenaGroup® provides comprehensive educational opportunities both on-line and in-person. Dr. Serena and his team conduct a 40-hour Introduction to Hyperbaric Medicine course on-site, which fulfills the Centers for Medicare Services (CMS) requirement for billing for hyperbaric therapy (HBOT). In addition, SerenaGroup® offers a two-day Wound Care Challenges™ course featuring both didactic lectures and hands-on symposia, enables nurses to obtain competencies in basic wound care procedures. Our unique compression training system allows us to monitor the amount of compression applied under a multilayer compression wrap. In addition to on-site education, monthly on-line webinars explore the latest topics in hyperbaric safety, wound care nursing, audits, and billing and reimbursement. The SerenaGroup® member portal houses enduring lectures on a wide variety of related topics including 15 minute “Tom Talks:” quick lectures on relevant wound care issues. Topics also include a lecture series reviewing The Practice of Wound Care, the SerenaGroup® text on basic wound care. Advance wound care procedures are covered in on-site and on-line. Continuing education credits are provided for select lectures and demonstrations.



SerenaGroup® Value

The definition of value in medicine, like most industries, encompasses the combination of cost and quality. SerenaGroup® delivers the highest clinical quality in the industry. What about cost? Borrowing a football analogy, we have a strong offense and defense. We defend against Medicare claw-backs and fat formularies. Our offense maximizes revenue through staff efficiencies and billing and coding education. We are on the field with our hospital partners, while our competition stands on the side lines.



Billing and reimbursement support, one of SerenaGroup's® most in-demand services, strives to maximize hospital revenue in a fully compliant fashion. Paired with the SerenaGroup® analysis of productivity and our value-based formulary, we expect the wound center to make a positive contribution to hospital revenue. Matt Schweyer CPCO leads the SerenaGroup® Compliance, Quality and Reimbursement Department. Matt has successfully guided our hospital partners through several T.P.E. and other audits.

Revenue support includes,

- Front & Back Office support
 - Billing and Coding, reviews & recommendations
 - CDM review including
 - Fee schedules
 - Revenue Code
 - CPT Code assignment
- NCD, LCD & Medical policy review
- Documentation for Medical Necessity including templates
- Virtual and on-site support
- SerenaGroup® Vigilant Audit Support™
 - Preparation for potential audits (e.g. OIG, TPE, RAC, ZPIC)
 - Assistance with audit defense



Matthew Schweyer
CPCO, CHT-A, CHWS
Chief Quality Officer
Certified
Professional
Compliance Officer

SerenaGroup® Formulary: *saving money through value-based purchasing.*

I have witnessed wound care centers unnecessarily fall into the red by failing to properly document medical necessity for advanced products or through overuse of expensive Cellular or Tissue-based Products (CTPs). How many patients occupy a hospital bed waiting for a negative pressure device before discharge? Our inpatient policies eliminate the wait and reduce length of stay. SerenaGroup® centers receive our frugal

formulary, policies and procedures addressing advanced products and devices, templates for medical necessity documentation and any preferred SerenaGroup® pricing.

- Access to SerenaGroup® frugal formulary™ (Inpatient and Outpatient)
- Utilization review for supplies and advanced products
- Medical Necessity documentation templates
- SerenaGroup® pricing
- Evaluation of new products and therapies

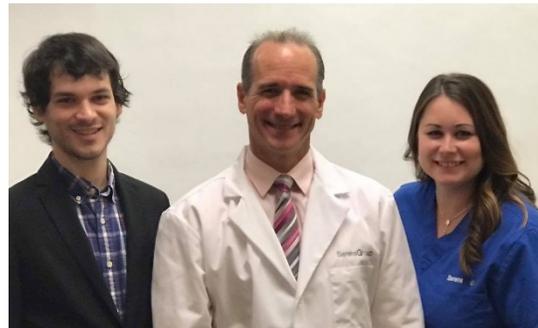


Jill Schroder Senior
Vice-President
Operations

Productivity analysis: *saving money through efficiency.*

SerenaGroup® continually reviews and assesses patient volume and staffing needs. SerenaGroup® program directors report new patient volumes on a weekly basis. Jill Schroder, senior vice president of operations, has her finger on the pulse of center productivity. She implements nurse-to-patient staffing ratios that have a proven record of efficiency and staff satisfaction. No two centers are alike. Once established, staffing is reevaluated on a regular basis. In addition, it is essential for all staff to function at the top of their licensure. SerenaGroup® has found that the best performance comes from a team with nurses and technicians with a variety of licensure levels focused on bringing their expertise to the care of our patients.

- Review of daily patient volume and scheduling
- Monthly new patient goals
- Efficiencies for the wound care team
- Staffing needs: determining the best nurse to patient staffing ratio
- Best staff mix (e.g. R.N., L.P.N.)



SerenaGroup® Operational Support

Wound Center Operations. under the direction of senior Vice-President, Jill Schroder, ensures the smooth functioning of the center. Jill's expertise focuses on the essential pieces for center performance such as annual competencies, up-to-date job descriptions, staffing, organizational charts, program director accountability and training, fiscal responsibility, trouble shooting, and hospital communication. She hosts

weekly meetings with the SerenaGroup® program directors and is readily available to help assist in all operational concerns/issues.

Hyperbaric safety falls under the purview Tim Mayhugh CHT. He assists the hyperbaric units with chamber maintenance, technician competencies, safety education and required fire drills. In addition, Tim teaches the technical portion of our 40-hour Introduction to Hyperbaric Medicine course. Tim and Dr. Serena have taught the course hundreds of times to rave reviews.



Timothy Mayhugh CHT
National Safety
Director

SerenaGroup® Delivers in All Patient Care Settings

When I opened my first wound clinic in the late 1990s, I saw patients in all care settings, acute care, the outpatient wound and hyperbaric center and in post-acute care. Unfortunately, over time wound centers became outpatient silos with little or no communication with the inpatient wound team. As a result, patients sat in hospitals waiting for negative pressure devices, length of stay for wound-related diagnoses increased and readmission rates climbed. SerenaGroup® suggests one cohesive team manages all wound services. SerenaGroup® guidelines on referral to the outpatient wound center will decrease length of stay and reduce readmissions. In addition, policies on wound supplies and device use will result in significant savings.

The current commercial wound center management paradigm places its primary emphasis on outpatient centers at the expense of continuity of care. SerenaGroup's® dedication to providing the best care for patients with chronic wounds means delivering care in all patient care settings. This practice improves clinical outcomes, decreases the cost of inpatient care, increases outpatient wound center volume, shortens length of stay, and reduces readmission rates for wound related diagnoses.

Summary of what SerenaGroup® can provide for the Wound Care and or Hyperbaric Program

- Operating policies and procedures, protocols, clinical pathways & checklists
- SerenaGroup® Practice of Wound Care: Guidelines for Excellence
- Billing, reimbursement and business office support
- SerenaGroup® Vigilant Audit Support™
- Quality metrics and benchmarking
- SerenaGroup® proprietary formulary
- On-site education and training programs: Introduction to Hyperbaric Medicine and Wound Care Challenges™ (One of each course annually)
- Monthly on-line webinars on hyperbaric safety, nursing education and revenue cycle
- Access to SerenaGroup® lectures including “Tom Talks. “through our members portal
- Hyperbaric chamber lease or preferred pricing on capital purchase
- Assistance in architectural design of the center
- HIPAA compliant data and outcome tracking system; quality assurance, process improvement & statistical reports
- Assistance with patient, physician and community education including promotional materials
- Program director education and advice with 24/7 access to SerenaGroup® Senior VP, Jill Schroder
- 24/7 access to the thought leaders in the field: Thomas E Serena MD FACS for clinical consultation, Timothy Mayhugh CHT for hyperbaric safety and Mathew Schweyer CPCO for billing and reimbursement support
- Inpatient policies and procedures and formulary. Assistance with the inpatient wound care program
- SerenaGroup® antibiotic stewardship program for the outpatient wound center-now mandated
- Joint Commission survey assistance
- On site technician, nursing or physician proctoring if needed (Hospital is responsible for travel expenses)
- Access to SerenaGroup® telemedicine program and patient app. (Developed and utilized during the COVID-19 crisis)
- Clinical trials & research program with training if desired
- Compassionate use of Hyperbaric Oxygen Therapy (HBOT) for COVID-19 protocol, informed consent and tacking app.

Frequently Asked Questions

- **How does SerenaGroup® handle the uninsured and under insured?** Up to 20% of patients can be enrolled in clinical trials that reimburse the hospital at or above Medicare rates. This reduces the financial impact of the uninsured on the wound clinic while at the same time providing state-of-the-art care for these patients.
- **Does SerenaGroup® have a standard contract for its hospital partners?** We are not a one size fits all company. We customize every contract to meet the needs of our hospital partner. For hospitals with established centers we individualize the contract to fill in gaps and address problem areas. Our goal is to enhance the center, building on the strong points and bringing the SerenaGroup® expertise to establish a center of excellence.
- **Who owns SerenaGroup®?** We are a physician owned and run company. Dr. Serena holds 100% of the voting stock and he and his father own more than 85% of the company stock. I started this company and put my name on it to bring a strong evidence-based clinical focus to the field. I remain dedicated to that ideal.
- **Management companies have faced criticism and penalties for the overuse of hyperbaric oxygen therapy. What is the right amount of HBOT for an advanced wound center?** As a physician run company, we have always stressed the appropriate use of HBOT for the patients that will benefit from this advanced therapy. The percentage of wound clinic patients that undergo HBOT varies between wound centers but typically runs between six and ten percent. This depends on the expertise of the woundologist in the center and patient demographics. We use check lists to assist physicians in choosing patients for HBOT and we randomly audit charts for medical necessity.
- **My hospital has an established wound center, but I had a bad experience with management companies in the past.** Management styles differ among companies. Sometimes the management company and hospital are not a good fit. However, that does not mean that the wound center would not benefit from a consulting or management group with a different approach. Hospital run centers must stay abreast of the rapidly changing clinical and reimbursement wound care landscape. W. Edwards Deming famously quipped, “you don’t know what you don’t know.” This best describes the difficulties associated with self-management. The financial viability of the center rests on the shoulders of a manager inundated with LCDs, NCDs and TPEs. SerenaGroup® stays in the know. We react quickly to changes that will affect our hospital partners.

- **What is the ideal staffing for a wound center?** This is one of the most frequently asked questions of our team. We have spent years developing the best model. After review of your center we can make specific staffing recommendations.

Free Thirty Minute Consult

If you like what you have read thus far, take advantage of a free trial of one of SerenaGroup's® many services.

- **Productivity:** what is an appropriate volume of patients in a day? How many new patients does the center need monthly? Should you abandon the case management model?
- **Staffing:** What is the “right” nurse to patient staffing ratio?
- **Wound Center Operations:** Do you have annual competencies, job descriptions, an organization chart, program director requirements/accountability
- **Hyperbaric Operations:** Do you have staff competencies, a chamber maintenance program, a trained safety director, safety education, and routine fire drills?
- **TPE:** Is your staff educated and prepared for the audits associated with TPE?
- **Routine Chart Audits:** Are you routinely reviewing charts for medical necessity documentation? IS your center “audit-proof.”
- **Clinical Concerns:** In the physician led model how are podiatry, nurses and physical therapists incorporated into the team? What is the best certification for physicians, nurses, physical therapists and technicians?
- **Quality Metrics:** What quality metrics is your center using? How are you benchmarking them?
- **Revenue Cycle:** Wound clinic reimbursement requires a team. Do you have the right team members?
- **Maximizing Reimbursement:** There are tried and true methods to maximize reimbursement. Does your center receive regular education on documentation, coding and billing?
- **Policies and Procedures:** Does your center have updated policies and procedures that will pass muster with Joint Commission. Do you have guidelines for an advanced center?
- **Wound Care Education:** How is your team staying current? Are you relying on expensive out-of-town conferences?
- **Hyperbaric Education:** How are your HBO technicians staying current with the latest safety information?
- **Formulary:** Wound care supplies and devices are expensive. Does your center have a value-based formulary?
- **Research:** Is your center interested in participating in clinical trials or multicenter quality initiatives?

For more information and to take advantage of this offer, e-mail serena@serenagroups.com or call (617-945-5225) to schedule a consultation today.

