SerenaGroup® 2022 Outpatient Advanced Wound Care Policies and Procedures

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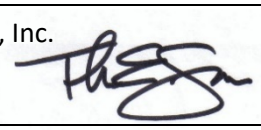
SerenaGroup
Building the Nation's Leading Wound Care Team

Title: Center Signature Page	Date: 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

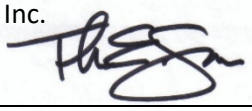
Outpatient Advanced Wound Care Policy & Procedure Manual

The SerenaGroup® outpatient advanced wound care policies and procedures are intended to support the general, patient care, and other policy and procedures of the hospital. These standards are superseded by hospital standards where applicable.

SerenaGroup® is committed to reviewing and updating every two years or more often when revision is deemed appropriate. As new policies are received, it is the responsibility of the Program Director/Nurses Manager to review and implement the new practice.

Print Medical Director Name	Signature of Medical Director	Date

Print Program Director Name	Signature of Program Director	Date

Title: Hospital Signature Page	Date: 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

Hospital Approval of Outpatient Advanced Wound Care Policy & Procedure Manual

In accordance with accreditation and regulatory requirements, I have reviewed the SerenaGroup® Outpatient Wound Care Policy and Procedure Manual. These policies address the delivery of patient care, treatment and services in the Outpatient Advanced Wound Care Center that is managed by SerenaGroup®.

These policies and procedures are approved for use in the Advanced Wound Care Center.

Print Hospital Liaison Name	Signature of Hospital Liaison	Date
Print Program Director Name	Signature of Program Director	Date

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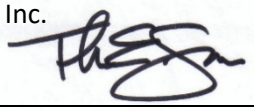
Title: Clinical Processes	Policy Number: OP.001.0
Date Issued: 1/1/2022	Date Revised:
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

POLICY:

Staff will refer to hospital partner policy and procedure manuals for additional policies that may apply to the center.

PROCEDURE:

1. For clinical guidelines, staff will refer to the Hospital Partner for policy and procedure manuals.
    a. SerenaGroup® Practice of Wound Care Guidelines
    b. SerenaGroup® Clinical Practice Disease Specific Guidelines
2. Program Director will identify the location of the hospital policies and procedures.
3. For other infection control, safety, administrative, human resources, and employee health manuals, refer the Hospital partner policy and procedure manual.

    a. All SerenaGroup® employed staff refer to SerenaGroup® HR Department.
    b. This is not applicable to SerenaGroup® free-standing clinics.

Title: Policy and Procedure Manual	Policy Number: OP.002.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Office Personnel
- Providers

PURPOSE:

These policies serve as a standard for measuring excellence in the wound center.

POLICY:

1. All SerenaGroup® policy and procedure manuals are reviewed bi-annually and revised as needed. All revisions will be provided to the center.

2. The SerenaGroup® Medical Director has the responsibility of reviewing and approving all policies and procedures. The Program Director (PD) has the responsibility to ensure all staff is knowledgeable and compliant with those policies. In addition, the PD will provide all updates to the appropriate hospital approval body.

3. The SerenaGroup® policy and procedure manual specific to the center will be located as a paper policy manual or in the hospital electronic system.

4. SerenaGroup® policies and procedures are proprietary and are valid only during the term of the SerenaGroup® contract.

Title: Business Hours	Policy Number: OP.003.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Business hours established for the Wound Center are based on the needs of the center and include an on-call procedure when applicable for managing after hour and holiday emergencies.

PURPOSE:

To meet the routine and emergency needs of the center's patients.

PROCEDURE:

1. The center's business hours are provided to patients with instructions on how to obtain assistance outside of business hours.

2. The Program Director establishes a procedure for managing calls received after hours including instructions on how to obtain emergency assistance.

Title: Clinical Emergencies	Policy Number: OP.004.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

POLICY:

In the event of a clinical emergency, the appropriate emergency activation response and/or resuscitative procedures will be followed.

PURPOSE:

To provide guidance for management in a clinical emergency in the Wound Center. A clinical emergency is defined as a condition or injury that poses an immediate risk to the welfare of the patient.

PROCEDURE:

1. For clinical emergencies, follow the hospital's applicable policy and procedure.

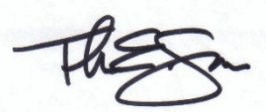
2. In the case of cardiopulmonary arrest, initiate resuscitation until hospital code team or emergency responders arrive.

3. Once the hospital code team or emergency responders arrive, they will assume responsibility for management of the patient.

4. Clinical wound center staff will maintain a minimum BLS certification as required by hospital policy.

5. The clinical emergency will be documented in the medical record in accordance with hospital policy.

6. Medical events will be reported in accordance with hospital policy.

Title: Collection of Copayments	Policy Number: OP.005.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

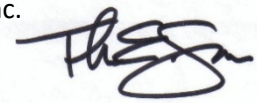
- Administrative Staff

PURPOSE:

The collection of facility copayments for the center.

PROCEDURE:

1. Patients are to pay their copayments in cash, credit, or check at appointment check-in.
2. Staff will collect the facility copayments and follow hospital policy for storage and transportation.
3. Provider copayments will be collected by the provider office and/or staff.
    a. Arrangements can be made between the facility and provider to have the front desk personnel collect provider copayments.

Title: Follow-up Visits	Policy Number: OP.006.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Administrative Staff
- Provider

PURPOSE:

Provide guidance on follow-up visits.

PROCEDURE:

1. Evidence-based guidelines suggest weekly visits for wound care patients.
    a. Reference the SerenaGroup® Practice of Wound Care Guidelines

Title: Medical Record	Policy Number: OP.007.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

PURPOSE:

To establish a complete medical record for each patient treated at the wound care center.

To establish measures that safeguard medical records against loss, destruction, tampering and unauthorized access or use.

To describe the role of scribes in the center.

POLICY:

1. Document all care provided.

2. Documentation must meet CMS medical necessity.

3. Documentation must be completed per hospital policy and medical staff bylaws.

    a. In the absence of hospital policy or medical staff bylaws, documentation must be completed within 72 hours of patient encounter.

    b. Entries should not be made in advance of the service provided to the patient. Predating, pre-timing or backdating an entry is prohibited.

4. When the course of treatment is complete, the entire medical record is stored in the electronic health record.

    a. In the absence of electronic health record, store the record per hospital policy.

5. Maintenance of patient records

    a. Must be stored per HIPAA regulation

    b. In some cases, the medical record may be hybrid, consisting of both electronic and paper

documentation and physically exist in separate and multiple locations in both paper and electronic formats.

6. Personnel with a “need to know” will have access to the minimally necessary information.

7. When the center is closed, the medical records are secured.

8. Records will be released in accordance with HIPAA policy.

9. Scribing for provider is permitted by SerenaGroup® within the following parameters:

    a. The scribe records what the provider dictates.

    b. This individual should not act independent of the provider.

    c. The provider is accountable for the documentation. Providers must sign the documents after the review of the scribe's entry.

    d. The scribe will notate any entry made in the medical record.

Title: Infection Control Guidelines	Policy Number: OP.008.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff

PURPOSE:

To establish infection control guidelines to be maintained in the wound care center.

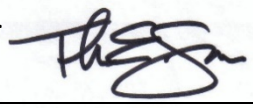
PROCEDURE:

1. Follow infection control policy and procedure manual regarding universal precautions on all patients.

2. Patient contact surfaces will be cleansed with an approved solution after each use.

3. All linen will be changed after each patient treatment regardless of soil content.

4. Isolation linen will be handled in accordance with infection control policy located in the wound care center.

Title: Pediatric and Adolescent Patients	Policy Number: OP.009.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff
- Providers

POLICY:

Pediatric and adolescent patients will be seen in accordance with the scope of services of the wound care center.

PURPOSE:

Center staff is capable of caring for the pediatric and adolescent patient.

PROCEDURE:

1. Clinical staff will consult with Family Practice and Pediatrics as needed to develop an appropriate plan of care for the pediatric and adolescent wound care patient. Information gathered may include:

    a. Growth and developmental needs
    b. Emotional, cognitive and social needs
    c. Immunization status
    d. Family or guardian expectations for and involvement in the continuing care of the patient

2. Clinical staff should:

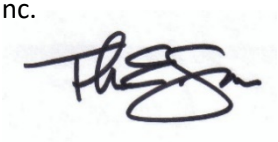
    a. Contact available pediatric and adolescent resources as needed.

3. Develop the patient plan of care for the pediatric and adolescent patient collaboratively with the pediatric and adolescent resource.

4. Participate in hospital provided and required in-service training regarding age specific competency and place documentation of such training in the employee's personnel file.

5. Treating provider must be credentialed for pediatric patients.

6. Follow additional hospital policies for the treatment of pediatric and adolescent patients.

Title: Reconciliation and Verification of Charges	Policy Number: OP.010.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff
- Providers

PURPOSE:

Charges and Billing Reconciliation.

Charges will be checked for accuracy by cross-referencing the daily billing list with the daily master department schedules from that day.

PROCEDURE:

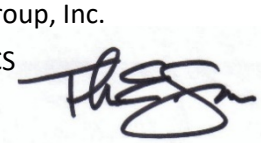
1. RN/LPN/LVN/Therapist will write the charges for the procedures performed on the daily master department schedules.

2. Support staff will enter the charges for each patient in hospital billing system as required.

3. At the end of each day a billing list is run by support staff.

4. Cross check the patient's charge(s) on the daily billing list with the therapist's charge(s) on the daily master department schedules.

5. If a discrepancy is identified, staff may seek support from SerenaGroup® CQO and hospital revenue cycle management.

Title: Sample Medications and Supplements	Policy Number: OP.011.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Providers

POLICY:

When distribution is permitted by the hospital, staff will track the receipt of and redistribution of samples, to include but not be limited to medications, dietary supplements, wound care supplies or other healthcare products, in such a manner that the individual patient receiving the sample can be identified.

PURPOSE:

To provide guidelines for staff to initiate and maintain a sample tracking process.

DEFINITIONS:

- **Dietary supplements** – product taken by mouth that is intended to supplement the diet and that contains one or more "dietary supplements" such as vitamins, minerals, herbs and other botanicals, amino acids and other substances found in the human diet such as enzymes.

- **Drug** – (per Federal Food, Drug and Cosmetic Act) an article that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease and an article intended to affect the structure or any function of the body of man.

PROCEDURE:

1. The Program Director will refer to the applicable policy prior to distributing samples.

2. Samples must be stored in a locked secure area.

3. Samples will be recorded in a sample log when applicable.

4. When samples are given to a patient, it must be recorded in the medical record.

5. In the event of a recall, the Program Director will:

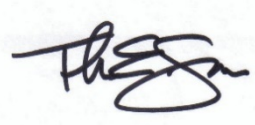
a. Identify and remove from storage all samples in inventory that have been recalled.

b. Notify the hospital's Pharmacy and/or Risk Management department of the recall and actions taken in response to the recall notice.

c. At the direction of the hospital's Pharmacy and/or Risk Management department, notify the patient according to the instructions in the recall notice.

d. Document actions taken and maintain a copy for the Center's files.

e. Original documentation shall be provided to the hospital's Pharmacy and/or Risk Management department for maintenance per hospital policy.

Title: Handling of Surgical Instruments	Policy Number: OP.012.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff

PURPOSE:

To safely transport contaminated non-disposable surgical instruments from the wound care center to central sterilization.

PROCEDURE:

Follow the facility standard for decontamination of instruments.

- Refer to infection control manual for handling, storage, transportation, and sterilization of soiled surgical instruments.

Title: Photography Documentation	Policy Number: OP.013.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS

SCOPE:

Entities operating under the Hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Providers

PURPOSE:

To ensure consistent quality of the photographic documentation of wounds within the center.

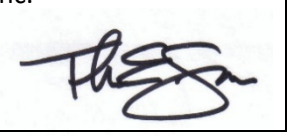
Photograph all wounds on initial visit, each week, with any significant clinical change, pre and post debridement and at discharge.

Each center will obtain permission from the patient, or their representative, to photograph patient wounds.

PROCEDURE:

1. Obtain written consent for medical photography.
    a. The patient has the right to refuse the photographic request.
    b. If refused, document the patient's refusal in progress note.
2. Wounds will be photographed on admission, follow-up, and discharge visits.
3. Photographs will be labeled with patient's identifiers;
    a. Date and wound number
    b. Pre and post debridement
4. When a wound changes significantly or a new wound appears.
5. Center the wound in the frame with minimal background or body area exposed. Avoid capturing the patient's face or other identifying marks.
6. Upload photographs in medical record and/or secured location.
7. Store photos in accordance with HIPAA regulations.
8. Appropriate personal protective equipment (PPE) will be worn during wound photography.

9. The device will be cleansed with approved solution upon completion of photography.

Title: Wound Measurements	Policy Number: OP.014.0
Date Issued: 04/01/2016	Date Revised: 01/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Providers

PURPOSE:

Documenting wound dimensions.

PROCEDURE:

Wound dimensions are measured in centimeters (cm) using a disposable measuring tape and sterile cotton tip applicator or digital photographic planimetry. All wound measurements will be documented in the patient medical record.

Wounds are measured:

- At initial assessment
- At all subsequent visits
- Prior to and after any debridement is performed

DEFINITIONS:

Length: The longest distance of the wound from 12 to 6 o'clock.

Width: The widest part of the wound of the wound from 3 to 9 o'clock.

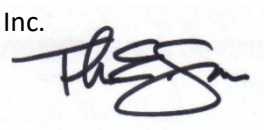
Depth: Using a sterile cotton tip applicator, locate the deepest point of the wound, measuring it at a 90-degree angle with the skin, to the level of the skin.

- ***Note:*** Wounds that have a depth of less than 0.1cm but are not fully epithelialized are rounded to 0.1cm. Only wounds that have a full layer of epithelial covering (and therefore are healed) are to be assigned a depth of 0 cm.

Sinus Track/Tunneling: The longest or deepest area which extends through a small opening or channel from the base of the wound to be measured using gentle probing with sterile cotton tip applicator and recorded indicating the general location through the reference of a clock - the patient's head representing 12 o'clock.

Undermining: The longest area extending from the margins of the wound into the subcutaneous tissue running parallel with the skin. Measure with a sterile cotton tip applicator indicating the location of the tunnel. Utilize the clock face method.

Clustering: When multiple wounds are located within 2cm measure them as one wound.

Title: Management of Cellular and Tissue Based Products	Policy Number: OP.015.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 8/16/2021 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Providers

POLICY:

The wound care center will follow a standardized process for acquiring, receiving, storing, and issuing cellular and tissue-based products (CTP).

PURPOSE:

Describe the process for managing CTPs.

DEFINITIONS:

Cellular and Tissue Based Products - Any human or nonhuman cellular-based transplantable and 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 this policy.

Ambient temperature - temperature of the immediate environment.

PROCEDURE:

1. On an annual basis, the Program Director with the assistance of compliance will confirm that a supplier is registered with the U.S. Food and Drug Administration (FDA).
    a. A list of all products utilized will be available in the electronic data base housed on the SerenaGroup Secure drive.
    b. If a HCTP is decided to be added to a center, the PD will consult with the CCO to ensure the product is included on the SerenaGroup electronic data base and added to the center.
    c. Documentation of specific products and the verification will be maintained in the center.
    d. This requirement does not apply to autologous tissue- or cellular-based products classified as medical devices by the FDA.

2. If the state in which the wound care center is located also requires a state license, registration, permit, or authorization this will also be verified.
    a. Documentation of the verification will be maintained in the wound care center.
    b. This requirement does not apply to autologous CTPs classified as medical devices by the FDA.

3. Staff will document the receipt of all CTPs in a SerenaGroup® tissue log.

4. If the log is supplied by the hospital, the Program Director must ensure that records are kept on all the following:
    a. Tissue supplier
    b. Original numeric or alphanumeric donor and lot identification
    c. Patient identifier
    d. Final disposition of each tissue (either fully used or partially used and partially discarded or fully discarded)
    e. Expiration dates of all tissues
    f. Dates, times, and staff involved in accepting, preparing, and issuing tissues

5. Upon receipt:
    a. The package will be inspected for damage.
    b. Staff will verify that the transport temperature was controlled and acceptable for products requiring a controlled environment. This verification is documented.
    c. If the distributor uses validated shipping containers, then the receiver may document that the shipping container was received undamaged and within the stated timeframe for use.
    d. Products requiring no greater control than ambient temperature for transport and storage would not need to have the temperature verified on receipt.
    e. Expiration date is noted, and pH (if applicable) should be verified.
    f. ***NOTE:*** If the product is expired, out of pH range and/or temperature range is not met, or there is any evidence of damage to the package, the manufacturer is to be notified so replacement can be arranged. **DO NOT USE THE PRODUCT**.

6. Staff will follow the suppliers' or manufacturers' written directions for transporting, handling, storing and using.
    a. Tissue/Product is to be stored at the temperature required per manufacturer's recommended guidelines until ready for use.

7. The Center will follow hospital policy for controlled temperature storage and maintenance of cellular tissue-based products.

8. Staff will utilize the materials and related instructions from the manufacturer to prepare or process the product.

9. Product shall be applied per the manufacturer's guidelines, for indications approved for its use.

10. The center will maintain a copy of the manufacturer's instructions that were used to process the product in a location where staff can easily access them for review.

11. It is recommended that the center keep the package receipt for each product with the Tissue Log.

12. Tissues/Products shall be used in conjunction with appropriate wound care, on wound beds free of infection and necrotic and fibrotic material.

13. Secondary dressings shall be applied per manufacturer's guidelines.

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

15. Staff will complete and return tissue/product usage information cards requested by the supplier as appropriate and per hospital policy.

16. Any unused tissue/product will be disposed of per hospital policy. Some products may require disposal as biohazard waste.

17. Tissues/Products labeled by the FDA as "single patient use" will be used on only one patient.

18. The Hospital/Center will retain the records for storage temperatures, all superseded procedures, manuals, manufacturer's instructions and publications, and any tissue/product record for a minimum of 10 years beyond the date of distribution, transplantation, disposition or expiration of tissue/product. The center shall retain tissue/product records longer than 10 years, if required by state and/or federal laws.

19. Staff will maintain sufficient documentation to allow bi-directional tracing of tissues/products and will investigate and report to the supplier any adverse events related to use.

Title: Prisoners	Policy Number: OP.016.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Providers
- Center Staff

POLICY:

Patients under police custody or inmates of penal institutions may be evaluated in the Wound Care Center, if allowed by hospital policy. These patients shall be guarded on a continuous basis during their wound care visit. The responsibility of ensuring detention is that of the local, state, or federal law enforcement officer who has accompanied patient to the Wound Care Center. To ensure consistent implementation throughout the hospital, any hospital policies regarding management of prisoners shall supersede this policy.

PURPOSE:

To provide a safe environment for patients, visitors and employees and protect the legal rights of incarcerated patients.

PROCEDURE:

1. The law enforcement agency or penal institution must make prior arrangements for scheduled visits by contacting the Program Director or designee to discuss custodial coverage for the patient prisoner.

2. The Program Director or designee will notify hospital security prior to a patient prisoner being seen in the wound care center.

3. Custodians of the patient prisoner will report to the security office of the hospital prior to each visit so that the security office can verify the identity of the law enforcement officer and ensure appropriate documentation of education/training is obtained according to hospital policy.

4. The hospital security office will communicate appropriate identification of law enforcement officer to the wound center.

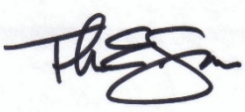
5. The security office shall instruct the law enforcement officer of his/her responsibilities as it pertains to the hospital.

6. The clinical staff shall provide the law enforcement officer with any necessary clinical information about the patient prisoner. This includes, but not limited to

    a. Infection control precautions
    b. Medical condition about the patient-prisoner that might result in the need to transport to a diagnostic or treatment area
    c. Medical condition about the patient-prisoner that might necessitate the removal of a forensic restraint (i.e., handcuffs or shackles used for security reasons)
    d. Changes in patient condition
    e. Specific positioning required secondary to medical conditions or interventions

7. The law enforcement officer shall comply with the clinical instructions provided and shall not hinder the staff or physicians from conducting normal patient care, treatment, or services.

8. The law enforcement officer assigned to the patient-prisoner is required to control and guard the patient prisoner at all times. The officer will stay in the patient's room unless the patient prisoner's behavior poses no immediate risk to the staff. The law enforcement officer may stay outside the room as long as the officer can see the patient.

Title: Patient Communications via Phone	Policy Number: OP.017.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

PURPOSE:

To appropriately document communications and provider orders when a patient calls or communicates with the center staff or providers.

POLICY:

Telecommunication must be documented in the medical record.

PROCEDURE:

1. Document all telecommunication with the patient or power of attorney (POA) in the medical record.

2. Document all communication with mutual patient providers and ancillary services.

3. All information entered in the medical record must be signed by the entering staff member and provider signature.

Title: Patient Complaint & Grievance	Policy Number: OP.018.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider
- All Administrative Staff

POLICY:

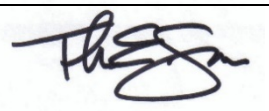
Patients and their families, guardians, or legal representatives will be informed of their right to present complaints or grievances. Wound care center employees will communicate patient complaints or grievances following the complaint resolution process.

PURPOSE:

Address patient complaints and grievances.

PROCEDURE:

1. Patients and their family are informed of the complaint resolution process.
2. Patients are provided with the phone number of the appropriate hospital liaison for registering complaints.
3. All complaints or grievances are reviewed by the Program Director.
4. All grievances are reported to hospital or appropriate representative.
5. All grievances are reported to SerenaGroup® compliance department.
6. Written notice of resolution will be provided to the patient.

Title: Patient Registration Initial Visit	Policy Number: OP.019.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

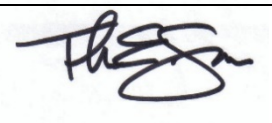
All outpatients scheduled for the clinic will be pre-registered.

PURPOSE:

Provide guidance for pre-registering process.

PROCEDURE:

1. Follow pre-registration process.
2. Upon arrival, the patient will complete registration and sign consent forms.
3. A copy of the patient's insurance card will be kept in the chart.

Title: Patient Rights and Responsibilities	Policy Number: OP.020.0
Date Issued: 04/01/2016	Date Revised: 1/01/2018,1/01/2020
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Providers

POLICY:

Staff will respect, protect, and promote patient rights and responsibilities. Patients will be notified of their rights and responsibilities prior to care, treatment, or services.

PURPOSE:

Identifying the patient's rights and responsibilities.

PROCEDURE:

1. Staff notifies the patient of his/her rights.

2. The rights and responsibilities will be posted in the wound care center.

Patient Rights

1. Staff will treat patients in a dignified and respectful manner.

2. Staff will respect the patient's right to and need for effective communication.

3. Staff will respect the patient's cultural and personal values, beliefs, and preferences.

4. Staff will respect the patient's right to privacy:

    a. Interview patients out of hearing range of patients in the waiting room. This may be accomplished by using an exam room or private office in the center for patient interviews and/or counseling.

    b. Maintain a professional speaking tone in communicating to patients and staff.

c. Obtain patient's permission for observers to be present in the examination room.

d. Minimize conversations unrelated to the patient by staff and observers while in the examination room.

e. Provide privacy while the patient is undressing by providing a sheet or blanket, drawing cubicle curtains or closing doors, and leaving the room.

5. Staff will respect the patient's right to pain management.

6. Staff will accommodate the patient's right to religious and other spiritual services by notifying the hospital's pastoral care department when requested by the patient.

7. Using the hospital's HIPAA policies and process, staff will allow the patient access to, request amendment to, and obtain information on disclosures of his or health information, in accordance with law and regulation.

Patient Responsibilities

Patients will be notified of their responsibilities in accordance with hospital policy. This can be accomplished verbally, in writing, or both. Responsibilities include but are not limited to the following:

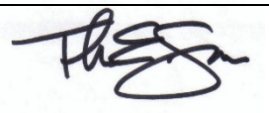
- Provide information that facilitates care, treatment, and services.

- Asking questions or acknowledging when he or she does not understand the treatment course or care decision.

- Follow instructions, policies, rules, and regulations in place to support quality care for patients and a safe environment for all individuals in the center.

- Support mutual consideration and respect by maintaining civil language and conduct in interactions with staff and physicians.

- Meet financial commitments.

Title: Scope of Services	Policy Number: OP.021.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

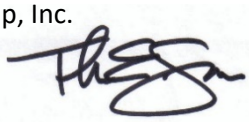
The wound care center accepts patients within their scope of services.

PURPOSE:

Describe the scope of services for the wound care center.

PROCEDURE:

1. The wound care center treats patients with wounds defined as a break in the skin with drainage.
    - It is not in the scope of the wound care center to treat post-surgical wounds unless a transfer of care agreement is in place.
    - It is not in the scope of the wound care center to provide a service available in the referring provider's office.
    - It is not in the scope of the wound care center to provide a lymphedema service.

Title: Security of Photo Documentation Device	Policy Number: OP.022.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff

POLICY:

Devices used in wound photography contain protected health information and will be treated in the same manner as a patient's medical record. Devices used for wound photography will be stored in a secure manner.

PURPOSE:

Provide guidelines to wound care staff on how to secure photographic devices.

PROCEDURE:

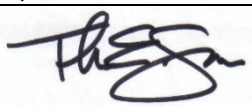
1. Personal cell phones may not be used for wound photography.
    a. SerenaGroup® or hospital provided devices and/or authorized devices are to be used.

2. Devices provided by the wound center for wound photography will be secured when not in use.

3. Devices are only used by authorized wound care employees.

4. When not in use, the devices will be secured according to HIPAA regulations.

5. When a device is being used by center staff, it must remain in the possession of the individual until secured.

Title: Waived Testing	Policy Number: OP.023.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

POLICY:

Performing waived testing in the wound care center. Staff will follow established policies for orientation, training, and documentation.

PURPOSE:

Standardization of practice in regard to accuracy, reliability, and timeliness of waived testing.

DEFINITION:

- **Waived testing** – Tests that meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988) for waived tests and are cleared by the Food and Drug Administration for home use. These tests employ methodologies that are so simple and accurate that the likelihood of erroneous results is negligible, or pose no risk of harm to the patient, resident, or individual served if the test is performed incorrectly.

- **Clinical Laboratory Improvement Amendments (CLIA)** – an amendment passed by Congress in 1988 establishing quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test is performed.

- **NOTE:** Since staff will be conducting capillary blood glucose checks, the center will need to have either its own CLIA license or be allowed to operate under the hospital's license. If operating under the hospital license, the hospital may need to add the wound care and hyperbaric center's location.

PROCEDURE:

1. Authorized staff perform waived testing in the center.

2. Staff authorized to perform waived testing receive training on instrument use and maintenance.

3. Competency in waived testing is assessed annually.

4. For instrument-based waived testing, quality control checks are performed each day on each instrument used for patient testing or per manufacturers' instructions. Quality control checks are not required on an instrument when not in use.

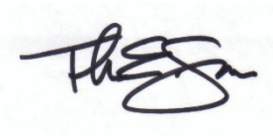
5. Quality control results are documented in QC log.

6. Test results are documented in the patient's medical record.

7. Quantitative test results reports in the medical record for waived testing are accompanied by reference interval (normal values) specific to the test method used and the population served. Note: Semi-quantitative results, such as urine macroscopic and urine are not required to comply with this unless it is required by the hospital policies.

8. Reference intervals (normal values) not documented on the same page as and adjacent to the waived test result, are located in the permanent record. The result will have a notation identifying the location of the reference intervals.

9. Quality control results records, test result records, and instrument records for waived testing are retained for at least two years.

Title: Case Studies	Policy Number: OP.024.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Case studies offer insight into the success of the wound care center.

PURPOSE:

The policy is to provide a standardized method for the development of case studies. These studies will be utilized for community and clinical education.

CASE STUDY SELECTION CRITERIA:

1. The following is a list of parameters for evaluation of potential case studies.

    a. Treatment provided based on evidence-based practice.
    b. Photographs demonstrate wound improvement.
    c. An unexpected recovery in the face of difficult obstacles or complications.
    d. Include lessons learned from the case study.

PROCEDURE:

1. The case study will be sent to the SerenaGroup® Education Committee via company email, who will coordinate completion. Centers are encouraged to submit relevant case studies as examples of healing success.

2. The case study will be produced utilizing the method described below. Photographs and information will not contain protected health information (PHI). The method is as follows:

    a. All case studies will have a minimum of two photographs. Photograph one will be of the wound at the start of care. The second photograph will be of a healed wound. Photographs with ungloved hands cannot be used.

        Step 1 Review Case Study Selection Criteria to choose the best possible case for development.

        Step 2 Complete case study.

        Step 3 E-mail the worksheets, digital photos, and any pertinent information to the Education Committee.

Step 4 The Education Committee will review the case study and provide feedback.

Step 5 The case study cannot be used until approved by the Education Committee.

3. De-identified information regarding the treatment course may be included.

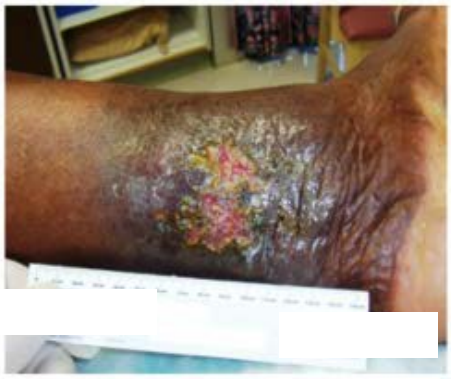
4. All completed case studies will fit on one side of a single sheet of paper.

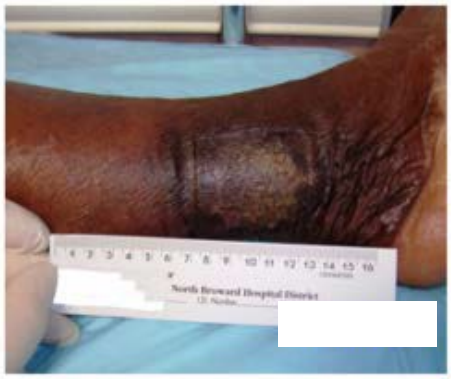
{CASE STUDY EXAMPLE}

SerenaGroup
Building the Nation's Leading Wound Care Team

Wound Care Case Study

Venous Stasis Ulcer





3/30/06

This 60 year old male patient presented with a non-healing venous stasis ulcer which appeared over two years ago. Pulses were palpable bilaterally with an ABI of 0.88. Capillary refill was immediate to all digits. There was +2 pitting edema and induration with brawny discoloration. The wound measurements 6cm x 6cm x 0.2cm pre-debridement and 6.5cm x 6.5cm x 0.2cm post. Wound was covered with necrotic tissue with a moderate amount of thick, yellowish drainage.

4/13/06

This wound was completely healed in 14 days with the patient discharged on his 5th visit. On the initial visit the wound was sharply debrided to viable bleeding tissue. Pain was controlled with 4% topical lidocaine and a Tens unit. Bi-weekly dressing changes were ordered with Promogran® applied to the base of the wound, covered with Contreet Foam® and an Unna boot for static compression was applied. Total of two debridements were performed.

Healed in 14 Days

Patient Information

Age:	60
Race:	African American
Sex:	Male
Systemic Disease:	PVD
Wound Classification:	Venous Stasis Ulcer
Wound Age Prior to Treatment:	Two Years
Treatment Modality:	Advanced Wound Products/Compression

Insert Hospital Logo *Wound Care Case Study*

(Wound Type)

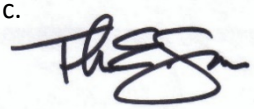
Insert Picture #1

Insert Picture #2

Date of Picture	**Date of Picture**
Tell a short story.	**What did you do, how was the wound healed.**

Time to Heal Patient Information

Age:	
Race:	
Gender:	
Systemic Disease:	
Wound Classification:	
Wound Age Prior to Treatment:	
Treatment Modality:	

Title: Consultation Guidelines	Policy Number: OP.025.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

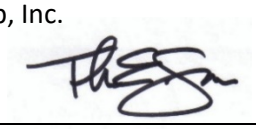
Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

PURPOSE:

PROCEDURE:

1. Once a consult is requested, the provider will be notified.
2. An appointment will be scheduled with the provider during normal clinic hours.
3. All available medical records for the new patient will be requested for review by the provider prior to consult.

Title: Charges for Services	Policy Number: OP.026.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

POLICY:

All charges for services will be accurately recorded and processed for billing in a timely manner.

PURPOSE:

To process charges timely and appropriately for services provided to the patient.

PROCEDURE:

Charges:

1. Clinical staff documents the appropriate charges on the superbill.
2. The superbill is completed by the end of each clinic session and copayments are calculated.
3. The staff member ensures accuracy of charge entry by verifying charges against the hospital-generated charge report.
4. Charges are to be reconciled daily.

Title: Universal Protocol	Policy Number: OP.027.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Clinical Staff
- Providers

POLICY:

Staff at the wound care center will implement a process to prevent wrong site, wrong procedure, and wrong person surgical and nonsurgical invasive procedures.

PURPOSE:

To promote patient safety by providing guidelines for verification of correct site and side, correct patient, and correct procedure for all surgical and nonsurgical invasive procedures.

PROCEDURE:

1. The process to prevent wrong site, wrong procedure, and wrong person surgical and nonsurgical invasive procedures is called the Universal Protocol.

2. The Universal Protocol includes three distinct activities:
    a. Pre-Procedure Verification process
    b. Site marking
    c. A Time-out prior to performance of the procedure

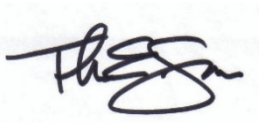
3. Pre-Procedure Verification
    a. The patient is involved in the verification process when possible.
    b. The patient care provider will identify:
        i. Correct patient.
        ii. Correct surgical or non-surgical invasive procedure.
        iii. correct site and side.

        i. Signed consent form.

ii. Appropriate images, scans, or test results that are properly labeled and displayed.
iii. Any special equipment needed for the procedure.

4. Site Marking
    a. If the individual performing the procedure is continuously present after discussing the planned procedure and consent is obtained from the patient, site marking is not required.
    b. If there are multiple wounds or lesions and only some of the them are to be treated, and the decision and direction for which ones are to be treated is determined at some time prior to the procedure itself, then the sites to be treated should be marked as soon as possible after the decision is made.
    c. The procedure site must be marked by the individual performing the procedure, who will be present when the procedure is performed.
    d. The mark to be utilized will be consistent with the process used in other settings of the hospital for site marking (e.g. surgeon's initials).
    e. The mark is made at or near the procedure site and is sufficiently permanent to be visible after skin preparation and draping.
    f. If a patient refuses to have the site marked, the patient's provider will review with the patient the rationale for site-marking. If the patient still refuses site marking, the alternative method per hospital policy should be used before the case can proceed. Patient's refusal and alternative method will be documented.

5. Time-out
    a. Immediately before initiation of the surgical or nonsurgical invasive procedure the team will pause (i.e. "time-out") to verify the following:
        i. Correct patient.
        ii. Correct surgical or non-surgical invasive procedure.
        iii. Correct site/side.
    b. All activities by members of the procedure team are suspended to the extent possible, at this point no member will leave the treatment area.
    c. This time-out will be conducted using active communication.
    d. A discrepancy at any point in time will stop the case from proceeding until resolved.
    e. The "Time-out" will be documented in the medical record.
    f. When two or more procedures are being performed on the same patient and the person performing the procedure changes, a second time-out is performed and documented.

Title: Patient Education	Policy Number: OP.028.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Nursing Staff

PURPOSE:

Establish guidelines for nursing staff to provide on-going patient education.

PROCEDURE:

Nursing staff will evaluate the patient's educational needs.

1. On initial visit to the center, nursing staff will assess patient's understanding of the treatment plan.
2. Document patient's learning capabilities.
3. Document the patient's support system.
4. All education performed is documented in the medical record as to material covered, learned, method utilized, and the patient's response to education.

Title: Family Education	Policy Number: OP.029.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Nursing Staff

PURPOSE:

The patient's family or caregiver will receive education and training on the treatment of the patient's wounds. The education and training will be specific to assessed needs, abilities, and will be appropriate to the anticipated length of treatment.

PROCEDURE:

1. Patient must give permission to educate the family or caregiver.

2. The nursing staff will assess the educational needs of the patient's family or caregiver at each clinic visit.

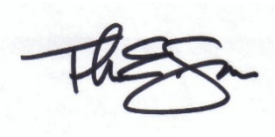
3. The nursing staff will consider cultural and religious practices, emotional barriers, desires and motivation to learn, physical or cognitive limitations, and language barriers to determine the appropriate teaching method.

4. Instructions consistent with the physician's orders and plan of care will be provided in a manner understandable to the patient's family or caregiver.

5. Additional education and instruction will include the following:
    a. Instruction on potential drug or food interactions.
    b. Counseling on nutrition intervention or modified diets.
    c. Access to available community resources.
    d. When and how to obtain further treatment.
    e. Instruction in rehabilitation techniques to facilitate adaptation to and/or functional. independence in the environment.

6. The patient's family or caregiver will be requested to perform a return demonstration and/or verbalize understanding of instructions.

7. Patient's family or caregiver will be advised when to contact the wound care nurse (changes in wound or related systemic conditions).

Title: Reporting Abuse	Policy Number: OP.030.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc.  Thomas E. Serena MD FACS

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

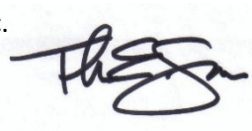
- Clinical Staff
- Provider

POLICY:

Reporting procedure for suspected incidents of abuse, neglect, or exploitation of any patient, child, or household member according to state regulations.

PROCEDURE:

1. Personnel who suspect abuse, neglect, or exploitation of a parent, child, or household member MUST promptly report this information according to their state guidelines.

Title: Center Chain of Command	Policy Number: OP.031.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Clinical Staff
- Provider

POLICY:

The policy is to establish an organizational structure for the center.

PROCEDURE:

1. It is the responsibility of the Program Director to prepare and maintain a pictorial display of the organizational structure.

2. This pictorial display demonstrates the center relationship to the hospital and to SerenaGroup®.

3. The center is directed and supervised by the Program Director who has 24-hour accountability and is responsible for staffing the center and communicating directives to all department employees.

4. The Program Director reports to the hospital administrator assigned oversight of the center. The Program Director also reports to the Senior VP of Operations or a Regional Manager to which the center is assigned.

5. The center operation is assessed, and problem areas identified, using performance improvement monitors and database reports on a routine basis by the Program Director and Medical Director.

Title: Nondiscrimination	Policy Number: OP.032.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018,1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

POLICY:

Staff will treat patients without regard to age, race, ethnicity, religion, culture, language, physical or mental disability, socioeconomic status, sexual orientation, and gender identity or expression.

PURPOSE:

To define the facility's policy regarding nondiscrimination.

PROCEDURE:

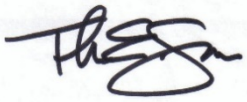
1. Patients, regardless of protected class, have the right to effective quality care and treatment. It is the responsibility of the Program Director to assure that treatment is given to all patients.

    a. At the time of the evaluation, it is the clinician's responsibility to assess the patient for any degree of disability. In addition, it is their responsibility to discuss specific needs and care requirements, in relation to the disability(s), with the disabled patient and their significant other. This discussion will include the degree of impairment, acceptable auxiliary aids which the patient will or will not accept, as well as a further discussion of alternatives in methods of delivering care.

2. For disabled patients unable to transport themselves, transportation to and from may be performed by community resources or covered by health insurance.

3. The Program Director is responsible for obtaining a list of available resources. These materials may include Braille material, videotapes, and other teaching tools.

4. A list of patient advocacy groups (state authority or a protection and advocacy network) for patients and disabled persons is maintained at the center and the list is provided to the patient/family upon request.

Title: Organizational Structure	Policy Number: OP.033.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

PURPOSE:

Establish an organization structure for the center.

STANDARD:

1. The center is directed and supervised by the Program Director, who is responsible for staffing the unit and communicating directives to all department employees.

2. The Program Director reports to the hospital administrator who has oversight of the center. The Program Director also reports to the Vice President of Clinical Operations SerenaGroup® and or Regional Managers to whom the center is assigned.

The Center operation is assessed, and problem areas identified through use of performance improvement monitors reviewed on a routine basis by the Program Director and Medical Director.

Title: Orientation & Initial Competency Review	Policy Number: OP.034.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

POLICY:

All staff will complete an orientation and competency review for their role that demonstrates the specific skills necessary to satisfy job description requirements.

PURPOSE:

Provide guidelines on the content and requirements for orientation and initial staff competency reviews.

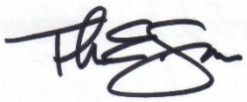
PROCEDURE:

1. The Program Director will ensure that each staff member completes an appropriate orientation (SerenaGroup®, hospital and department) as well as initial competency validations.

2. The Program Director will complete orientation and competency reviews and file in the center's employee file.

3. Staff competence is initially assessed and documented as part of orientation.

4. Staff competence is re-assessed and documented.

Title: Staff Development	Policy Number: OP.035.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including but not limited to, the following:

- All Center Staff

PURPOSE:

Staff education enhances the quality of patient care.

PROCEDURE:

1. The Education Committee will provide monthly education topic.
2. Monthly education is provided on the SerenaGroup® Member's Portal for staff to complete.
3. The Education Committee is responsible for developing, implementing, and revising the staff development program.
4. Annual reviews with goals assessment for each staff member will be performed by the Program Director.

Title: Staff Meetings	Policy Number: OP.036.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

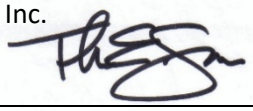
- All Center Staff

PURPOSE:

Establish standard criteria for monthly staff meetings.

PROCEDURE:

1. Staff meetings are conducted monthly by the Program Director or designee.
2. Minutes of staff meetings are recorded and will include personnel in attendance, personnel absent, issues discussed, and action plan for resolution of identified problems.
    a. It is recommended that personnel not in attendance read and initial the minutes.
3. Communication outside of monthly staff meetings will be distributed via e-mail, written memo, or staff huddles.

Title: Social Media	Policy Number: OP.037.0
Date Issued: 01/01/2022	Date Revised:
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

POLICY:

Social media creates a forum for both individuals and healthcare professional practicing in the field of advanced wound care management including patients who are receiving hyperbaric medicine treatments, patients in a program addressing many other types of wounds and patients who have been discharged from the center, and who remain interested in community activities that promote a positive interaction between the wound clinic and the public.

PURPOSE:

The purpose of the social media policy is to provide practical guidelines to promote best practice and professionalism in the use of social media.

SerenaGroup objectives in using social media are to:

- Feature best practices and current research.
- Influence best practices positively.
- Connect with members and healthcare professionals in their respective spheres of practice.
- Provide timely information about SerenaGroup events, dates, location.
- Promote projects in addition to using other established means of communication.
- Increase awareness of members' activities with regard to causes, prevention and management, publications, and awards in the wound care space.
- Share information from the SerenaGroup Education Committee.
- Expand educational initiatives.
- Post photographs of events in which SerenaGroup is involved to create awareness of the prevention and management of surgical wound complications.

DEFINITIONS:

Social media represents any electronic communication through which information, messages, notions, videos, photographs, and other contents is shared and is continually evolving.

Facebook, LinkedIn, Instagram is a free worldwide social network site accessed from any internet-enabled device where a profile revealing selective information about the user is created by themselves and where multimedia e.g. photographs, text, private messages, activities, and public comments are shared with the community.

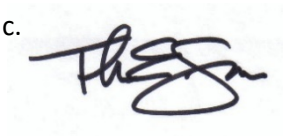
Twitter is a microblogging platform used to post short public messages of less than 280 characters, called “tweets”, allowing users to provide and access information, reply directly or support them with “retweets” or “favorites” suggesting the user considered them accurate and useful, and indicating to users what content creates the most response.

PROCEDURE:

- Posts to reflect positively on SerenaGroup pages as a professional association.
- Privacy, copyright and all laws that apply on or off-line are to be respected when postings are made online.
- Information and links from different sources are to be appropriately credited.
- All SerenaGroup posts are to be professional and are to exclude:
    - Personal medical advice
    - Patient identification
    - Personal information e.g. members’ birth dates, addresses, telephone numbers, or relatives names of relatives
- To promote SerenaGroup conferences and events;
    - A disclaimer is to be included with all activity registrations
    - Consent from conference participants for pictures to be taken and posted on social media to promote SerenaGroup must be obtained
- SerenaGroup social media sites are not monitored 24 hours a day, 7 days a week.
- A SerenaGroup administrator shall be appointed to review the social media.

Approval Process for Posts on Social Media Sites

The SerenaGroup Education Committee must review and approve all information before being posted on the SerenaGroup social media sites.

Title: Vendor Access	Policy Number: OP.038.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- All Center Staff

INTRODUCTION:

Vendors that conduct business at or with the Wound Care Center will do so in accordance with Hospital or SerenaGroup® policy guidelines. Providers, nurse practitioners, students, and staff that work in the Wound Care Center will interact with vendors in a manner that meets ethical standards, protects patient confidentiality, does not interfere with the process of patient care, and encourages the appropriate, efficient, and cost-effective use of equipment, supplies, and pharmaceuticals in the wound care center. It is the responsibility of all staff to monitor and assure that vendors are compliant with these guidelines.

POLICY:

Establish guidelines for vendors doing business at the wound care center.

DEFINITIONS:

Vendor - any representative of a manufacturer or company who visits the wound care center for the purpose of soliciting, marketing, or distributing information regarding the use of medications, products, equipment, and services. Specified portions of the policy do not apply to vendors whose non-pharmaceutical products are already in place in the institution when the purpose of the visit is specifically to provide information to the wound care center personnel concerning the implementation and appropriate use of their non-pharmaceutical product.

POLICY STANDARDS

Providers and staff are expected to uphold the highest ethical standards in interactions with vendors. Each member of the wound care center is responsible for reporting violations of this policy to the Program Director.

PROCEDURE STANDARDS

General

- Any vendor visiting wound care centers at any site owned or managed by SerenaGroup® will be required to register in the facility's vendor management program.

- Vendors must have an appointment before visiting the wound care center. Vendors must contact the Program Director to schedule an appointment during normal business hours. Vendors are not permitted in the center without an appointment or the consent of the Program Director.

- If a vendor does not adhere to this policy, the center will take action as appropriate, such as requesting a replacement vendor or limiting new business with the center.

- The center reserves the right to limit the number of vendors that any single company has visiting the center.

- Vendors visiting the center may only discuss products on existing hospital formulary.

- The use of samples is not permitted in the center. Industry representatives who wish to trial their product should contact Dr. Thomas Serena to arrange for an IRB approved clinical case series or trial.

Access

- Vendors are restricted to physicians' offices, department offices, conference rooms (invitation only), and public areas.

- Under most circumstances, vendors are prohibited from entering patient care areas in the center.

    - An **exception** to this is a situation in which a vendor is required for training on new equipment or devices already purchased by the center, setting up such equipment, or similar activities associated with a contractually agreed-to business purpose associated with new technology or devices.
    - These cases must be approved by the Program Director with consent given by the patient. The presence of the vendor should be noted in the medical record.

- Vendors are prohibited from attending any conference where patient-specific information or quality assurance activities are being discussed.

- Vendors are not permitted to distribute information unless specifically requested by the Program Director.

Food and Beverages

- Food or drink may not be provided directly by vendors.

- Vendors may provide an educational grant to a department and the department is responsible for educational program, content, and speaker. The department may decide to use some of the educational grant funds to provide lunch to the attendees.

- Off-site dinner programs are permitted following Hospital regulations.

Promotional Activities

- Cash or other incentive programs are strictly prohibited at the center.

- No personal gifts of any kind from vendors to physicians, nurse practitioners, or staff are permitted.

- Vendors are not permitted to distribute, post, or leave any type of printed or handwritten material, advertisements, signs, or other such promotional materials anywhere in the Wound Care Centers. Unsolicited materials may not be provided to clinicians; any promotional or informational material provided by a vendor must be explicitly requested by faculty or staff.

- Distribution of vendor patient educational material that may be useful to our patients should be left with the Program Director. Vendors are strictly prohibited from providing educational material of any type directly to patients or from leaving them in areas accessible to patients.

- Only pricing/cost information which has been approved by the hospital partner Entity's Materials Management/Supply Chain Department may be discussed with clinicians. **Absolutely, no contracts may be presented to clinical staff; all contracts must be routed through the appropriate department.**

- Raffles, lotteries, or contests that provide the winner with gifts of any value are not permitted.

- Pre-printed prescription pads may not be distributed.

Product Approval Process

- The Vendor's product must be approved by the partner hospital. Please contact the partner hospital Entity's Materials Management/Supply Chain Department to verify.

- If it is not approved, the vendor must work with the department directly to get approval with the hospital partner in order for the product to be used within the center.

Grants/Gifts

- No personal gifts of any kind from vendors to faculty or staff are permitted.

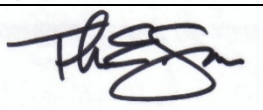
- Vendor representatives may not give to individuals or the Wound Care Center any promotional gifts (such as pens, pads, etc.) featuring product names. All gifts to the institution must be

consistent with hospital partner's policies concerning conflicts of interest.

Responsibility

- Staff are responsibility for assuring that vendors interacting with our center comply with this policy. Non-compliant vendors are to be immediately reported to the Program Director.

- Security may, at any time, request to inspect a vendor's identification badge. Vendors without proper identification badges will be escorted to the appropriate vendor check-in area. Uncooperative vendors or those violation of hospital policies may be escorted off the premises.

Title: Process of Obtaining Unit Licensure	Policy Number: OP.039.0
Date Issued: 04/01/2016	Date Revised: 1/1/2018, 1/1/2020, 1/1/2022
Source: SerenaGroup® Inc. SerenaGroup Building the Nation's Leading Wound Care Team	Medical Director SerenaGroup, Inc. Thomas E. Serena MD FACS 

SCOPE:

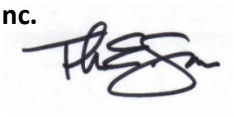
All licensed personnel who work for SerenaGroup®.

PURPOSE:

- SerenaGroup® Human Resources will obtain at the time of hire of all licensed personnel and every year in the calendar month of January the Public Health Licensure Unit Certification of Licensure.

- The certificate will have a date stamp as well as name, type, compact, number, status, issued, expiration, education as well as disciplinary/non-disciplinary information.

- This information will be filed in the staff members employee file.

Title: Fluorescence Imaging	**Policy Number:** OP.040.0
Date Issued: 01/01/2022	**Date Revised:**
Source: SerenaGroup™ Inc. SerenaGroup Building the Nation's Leading Wound Care Team	**Medical Director SerenaGroup, Inc.** Thomas E. Serena MD FACS 

SCOPE:

All company facilities, including hospitals and any entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

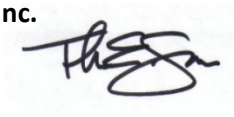
- Nursing Personnel
- Staff Physician/Non-Physician Provider

PROCEDURE: To ensure appropriate clinical documentation is provided to assure Medical Necessity is met, documented, and captured in the hospital approved Wound Care EMR.

SG approved Template:

Patient has _____ **(number/anatomical location/wound type)** that is nonhealing or suspicious for moderate-to-heavy bacterial load. This **ulcer/wound** has been present for **(duration)_____.** The patient's plan of care includes debridement(s), off -loading, compression, glycemic control as evident by HgBA1C of_____, a vascular assessment as evident by (**ABI/toe pressure or other quantitative measure) (mention all that apply). Today the** goal is to determine presence of moderate-to-heavy bacterial load present using the MLiX procedure.

After consenting the patient, the patient was positioned to expose the _____(number or anatomical location) wound(s) the area around the ulcer was draped to remove background clutter. Approved MLi:X dots were placed above and below the ulcer. A first image was taken on standard imaging mode. The MLi:X green light illuminated indicating the proper distance from the wound for imaging. The MLi:X procedure reported the surface area, length and width. The dots were removed. The room lights were turned off in preparation for the fluorescent image. **A dark drape was attached to the device to eliminate ambient light that could interfere with the procedure.** The device was placed in Fluorescence mode. Watching the MLlight indicator for the appropriate distance from the wound, the fluorescence image was captured. The room lights were turned back on. I reviewed the image. **Red/Cyan fluorescence was positive in the wound _____(add location) indicated that the wound contained moderate-to-heavy bacteria in that area. (No fluorescence was detected indicating that wound did not contain moderate-to-high bacterial load).**

Title: Sterilization	**Policy Number:** OP.042.0
Date Issued: 01/01/2022	**Date Revised:**
Source: SerenaGroup™ Inc. SerenaGroup Building the Nation's Leading Wound Care Team	**Medical Director SerenaGroup, Inc.** Thomas E. Serena MD FACS 

SCOPE:

All company facilities, including hospitals and any entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Nursing Personnel
- Clinical Personnel
- Staff Physician/Non-Physician Provider

PURPOSE: To provide guidelines for sterilization or disinfecting instruments and, patient care devices that are utilized in the wound care center.

PROCEDURE:

Instruments typically utilized in wound care for procedure (e.g., debridement's, application of cellular tissue products) are consider Critical Items (will enter tissue or vascular system or blood will flow through them) as defined by the CDC. All Critical Items are to be sterilized by high-heat, steam, or gas sterilization. For all for patient-care equipment and other patient care items considered semi-critical as defined by the CDC standard sterilization and disinfection procedures are adequate to sterilize or disinfect instruments or devices.

Title: Pain Management in the Wound Patient	Policy Number: OP.043.0
Date Issued: 8/1/2021	Date Revised: 1/1/2022
Source: SerenaGroup® Inc.	Medical Director SerenaGroup® Inc. Thomas E. Serena MD FACS

SCOPE:

Entities operating under the hospital's Medicare Provider Number including, but not limited to, the following:

- Non-Nursing Staff
- Nursing Staff
- Providers

POLICY:

To assess, document and manage chronic pain associated with wounds in accordance with accepted practice guidelines for chronic wound management. To develop a process for referral of patients to pain specialists when the discomfort associated with the wound cannot be effectively managed in the wound care center.

PROCEDURE:

1. Evaluate the degree, severity, location, intensity and exacerbating factors in wound care patients suffering from chronic pain.
2. Document the patient's current pain management regimen. This documentation is entered by a Registered Nurse.

3. Re-assess all aspects of pain at each clinic visit including any discomfort the patient experienced between visits.
4. if the patient continues to complain of pain despite interventions, the Registered Nurse should determine if it is situational or constant.

    a. In the case of Situational-pain, a plan of care is developed to address the reasons for the pain (e.g., dressing removal or a debridement procedure). The RN will assess the adequacy of topical analgesics, the type of dressing used and the dressing change procedure. The RN will review techniques used to control pain during the dressing removal and application as well as during any procedures.

    b. In the case of constant pain, educate the patient on available options such as referral to a pain management specialist.

5. Pain management decisions will be ordered by the provider overseeing the patient's plan of care.

6. Opioids are not indicated in the control of chronic pain. If opioids are prescribed for acute pain, the prescription should be written for a total of 3 to 7 days of medication and an opioid contract must be executed and placed in the medical record.