Cellular Tissue Products (CTP)

September 2021 Monthly Education

Title: Management of Cellular and Tissue Based Products	**Policy Number:** OP.068.0
Date Issued: 04/01/2016	**Date Revised:** 04/01/2016, 01/01/2018
Source: SerenaGroup™ Inc.	**Revisions:**
SerenaGroup	**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 Physicians/Non-Physician Provider

POLICY:

The Center will follow a standardized process for acquiring, receiving, storing and issuing cellular and tissue based products. The hospital has ultimate oversight responsibility of this process.

PURPOSE:

To outline the process for managing cellular and tissue based products.

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 Corporate Reimbursement Director will confirm that a supplier is registered with the U.S. Food and Drug Administration (FDA).
    - Web links to verify registration can be found on the portal or
    - Go directly to the FDA's online database:
    - Documentation of this verification will be maintained in the center.
    - 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.
    - Documentation of the verification will be maintained in the Wound Care Center.
    - State requirements can be found at: http://www.aatb.org/State-Requirements-for-Tissue-Bank-Licensure-Registration-or-Certification
    - This requirement does not apply to autologous tissue- or cellular-based products classified as medical devices by the FDA.
3. Staff will document the receipt of all cellular and tissue based products in a SerenaGroup tissue log or in a log supplied by the hospital.
4. If the log is supplied by the hospital, the Program Director must ensure that records are kept on all of following:
    - Tissue supplier
    - Original numeric or alphanumeric donor and lot identification
    - Name of the recipient
    - Final disposition of each tissue (either fully used or partially used and partially discarded or fully discarded)
    - Expiration dates of all tissues
    - Dates, times and staff involved in accepting, preparing, and issuing tissues
5. Upon receipt:
    - The package will be inspected for damage
    - Staff will verify that the transport temperature was controlled and acceptable for tissues/products requiring a controlled environment. This verification is documented.
    - 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.
    - Tissues/Products requiring no greater control than ambient temperature for transport and storage would not need to have the temperature verified on receipt.
    - Expiration date is noted and pH (if applicable) should be verified.
    - **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.
    - Tissue/Product is to be stored at the temperature required per manufacturer's recommended guidelines until ready for use.
    - NOTE: Dermagraft® may be stored in the original, unopened, validated shipping container rather than transferred to a freezer. The package must remain unopened until ready to be used.

- The time from shipping to opening the shipping container must not exceed 104 hours for the "Dermagraft ® Shipper 1 – 5pieces."
- The time from shipping to opening the shipping container must not exceed 100 hours for the "Dermagraft ® Shipper 1 –27pieces."
- NOTE: Apligraf® may be stored in the original, validated shipping container. The box can be opened upon receipt to visually inspect the product but the box must be re-assembled as packaged by Organogenesis and stored within the closed box until the time of clinical use.
- Per instruction of Organogenesis, letter dated 9/10/2013, the temperature of the room in which Apligraf is stored must be recorded once daily to ensure storage in a controlled environment of 68 F - 73 F (20 C - 23 C).

7. The Center will maintain daily records to demonstrate that tissues/products requiring a controlled environment are stored at the requiredtemperatures.
   - Types of storage include room temperature, refrigerated, frozen and liquid nitrogen storage.
   - It is not necessary to monitor the temperature inside of validated shipping containers.
   - Unless otherwise instructed by the manufacturer, tissues/products requiring no greater control than ambient temperature for storage would not require temperature monitoring.
   - If tissue/product is stored over weekends or holidays when the center is not open, there must be a process to monitor and record the temperature eachday.
   - Staff will continuously monitor the temperature of refrigerators, freezers, nitrogen tanks, and other storage equipment.
   - Continuous temperature recording is not required but may be available with some continuous temperature monitoring systems.
   - Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store at a controlled temperature shall have functional alarms and an emergency backup plan.
   - For tissue/product stored at room temperature, alarm systems are notrequired.
8. Staff will utilize the materials and related instructions from the manufacturer to prepare or process the tissue/product.
9. Tissue/Product shall be applied per the manufacturer's guidelines, for indications approved for its use.
10. The center shall maintain a copy of the manufacturer's instructions that were used to process the tissue in a location where staff can easily access them forreview.
11. It is recommended that the center keep the package receipt for each tissue/product with the Tissue Log.
12. Tissues/Products shall be used is conjunction with good wound care, on wound beds free of infection and necrotic and fibroticmaterial.
13. Secondary dressings shall be applied per manufacturer's guidelines.
14. A product identification label (tissue/product type and unique identifier), as applicable, shall be placed in the patient's chart as part of that visit's documentation.
15. Staff shall complete and return tissue/product usage information cards requested by the supplier as appropriate and per hospitalpolicy.
16. Any unused tissue/product shall be disposed of per hospital policy. Some products may require disposal as biohazardwaste.
17. Tissues/Products labeled by the FDA as "single patient use" will be used on only one patient.
18. The center shall 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 federallaws.
19. Staff will maintain sufficient documentation to allow bi-directional tracing of tissues/products, and shall investigate and report to the supplier any adverse events related to use.

Title: Pre and Post Care of Cellular or Tissue Based Products	**Policy Number:** OP.069.0
Date Issued: 04/01/2016	**Date Revised:** 04/01/2016, 01/01/2018
Source: SerenaGroup™ Inc.	**Revisions:**
SerenaGroup	**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 Physicians/Non-Physician Provider

POLICY:

Staff will follow the suppliers' or manufacturers' guidelines regarding the pre and post application care of the patient receiving cellular or tissue based products.

PURPOSE:

To ensure patient safety in the use of cellular or tissue based products.

NOTES:

Please consult your Local Coverage Determination (LCD) to review the conditions that must be met for medical necessity.

Please review your LCD for those cellular or tissue based products that are considered investigational.

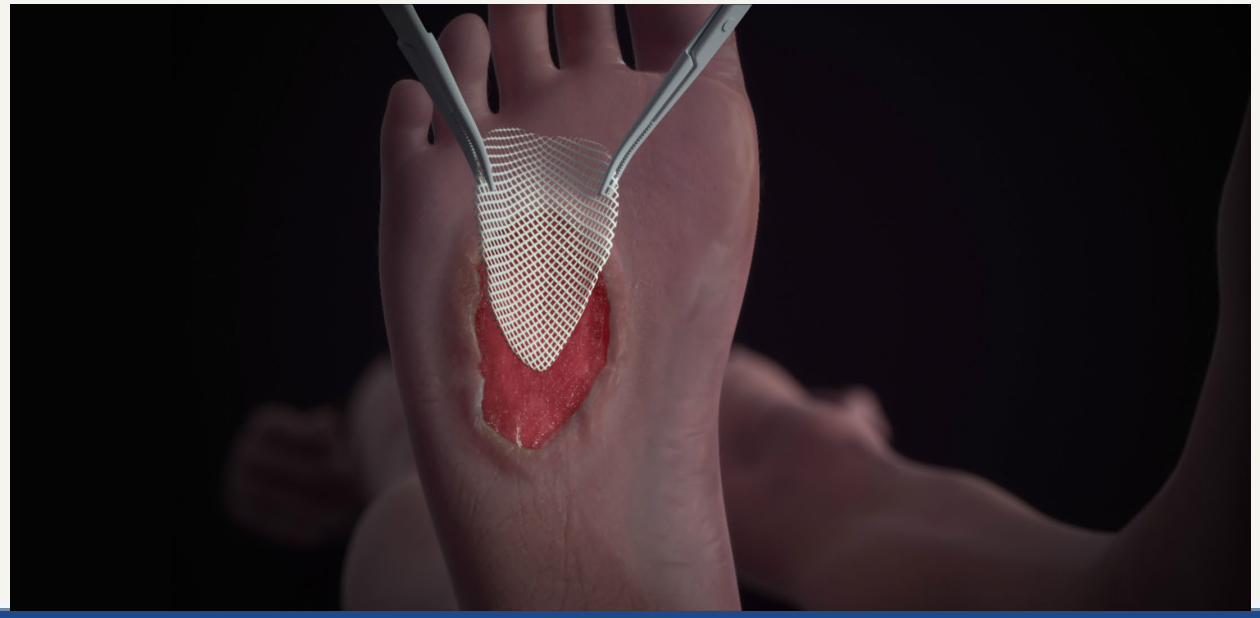
A cellular or tissue based product package labeled by the Food and Drug Administration (FDA) as "Single Patient Use" must be used on a single patient. Sharing or splitting unused portions is prohibited.

PROCEDURE:

1. A physician's order for the product is required. Application of the product is to be performed by the physician, nurse practitioner or physician assistant with hospital-approved privileges.
2. Many Medicare LCD's and Insurance Medical Policies require a recent ABI be performed and recorded, some LCD's have a minimum ABI number to qualify for application.
3. Ensure that all elements of Medical Necessity are met per the LCD or Insurance medical policy.
4. Follow manufacturers' guidelines for pre and postapplication and ensure all elements are documented in the patient's medical record.

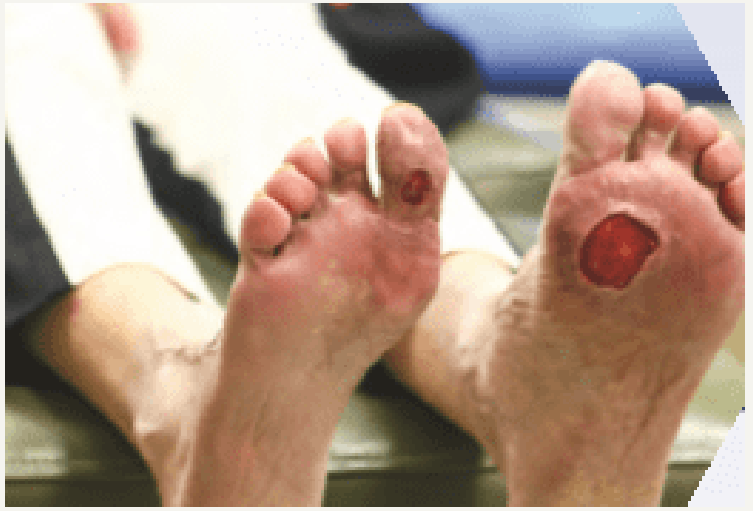
What is a Cellular Tissue Product (CTP)?

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



When and where do we use a CTP?

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



Examples of Cellular Tissue Products (CTP)

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

Local Cover Determination (LCD)

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

Compliance Regulations

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

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

CTP Log

- Staff are to document the receipt of all cellular and tissue-based products in SerenaGroup tissue log or in a log provided by the hospital.
- The log should document the following:
  - Tissue supplier
  - Original numeric or alphanumeric donor and lot identification
  - Patient identifier
  - Final disposition of each tissue (fully used/partially used/partially discarded/fully discarded)
  - Expiration date of tissue
  - Date, time, and staff involved in accepting, preparing, and issuing tissues

Receiving the CTP

- Inspect the package for damage upon arrival
- Verify that the transport temperature was controlled and acceptable for products requiring a controlled environment. This verification is documented
- If the distributor uses validated shipping containers, the receiver may document that the shipping container was received undamaged and within the stated timeframe for use
- Tissues/Products requiring no greater control than ambient temperature for transport and storage would not need to have the temperature verified on receipt
- Expiration date is noted on pH; (if applicable) should be verified
- 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

Transporting, Handling, Storing, and Using CTPs

- Staff will follow the suppliers' or manufacturers' written directions for transporting, handling, storing, and using.
- Tissue/Product is to be stored at the temperature required per the manufacturer's recommended guidelines until ready for use.
- Follow hospital policy for controlled temperature storage and maintenance of cellular tissue-based product.
- Utilize the materials and related instructions from the manufacturer to prepare or process the tissue/product.
- Apply product per the manufacturer's guidelines for indications approved for its use.
- The center shall maintain a copy of the manufacturer's instructions that were used to process the tissue in a location where staff can easily access them for review
- It is recommended that the center keep the package receipt for each tissue/product with the Tissue Log.

Continued…

- Tissues/ Products shall be used in conjunction with appropriate wound care, on wound beds free of infection, necrotic, and fibrotic material.
- Secondary dressings shall be applied per manufacturer’s guidelines.
- Tissues/Products labeled as “single patient use” will be used on only one patient. Sharing or splitting unused portions of the CTP is prohibited.

Medical Documentation

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

After Application

- Staff will complete and return tissue/product usage information cards required by the supplier as appropriate and per hospital policy.
- Any unused tissue/product will be disposed of per hospital policy. Some products may require disposal as biohazard waste.
- The center will retain the records for storage temperatures, all superseded procedures, manuals, manufacturer's instructions and publications, and any tissue/product records 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.
- 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.


QUIZ TIME

QUESTION 1:

1. Despite being labelled “single patient use,” if there are remaining usable pieces of a graft, they may be used on another patient.

Answer: FALSE. Sharing or splitting unused portions of a “single patient use” CTP is prohibited.

QUESTION 2:

1. If a delivered package containing a graft is damaged, it cannot be used.

Answer: TRUE. The manufacturer should be notified for a replacement.

QUESTION 3:

1. The protocols discussed in this PowerPoint pertain to plastic, polymer, human, and non-human cellular tissue products.

Answer: FALSE. Theses guidelines are for human and non-human cellular tissue products, not for collagen and tissue products derived from plastics or polymers.

Thank you for taking the time to complete SerenaGroup Education for September 2021. SerenaGroup continues to focus on providing education to all clinical staff. If you have ideas, questions, comments around education – please reach out to the Education Committee Members.

SerenaGroup Education Committee Members,
Nick Duquette
Ally George
Blair Flinn
Nancy Trafelet
Jill Schroder