October 2022 Education

Cellular Tissue Transplant Book

What and Why is the Tissuelog book needed?

- **What?** The Tissue Transplant Log (TTL) is required item in the Wound Center. There are regulatory requirements around the transplantation of tissue.
- **Why?**
  - Anytime transplantation of an organ, skin, bone, or other human living cell, there is a potential for rejection, recall from the manufacturer, etc., and there must be an adequate tracking documentation workflow.
  - Appears current policy and process is not hardwired. This has caused issues at re-accreditation for facilities.

SerenaGroup Directives

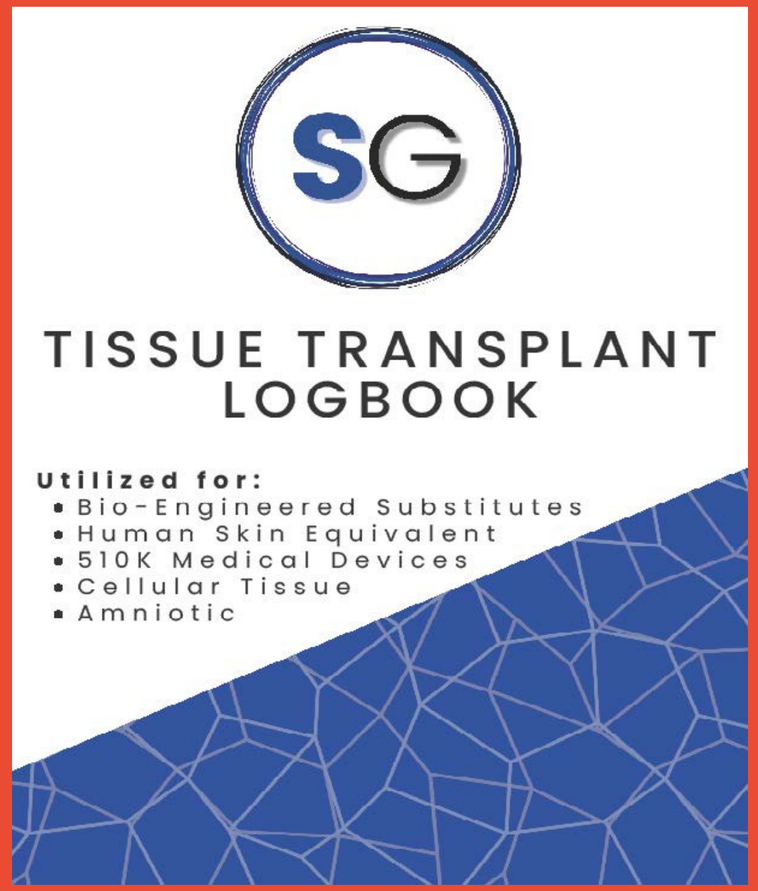
1. One tissuelog book per center ONLY
    a. Different tissuelog books is unacceptable and a bad practice
2. Retired all product literature in the active file
3. Ensure there is NO missing FDA documentation
4. Educate yourself on the 10-year archive rule

Why is this a problem?

SerenaGroup Process

1. Only the SerenaGroup Approved Logbook will be utilized
2. All CTP/HSE will be placed on the same tissue log sheet
3. Generally, all products are documented with the same elements
    a. *NOTE: THE ONLY PRODUCTS THAT REQUIRE THE COMPLETION OF TRANSPORT OF TEMPERTURE AND CONTROL ARE THOSE IN SHIPPING CONTAINERS*
4. All SerenaGroup approved CTP/HSE FDA documentation is on the SerenaGroup Share Drive (directors have access)
    a. *NOTE: If your center introduces a new product, you must send the information to the CCO to ensure the FDA documents are stored on the share drive.*

Approved Tissue Transplant Logbook (TTL) Covers



What is Inside the Tissuelog Book?

- Policy and Regulatory Tab
  - Management of Cellular and Tissue Based Products Policy OP.015.1 and/or Hospital Policy
  - *NOTE: SerenaGroup or Hospitals (know which)*
  - Regulartory (Joint Commission or DNV) EOP
- Tissue Logs (one form all types)
- Tissue Bank Registration Form (all companies) segregated
- Product Inserts (all products) segregated
- Completed Logs

What does the Regulatory Agency say? excerpt Joint Commission – Tab #1)

The tissue standards apply to human and non-human cellular based products and any product classified as tissue by state law, regulation or the FDA, even if it is acellular (containing no cells). Acellular dermal matrix, bone putty, and cancellous chips are examples of acellular products classified by the FDA as tissues, therefore, the tissue standards **do** apply based on FDA classification.

Products that are derived from human or non-human tissue and cellular materials, but rendered acellular at the time of use for the patient, are not surveyed under the tissue standards. Albumin and gamma globulin are examples of products derived from cellular products but rendered acellular through the manufacturing process. They are acellular at the time of patient use **are not** classified by the FDA as tissues, therefore, the tissue standards **do not** apply. Please check the manufacturer's package insert for the product's composition. If the FDA classification is not noted on the package insert, it may be necessary to research the product on the FDA website to determine classification. A list of common tissue and cell products can also be found in the Transplant Safety chapter of the accreditation manual on pages TS-7 and TS-8.

The tissue standards do not apply to products that do not meet the above description, including those that have tissue-like names or are otherwise associated with tissue usage. Examples include medical devices (acellular), medications, blood derivatives and combination products. These items may also require tracking to support patient notification in the event of a recall or investigation for an unexpected adverse event. However, the Joint Commission standards do not specify the same level of stringent documentation as is required for tracking tissue products.

Where can I find the information?

Joint Commission
Transplant Safety Standard

- TS.02.01.01 (10 year rule)
- TS.03.02.01 (Tissue Log and Chain of Custody and Storage of Tissue)
- TS.03.03.01 (Adverse events) (FDA registry)

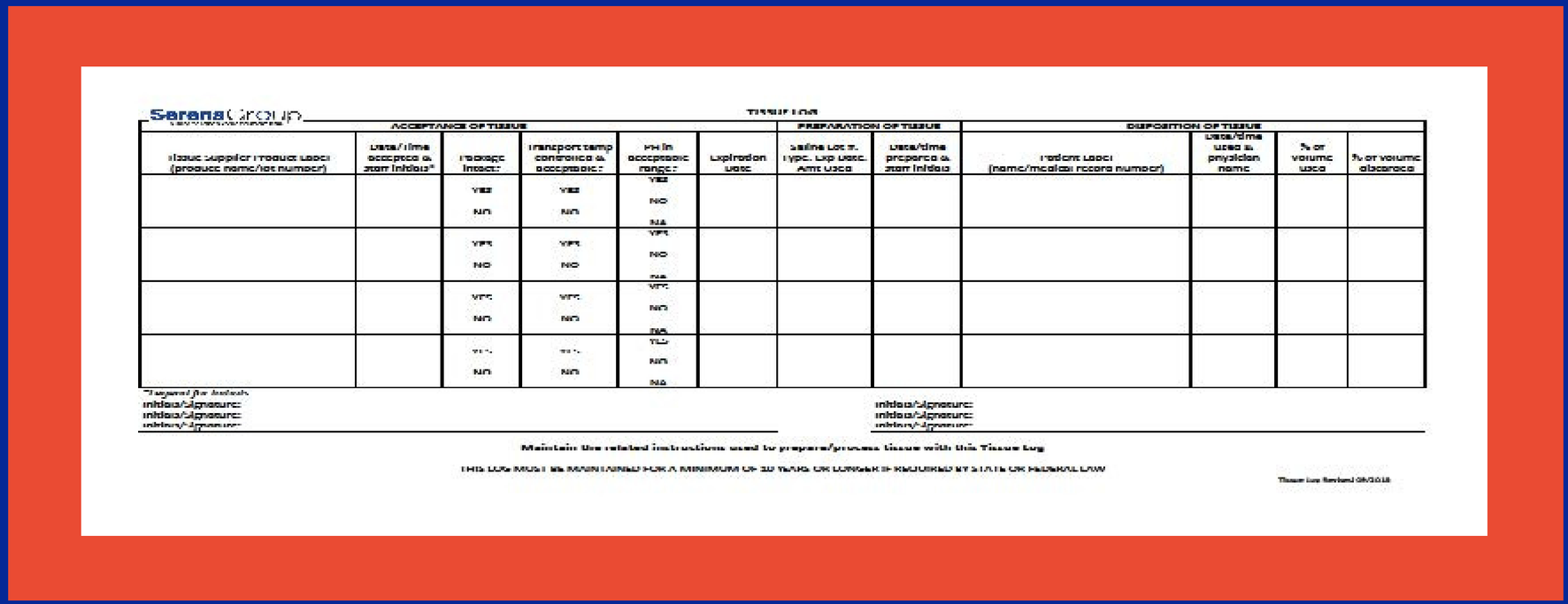
Pages 553-563
CAMH (PDF manual), January 2021 CAMH, January 2021 | 2021 The Joint Commission. Do not reproduce or distribute

DNV-GL
Documentation/Transplantation

- TO.5 Documentation (FDA Registry) (adverse events)
- TO.6 (10 year rule)
- TO.7 (Tissue Log and Chain of Custody and Storage of Tissue

Pages 203 and 204
NIAHO Accreditation Requirements, Intrepretive Guidelines and Surveyor Guidance Revision 20-1, 09-21-2020

Approved Tissue Log (tab #2)



Serena Group

TISSUE LOG

ACCEPTANCE OF TISSUE						PREPARATION OF TISSUE		DISPOSITION OF TISSUE			
Tissue supplier / product used (product name/lot number)	Date/Time accepted & start initials*	Package intact:	Transport temp confirmed & acceptable:	pH in acceptable range:	Expiration date	Saline Lot #, Type, Exp date, Amt used	Date/time prepared & start initials	Patient used (name/medical record number)	Date/time used & physician name	% or volume used	% or volume discarded
		YES NO	YES NO	YES NO NA							
		YES NO	YES NO	YES NO NA							
		YES NO	YES NO	YES NO NA							
		YES NO	YES NO	YES NO NA							

*Required for Initials

Initials/Signature:
Initials/Signature:
Initials/Signature:

Initials/Signature:
Initials/Signature:
Initials/Signature:

Maintain the related instructions used to prepare/process tissue with this Tissue Log

THIS LOG MUST BE MAINTAINED FOR A MINIMUM OF 10 YEARS OR LONGER IF REQUIRED BY STATE OR FEDERAL LAW

Tissue Log Revised 09/2018

FDA Tissue Registry Form (tab #3)

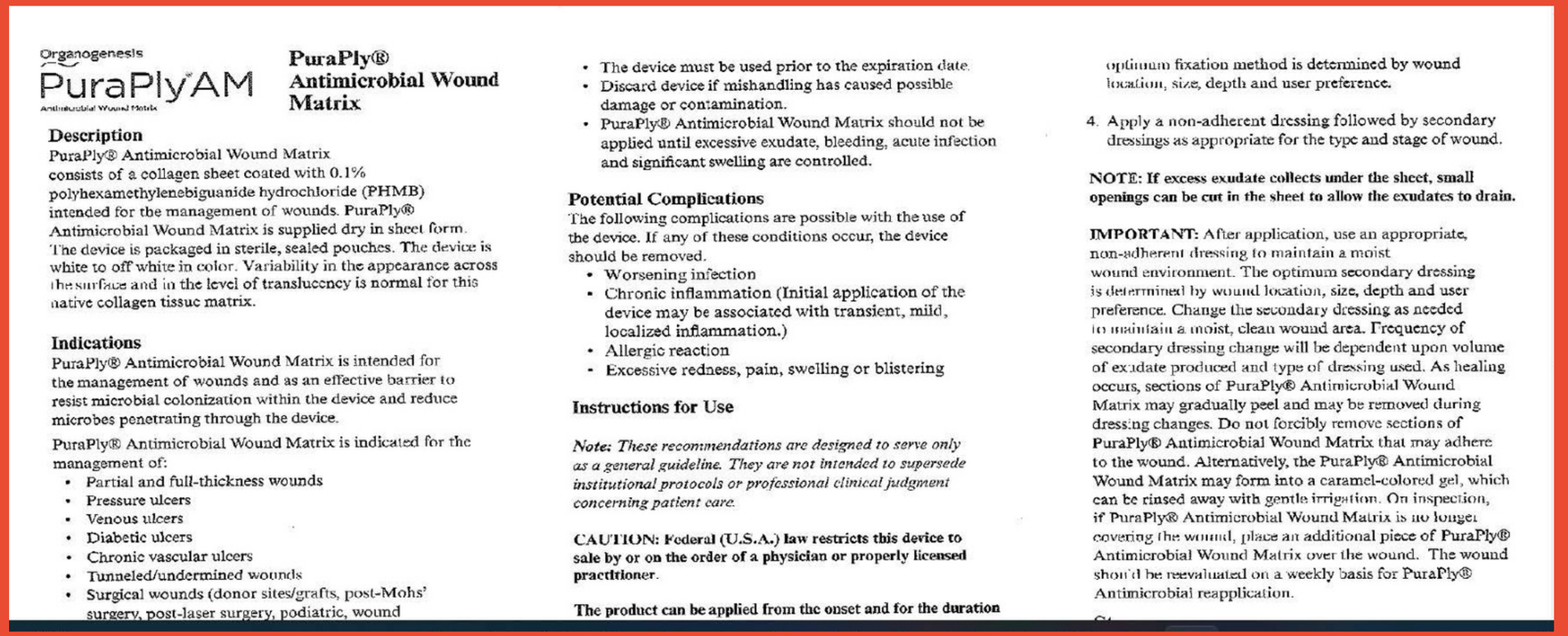
Where can I find this?

All approved and utilized will be on the SerenaGroup Share Drive (directors have access)

https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration

Product Insert – All (tab #4)

EXAMPLE



Organogenesis
PuraPly AM
Antimicrobial Wound Matrix

PuraPly® Antimicrobial Wound Matrix

Description

PuraPly® Antimicrobial Wound Matrix consists of a collagen sheet coated with 0.1% polyhexamethylenebiguanide hydrochloride (PHMB) intended for the management of wounds. PuraPly® Antimicrobial Wound Matrix is supplied dry in sheet form. The device is packaged in sterile, sealed pouches. The device is white to off white in color. Variability in the appearance across the surface and in the level of translucency is normal for this native collagen tissue matrix.

Indications

PuraPly® Antimicrobial Wound Matrix is intended for the management of wounds and as an effective barrier to resist microbial colonization within the device and reduce microbes penetrating through the device.

PuraPly® Antimicrobial Wound Matrix is indicated for the management of:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound

- The device must be used prior to the expiration date.
- Discard device if mishandling has caused possible damage or contamination.
- PuraPly® Antimicrobial Wound Matrix should not be applied until excessive exudate, bleeding, acute infection and significant swelling are controlled.

Potential Complications

The following complications are possible with the use of the device. If any of these conditions occur, the device should be removed.

- Worsening infection
- Chronic inflammation (Initial application of the device may be associated with transient, mild, localized inflammation.)
- Allergic reaction
- Excessive redness, pain, swelling or blistering

Instructions for Use

Note: These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

The product can be applied from the onset and for the duration

optimum fixation method is determined by wound location, size, depth and user preference.

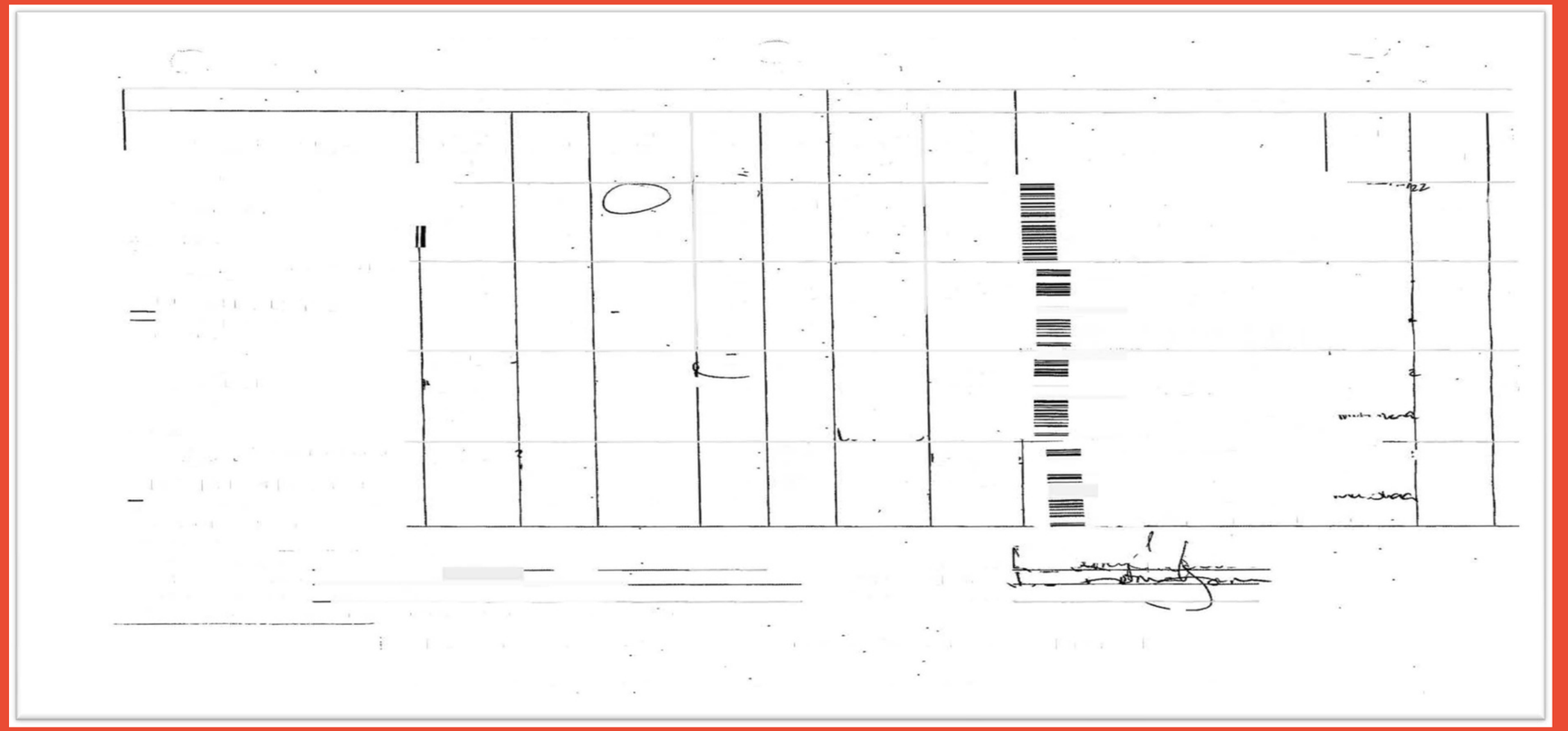
4. Apply a non-adherent dressing followed by secondary dressings as appropriate for the type and stage of wound.

NOTE: If excess exudate collects under the sheet, small openings can be cut in the sheet to allow the exudates to drain.

IMPORTANT: After application, use an appropriate, non-adherent dressing to maintain a moist wound environment. The optimum secondary dressing is determined by wound location, size, depth and user preference. Change the secondary dressing as needed to maintain a moist, clean wound area. Frequency of secondary dressing change will be dependent upon volume of exudate produced and type of dressing used. As healing occurs, sections of PuraPly® Antimicrobial Wound Matrix may gradually peel and may be removed during dressing changes. Do not forcibly remove sections of PuraPly® Antimicrobial Wound Matrix that may adhere to the wound. Alternatively, the PuraPly® Antimicrobial Wound Matrix may form into a caramel-colored gel, which can be rinsed away with gentle irrigation. On inspection, if PuraPly® Antimicrobial Wound Matrix is no longer covering the wound, place an additional piece of PuraPly® Antimicrobial Wound Matrix over the wound. The wound should be reevaluated on a weekly basis for PuraPly® Antimicrobial reapplication.

Completed Tissue Log (tab #5)

EXAMPLE



SerenaGroup Expectations

All SerenaGroup Centers will implement an **approved** TissueLog book that has been inspected by the SerenaGroup CCO (either onsite or virtually).

SerenaGroup Tissue Log

SerenaGroup
Building the Nation's Leading Wound Care Team

TISSUE LOG

ACCEPTANCE OF TISSUE						PREPARATION OF TISSUE		DISPOSITION OF TISSUE			
Tissue Supplier Product Label (produce name/lot number)	Date/Time accepted & staff initials*	Package intact?	Transport temp controlled & acceptable?	PH in acceptable range?	Expiration Date	Saline Lot #, Type, Exp Date, Amt Used	Date/time prepared & staff initials	Patient Label (name/medical record number)	Date/time used & physician name	% of volume used	% of volume discarded
		YES NO	YES NO	YES NO NA							
		YES NO	YES NO	YES NO NA							

Legend for Initials

Initials/Signature:

Initials/Signature:

Initials/Signature:

Initials/Signature:

Initials/Signature:

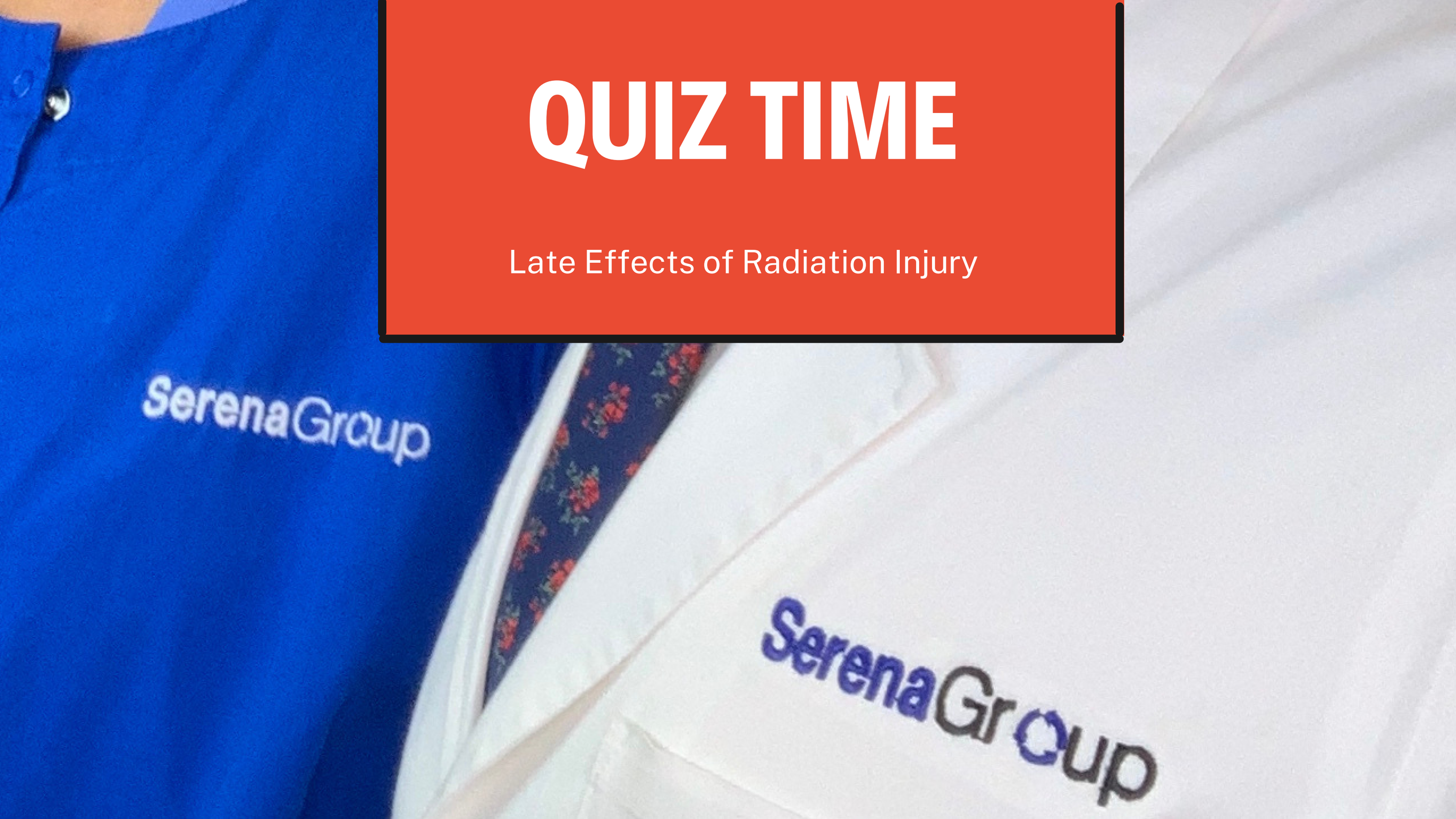
Initials/Signature:

Maintain the related instructions used to prepare/process tissue with this Tissue Log

THIS LOG MUST BE MAINTAINED FOR A MINIMUM OF 10 YEARS OR LONGER IF REQUIRED BY STATE OR FEDERAL LAW

Upcoming Regulatory Changes – 2022

- NOVITAS
  - Draft LCD, closed for comments, awaiting final LCD
- CMS PFFS Fee Schedule
  - Changing CTP language to wound care material or similiar language
  - Elimination to all Q-codes and revising to A-codes (supply)
- HOPD OPPS 2023 proposed rule
  - Anticipate similar language as in PFFS
  - Anticipate ulcer size limitation
  - All elements of MN
  - One and done



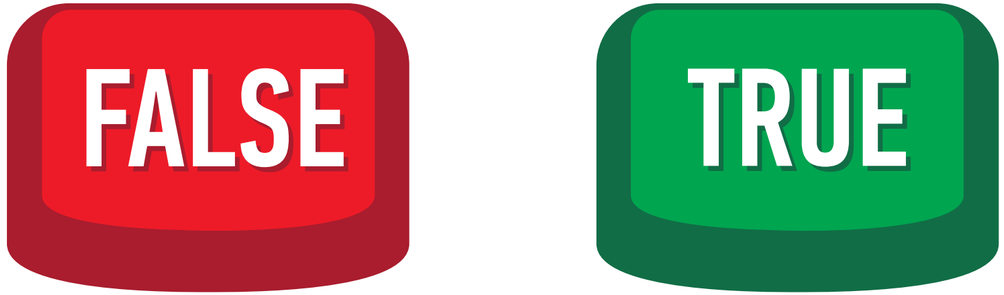
QUIZ TIME

Late Effects of Radiation Injury

Question 1

Cellular Tissue Transplant Book

The Tissue Transplant Log is required item in the Wound Center.



Answer 1

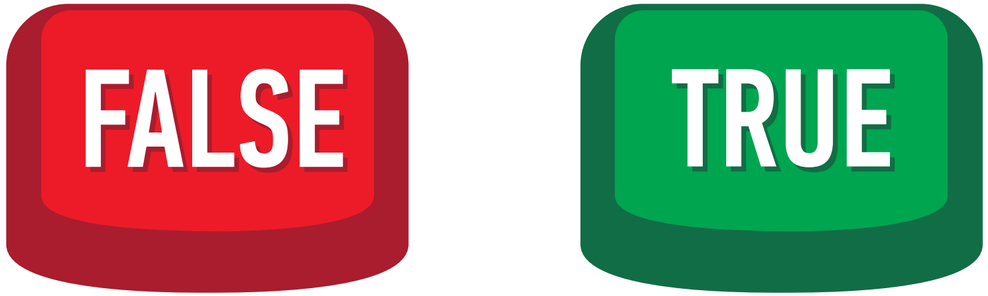
Cellular Tissue Transplant Book

The Tissue Transplant Log is required item in the Wound Center.

Question 2

Cellular Tissue Transplant Book

The only products that require the completion of transport of temperture and control are those in an envelope.



Answer 2

Cellular Tissue Transplant Book

The only products that require the completion of transport of temperture and control are those in an **envelope**.

shipping containers

Question 3

Cellular Tissue Transplant Book

SerenaGroup Wound Care Centers should have 5 tissue log books.

Question 3

Cellular Tissue Transplant Book

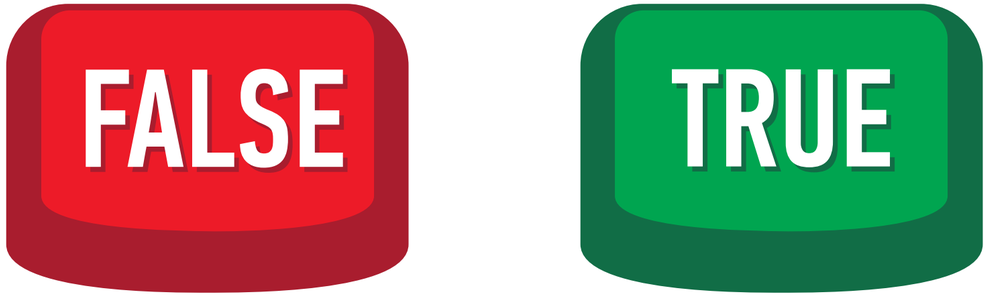
SerenaGroup Wound Care Centers should have **5** tissue log books.

1

Question 4

Cellular Tissue Transplant Book

All SerenaGroup Centers will implement an approved Tissue Log that has been inspected by the SerenaGroup CCO (either onsite or virtually).

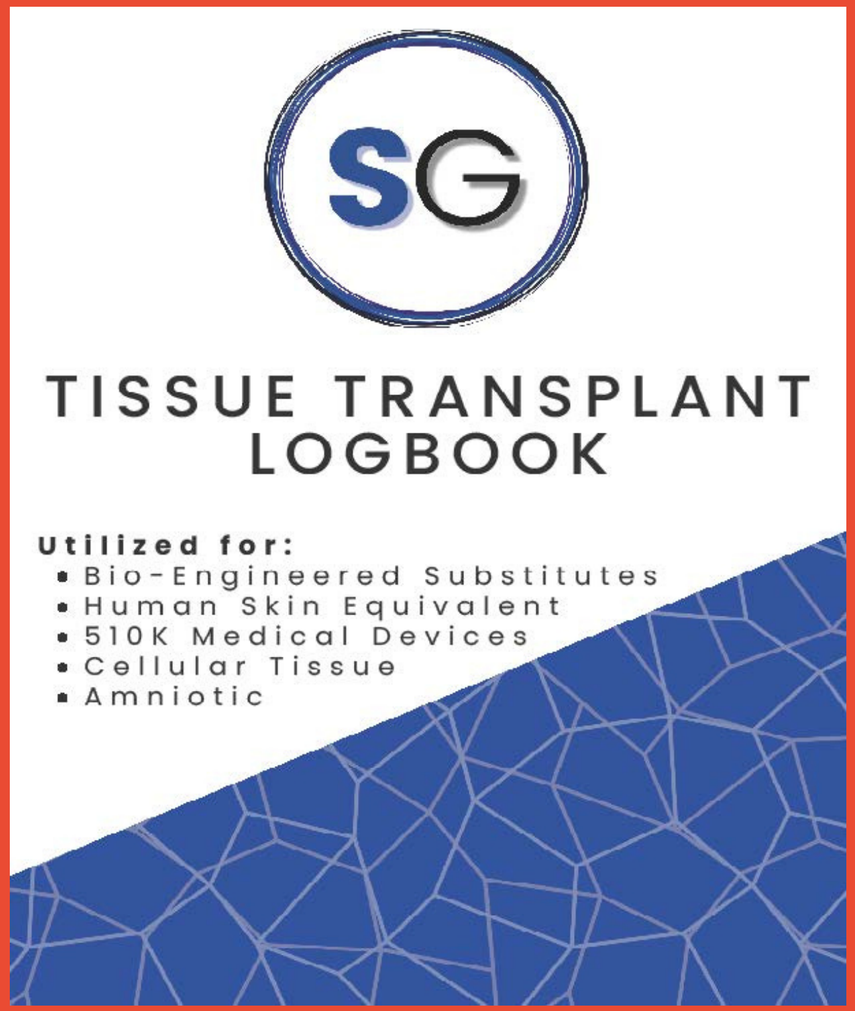


Answer 4

Late Effects of Radiation Injury

All SerenaGroup Centers will implement an approved Tissue Log that has been inspected by the SerenaGroup CCO (either onsite or virtually).

Reference


SG
TISSUE TRANSPLANT LOGBOOK
Utilized for:
• Bio-Engineered Substitutes
• Human Skin Equivalent
• 510K Medical Devices
• Cellular Tissue
• Amniotic


TISSUE TRANSPLANT LOGBOOK
SG
Utilized for:
Bio-Engineered Substitutes
Human Skin Equivalent
510K Medical Devices
Cellular Tissue
Amniotic

Thank you!

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