LifeNet Health's Instructions for Cardiovascular Allografts: Document Analysis and Recommendations

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ENGL 334

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02/15/2023

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ABSTRACT

This document critically analyzes LifeNet Health's Cryopreserved Cardiac and Vascular Allograft and Bio-implant Instructions, then provides detailed suggestions to resolve each issue. This document aims to improve the Cryopreserved Cardiac and Vascular Allograft and Bio-implant Instructions' readability, usability, and legibility by targeting problematic formatting and functionality issues.

LIFENET HEALTH

Established in 1982, LifeNet Health is an accredited member of the American Association of Tissue Banks (AATB), and an Organ Procurement Organization (OPO) in Virginia (LifeNet Health, 2023). For 41 years, LifeNet Health has "saved lives, restored health, and given hope" by globally leading in the arena of regenerative medicine, and providing high-quality allografts and bioimplants, and organ transplants (LifeNet Health, 2023).

ALLOGRAFTS AND BIO-IMPLANTS

Through the gift of donation, LifeNet Health provides recipients with tissues such as heart valves to correct anatomical and functional abnormalities, vascular tissues such as veins to restore circulation after trauma or cardiovascular disease, bone and tendons to save limbs from cancers, trauma, and infections, and skin to stimulate healing in wounds and burns (AATB, 2023; LifeNet Health, 2023). As a tissue bank and processor, LifeNet Health has engineered and

safely allocated over 400,000 high-quality bio-implants a year to meet the demands of recipients in need (LifeNet Health, 2023).

CRYOPRESERVED CARDIAC AND VASCULAR ALLOGRAFT AND BIO-IMPLANTS INSTRUCTIONS

ANALYSIS



Figure 1 LifeNet Health Logo lifenethealth.org - Compare the logos. The top logo is from the instructional documents while the bottom is from the webpage.

The document immediately identifies itself with the organization by providing the logo at the top left-hand corner of each page and consistently employing the same sans-serif font used across all documents and webpages originating from LifeNet Health as seen in figure 1. The use of the sans-serif font is an intentional choice not only because it matches the logo but because it impedes readability, the ease with which a person can scan a document (Kimball & Hawkins, 2008, p. 166), to force the user to slow down, pay attention and read each statement because of the nature of these instructions (Tucker, n.d.).

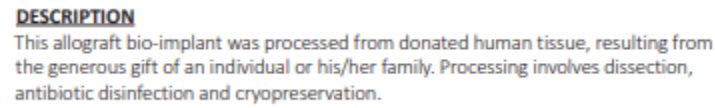
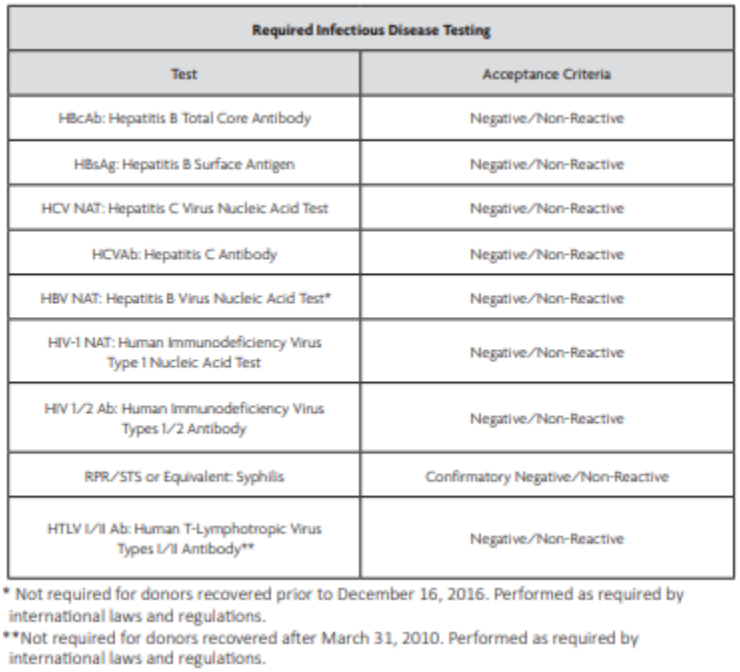


Figure 2 Header vs. paragraph text

Because the document is designed to be printed and distributed with the cardiovascular grafts, it is grayscale to reduce the use of ink. In addition, to provide a contrast between headings, critical information like warnings, and the rest of the document, the designers chose to make

headings and critical information larger, bold, and black, whereas the rest of the document's font is smaller and gray, as seen in figure 2.

The document, formatted for usability, employs a two-column structure. The columns help guide the gaze down the page, giving the user a "clear path through the document" (Kimball & Hawkins, 2008, p. 126). In addition, this formatting helps users discern the order in which to read —left column, then right (Kimball & Hawkins, 2008, p. 125). It also provides the hierarchy of information. For example, the document's body begins with information like uses, contraindications, warnings, and storage requirements. It then ends with instructions on how to thaw the grafts for use. The two-column structure also breaks down the text into smaller, bite-sized pieces for clear understanding and use of instructions (Kimball & Hawkins, 2008, p. 125). Lastly, the columns help conserve space and paper, especially since it is designed for printing.



Required Infectious Disease Testing	
Test	Acceptance Criteria
HBcAb: Hepatitis B Total Core Antibody	Negative/Non-Reactive
HBsAg: Hepatitis B Surface Antigen	Negative/Non-Reactive
HCV NAT: Hepatitis C Virus Nucleic Acid Test	Negative/Non-Reactive
HCVAb: Hepatitis C Antibody	Negative/Non-Reactive
HBV NAT: Hepatitis B Virus Nucleic Acid Test*	Negative/Non-Reactive
HIV-1 NAT: Human Immunodeficiency Virus Type 1 Nucleic Acid Test	Negative/Non-Reactive
HIV 1/2 Ab: Human Immunodeficiency Virus Types 1/2 Antibody	Negative/Non-Reactive
RPR/STS or Equivalent: Syphilis	Confirmatory Negative/Non-Reactive
HTLV I/II Ab: Human T-Lymphotropic Virus Types I/II Antibody**	Negative/Non-Reactive

* Not required for donors recovered prior to December 16, 2016. Performed as required by international laws and regulations.
**Not required for donors recovered after March 31, 2010. Performed as required by international laws and regulations.

Figure 3 Serological Testing Requirements for tissue donors**.**

This document utilizes two tables that summarize critical information for users. These tables draw the user's attention because they differ from anything else within the document. The first table explains the storage requirements to maintain the grafts' integrity before implantation. The second table outlines the serological testing and results that each donor is subject to (see figure 3). Both summarize the information clearly and concisely by providing precise language and utilize

lines to mark column boundaries for usability. While Draggas and Tebeaux (2017) recommend "omitting lines between rows and columns [and using space] to avoid a crowded appearance" (p. 113), the lines in these tables are critical because they provide boundaries and relationships between the information in each row and column.

Draggas and Tebeaux (2017) recommend that document designers avoid jargon for simplicity and to increase readability unless the users are familiar with the information (p. 67). The jargon in this document is as minimal as possible and essential to the overall functionality of the document. The jargon provides precise language to the user for preparing the grafts for implantation. Based on word choice, it is evident that the users or audience for this document are doctors, surgeons, or other healthcare providers.

RECOMMENDATIONS

Following are six recommendations in five categories to enhance the usability, readability, and legibility of Lifenet Health's Cryopreserved Cardiac and Vascular Allograft and Bio-implant Instructions:

- **Consistency**
- **Font Sizes**
- **Contrast**
- **Contact Information Formatitng**
- **Formatting**

CONSISTENCY

Document consistency is recommended for useability. There are two instances in which warnings are not bolded. Before and after these instances, all warnings are denoted with an icon and boldface. Compare the two warnings in figure 4.

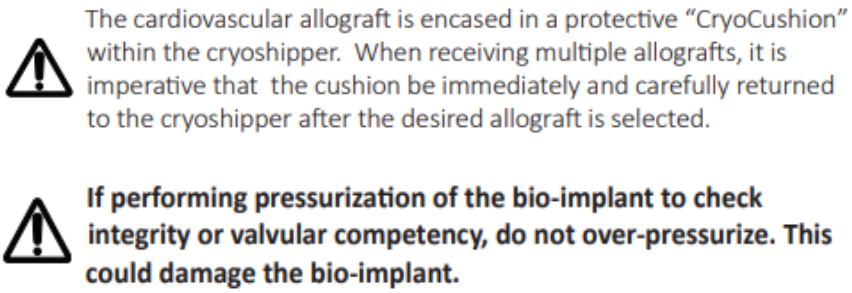


Figure 4 Light vs. boldfaced warnings

The boldface text carries a heavier weight, creating a contrast within the document. This boldface draws the user's attention to the information.

There is one instance in which a warning is also italicized.

Due to the nature of the document, all warnings must be consistent and discernable throughout the text for the integrity of the grafts and the safety of the recipients.

It is recommended that all warnings are boldfaced; however, the use of italics may be permitted, provided it is also consistently used the same throughout the document.

FONT SIZES

Another recommendation to improve usability, legibility, and readability is to increase the font size of the warnings. While most of the warnings are boldfaced and accompanied by a warning icon, some warnings sandwiched between headers that are also boldfaced may be missed because there is not enough contrast between the two (see figure 5). Creating a contrast between the warning and the headings will draw the user's attention to the critical information and establish an information hierarchy. By making the font larger and more significant, we signal to the users that the information is vital.

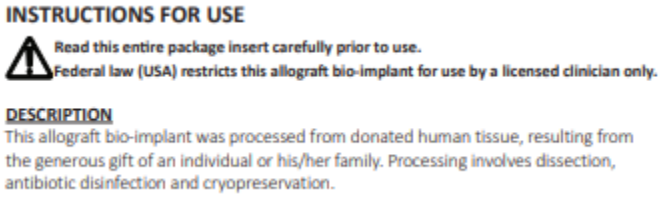


Figure 5 Warning between headers

CONTRAST

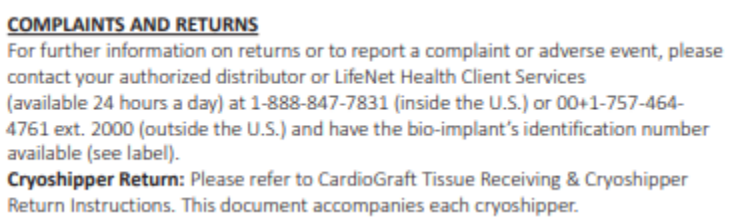


Figure 6 Warning

The next recommendation is to create contrast with the warning icons so they stand out in the document. The warning icon is currently a hollow triangle with a bold black exclamation mark. Initially, utilizing one of LifeNet Health's organizational colors was going to be suggested; however, that may translate poorly if the document is printed. So instead, it is recommended to invert the warning icon to create contrast (see figure 6.)

CONTACT INFORMATION FORMATTING

The document provides contact information for LifeNet Health in case of complaints and returns of grafts. As seen in figure 7, the contact information is situated inside the paragraph, making it difficult to obtain quickly. Here is a suggested format for the complaints and returns section:



COMPLAINTS AND RETURNS
For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or LifeNet Health Client Services (available 24 hours a day) at 1-888-847-7831 (inside the U.S.) or 00+1-757-464-4761 ext. 2000 (outside the U.S.) and have the bio-implant's identification number available (see label).
Cryoshipper Return: Please refer to CardioGraft Tissue Receiving & Cryoshipper Return Instructions. This document accompanies each cryoshipper.

Figure 7 LifeNet Health contact information

COMPLAINTS AND RETURNS

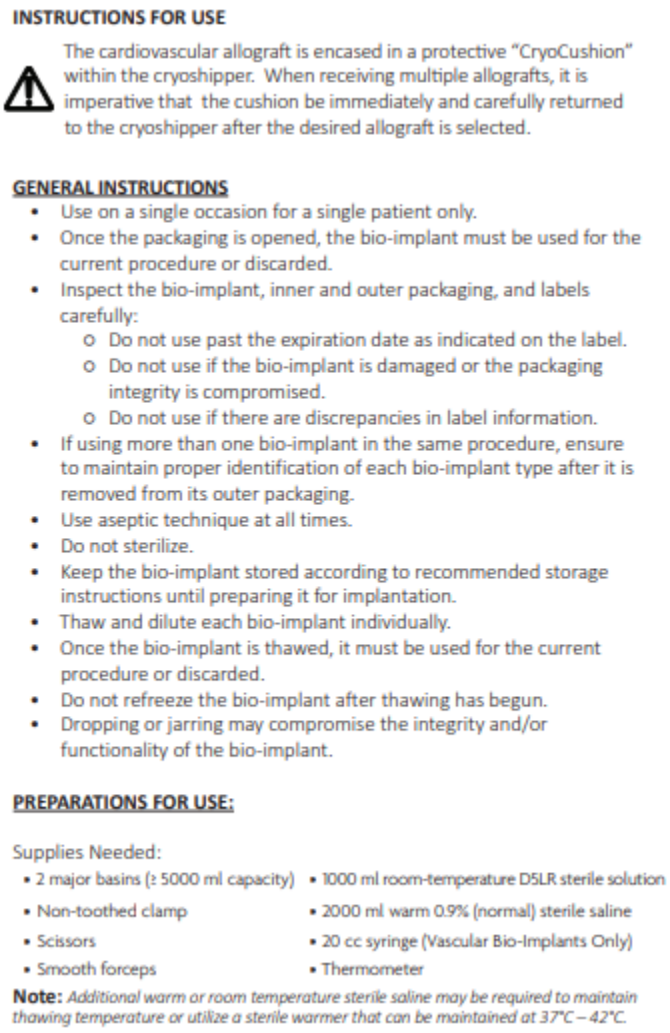
For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or LifeNet Health Client Services 24 hours a day at:

- 1-888-847-7831 (U.S.)
- 00+1-757-464-4761 ext. 2000 (Outside the U.S.)

Please have your bio-implant's identification number available (see label) to expedite resolutions.

In the revised complaints and returns section, please note that the contact information for LifeNet Health Client Services has been listed so that the numbers are easily accessible to users. The information about the bio-implant identification number has been italicized to draw attention and express that the information is essential to provide the user with expedient service.

FORMATTING



INSTRUCTIONS FOR USE

The cardiovascular allograft is encased in a protective "CryoCushion" within the cryoshipper. When receiving multiple allografts, it is imperative that the cushion be immediately and carefully returned to the cryoshipper after the desired allograft is selected.

GENERAL INSTRUCTIONS

- Use on a single occasion for a single patient only.
- Once the packaging is opened, the bio-implant must be used for the current procedure or discarded.
- Inspect the bio-implant, inner and outer packaging, and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the bio-implant is damaged or the packaging integrity is compromised.
  - Do not use if there are discrepancies in label information.
- If using more than one bio-implant in the same procedure, ensure to maintain proper identification of each bio-implant type after it is removed from its outer packaging.
- Use aseptic technique at all times.
- Do not sterilize.
- Keep the bio-implant stored according to recommended storage instructions until preparing it for implantation.
- Thaw and dilute each bio-implant individually.
- Once the bio-implant is thawed, it must be used for the current procedure or discarded.
- Do not refreeze the bio-implant after thawing has begun.
- Dropping or jarring may compromise the integrity and/or functionality of the bio-implant.

PREPARATIONS FOR USE:

Supplies Needed:

- 2 major basins (≥ 5000 ml capacity)
- Non-toothed clamp
- Scissors
- Smooth forceps
- 1000 ml room-temperature D5LR sterile solution
- 2000 ml warm 0.9% (normal) sterile saline
- 20 cc syringe (Vascular Bio-Implants Only)
- Thermometer

Note: *Additional warm or room temperature sterile saline may be required to maintain thawing temperature or utilize a sterile warmer that can be maintained at 37°C – 42°C.*

Figure 8 General instructions and Preparation for use

The format allows the user to move through the document, as previously mentioned; however, it would be easier to read if all the opening and thawing instructions were in the left column and all the individual graft instructions in the right column. To accomplish this, the warning, general instructions, and preparation for use would have to change positions. Considering there is no room on the previous page, two suggestions exist to resolve the issue.

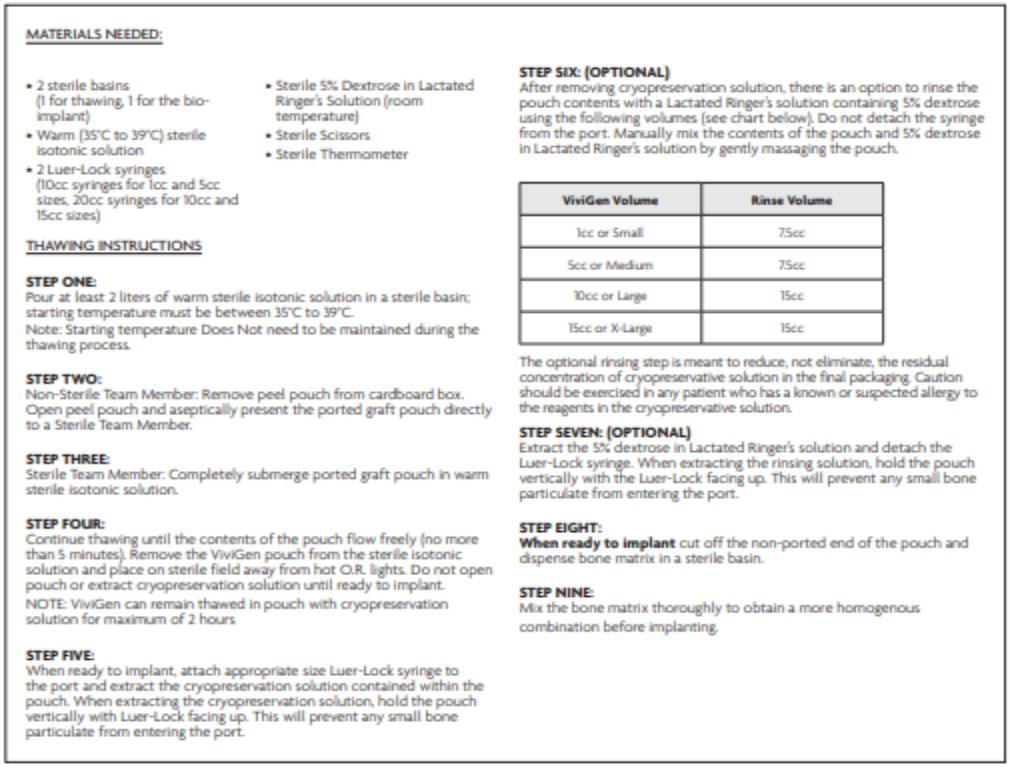
Firstly, the warning, general instructions, and preparation for use (as seen in figure 8) could be positioned on a separate page in a single, centered column and placed prior to the opening and thawing instructions. The importance of those instructions could warrant a separate page, bringing the overall page count of the document to three. Once the warning, general instructions, and preparation for use are no longer there, the opening and thawing instructions can move up the page so that those instructions are all in one column. While these changes would help with document readability while in PDF form, they may impede usability, considering it is made to be printed. A third page could be costly to the company.

A second suggestion is to create obvious boundaries around each tissue instruction. LifeNet Health has used boundaries in design before, like placing a box around the instructions for the use of Vivigen Cellular Bone Matrix (see figure 9). Creating these boundaries draws attention to the instructions and allows users to see which information should be grouped together. It would be easy to create boundaries for each graft instruction, and it would take up minimal space. Examples of boundaries for the cardiovascular grafts.

FOR CARDIAC IMPLANTS:
(Cont. from Opening and Thawing Instructions)
8. **Non-Sterile Team Member:** Pour 1000 ml of room temperature D5LR into second sterile major basin.

9. **Sterile Team Member:** Gently remove the bio-implant from the pouch with smooth forceps and carefully place into the basin containing the D5LR. All the bio-implant to passively rinse in this solution for a minimum of 5 min.

FOR AORTOILIAC ARTERTY, DISTAL AORTOILIAC, ABDOMINAL AORTA BIO-IMPLANTS:
(Cont. from Opening and Thawing Instructions)
8. **Non-Sterile Team Member:** Pour 1000 ml of room temperature D5LR into second sterile major basin.
9. **Sterile Team Member:** Gently remove the bio-implant from the pouch with smooth forceps, allow cryosolution to drain completely into the first major basin and carefully place into the second major basin containing the D5LR
10. **Sterile Team Member:** Fully submerge the bio-implant to remove all air bubbles and allow the bio-implant to passively rinse fully submerged in the solution for a minimum of 5 min.



MATERIALS NEEDED:

- 2 sterile basins (1 for thawing, 1 for the bio-implant)
- Warm (35°C to 39°C) sterile isotonic solution
- 2 Luer-Lock syringes (10cc syringes for 1cc and 5cc sizes, 20cc syringes for 10cc and 15cc sizes)
- Sterile 5% Dextrose in Lactated Ringer's Solution (room temperature)
- Sterile Scissors
- Sterile Thermometer

THAWING INSTRUCTIONS

STEP ONE:
Pour at least 2 liters of warm sterile isotonic solution in a sterile basin; starting temperature must be between 35°C to 39°C.
Note: Starting temperature Does Not need to be maintained during the thawing process.

STEP TWO:
Non-Sterile Team Member: Remove peel pouch from cardboard box. Open peel pouch and aseptically present the ported graft pouch directly to a Sterile Team Member.

STEP THREE:
Sterile Team Member: Completely submerge ported graft pouch in warm sterile isotonic solution.

STEP FOUR:
Continue thawing until the contents of the pouch flow freely (no more than 5 minutes). Remove the ViviGen pouch from the sterile isotonic solution and place on sterile field away from hot O.R. lights. Do not open pouch or extract cryopreservation solution until ready to implant.
NOTE: ViviGen can remain thawed in pouch with cryopreservation solution for maximum of 2 hours

STEP FIVE:
When ready to implant, attach appropriate size Luer-Lock syringe to the port and extract the cryopreservation solution contained within the pouch. When extracting the cryopreservation solution, hold the pouch vertically with Luer-Lock facing up. This will prevent any small bone particulate from entering the port.

STEP SIX: (OPTIONAL)
After removing cryopreservation solution, there is an option to rinse the pouch contents with a Lactated Ringer's solution containing 5% dextrose using the following volumes (see chart below). Do not detach the syringe from the port. Manually mix the contents of the pouch and 5% dextrose in Lactated Ringer's solution by gently massaging the pouch.

ViviGen Volume	Rinse Volume
1cc or Small	7.5cc
5cc or Medium	7.5cc
10cc or Large	15cc
15cc or X-Large	15cc

The optional rinsing step is meant to reduce, not eliminate, the residual concentration of cryopreservative solution in the final packaging. Caution should be exercised in any patient who has a known or suspected allergy to the reagents in the cryopreservative solution.

STEP SEVEN: (OPTIONAL)
Extract the 5% dextrose in Lactated Ringer's solution and detach the Luer-Lock syringe. When extracting the rinsing solution, hold the pouch vertically with the Luer-Lock facing up. This will prevent any small bone particulate from entering the port.

STEP EIGHT:
When ready to implant cut off the non-ported end of the pouch and dispense bone matrix in a sterile basin.

STEP NINE:
Mix the bone matrix thoroughly to obtain a more homogenous combination before implanting.

Figure 9 LifeNet Health's Vivigen Cellular Bone Matrix Instructions

CONCLUSION

In conclusion, while LifeNet Health provides clear and concise instructions that utilize precise language to help users maintain graft integrity and recipient safety, there are at least six potential document design issues. However, these issues are effectively resolved by the previous suggestions to improve readability, usability, and legibility allowing LifeNet Health to continue to be a caring and global leader in tissue banking.

REFERENCES

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