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LIFENET MEETS THE DEMAND FOR SAFER TISSUE

Tissue Safety—A Major Concern in Transplantation

Allograft usage has risen dramatically over the past two decades. This dramatic rise in usage has been associated with a small number of incidents of disease transmissions, most from graft associated with a single tissue processor, and **LifeNet** (Virginia Beach, VA), felt it was important to clarify issues surrounding tissue safety.

Recently, an urgent concern about allograft safety was raised when an implant contaminated with *Clostridium sordellii* caused the death of a 21-year old man. The Food and Drug Administration (FDA) responded by proposing requirements for Good Tissue Practices (GTPs) covering procedures, facilities, personnel, equipment, supplies, reagents, process and labeling controls, process changes and validation, storage, receipt and distribution, records, tracking, and handling of complaints (1). Some of these issues are discussed in more detail here in.

Current Tissue Bank Methods—Major Safety Limitations

The goal of allograft tissue processing is to provide the safest possible material to the surgeon while preserving the inherent tissue characteristics of the graft. Even with adequate donor screening, however, there remains a risk of allograft contamination. Oversight of tissue-banking practices has become more stringent to include monitoring by the FDA, the American Association of Tissue Banks (AATB), and individual state agencies.

As a general rule, implanted tissues are not processed with sporicidal methods.

Moreover, current regulations do not require tissue banks to eliminate bacteria present on tissues at time of recovery or to use processing methods that guarantee tissue sterility (1). Most tissue banks process musculoskeletal allografts aseptically by treating the tissue using various chemical, mechanical, and detergent steps.

Two sterilization methods that can be used to eliminate spores are gamma irradiation and treatment with ethylene oxide. However, both methods have the potential to create technical problems with allografts, limiting their usefulness in tissue processing (2). Further, high doses of gamma irradiation may adversely affect the biomechanical properties of allografts (3,4,5,6). Ethylene oxide has a limited ability to penetrate tissue and has been associated with adverse outcomes such as synovitis or damage to musculoskeletal tissue, resulting in an unacceptable high rate of mechanical failure (7).

To investigate true reduction of risk, several banks have developed low-temperature sterilization approaches to kill spores, while preserving allograft biomechanical integrity and function. Any such sterilization technique must be validated before put into practice.

Genuine Sterility—Confidence Using Allowash XG[™]

In 1995, LifeNet introduced **Allowash[®]**, a revolutionary process in cleaning and disinfection. Allowash Solution is a combination of three detergents which have demonstrated superiority in the solubilization of bone marrow. In addition, hydrogen peroxide in a

3% solution is used as a “scrubber” and disinfectant, and a 70% isopropyl alcohol solution is used as a disinfectant and drying agent. During the Allowash process, detergents in the “cleaning” steps remove bone marrow and other cellular elements associated with bone. The hydrogen peroxide and alcohol processing steps further reduce potential bioburden by acting as disinfectants.

Allowash XG is LifeNet’s proprietary comprehensive and validated process, which begins by controlling incoming bioburden, reduces bioburden through a controlled (patent protected) cleaning and disinfecting process, and ends with terminally sterilized allograft tissue. Allowash XG-associated terminal sterilization ensures that all allograft tissue is free of bacteria.

Steps to Sterilization	Description Summary
1. Bioburden Control	Meticulous and rigorous screening routine; based on FDA and AATB guidelines; strict donor exclusions.
2. Bioburden Assessment	Extensive serologic testing for microbiological contamination, including bacteria, fungi and infectious diseases.
3. Minimizing Contamination	State-of-the-art processing to maintain or further reduce an already low bioburden.
4. Rigorous Cleaning, Blood and Marrow Removal	Flushing, centrifugation, hypotonic processes and ultrasonication to solubilize and remove blood elements, (i.e., marrow and lipids).
5. Disinfection and Rinsing Regimen	Intensive decontamination, disinfection and scrubbing regimen designed to remove and eliminate viruses and bacteria, and centrifugation or microabsorption to remove residual water.
6. Terminal Sterilization	Low-level dose of gamma irradiation at low temperatures.

It is important to note that Allowash XG offers sterility without compromising the biomechanical or biochemical properties of allografts needed for surgical applications. See table for summary of Allowash XG steps.

Conclusion

By using a validated ISO standard methodology and a tissue cleaning process like Allowash XG, bioburden on allografts can be reduced to extremely low levels. The Allowash process accomplishes significant bioburden reduction through simple cleaning of tissues and thus anticipates the need for reducing problems associated with emerging infectious diseases.

The literature, animal testing, and clinical data all indicate that allografts processed by Allowash XG exhibit no measurable detrimental effects to the properties of the tissues. While other tissue banks may claim sterility with a sterility assurance level (SAL) at 10^{-3} , LifeNet and its Allowash XG deliver sterile tissue to the 10^{-6} SAL.

Allograft users now have more options than ever in the choice of their tissue supplier. It is more than critical today that clinicians and hospital administrators rely on sterile tissue provided by well-known, accredited tissue banks such as LifeNet. To date, more than 500,000 Allowash-processed grafts have been safely distributed

and used without report of bacterial or viral allograft-associated infection directly linked to a graft screened and processed by LifeNet. With the introduction of Allowash XG, LifeNet takes tissue safety to the next level.



Note: All information taken from “Sterilization of Allografts”, © 2004 LifeNet. For a copy of the complete white paper, please contact LifeNet at 1-888-847-7831.

For more information concerning LifeNet call 1-888-847-7831, or visit the company’s Web site at www.accesslifenet.org.

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