

## **INTRODUCTION**

Surgical procedures using biologic tissues can often improve or enhance a recipient's quality of life. As surgical techniques continue to advance, so does the development of biological tissue forms to support these new treatment options. With an increase in options, comes an increased need to provide safe, high quality tissue forms that offer the best clinical outcomes for patients. Additionally, increased scrutiny by various regulatory, accrediting, and professional associations has led to new regulations and standards addressing the issue of tissue management. PalinGen products are processed with the highest level of scrutiny possible, overseen using ISO 13485 designed SOP's, and guidelines promulgated by the American Association of Tissue Banks.

## **BIOLOGIC TISSUE TRANSPLANTS'**

The simplest definition of a biologic is: products that are made from living organisms, that is, products that are derived from living material - human, plant, animal, or microorganism - and are used for the prevention, or cure of disease in humans. Certain tissues can be transplanted and grafted to restore bodily function. The type of transplant selected depends on the purpose of the graft, the anatomic function, and the availability of the tissue.

PalinGen products are Allografts – (tissue grafted between different or genetically dissimilar individuals of the same species.) our donated tissue comes from women who give birth via Caesarian section type delivery. These generous women are tested prior to delivery and the donated tissue is tested extensively throughout the process.

It is important to note that biologics are regulated in different ways. The United States Food and Drug Administration (FDA) categorizes human tissue (allograft). PalinGen products are registered with the FDA.

## **REGULATIONS, STANDARDS, AND RECOMMENDED PRACTICES RELATED TO TISSUE MANAGEMENT**

### **United States Food and Drug Administration (US FDA)<sup>234</sup>**

The US FDA is the regulatory body in the tissue banking industry; its primary focus is on preventing the transmission of communicable disease associated with the use of donated tissues. Human cells and/or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient are regulated as human cells, tissues, and cellular and tissue-based products (HCT/Ps) by the Center for Biologics Evaluation and Research (CBER). Examples of such tissues are bone, skin, corneas, ligaments, tendons, durra mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, acolytes and semen.

### **American Association of Tissue Banks (AATB)<sup>5A1</sup>**

The AATB is an association of organizations dedicated to ensuring that human tissues intended for transplantation are safe and free of infectious disease, of uniform high quality, and available in quantities sufficient to meet national needs. To fulfill this mission, the AATB published authoritative industry standards for tissue banks, the "AATB Standards for Tissue Banking" (which are one step above the standards published by the FDA). The AATB conducts a voluntary accreditation program. Not only do they require donor screening and testing similar to the FDA, but they also focus on the operational and organizational aspects of an organization. The AATB reviews qualifications of tissue bank personnel and the tissue banks safety practices, equipment testing, facilities, labeling and quality assurance programs. AATB accreditation is similar to The Joint Commission accreditation; it is not required but is a voluntary. The accreditation program ensures that all members are performing tissue banking activities in a professional manner consistent with the AATB Standards. It is recommended



that only allograft tissues supplied by AATB-accredited tissue banks should be used. In developing its new federal regulations for tissue banking, the FDA relied heavily on the expertise of the AATB.

- **Obtaining complete donor medical and behavioral history data from all pertinent sources, including the most recent medical records;**
- **Obtaining valid informed consent for donation from the donor's next-of-kin; Performing tissue recovery using advanced zone and sequencing protocols to decrease the risk of graft contamination;**
- **Using the most reliable blood testing methods currently available to ensure the minimum risk of transmission of infectious disease;**
- **Using other information, e.g., autopsy reports, to further ensure allograft safety;**
- **Using extensive culture analysis of donor tissue before suspending it in antimicrobial solutions;**
- **Using additional culture analysis as a final step in processing;**
- **Validating that residual antimicrobials in the treatment solutions do not result in false negative culture results;**
- **Applying tissue-cleaning processes that further decrease the possibility of disease transmission without causing biological or mechanical harm to the allografts;**
- **Employing tissue preservation processes that ensure the optimal performance of the allografts after implantation;**
- **Storing and transporting the released allografts within temperature and packaging conditions that ensure continuing safety and integrity of the package in which they are sealed; and providing documented, routine, in-depth training to technical staff members to ensure knowledge in all of their job responsibilities.**

#### **SUMMARY**

The use of biologic tissue transplants offers an improved quality of life for many surgical patients. As advances in the procurement and processing of biologics continue to evolve, and the numbers and types of biologic tissue forms continue to expand, so do the challenges related to tissue management and compliance with all applicable regulations and guidelines.

PalinGen products follow all appropriate guidelines, in testing, as well as processing and ultimately delivery of a healthy viable allograft to the patient to amplify tissue regeneration.

The risks of using PalinGen products is exceptionally small, but a very small risk of disease transmission cannot not be 100% ruled out, none has ever been reported, no adverse side effects has ever been reported. But with every product, there is some risk, and you are being informed today of all of the precautions we take in bringing the product to you, and that a potential risk does exist no matter how small, when this product is used on you or in you.

Please acknowledge that you understand this risk by signing and dating this form.

Your signature \_\_\_\_\_

Print Name \_\_\_\_\_

Date \_\_\_\_\_