Overview of the GraftShield™ Process

While the options for surgical musculoskeletal repair continue to expand, a growing number of surgeons worldwide choose bone and soft tissue allografts as a safe, effective and convenient surgical option. Allografts bearing the SteriGraft™ label fulfill the discriminating surgeon’s desire to extend extraordinary patient care. Our superior level of allograft processing begins with rigorous Donor Screening and meticulous Donor Recovery Procedures, Certified Laboratory Testing, validated Tissue Cleansing, Sterile Packaging, and a meticulous Quality Assurance & Documentation system that ranks second to none.

The GraftShield™ allograft processing system is designed to set an entirely new standard in allograft sterilization. This system offers scientifically validated tissue sterilization (validated to SAL $10^{-6}$ in accordance with ISO 11137-2 Method 1) which virtually eliminates the risk of bacterial disease transmission.

Donor Screening & Reviews

Our donor screening and recovery partners meet or exceed all industry standards set forth by the American Association of Tissue Banks. Following donation consent, our extensive evaluation process includes:

- A detailed potential donor screening and evaluation process to review medical history as well as any lifestyle or behavioral issues which may disqualify donation. Individuals identified with risk factors for or clinical evidence of relevant communicable diseases and disease agents (RCDADS) such as AIDS, viral Hepatitis, Sepsis, etc., are ruled out as potential donors or are later disqualified if subsequent investigation reveals high risk markers.
- An on-site review of the potential donor’s relevant medical records to evaluate other rule out conditions.
- A physical assessment of each donor candidate just prior to tissue recovery to confirm donor identity, evaluate the accuracy of medical and social history collected, and to look for signs/symptoms of other disqualifying conditions or risk factors.

Donor Recovery & Processing

Extreme care is taken to ensure donor tissues are recovered, processed and packaged appropriately so that the donor gift materializes in the most beneficial way for transplant recipients. We believe the best way to honor donors is to maximize the number of individuals helped through their generous donation. Maximizing the gift while safeguarding the public trust by providing safe, sterile human allograft tissue is the primary goal of our processing efforts.

Stringent tissue donor screening, recovery, storage and shipping guidelines are followed to best preserve the allografts for their intended function.
Certified Laboratory Testing

In accordance with FDA and AATB Standards, donor specimens are collected and sent to an independent laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to test for the following infectious diseases and antibody or antigen markers listed below:

- Human Immunodeficiency Virus Type I Ab
- HIV I Antibody
- HIV I Nucleic Acid Test
- Human Immunodeficiency Virus Type II Ab
- HIV II Antibody
- Human T-Lymphotrophic Virus Type I
- HTLV I Antibody
- Human T-Lymphotrophic Virus Type II
- HTLV II Antibody
- Hepatitis B Virus
- HBe Antibody (total)
- HBs Antigen
- Hepatitis C Virus
- HCV Antibody
- HCV Nucleic Acid Test
- Syphilis
- Rapid Plasma Reagin Test
- FTA Confirmation

All donors are evaluated for hemodilution which could potentially affect test results. Only a licensed physician determines final donor suitability.

GraftCleanse™ Tissue Cleansing

The GraftShield™ process requires aseptic handling of all tissue throughout processing and is based on a scientifically validated sterilization method which results in a Sterility Assurance Level (SAL) of $10^{-6}$ in accordance with ISO 11137-2 Method 1. This validated process is designed to protect the biomechanical properties of each allograft while virtually eliminating patient risk.

During processing, tissues are treated with the GraftCleanse™ process which includes chemical and physical cleaning procedures that reduce the bone marrow and lipid elements associated with normal human tissue.
**Tissue Processing**

Our proprietary GraftShield™ processing system was developed to offer the following advantages:

- Validated GraftCleanse™ tissue cleansing method
- Custom machinery designed exclusively by THB for tissue manufacturing and sterilization between each donor case
- Load strength testing
- Controlled exposure to freeze/thaw cycles

**Sterile Packaging**

SteriGraft™ bone and soft tissue allografts are packaged with extreme care to preserve the validated sterile nature of the tissue. Packaging steps are cautiously taken to ensure that our allografts arrive to the end user in a manner that promises the highest patient safety and allograft quality.

The following details outline our packaging advantages:

- Double Tyvek pouches and easy to read labeling
- Outer package which provides a durable moisture barrier designed to accommodate both ultra-low and ambient temperature storage
- Sterile inner pouch designed for easy delivery to the sterile field
- Terminal sterilization of product in its final packaging
- Validated three year expiration dating
- Included product insert which provides details regarding donor screening, testing and tissue processing
- Transplant record and multiple tissue ID barcode labels for operating room staff
- SteriGraft™ box allows for convenient stacking and storage

**Quality Assurance**

Our donor tracking, documentation, tissue processing, allograft packaging, storage and shipping processes ensure the availability of safe, high quality allografts. A three-level pre-processing review is performed by our highly trained Quality Assurance staff and Medical Director. The following items are carefully reviewed and documented:

- Donor qualification
- Medical/behavioral risk profile
- Review of consent/authorization to recover tissues for transplantation
- Review of recovery process/time frames/reconciliation of refrigeration times/recovery site assessment/recovery sequence

The GraftShield™ Advantage

- Sterile human allograft tissues
- Final package sterilization
- Proprietary cleansing processes
- Bone Bank Allografts meets the exacting FDA regulations and AATB standards
Our Processing Partner Facility

Located in the Texas Research Park in San Antonio, Texas Human Biologics (THB) has recently opened its new state-of-the-art human tissue processing center. The facility was designed and built to be in full compliance with environmental condition requirements for handling human tissue. All human tissues are handled in an ultra clean environment.

Specialty features include:
- Continuous sheet, seam welded cove base flooring
- Gasketed, sealed, and washable ceilings
- Full sheet glued Fiberglass Reinforced Polyester (FRP), seam sealed walls
- Point of passage, magnehelic gauges for continuous monitoring of clean room zone pressures
- Fully adjustable High Efficiency Particulate Air (HEPA) filter air handling system
- Magnetic door interlocks for facility security and air pressure maintenance
- Validated ethylene oxide sterilization of supplies and equipment
- Validated steam sterilization of supplies and equipment