

Concerned About

the
safety?
of your Allograft



 **OSTEOTECH**^{INC}[®]

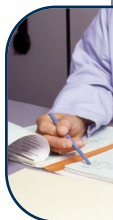
What is Allograft Bone?

Allograft bone is human bone that has been generously donated by the family of a deceased loved one to enhance the life of another individual. Allograft bone helps to provide your body with the ability to regenerate its own bone over time.



Allograft Bone From Osteotech

Your Doctor uses bone processed by Osteotech, Inc., the leading supplier of allograft bone to the orthopedic and dental industry. Your doctor may use these products alone or in combination with another graft material.



safety



Where Does Osteotech Get Donors From?

Osteotech works in conjunction with several reputable not-for-profit tissue banks. These tissue banks partner with local hospitals to procure tissue utilizing sterile techniques to ensure the tissue is not contaminated.

Donor Screening:

The medical and social screening process for donors whose tissue is recovered for processing by Osteotech is conducted in accordance with AATB (American Association of Tissue Banks) standards, FDA regulations and applicable Public Health Service Guidelines for donor screening. Key elements of that process are as follows:

Step 1:

A physical examination of the donor is performed to assess for evidence of high risk behavior.

Step 2:

A comprehensive medical and social history is taken with the next of kin in

accordance with the US Public Health Service Guidelines.

Step 3:

Consent for recovery of tissue is obtained and proper paperwork completed.

Step 4:

A thorough evaluation of the donor's medical records is conducted by a qualified physician to determine if donor suitability criteria have been met. These criteria include but are not limited to: previous medical history, laboratory test results, and autopsy and/or coroner reports.



How Safe is Allograft Bone?

Osteotech has produced over 4.0 million grafts, from over 66,000 donors, since 1986 with no confirmed report of disease transmission. All procedures are performed in accordance with rules established by the FDA and standards set by the AATB.



rely on

The FDA and AATB have oversight inspection of our establishment and practices. Aseptic surgical techniques are utilized when recovering and processing donor tissue.



Osteotech works in conjunction with several reputable not-for-profit tissue banks. These banks partner with local hospitals to recover tissue and are audited by Osteotech to ensure they comply with industry rules and standards. They utilize aseptic techniques to ensure the tissue is not contaminated.





When the tissue is recovered, samples are obtained and evaluated to ensure the tissue does not contain certain bacteria and microorganisms.



Testing for infectious diseases IS performed. Some of the key tests screen for HIV-1, HIV-2, Hepatitis B, Hepatitis C, and Syphilis. All testing is done under AATB and FDA guidelines. Any donor that tests positive for any of the above diseases is immediately declined as a potential donor.

safety

Aseptic Recovery

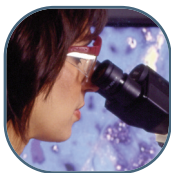
All musculoskeletal tissues are aseptically recovered from the donor in accordance with AATB standards and FDA regulations. Osteotech was the first company to use aseptic processing methods, exclusively, for all musculoskeletal tissue and was instrumental in making this an industry standard.

Processing:

Osteotech's process has been demonstrated to produce consistently safe and effective product. There are a number of in-process checks and balances to assure all tissue is processed within the necessary guidelines.

Osteotech technicians work aseptically in class 100 rooms that are much cleaner than an operating room. Isolators are used to prevent cross-contamination. Prior to distribution, all Osteotech processed tissue is terminally sterilized or tested for sterility.

All allograft processing performed is single-donor processing. Osteotech does not “batch-process” tissue. All tissue can be traced to the donor from whose tissue it was processed.



Osteotech, Inc.

Since 1986, Osteotech, Inc. has processed over 66,000 donors with more than 4.0 million allografts produced. Tissues processed by Osteotech improve the quality of life for more than 500 transplant recipients everyday. Osteotech has been an active member of the American Association of Tissue Banks since 1990. Osteotech’s processing meets or exceeds all AATB and FDA regulations.



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