



Your
medical
professional has
recommended that
you have a surgical
procedure in which a
bone graft material from
IsoTis OrthoBiologics™ will
be used. This brochure
will answer some
questions about your
procedure.



WHAT IS THE DIFFERENCE BETWEEN AUTOGRAFT AND ALLOGRAFT BONE?

Bone transplanted from one part of a person's body to another part is called an autograft. Donated bone or tissue transplanted from the body of one person to another person is called an allograft. Demineralized Bone Matrix (DBM) is considered an allograft.

HOW IS THE BONE RECOVERED FROM THE DONOR?

A tissue bank is an organization that provides donor screening, recovery, processing, storage, and/or distribution of allograft tissue. Specialists trained in transplantation recover and process donated musculoskeletal tissues. These professionals are typically well trained and most have passed a rigorous examination that certifies them on the basis of their knowledge in all areas of tissue banking including decontamination techniques, quality assurance, quality control, product testing, labeling and record keeping.

The American Association of Tissue Banks (AATB) is the national standard-setting organization that provides this certification. Presently, not all tissue banks are AATB accredited, however, all tissue banks associated with IsoTis have undergone this voluntary accreditation.

HOW SAFE IS IT?

There has never been a case of bacterial or viral disease transmission with DBM, the bone component in IsoTis bone graft materials*. Still, safety remains a primary concern among surgeons and patients alike. To uphold the highest commitment to quality and safety, IsoTis only uses bone from tissue banks accredited by the AATB. Each lot of DBM is obtained from a single donor and is rigorously screened. The rigorous donor screening, serological testing, formal processing and tissue-testing standards significantly lower the risk of disease transmission. Furthermore, there is evidence that the demineralization process reduces the risk of infectious disease transmission to an incidence of 1 in 2.8 billion.** The final step is electron beam sterilization.

WHY IS ALLOGRAFT BONE USED?

Because of the inadequate amounts of available autograft (a person's own bone), and the limited size and shape of a person's

own bone, allograft bone is commonly used for many indications. Using allograft bone from another person will reduce or eliminate the need for a second operative site to remove autograft bone, will reduce the risk of infection, and safeguard against temporary pain and loss of function at or near the secondary site. The DBM used in Isotis bone graft materials contain a variety of biologically active proteins that promote new bone growth. Each lot of DBM used by Isotis has passed an assay to ensure a minimum level of bone-forming potential.

WHAT HAPPENS TO THE BONE TISSUE GRAFT AFTER TRANSPLANTATION?

Once the transplanted bone tissue graft is accepted by the body, it is slowly converted into new living bone and incorporated into the body as a functional unit.

SUMMARY:

- Allograft bone is bone recovered from a tissue donor, processed and used to help form new bone.
- Isotis bone graft materials contain biologically active proteins that promote new bone formation activity.
- IsoTis is AATB accredited and only uses bone from AATB accredited tissue banks.
- The use of Isotis bone graft materials can eliminate the need for a second operative site to remove autograft bone.
- Elimination of the secondary surgery will reduce the risk of infection and safeguard against temporary pain and loss of function at or near the donor site.

* Joyce MJ, Greenwald AS, Boden S et al. Musculoskeletal allograft tissue safety. Amer Acad Orthop Surg, 73rd Annual Meeting. Mar 22-26, 2006.

** Scarborough NL, White EM, Hughes JV, et al. Allograft safety: viral inactivation with bone demineralization. Contemp Orthop 1995;31 (4):257-61.

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dynaGRAFT® **II**



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The IsoTis OrthoBiologics North American production facility is located in Irvine, California. It is comprised of approximately 26,000 square feet for the production and distribution of IsoTis OrthoBiologics' bioimplant products. IsoTis OrthoBiologics' facility is registered with the FDA and the Quality Management System is ISO certified, accredited by the AATB, and licensed by the FDA as an approved device manufacturer. In addition, IsoTis has a cleanroom manufacturing facility (class 10,000) for the production of its products.