



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

WHAT IS DYNAGRAFT II?

DynaGraft II is a unique bone graft substitute composed of demineralized bone matrix (DBM) in a reverse phase medium manufactured by IsoTis OrthoBiologics in Irvine, California. Containing a high content of DBM, DynaGraft II is designed to stimulate the natural bone formation process.

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. 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 DynaGraft II[±]. Still, safety remains a primary concern among surgeons and patients alike. To uphold the highest commitment to quality and safety, IsoTis, the maker of DynaGraft II, 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 in the production of DynaGraft II is electron beam sterilization.

WHY IS DYNAGRAFT II OR ANY 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 DynaGraft II contains 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.

DYNAGRAFT II SUMMARY:

- Allograft bone is bone recovered from a tissue donor, processed and used to help form new bone.
- DynaGraft II contains 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 DynaGraft II 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, Greenwals AS, Mowe J et al. Musculoskeletal allograft tissue safety. Amer Acad Orthop Surg, 70th Annual Meeting, Feb 5-9, 2003.

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



dynaGRAFT[®]
PUTTY & GEL

IsoTis OrthoBiologics, Inc.
2 Goodyear
Irvine, California 92618
1.800.550.7155

www.isotis.com

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.