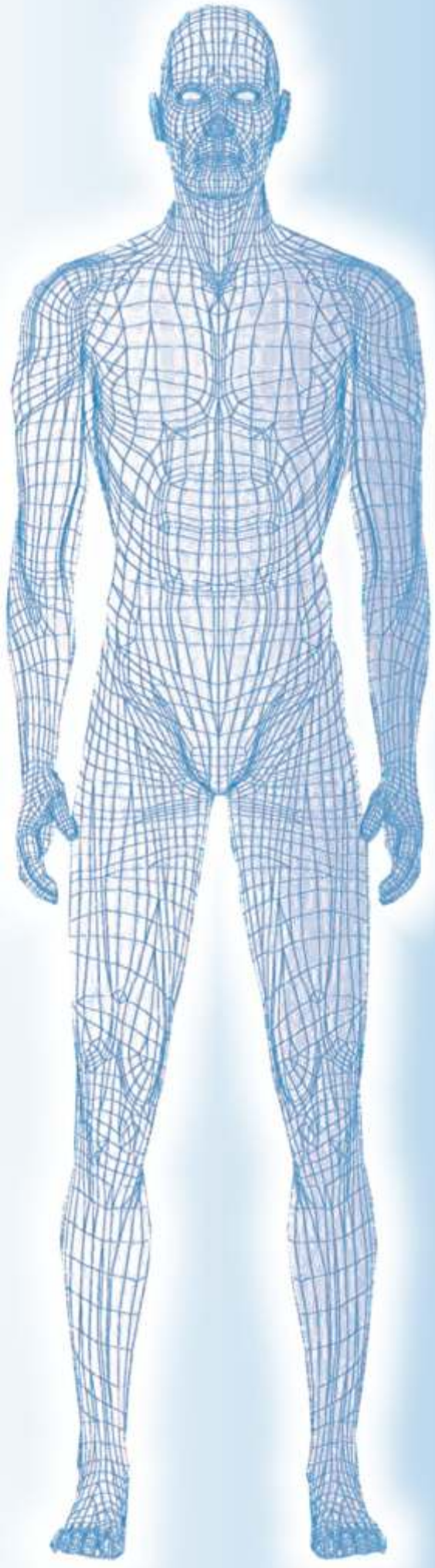

TISSUENET
ALLOGRAFT TISSUE SPECIALISTS

Spinal Implants

Sports Medicine

General Orthopedics

Trauma

TÜRKİYE DİSTRİBÜTÖRÜ

LGN MEDİKAL

Mustafa YILMAZ

Bülent Angın Blv. Yeni Baraj Mh. 48. Sk. Uyanık Apt.
B Blok Kat: 2 Daire: 4 Seyhan ADANA

Tel.: 0.322 225 48 28 - Fax: 0.322 225 48 38

Code	Description	Size
	Freeze Dried Allografts	
FD54315	Cancellous Cubes	15cc
FD54330	Cancellous Cubes	30cc
FD55315	Cancellous Crushed	15cc
FD55330	Cancellous Crushed	30cc
FD55360	Cancellous Crushed	60cc
FD52475	Cortical Cancellous Crushed	13.35mm(7.5cc)
FD52415	Cortical Cancellous Crushed	13.35mm(15cc)
FD52430	Cortical Cancellous Crushed	13.35mm(30cc)
FD52460	Cortical Cancellous Crushed	13.35mm(60cc)
FD52467	DBM Cortical-Cancellous Crunch	1cc
FD52461	DBM Cortical-Cancellous Crunch	10cc
FD52462	DBM Cortical-Cancellous Crunch	10cc
FD52463	DBM Cortical-Cancellous Crunch	10cc
FD52464	DBM Cortical-Cancellous Crunch	15cc
FD52465	DBM Cortical-Cancellous Crunch	15cc
FD52466	DBM Cortical-Cancellous Crunch	15cc
RT53005	UltraFill DBM Putty	5 cc
RT53010	UltraFill DBM Putty	10 cc
RT53105	UltraForm DBM Crunch	5 cc
RT53110	UltraForm DBM Crunch	10 cc
RT53115	UltraForm DBM Crunch	15 cc
FD57505	UltraC1™ ,Cervical Implant	5 mm
FD57506	UltraC1™ ,Cervical Implant	6 mm
FD57507	UltraC1™ ,Cervical Implant	7 mm
FD57508	UltraC1™ ,Cervical Implant	8 mm
FD57509	UltraC1™ ,Cervical Implant	9 mm
FD57510	UltraC1™ ,Cervical Implant	10 mm

Irradiation	Sterility
No	SAL10^{-6}

UltraFill™ DBM Putty

UltraForm™ DBM Crunch

Featuring:

- Ready to Use.
- Room Temperature Storage.
- Resists migration from graft site.
- Osteoinductive.
- Terminal Sterilized.
- Hydrophilic carrier with potential to absorb and retain autogenous growth factors.

TISSUENET

UltraGraft™?

UltraGraft™ products are allograft tissue products put through a novel & validated sterilization system called: **T10⁶™ Terminal Sterilization System***
All tissues are terminally sterilized to {SAL 10^{-6}} through a proprietary sterilization system free of irradiation.

Introduction

Sterilization has been defined as the process or act of inactivating or killing all forms of life, especially microorganisms. [I] According to the Association for the Advancement of Medical Instrumentation (AAMI), a standards - setting organization for the medical industry, sterility assurance level (SAL) is defined as the probability of an item being non - sterile after it has been exposed to a validated sterilization process. [II] To achieve a {SAL of 10^{-6}}proves that there is less than a 1 in 1,000,000 possibility of a contaminating organism surviving the treatment. Sterilization of musculoskeletal tissues has several inherent problems that were not overcome until recently. First, the biomechanical integrity of tissue can be significantly altered by heat and irradiation. [III,IV,V,VI] Second, not all sterilants have adequate tissue penetration, especially gases and liquids. Without complete penetration, sterility cannot be assured. Third, musculoskeletal tissues are often contaminated with a large number of organisms (i.e., bioburden). For human allograft tissue to be considered sterile, it must achieve a SAL=10^{-6} as expressed in logarithms, i.e. exponents of 10. For example, 1 log reduction means 90% inactivation and 6 logs means 99.999% inactivation, with survival of less than one in 1,000,000 pathogens. Very few processes being used today can achieve this type of reduction; however, no known process reaches "terminal" sterility without the use of low dose irradiation.

Terminal Sterilization

Terminal sterilization of human allograft tissue is only achieved after final packaging. This process assures that no contaminants remain on the graft after final handling and packaging procedures are performed.

Irradiation of Human Allografts

It is widely known that the use of irradiation on allograft tissue, in particular soft tissue, will weaken or decrease the performance and the graft. Therefore, the medical community has been forced to utilize tissue processed aseptically, cleansed with low dose terminal irradiation or irradiated.

Cleansing of Allograft Tissue

Processes claiming "cleansing" of bone will, in most cases, sterilize bone but the product must be *handled* and *packaged* post cleansing. Bone is then terminally sterilized by low dose irradiation.

Aseptic Techniques

Processes utilizing aseptic processing techniques rely on human processing techniques and serology testing of allograft tissue with no terminal sterilization. These grafts are not irradiated and are not sterile (SAL=10^{-6}).

TISSUENET

Supercritical CO2

Supercritical CO2 technology uses the powerful solvent properties of carbon dioxide gas compressed to its critical point. Carbon dioxide has a unique critical point, defined by the pressure (Pc= 1,099 psi) and temperature (Tc=31.1°C) at which the liquid and vapor phases become indistinguishable. Supercritical carbon dioxide has a useful combination of liquid properties such as density and solvency, and gas like viscosity, diffusivity, compressibility and very low surface tension. These inherent properties predict that supercritical Co2 will readily gain access to the interior of bone tissue thereby allowing inactivation of many embedded pathogens. [VII] The critical region is characterized by an ability to control solvent power with only minor changes in pressure and temperature. Processes utilizing only CO2 did have a broad viral inactivation rate including HIV-1_2, Sindbis$_2$, Polio Sabin type I_2, PRV$_2$, T4 Bacteriophage & Parvo, however, it does not seem to have the same broad spectrum kill on all pertinent Bacteria, Fungi. [VIII]

UltraGraft™ implants are terminally Sterile {SAL 10^{-6}} Non-Irradiated

Discussion

Increasing the safety of human allograft tissue is of significant importance and of great benefit to patients. Often, the decision to use an autograft rather than an allograft tissue is based on the perceived risk of viral or bacterial transmission. Until now, no technology has been capable of substantially reducing all types of pathogens in biological products without the use of low - dose irradiation, while maintaining the integrity of the underlying protein in the product. Various current sterilization and cleansing methods exist but can only destroy limited or specific types of pathogens (such as bacteria or lipid enveloped viruses). Validated testing proved T10$^{6™}$ Terminal Sterilization System substantially inactivates these types of known pathogens, including Clostridium sporogenes a more common and resistant pathogen than C. sordellii, in allograft tissue products.

Conclusion

The T10$^{6™}$ Terminal Sterilization System process reduced the titer of all viruses, bacteria and fungi tested by at least 1,000,000, producing a SAL=10^{-6} terminally sterile allograft tissue graft, greatly increasing the safety of allograft tissue while simultaneously passing biocompatibility and biomechanical testing. While T10^{6}™ Terminal Sterilization System not only preserves graft integrity, the elimination of viral, bacterial and fungal organisms, it has been proven a safe and effective non - irradiated "sterile" graft for clinical use.

I) Block SS: Disinfection, Sterilization, and Preservation. Fifth edition. Philadelphia, Lippincott, Williams and Wilkins, 2001, pp. xvi, 1162.

II) Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices. Standard 14937. Arlington, VA, Association for the Advancement of Medical Instrumentation, 2000.

III) Bianchi JR, Ross K, James E, et al: The effect of preservation/sterilization processes on the shear strength of cortical bone, in Goel VR, Spilker RL, Ateshian GA, et al. (eds.): Proceedings of the Bioengineering conference. BED Volume 42. New York, The American Society of Mechanical Engineering, pp 407 - 408, 1999

IV) Loty B, Courpied JP, Tomeno B, et al: Bone allografts sterilized by irradiation. Biological properties, procurement and results of 150 massive allografts. Int Orthop 14: 237 - 242, 1990.

V) Rasmussen TJ, Feder SM, Butler DL, et al: The effects of 4 Mrad of gamma irradiation on the initial mechanical properties of bone - patellar tendon - bone allografts. Two year results in thirty - six patients. Am J Sports Med 10: 188 - 197, 1994

VI) Simonian PT, Conrad EU, Chapman JR, et al: Effect of sterilization and storage treatments on screw pullout strength in human allograft bone. Clin Orthop 302: 290 - 296, 1994

VII) NOVASTERILIS Website August 2007

VIII) Dillow, A.K. et al, PNAS, 1999. 96(18): p. 10344 - 8

TISSUENET