Barcelona Tissue Bank
Banc de Sang i Teixits

CORTICAL BONE PASTE 56
FREEZE-DRIED DEMINERALISED

BT1012 BT1013 BT1014 BT1015



Specifications

Ground cortical bone paste obtained from the diaphysis of large bones (femur, tibia and humerus), mixed with glycerol.
Available in 1, 2.5, 5 and 10 cc.

Characteristics:
- Bone fragments free of soft tissues
- No spongy bone
- Bone particle size ranges from 250-850 micras
- Osteoinductive Potential

Clinical applications

- Sinus lift surgery
- Alveolar tissue preservation
- Filling after tooth extraction
- Bone defect filling
- Maxillofacial reconstruction

Code	Description	Presentation (cc)
BT1012	DBM Putty 1 cc Demineralised bone matrix in paste	1
BT1013	DBM Putty 2.5 cc Demineralised bone matrix in paste	2.5
BT1014	DBM Putty 5 cc Demineralised bone matrix in paste	5
BT1015	DBM Putty 10 cc Demineralised bone matrix in paste	10

For more information:
bt@bst.cat
93 557 36 20
bancsang.net/tissue

Banc de Sang i Teixits

Generalitat de Catalunya

Tissue acquisition

The tissue is obtained from donors who undergo careful assessment of their medical-social history and a thorough physical examination. The standard serological screening includes: HIV-1/2 antibodies, HIV-antigen, HIV 1 -RNA, HBsAg, HBc antibodies, HBV-DNA, HCV-antibodies, HCV-RNA, syphilis and HTLV I/II antibodies.
Microbiological screening and the supplementary tests considered necessary are also carried out. The tissues are extracted within 24 hours of death in the operating theatre using sterile techniques. Once the tissue is obtained, it is kept at -80 ºC until processing and final preservation.

Processing

All processes carried out at the Barcelona Tissue Bank (BTB) are subject to a quality system designed to meet the requirements established in the Good Tissue Practices (GTPs) principles and guides and the European Union's Good Manufacturing Practices (GMP). They also meet the requirements arising from the authorisations for investigational drugs, the requirements established in Royal Decree-law 9/2014 for the processing, preservation and distribution of tissues and cells for transplantation, the quality management requirements established in Standard ISO 9001 and the technical specifications for the products obtained, ensuring quality, safety and efficacy.

The tissues undergo a decontamination process that includes a series of mechanical and chemical treatments (gentamicin, alcohol, hydrogen peroxide and detergent). For this reason, traces of these agents may be present. The tissue is then decalcified, obtaining residual Ca^{2+} values ≤8%. Next, the tissue is freeze-dried, reducing residual water to less than 5%.
Finally the tissue undergoes microbiological control. It is stored at room temperature (4-30º) until the results are obtained. After the final quality control, the tissue is made available for distribution and prescribed use in patients.

Storage

The tissue must be kept at room temperature (4-30º) until used. The product expiry date is five years from its processing, as long as the integrity of the packaging is maintained. Do not use if any of the packaging is compromised.

Transport

The tissue is packaged in a vial or syringe and Tyvek bag. The vial or syringe and bag inside are sterile.
It is transported by placing the packaged graft in a container, protecting its integrity at all times.

Coding

In compliance with the legal requirements of the Commission Directive (EU) 2015/565, all tissues are identified and labelled with the "Single European Code" (SEC). This code is a unique identifier that facilitates traceability and provides information on the main characteristics and properties of those tissues and cells distributed in the European Union. The SEC consists in 40 alphanumeric characters, representing the donation identification sequence and product identification sequence. The last 8 characters correspond to the expiry date of the product, represented in the format YYYYMMDD.

Traceability

The clinical use of tissues and cells of human origin provides major benefits for recipients. Like any product of human origin, their use is not free of risks, which although infrequent, can be serious.
A robust system is required, capable of placing, locating and identifying the cells and tissues at any point in the process, from donation to recipient, to ensure rapid intervention. This prevents damage or potential risk when the quality and safety of the donated tissues and cells are compromised. Each tissue is identified with a unique code to permit tracking from origin to destination.
Once the tissue is transplanted, the code must be attached to the recipient's clinical history. The tissue bank must be informed when it has been transplanted, providing the recipient's clinical history number or initials. The bank should also be informed if the tissue is not transplanted.

Biovigilance

If there is suspicion or evidence of a severe adverse reaction or effect in the recipient possibly related to the safety and quality of the transplanted tissue or cells, the physician must immediately contact the tissue bank or competent health authority.
A severe adverse reaction or adverse effect notification form is provided for each tissue.

Regulatory legislation on tissues

The Barcelona Tissue Bank has administrative authorisation no. E08796463 issued by the competent authority. The regulated activities include donation, acquisition, assessment, processing, preservation, storage and distribution. Human tissues processed under the control of the bank meet the requirements of Spanish legislation (Royal Decree law 09/2014) and European Directive 2004/23 and directives 2006/17/EC, 2006/86/EC, 2012/39/EU developing it.
BTB follows the standards of the principal scientific associations: *Asociación Española de Bancos de Tejidos* (AEBT), European Association of Tissue Banks (EATB), American Association of Tissue Banks (AATB), European Eye Bank Association (EEBA), and the recommendations of: Good Tissue Practices (Euro-GTP) and the Council of Europe EDQM Guide to the quality and safety of tissues and cells for human application.