Barcelona Tissue Bank
Banc de Sang i Teixits

ACELLULAR DERMAL MATRIX

BT5006 BT5007 BT5016 BT5017 BT5018 BT5020 BT5021 BT5022 BT5023

BT5006

BT5007

BT5018

Specifications

The acellular dermal matrix is decellularized skin tissue.

Characteristics:
- Lack of epidermis
- Basement membrane maintained
- No cells in the dermis

Clinical applications

- Reinforcement of soft tissue
- Filling of soft tissue loss
- Gingival recession
- Treatment of burn wounds in face, neck and hands
- Other wounds closure
- Hernia repair
- Ulcer healing
- Tendon reinforcement: rotator cuff, superior capsular reconstruction

Code	Description	Dimensions (cm)	Thickness (mm)	Storage temperature
BT5006	Acellular dermal matrix	2 x 1	0.5 – 1.5	Room temp.
BT5007	Acellular dermal matrix	3 x 3	0.5 – 1.5	Room temp.
BT5016	Acellular dermal matrix	10 x 5	0.8 – 1.9	Room temp.
BT5017	Acellular dermal matrix	10 x 5	2 – 2.9	Room temp.
BT5018	Acellular dermal matrix	10 x 5	≥ 3	Room temp.
BT5020	Acellular dermal matrix	10 x 15	≥ 2	Room temp.
BT5021	Acellular dermal matrix	20 x 15	≥ 2	Room temp.
BT5022	Acellular dermal matrix	5 x 5	> 3	Room temp.
BT5023	Acellular dermal matrix	5 x 5	2 – 2.9	Room temp.

Ask bank about availability of other sizes

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

Salut/ Banc de Sang i Teixits

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 1/2 -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 tissue is extracted within 24 hours of death in the operating theatre using sterile techniques. Once the tissue is obtained, it is kept at room temperature until processed.

Processing

All processes carried out under the control of the Barcelona Tissue Bank (BTB) are subject to a quality system designed to meet the requirements established in the principles and guides of Good Tissue Practices (GTPs) and the European Union's Good Manufacturing Practices (GMP), 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.
Irregular fragments are removed during processing. The tissues undergo a decontamination process by means of antibiotic incubation (amphotericin B, metronidazole, vancomycin and amikacin). The skin fragments are subjected to different incubations in hypertonic and hypotonic reagents for their decellularization. Finally the tissue is stored at room temperature in quarantine until all the quality controls are reviewed and approved.

Storage

Store at room temperature until used. The tissue is packaged in a double bag, the internal bag being sterile. Do not use if any of the packaging is compromised.

Transport

The validated transport system from the Barcelona Tissue Bank (BTB) consists of placing the packaged dermal matrix in an external container, whose integrity is protected at all times.
The expiry date is three years from its processing, as stated on the label and the attached documentation.

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.