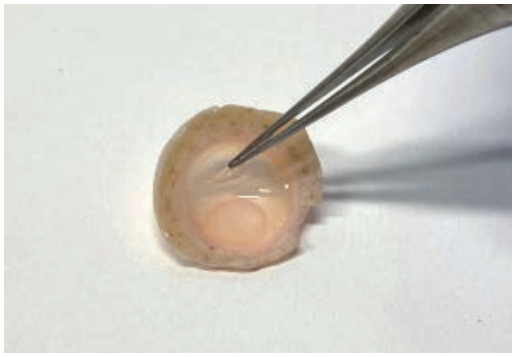
Barcelona Tissue Bank
BANC DE SANG I TEIXITS

ENDOTHELIAL MEMBRANE FOR DMEK

BT7019 **BT7027**



BT7019 **BT7027**

Specifications

Cornea with endothelial count equal to or greater than 2,300 cells/mm².

The endothelial membrane is attached in approximately 20% of its periphery.

A notch in the scleral ring indicates the adhesion zone.

Clinical applications

- Endothelial lamellar keratoplasties (DMEK).
- Replacement of the patient's Descemet membrane with endothelial dysfunction, dystrophy or decompensation.

Code	Description	Storage temperature
BT7027	Fresh endothelial membrane for DMEK	Hypothermia
BT7019	Cultivated endothelial membrane for DMEK	Room temp.

For more information:
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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 tissues are extracted within 24 hours of death in the operating theatre using sterile techniques. Once the tissue is obtained, it is kept in quarantine at 4 ºC until processed in the Tissue Bank.

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.
For the preparation of corneas, after an initial surface trephination measuring 10 mm in diameter, around 80% of the endothelial membrane is manually stripped.
The complete separation of the membrane and final trephination (if a smaller diameter is required) should be performed by the ophthalmologist before implant.

Storage

Depending on the type of source cornea, the product is stored at 2-10 ºC or room temperature until use.
The tissue expiry date is given on the label.

Transport

The pre-dissected membrane is sent adhered to the cornea in an airtight container containing a nutritional medium. This receptacle is packaged and placed in a transport container, whose integrity is protected at all times while maintaining it at an adequate temperature.
The expiry date is provided on the label and the attached documentation. The product should not be used if the integrity of the container has been compromised.

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.