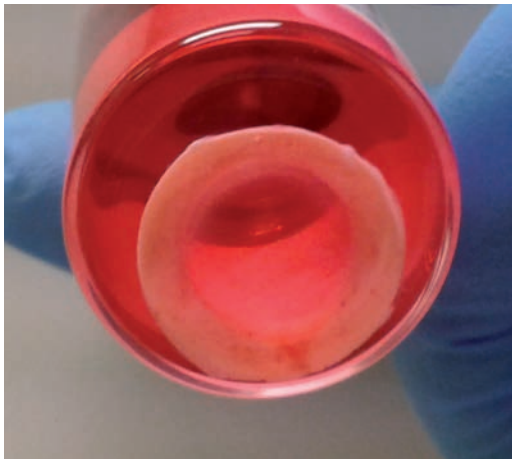
CORNEA

BT7003 BT7005 BT7023 BT7028 BT7029 BT7034



BT7034

Specifications

Fresh cornea:
Sclerocorneal button (diameter ≥17 mm) kept in hypothermal conditions, with an endothelial count equal to or greater than 2,000 cells/mm^2.

Cultivated cornea:
Sclerocorneal button (diameter ≥17 mm) kept at room temperature in culture medium with an endothelial count equal to or greater than 2,000 cells/mm^2.

Tectonic cornea:
Sclerocorneal button (diameter ≥17 mm) kept at room temperature, with an endothelial count below 2,000 cells/mm^2.

Clinical applications

Fresh and cultivated cornea:
- Penetrating keratoplasty
- Posterior lamellar keratoplasties and endothelial keratoplasties
- Limbal transplantation (in donors who meet multi-tissue criteria)

Tectonic cornea:
- Anterior lamellar keratoplasties
- Tectonic purposes

Code	Description	Presentation	Storage temperature
BT7034	Fresh cornea	Maintenance medium	2 ºC – 10 ºC
BT7003	Cultivated cornea	Deswelling medium	Room temp.
BT7023	Cornea keratoprosthesis	Deswelling medium	Room temp.
BT7005	Cornea keratoprosthesis	Maintenance medium	2 ºC - 10 ºC
BT7028	Limbal cornea transplant	Maintenance medium	2 ºC - 10 ºC
BT7029	Tectonic cornea	Cryopreservation medium	-196 ºC

For more information:
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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 in quarantine at 4 ºC until processed in the Tissue Bank.

Processing and storage

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 sclereocorneal button is isolated from the eye ball and preserved in a medium that provides the appropriate environment for endothelial and epithelial cells.
The cornea is assessed by slit lamp and the endothelial count is performed by specular microscopy. In the case of the cultivated cornea, once the preservation period at 31 ºC is over, a new endothelial count is carried out by optical microscope and the tissue is transported in deswelling medium.

Transport

The validated transport system from the Barcelona Tissue Bank (BTB) for the cornea at 2-10º consists of placing the packaged cornea in cold accumulators in an external container, whose integrity is protected at all times. The cultivated cornea is transported and maintained at room temperature until use. The expiry date for the tissue is given on the label and in the attached documentation. The tissue should not be used if the packaging is 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.