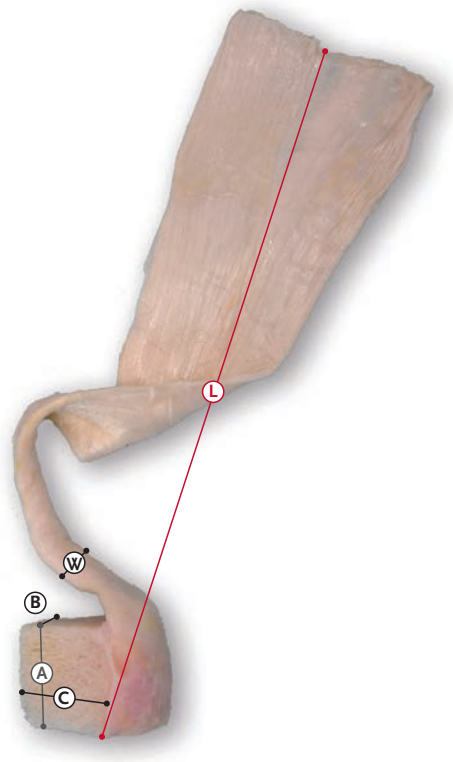
ACHILLES TENDON

BT2139 BT2140 BT2141 BT2210 BT2211 BT2212



BT2139

Specifications

Tendon graft from the Achilles tendon. Includes distal block of calcaneus bone (except for the Achilles tendon without block).

Characteristics:

- Soft muscle tissues removed
- No lesions, fibre separation or hematomas
- Permits surgeons to adapt the size of the calcaneus block to requirements (except for Achilles tendon without block)

Clinical applications

- Ligamentoplasty
- Tendon reconstruction
- Joint reconstruction

Code	Description	Achilles Calcaneus (cm)	Achilles block length (cm)	Achilles block width (cm)
BT2210	Achilles tendon ≥ 15 cm	≥ 1.0 x 1.0 x 2.5	≥ 15	≥ 1.0
BT2139	Achilles tendon 10-15 cm	≥ 1.0 x 1.0 x 2.5	10-15	≥ 1.0
BT2211	Half Achilles tendon ≥ 15 cm	≥ 1.0 x 1.0 x 2.5	≥ 15	≥ 1.0
BT2141	Half Achilles tendon 10-15 cm	≥ 1.0 x 1.0 x 2.5	10-15	≥ 1.0
BT2212	Achilles tendon with no block ≥ 15 cm	Not applicable	≥ 15	≥ 1.0
BT2140	Achilles tendon with no block 10-15 cm	Not applicable	10-15	≥ 1.0

Code	Dimension
L	Achilles tendon length
W	Achilles tendon thickness
A	Calcaneus block length
B	Calcaneus block width
C	Calcaneus block thickness

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, HIV1 -RNA, HBsAg, HBc antibodies, HBV-DNA, HCV-antibodies, HCV-RNA, syphilis, 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 all 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. Finally, the tissue undergoes microbiological control, and is then stored at -80 ºC in quarantine 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 in the freezer until used.
The product expiry date is five years from its processing, as long as it is kept at -80 ºC. Do not use the tissue if the packaging bags are compromised (except the external plastic bag).

Transport

The tissue is packaged in a plastic bag, a Tyvek bag and a plastic container. The plastic container and Tyvek bag inside are sterile. The validated transport system from the Barcelona Tissue Bank (BTB) consists of placing the packaged graft in a transport container containing dry ice (solid carbon dioxide).
It is a validated transport system that preserves the properties of the graft until the time and date of delivery shown on the package label.

CAUTION: Dry ice can cause burns. The product should be unpacked using safety gloves that permit product handling at -80 ºC.
High levels of carbon dioxide should be avoided as they may cause asphyxia. Therefore, the packaging should be opened with caution in a room with adequate ventilation. The remaining ice should be left to evaporate in a ventilated area.

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.