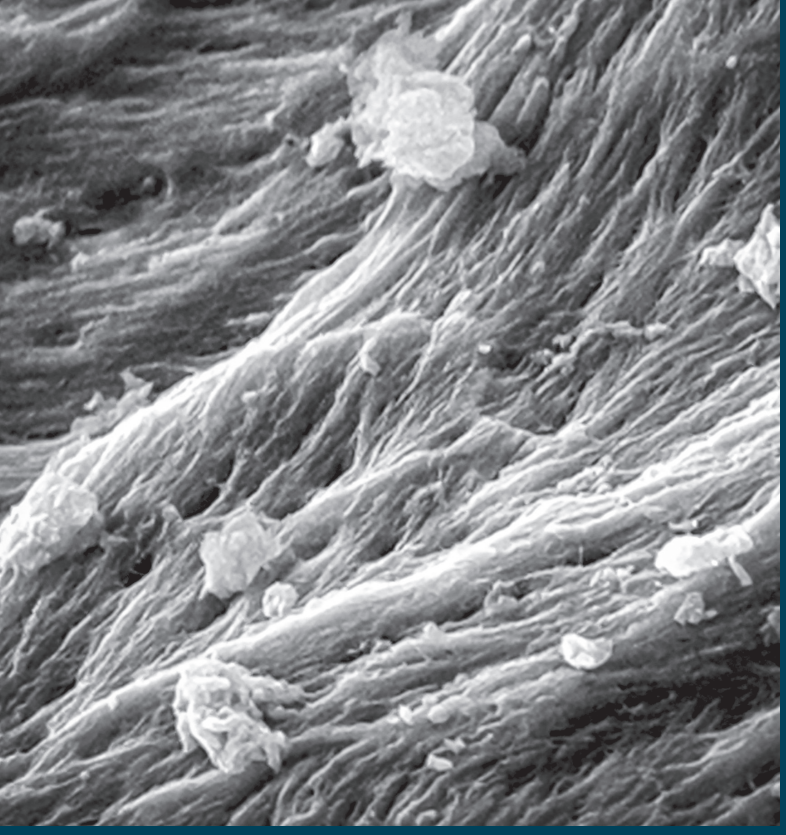
SURGMED

BONE BANK + ALLOGRAFTS

Overview and Order Information

ALLOGENIC TISSUE



Scanning electron micrograph (SEM) of allogenic granules of C^{+}TBA showing micropores of natural bone.

Operation of the freeze-drying system in the clean rooms of C^{+}TBA in Krems on the Danube. Freeze drying is a gentle method of preserving bone grafts.

ABBREVIATIONS

DIMENSIONS	ABBREVIATIONS
Length	L
Width	W
Height	H
Diameter	D
Inner Diameter	iD
Size	S
Angle	A
Volume	V

CONTENT

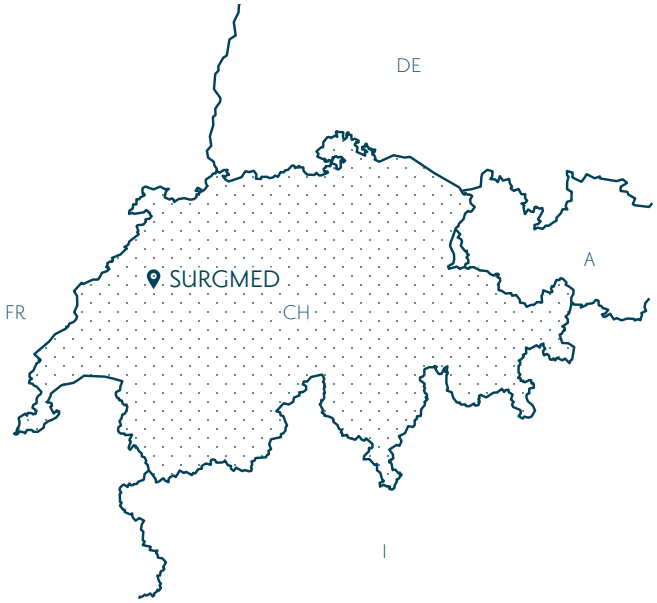
Assume Initiative

SURGMED

SURGMED GmbH was founded in 2022 as a specialized distribution company for the areas of bone bank systems and allogeneic bone transplants for the Swiss hospital sector, with headquarters in Môtier (Mont-Vully), canton of Fribourg.

SURGMED‘s aim is to meet the high quality requirements of clinics with clinically proven products to meet the high quality requirements of clinics.

SURGMED is in constant dialog with clinic employees and partners from research, development and production, and is thus able to offer innovative technologies and proven products in the field of operative surgery and related disciplines at a fair price-performance ratio.



Centrifugation of blood samples to prepare the serological examination

Optical in-process control

Take Responsibility

QUALITY & SAFETY

Human bone substitute

Various substitute materials are available for remodelling of bone tissue. Autogenous (patient's own) tissues are considered to be the gold standard, but their availability is limited, and removal is often associated with secondary pain and morbidity at the removal site.[1-3]

The application of purified allogenic tissue is a safe alternative to autogenous grafts. Clinical studies show that processed allogenic bone tissue does not differ from autogenous bone in terms of tolerability.4 Furthermore, it has been proven that allogenic and autogenous bone transplants are radiologically, histologically, and morphologically equivalent with respect to the final remodelling of bone tissue.[5-7]

Tissue donation and procurement

The allogenic bone grafts from C⁺TBA come from voluntary and unpaid tissue donations, which are collected in accordance with the quality and safety criteria of the respective European guidelines.

The vast majority of C⁺TBA bone grafts are derived from femoral heads that are resected as part of a hip surgery (living donation). The harvesting of the tissue is standardized and executed in certified procurement centres. All tissue donations are subject to strict exclusion criteria regarding the health status of the donor.

Testing of each tissue donation

The donated tissue is only released for processing after the mandatory testing in order to minimize potential infection risks. In addition to the antibody screening, nucleic acid tests (NAT) are carried out for each tissue donation.

PATHOGEN	TEST	SPEZIFIKATION
Hepatitis-B-Virus (HBV)	HBsAg, NAT	negative
Hepatitis-C-Virus (HCV)	Ab, NAT	negative
HIV I/2, Ag p-24	Ab, NAT	negative
Treponema pallidum	Ab	negative

Proof of safety

In case of negative donation test results, the tissues are released for purification. The multi-stage Allotec® purification procedure of C⁺TBA is based on highly volatile reagents.

The depletion potential of the cleaning steps was checked by an independent test laboratory according to international guidelines and standards. For this purpose, suspensions of model viruses for enveloped (HBV) and non-enveloped DNA viruses (PPV parvovirus) as well as enveloped (HIV, HCV, HTLV) and non-enveloped RNA viruses (HAV) were applied to C⁺TBA bone grafts.

The grafts were then treated under controlled conditions with the Allotec® purification procedure. The same was conducted for model bacteria. A reduction of all test viruses and bacteria of at least ≥6.0 Log10 was demonstrated. This corresponds to pharmaceutical safety standards and the Allotec® purification procedure has thus been proven to be effective for inactivating the model germs.[8, 9]

Sterility

After cleaning is completed, the grafts are freeze-dried, double-wrapped and terminally sterilized.

ALLOTEC® PURIFICATION PROCEDURE

Allotec® is a multi-stage purification procedure for allogenic bone tissue of human origin. It was specially developed to ensure the highest level of transplant safety while at the same time maintaining the natural integrity of the tissue. The gentle cleansing with volatile reagents preserves the biomechanical and biological properties of the bone tissue.[10] The natural bone structure for revascularization and migration of osteoblasts and precursor cells are preserved, so that physiological bone formation and the subsequent remodelling (osteoconduction) are reliably supported.17

1 Shaping
After the mechanical removal of soft tissue, fat and cartilage, the tissue is given its final shape, e.g. block, wedge, granules, cylinder.

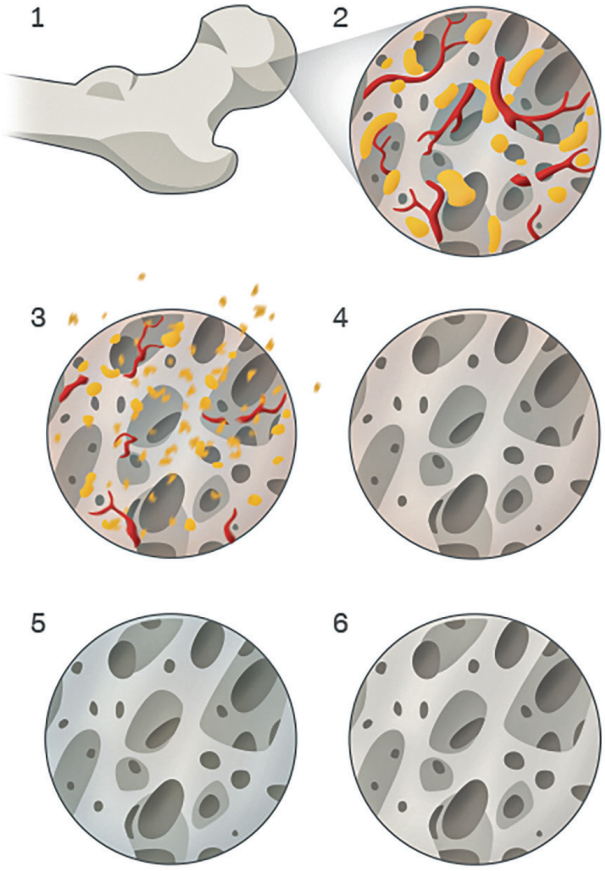
2 Ultrasonic bath
Ultrasonic cleaning removes blood as well as cell and tissue components. During this step, fat is also loosened from the trabecular structures of the bone tissue, which reduces the immunogenic potential and facilitates the penetration of reagents during the further process.[10, 11]

3 Purification with volatile reagents
Repeated rinsing with diethyl ether and ethanol dissolves cellular components from the tissue and denatures non-collagenous proteins, potentially existing viruses are inactivated and bacteria are destroyed.[12, 13]

4 Oxidative treatment
The hydrogen peroxide denatures persistent soluble proteins, specifically inactivates uncoated viruses and bacterial endospores, and reduces antigenicity to a minimum.[14] The collagen matrix remains intact.

5 Freeze drying
Freeze drying (lyophilization) enables the tissue-preserving withdrawal of water. The structural integrity of the tissue remains unchanged during freeze drying. The residual moisture of ≤10%, combined with the double packaging, guarantees a shelf life of five years at room temperature.

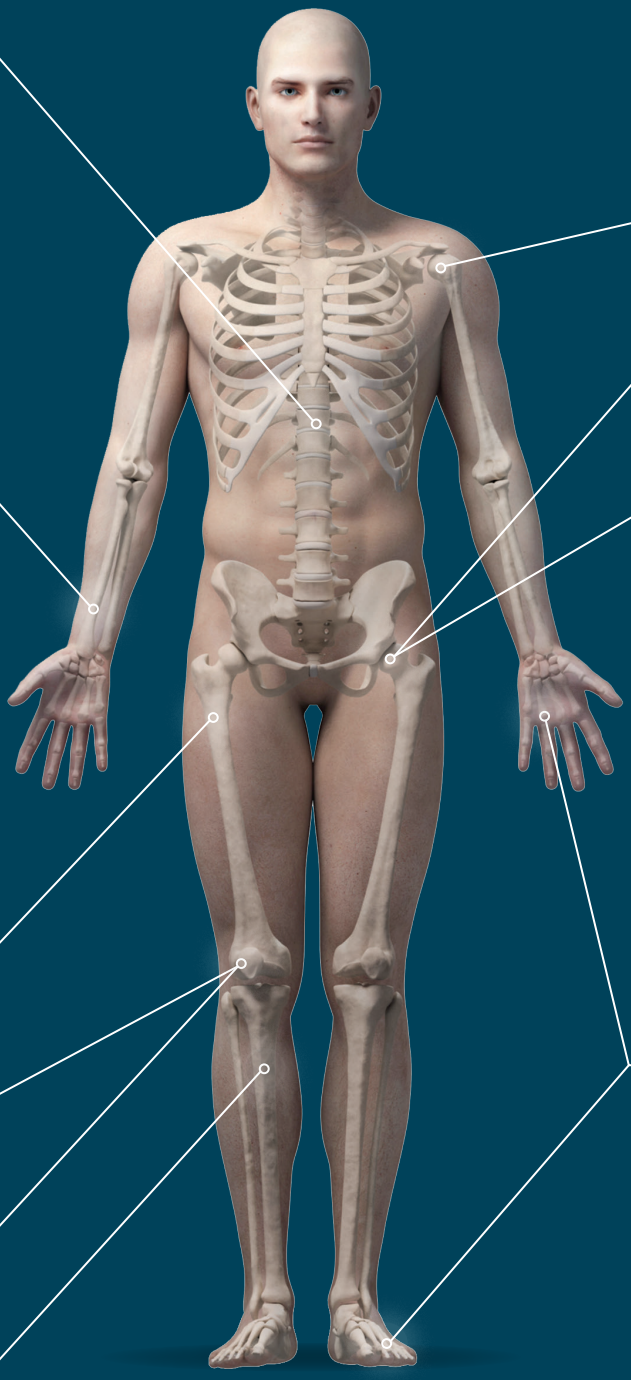
6 Terminal sterilization
The final tissue-preserving irradiation at a controlled low temperature – together with the preceding cleaning steps – leads to a safety level SAL of $\geq 10^{-6}$).[15, 16]



The figure shows the changes in bone tissue during the Allotec® cleaning process: (1) Shaping, (2) Ultrasonic bath, (3) Purification with volatile reagents, (4) Oxidative treatment, (5) Freeze drying, (6) Terminal sterilization.

Improve Results

CLINICAL APPLICATION



Spinal fusion

Granules, DBM

Trauma

Granules, Diaphysis

Tumor, Cyst

Granules, Cube, Diaphysis

Replacement of cruciate ligament

Tendon, Cylinder

Corrective osteotomy

Wedge, Block

Pseudarthrosis

Granules

Shoulder instability, Endoprothesis

|-Chip, Cancellous ring

Acetabular reconstruction

Femoral head

Hip revision

Granules, Block

Hand and foot surgery

Granules

Please carefully read the instructions for use before application.

GRANULES & CUBES

C⁺TBA-granules are available as pure cancellous and as cortico-cancellous granules. The natural structure enables rapid integration. Particle sizes and volumes can be selected according to indication and defect size.

Granules & Cubes, Cancellous

Origin:	Human
Tissue:	Cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiation
Application:	Bone void filler
Rehydration:	Min. 10 minutes

Granules, Cortico-cancellous

Origin:	Human
Tissue:	Cortico-cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiation
Application:	Bone void filler
Rehydration:	Min. 10 minutes

Grain Sizes of Granules

The granule sizes are achieved by sieving. The different perforation of the sieves leads to the sizes listed to the left. Depending on the direction of fall, particles may be slightly larger than specified in one dimension.

ORDER INFORMATION*

DESCRIPTION	G [MM]	ITEM NUMBER	VOLUME [cc]
Cancellous Granules	2 - 5	9204003	3
		9204005	5
	> 8	9204215	15
		9204230	30
Cancellous Granules - Spierings	5 - 10	9204042	30
	2 - 8	9204006	5
		9204010	10
		9204015	15
		9204030	30
Cancellous Cubes	5 x 5 x 5	9204042	10
Cancellous Granules sawn	< 10	9204310	10
		9204315	15
		9204330	30

* Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.

CANCELLOUS GRANULES IN THE APPLICATOR

Cancellous Granules

Origin:	Human
Tissue:	Cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL 10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiation
Application:	Bone void filler
Rehydration:	Min. 10 minutes

The applicator of C^{+}TBA is a special form of primary packaging for cancellous bone granules, which simplifies both the rehydration with a physiological medium as well as the application of the granules into the defect zone.

ORDER INFORMATION*

DESCRIPTION	ITEM NUMBER	VOLUME [cc]
Cancellous Granules in the Applicator	9204170	7
	9204171	15
	9204172	30

* Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.

FEMORAL HEAD

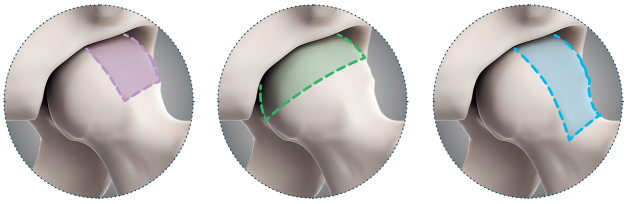
Halved or longitudinally halved (bisected) femoral heads are used, for example, in acetabular reconstruction alone or in combination with granules. Halved femoral heads are available in two different diameters (<45 mm and >45 mm), bisected femoral heads in two different lengths. The height is approx. 20 mm in each case.

Femoral Head, Halved

Origin:	Human
Tissue:	Cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiation
Application:	Bone void filler
Rehydration:	Min. 10 minutes

Femoral Head, Bisected

Origin:	Human
Tissue:	Cortico-cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiation
Application:	Bone void filler
Rehydration:	Min. 10 minutes



Illustrations from left to right:
Bisected Femoral Head – short
Halved Femoral Head
Bisected Femoral Head – long

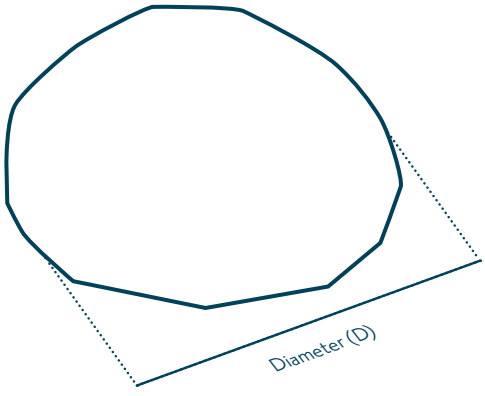
ORDER INFORMATION*

Bisected Femoral Head

DESCRIPTION	ITEM NUMBER	SIZE
Bisected Femoral Head	9009015	short
	9009010	long

Femurkopf, halbiert

DESCRIPTION	ITEM NUMBER	D [mm]	H [mm]
Halved Femoral Head	9009004	< 45	20
	9009000	> 45	20



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BLOCKS

Cancellous Block

Origin:	Human
Tissue:	Cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiation
Application:	Bone void filler
Rehydration:	Min. 10 minutes

Tricortical Block

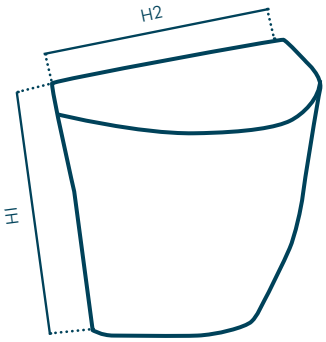
Origin:	Human
Tissue:	Cortical and cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Bone replacement
Rehydration:	Min. 10 minutes

Cancellous block

Cortico-cancellous block

Tricortical block

The cortical layer covers the entire longitudinal surface of the block.



Tricortical block

ORDER INFORMATION*

Blocks

DESCRIPTION	ITEM NUMBER	L [mm]	W [mm]	H [mm]
Cancellous Block	9204040	10	10	10
	9204045	20	10	10
	9204050	30	10	10
	9204060	30	30	10
	9204070	40	30	10
Cancellous Block 3 pieces	9204041	10	10	10
	9204051	30	10	10

Tricortical Block

DESCRIPTION	ITEM NUMBER	H1 x H2 [mm]
Tricortical Block	9204251	10 x 10
	9204252	20 x 10
	9204253	20 x 20
	9204254	20 x 30
	9204255	30 x 20
	9204256	40 x 20

* Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.

WEDGES

Wedges are preshaped cancellous or corticocancellous bone grafts, mainly used in corrective osteotomy. C+TBA provides a wide range of wedges (cancellous or cortico-cancellous) with different angles and sizes to precisely address the indication and the patient's individual anatomic preconditions.

Cancellous Wedge

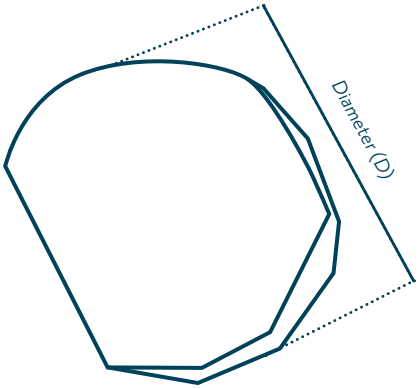
Origin:	Human
Tissue:	Cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL 10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Corrective osteotomy
Rehydration:	Min. 10 minutes

Cortico-cancellous Wedge

Origin:	Human
Tissue:	Cortical and cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL 10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Corrective osteotomy
Rehydration:	Min. 10 minutes

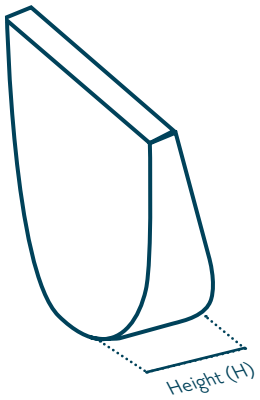
Cancellous wedge

Cortico-cancellous wedge



ORDER INFORMATION*

DESCRIPTION	W	ITEM NUMBER	G	D [mm]	H [mm]
Cancellous wedge	10°	9204151	S	<45	7,0
		9204152	L	≥45	10,0
	13°	9204153	S	<45	10,0
		9204154	L	≥45	13,0
	16°	9204156	S	<45	13,0
		9204157	L	≥45	16,0
Corticocancellous wedge	15°	9204150	-	n.a.	10,0



* Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.

CANCELLOUS CYLINDER & RING

Cancellous bone cylinders are preferably used in sports medicine for filling drill channels in cruciate ligament revisions.
The cancellous ring was specially developed to simplify the reconstruction of the glenoid in a total shoulder endoprosthesis.

Cancellous Cylinder

Origin:	Human
Tissue:	Cancellous bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Tunnel filling
Rehydration:	Min. 10 minutes

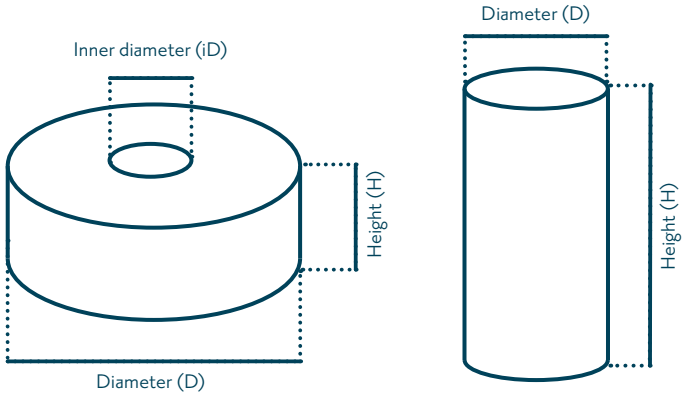
Cancellous Ring

Origin:	Human
Tissue:	Cancellouse bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Remodelling of the glenoid in case of shoulder endoprosthesis
Rehydration:	Min. 10 minutes

ORDER INFORMATION*

Cancellous Ring

DESCRIPTION	D_{inner} [mm]	ITEM NUMBER	D [mm]	H [mm]
Cancellous Ring	1,5	9204155	26	10
		9204158	26	20
		9204159	32	10
		9204151	32	20
	7,7	9204160	26	10
		9204161	26	20
		9204162	32	10
		9204163	32	20



Fibular ring

DESCRIPTION	ITEM NUMBER	ABMESSUNG [mm]
Fibular ring	9204241	5
	9204242	7
	9204243	10
	9204244	35
	9204245	75
	9204246	100

Cancellous Cylinder

DESCRIPTION	ITEM NUMBER	D [mm]	H [mm]
Cancellous Cylinder	9204100	20	15
	9204120	10	20
	9204130	10	30
	9204122	12	20
	9204132	12	30
	9204124	14	20
	9204134	14	30

* Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.

HALVED DIAPHYSIS & J-CHIP

Cortical bone grafts derived from the femoral or tibial diaphysis are used in case additional structural stability is required, but only if the function is not weight-bearing. An application example is the splinting of periprosthetic fractures in combination with e.g. plates.

Halved Diaphysis

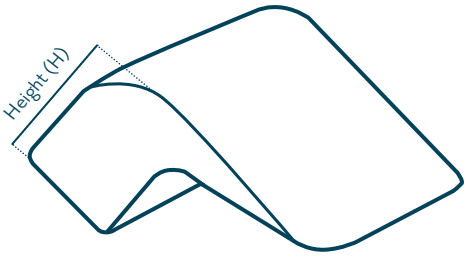
Origin:	Human
Tissue:	Cortical bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Bone replacement
Rehydration:	Min. 10 minutes

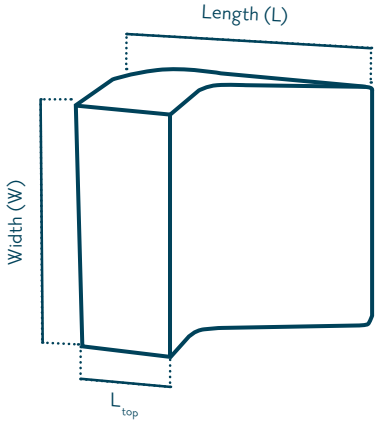
J-Chip

Origin:	Human
Tissue:	Cortical bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Shoulder instability
Rehydration:	Min. 10 minutes

Halved diaphysis
J-Chip

Developed in the 1980s, the J-Chip operation is a technique used to treat patients with recurrent shoulder dislocations after trauma.[18, 19] The J-Chip consists entirely of cortical bone, leading to high stability during insertion and better support. The round back provides a smooth surface for soft tissue.





ORDER INFORMATION*

Halved Diaphysis

DESCRIPTION	ITEM NUMBER	L [mm]
Halved Diaphysis	9204205	100
	9204004	150
	9204200	200

J-Chip

DESCRIPTION	ITEM NUMBER	L [mm]	W [mm]	H [mm]	L_{top} [mm]
J-Chip	9200000	15	15	10	5

* Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.

Tendons & Ligaments

QUALITY & SAFETY

The tendons and ligaments offered by C⁺TBA are procured and processed by our partner tissue banks.
The applied cleansing procedures are officially approved.

For the soft tissues that are processed by C⁺TBA's partner tissue banks, C⁺TBA ensures compliance with European standards and with the strict Austrian legislation for allogenic tissues.

Voluntary and unpaid tissue donations are checked according to the specifications of C⁺TBA. A medical history, a donor test for hepatitis B & C, HIV, HTLV, and Treponema pallidum as well as a PCR test for HBV, HCV, HIV are carried out. The tests are conducted in specially certified laboratories.

All processing steps after tissue procurement are executed under pharmaceutical quality criteria in clean room class A. The purification is carried out according to officially approved processes, which have been proven to have a depletion potential for infectious agents, but impair the physical properties of the soft tissues as little as possible.

The cleansed soft tissues are offered without gamma irradiation after an obligatory sterility test.
All soft tissues are stored at ≤-40°C and delivered on dry ice.

Images bottom to top:
Achilles tendon
Patellar ligament with bone, bisected
Non-bone tendon

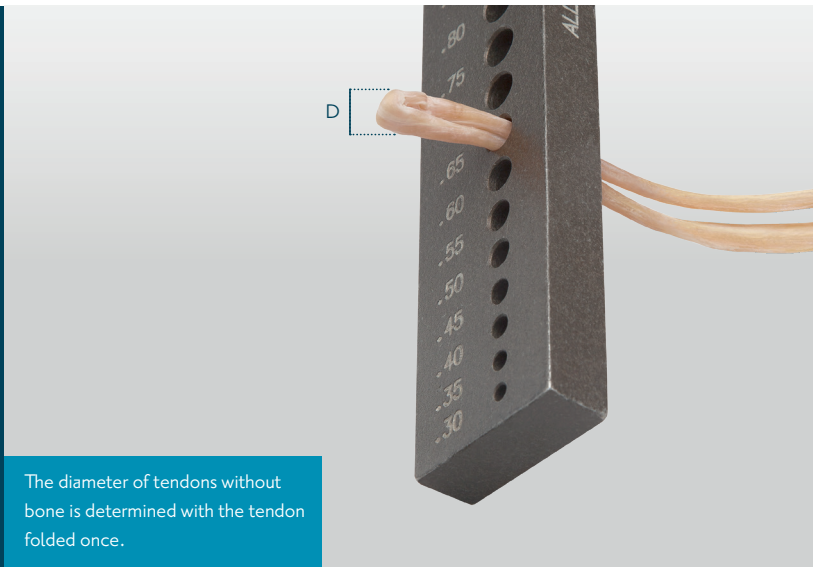
Fresh Frozen

TENDONS & LIGAMENTS

Tendons & Ligaments

Origin:	Human
Tissue:	Allogenic soft tissue
Processing:	Offically approved cleansing procedure
Preservation:	Frozen
Application:	Replacement of tendons and ligaments

Please note that the size information regarding «Non-bone Tendons» and «Tendons & Ligaments with Bone» do not reflect all available dimensions. Additional tendon sizes are available upon request. You can find the exact information about ordering on the next page.



The diameter of tendons without bone is determined with the tendon folded once.

ORDER INFORMATION

Non-bone Tendons

DESCRIPTION	ITEM NUMBER	L [mm]	D [mm]
Semitendinosus	ALO760	≥180	
Gracilis	ALO762	≥180	
Tibialis, anterior	ALO765	230-255	6-8
	ALO766	≥260	6-8
	ALO767	230-255	≥9
	ALO768	≥260	≥9
Tibialis, posterior	ALO770	230-255	6-8
	ALO771	≥260	6-8
	ALO772	230-255	≥9
	ALO773	≥260	≥9
Semimembranosus	ALO740	230-255	6-8
	ALO741	≥260	6-8
	ALO742	230-255	≥9
	ALO743	≥260	≥9
Peroneus longus	ALO745	230-255	6-8
	ALO746	≥260	6-8
	ALO747	230-255	≥9
	ALO748	≥260	≥9

Rippenknorpel

DESCRIPTION	ITEM NUMBER	L [mm]
Costal cartilage or Rib cartilage	ALO784	40
	ALO785	30
	ALO786	20

Tendons & Ligaments with Bone

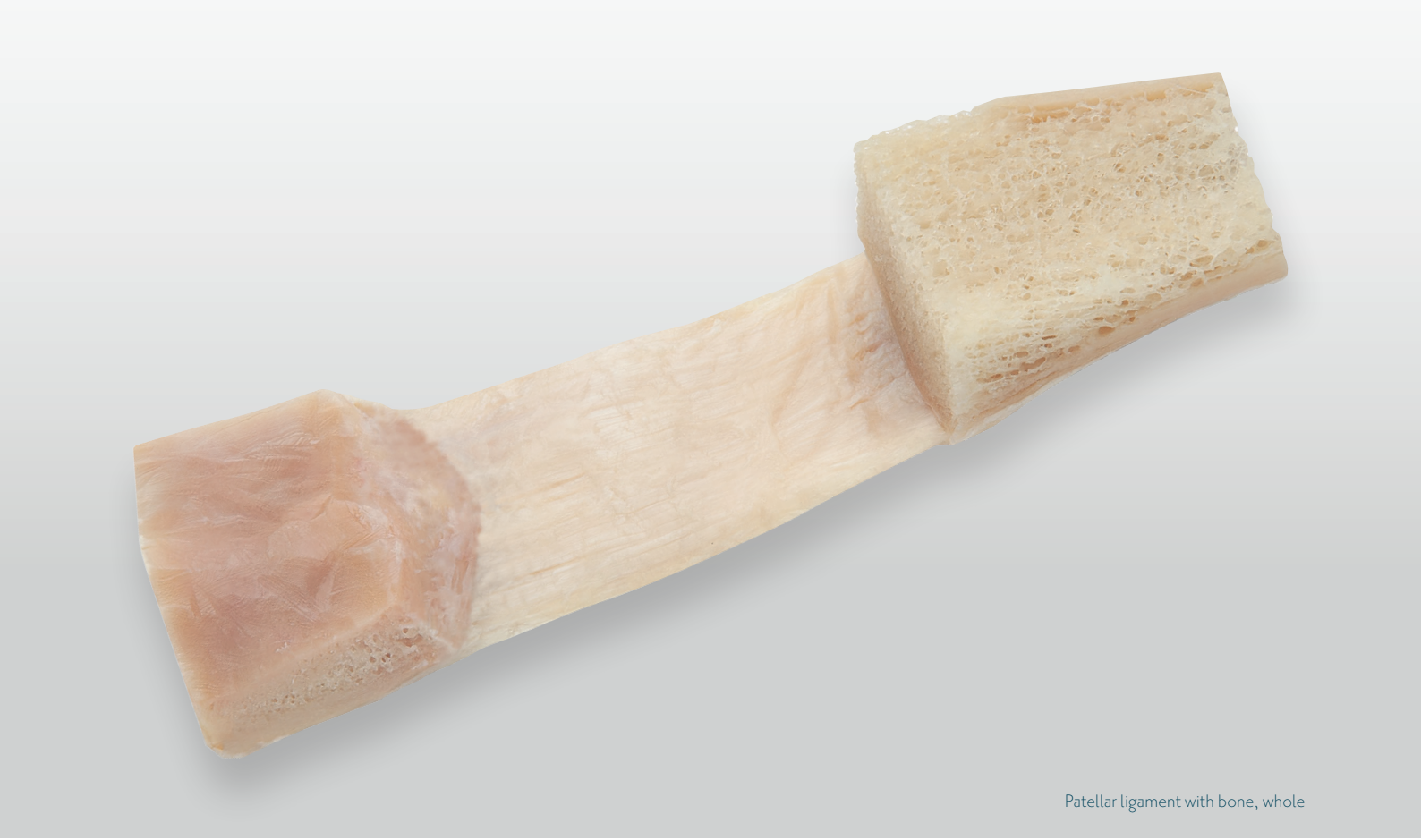
DESCRIPTION	ITEM NUMBER	L [mm]	B [mm]
Patellar ligament with Bone, bisected	ALO775		upon request
Patellar ligament with Bone, whole	ALO776		
Achilles tendon	ALO777	≥ 150 < 160	
	ALO778	≥ 160	

Menisken

DESCRIPTION	ITEM NUMBER
Meniscus medial right	ALO780
Meniscus medial left	ALO781
Meniscus lateral right	ALO782
Meniscus lateral left	ALO783

Streckapparat Knie

DESCRIPTION	ITEM NUMBER
Patella with patellar tendon (incl. bone block) and quadriceps tendon - right	ALO790
Patella with patellar tendon (incl. bone block) and quadriceps tendon - left	ALO791



Patellar ligament with bone, whole

Soft Tissue

ORDER PROCESS

1

ENQUIRY

The responsible surgeon sends a request to C⁺TBA or a local service partner of C⁺TBA. The request form contains information about the indication as well as the exact specification of the required transplant and the desired delivery date. The request form is provided by a local service partner or can be downloaded from www.ctba.at/st-request.pdf.

2

ORDER

SURGMED either confirms the availability of the transplant according to the request or names alternatives if the required transplant is not available. The treating surgeon makes his/her decision on the basis of the SURGMED's proposal and, if necessary, transmits the binding order.

3

SHIPPING

The soft tissues are transported in validated shipping boxes on dry ice. Storage in these boxes is possible for up to five days (including shipping days). Due to transportation requirements, the preferred days of delivery are Tuesday to Friday.

ACL APPLICATION AID FOR CANAL FILLING

Tunnel Filling with Bone Cylinders

ACL Application Aid
Easy to use
Available in 3 different sizes in the diameters
10, 12 and 14 mm
Matched to the dimensions of the C+TBA bone cylinder

Anterior cruciate ligament (ACL) reconstruction is a standard procedure in the active patient. However, the number of ACL re-ruptures also rises, with an increasing number of ACL reconstructions (ACLR). In ACL revision surgery faulty tunnel position and widening require a two-staged treatment with tunnel filling and secondary ACLR to secure a proper fixation of the transplant.[20] The current gold standard for tunnel filling is autologous corticocancellous iliac crest graft harvesting.[21] But, the iliac crest donor site is associated with a significant number of complications causing the quest for alternative tunnel filling materials.[22]

Allogenic bone provides an alternative. Cylinders can be inserted openly or, with the help of the new applicator, arthroscopically into the drill canals. Thanks to this modern method of bore canal filling, patients can be spared an additional procedure on the iliac crest.

ORDER INFORMATION

DESCRIPTION	ITEM NUMBER
Application Aid Set 1 Application aid incl. tray and 3 available adapters: Application head + Application aid thorn Ø 10mm Application head + Application aid thorn Ø 12mm Application head + Application aid thorn Ø 14mm	2800130
Application Aid Set 2 Applicator with 1 adapter of choice (without tray): Application head + Application aid thorn Ø 10mm Application head + Application aid thorn Ø 12mm Application head + Application aid thorn Ø 14mm	2800140

LITERATURE

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