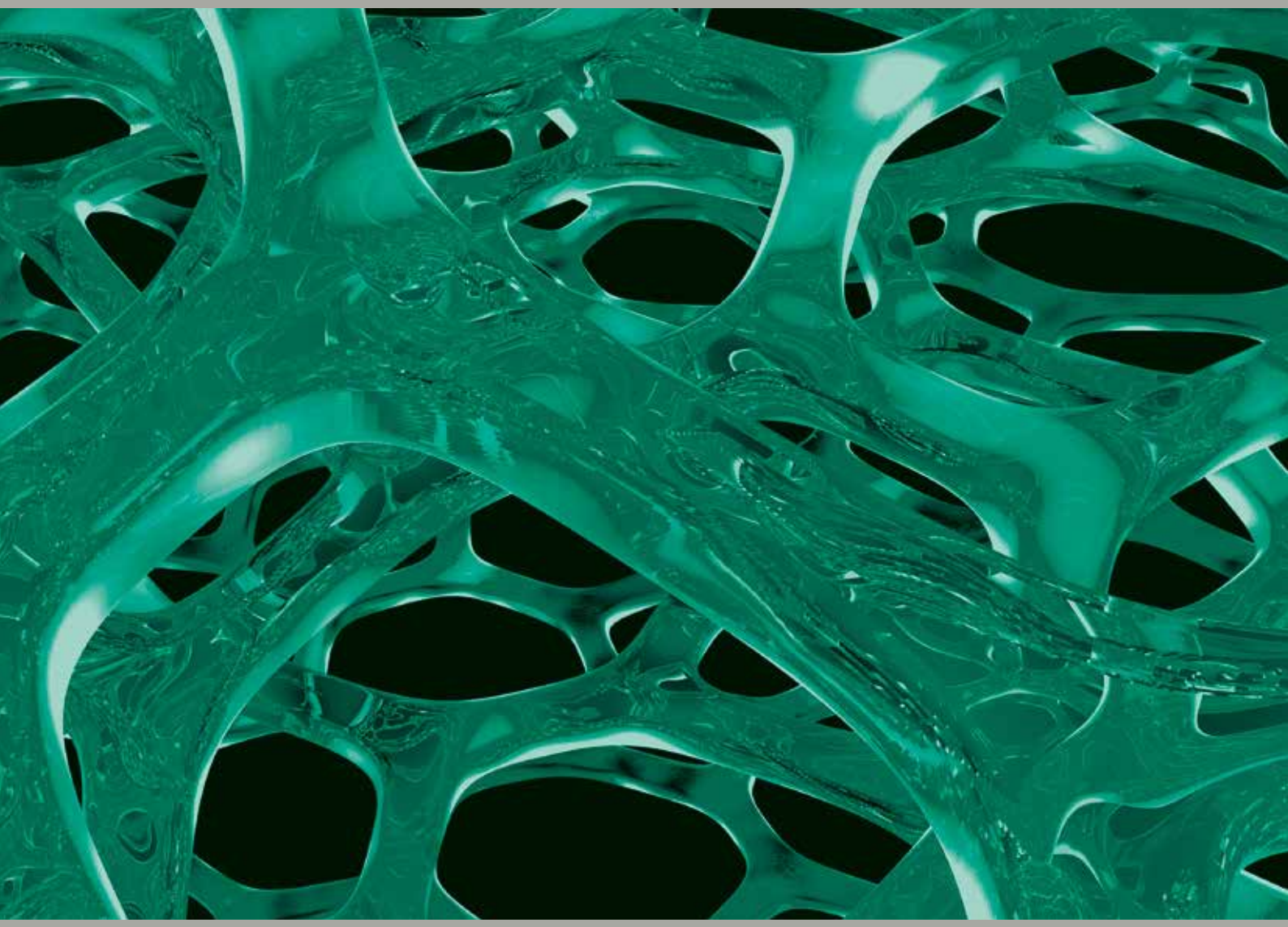
BT medicals
nordics & baltics

Overview and order information

ALLOGENIC TISSUE



BT Medicals
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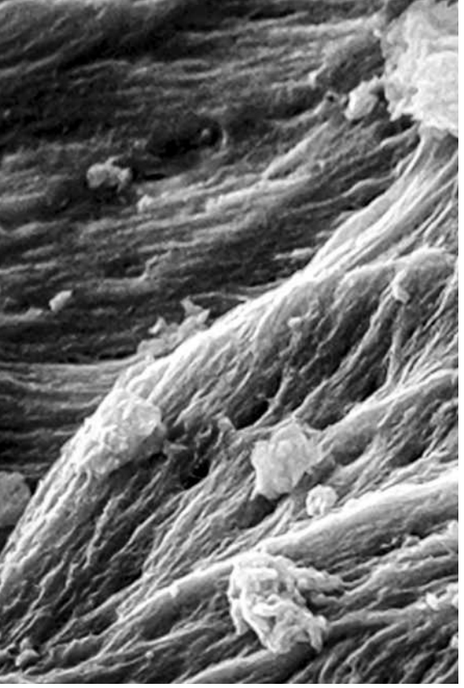


Top: Scanning electron micrograph (SEM) of allogenic granules of C⁺TBA showing micropores of natural bone.

Bottom: 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

Take Initiative

BT MEDICALS

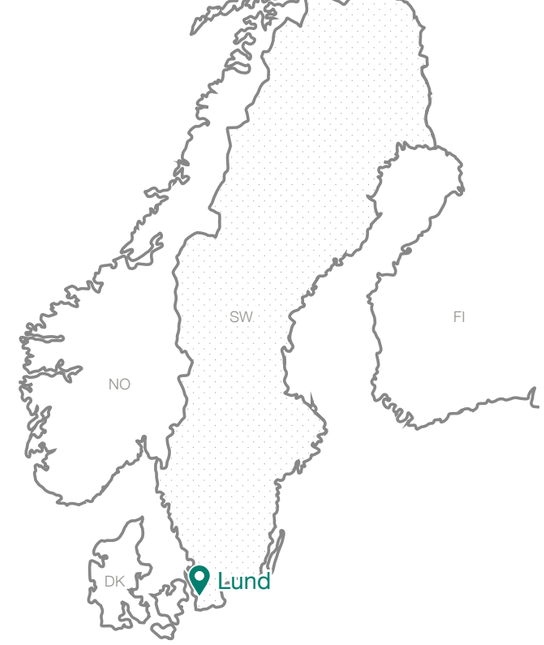
BT Medicals is distribution partner of Cells+Tissuebank Austria (C⁺TBA) for Scandinavia and the Baltic countries. The C⁺TBA is a non-profit tissue bank with the aim to ensure the supply of allogenic tissues for patients – in line with the continuously growing medical need.

C⁺TBA is one of the leading tissue banks in Europe, thus accompanies and is responsible for the entire process tissue donation to processing with the Allotec® purification procedure and the final distribution by local service partners like BT Medicals.

C⁺TBA grafts are safe, indication-based and easy to use.

In the clean rooms of C⁺TBA in Krems/Danube, up to 150,000 tissue transplants can be processed per year, and the capacities are constantly being expanded.

Compliance with the highest quality and safety standards has top priority. C⁺TBA is certified for tissue donation, procurement, storage, distribution and import of tissue of the human musculoskeletal system by the Austrian Federal Office for Safety in Health Care (BASG).



The safety and effectiveness of the bone transplants was confirmed by the Paul Ehrlich Institute as part of a drug approval in Germany.

As a full-service provider for human transplants, C⁺TBA also provides soft tissue and DBM. The supply in this area is guaranteed by the close cooperation with partner tissue banks in Europe.

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	SPECIFICATION
Hepatitis B virus (HBV)	HBsAg, NAT	negative
Hepatitis C virus (HCV)	Ab, NAT	negative
HIV 1/2, 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.

Understand Potentials

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]

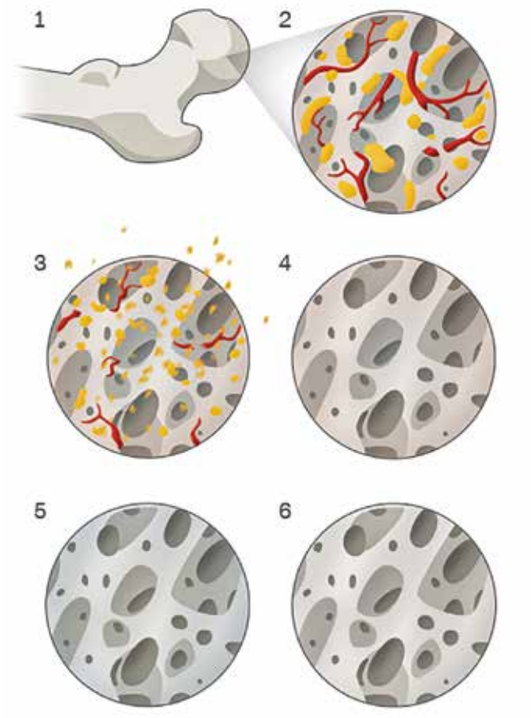
3 Purification with volatile reagents
Repeated rinsing with diethyl ether and ethanol dissolves cellular components from the tissue and denatures non-collagenous proteins, potentially existing viruses are inactivated and bacteria are destroyed.[12, 13]

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.

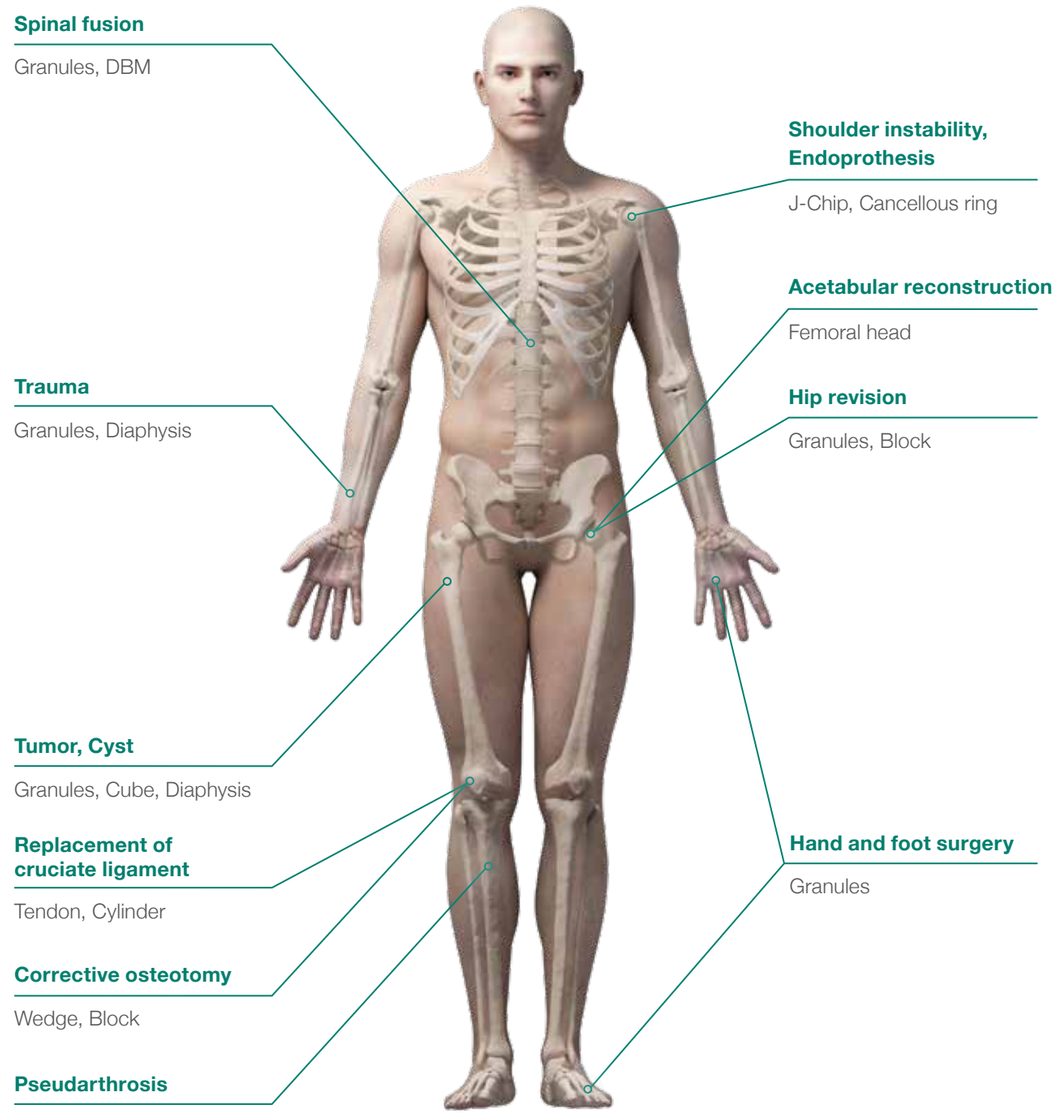
6 Terminal sterilization
The final tissue-preserving irradiation at a controlled low temperature – together with the preceding cleaning steps – leads to a safety level SAL of $\geq 10^{-6}$. [15, 16]



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



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

ORDER INFORMATION*

DESCRIPTION	G [mm]	ITEM NUMBER	VOLUME [cc]
Cancellous granules	2 - 5	ALO319	5
		ALO315	15
		ALO309	30
		ALO317	45
	5 - 8	ALO326	5
		ALO316	15
		ALO310	30
		ALO331	45
	2 - 8	ALO305	5
		ALO306	15
		ALO307	30
		ALO308	45
	> 8	ALO300	15
		ALO301	30
Cancellous granules - Spierings	5 - 10	ALO350	30
	2 - 8	ALO351	10
		ALO352	15
		ALO353	30
Cortico-cancellous granules	2 - 8	ALO340	15
		ALO341	30
Cancellous cubes*	5 x 5 x 5	ALO325	10
		ALO314	20
Cancellous granules sawn	< 10	ALO370	5
		ALO371	10
		ALO372	15
		ALO373	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.*

Gr. Size

Gr. Size

LxWxH

<10

Grain sizes of granules (G)

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.

Granules sawn

Granules Spierings 5-10 mm

CANCELLOUS GRANULES IN THE APPLICATOR

Cancellous cubes

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

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	ALO360	7
	ALO361	15
	ALO362	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

Bisected Femoral Head – long

Bisected Femoral Head – short

ORDER INFORMATION*

Bisected femoral head

DESCRIPTION	ITEM NUMBER	SIZE
Bisected femoral head	ALO446	short
	ALO447	long

Halved femoral head

DESCRIPTION	ITEM NUMBER	D [mm]	H [mm]
Halved femoral head	ALO441	< 45	20
	ALO444	> 45	20

Halved Femoral Head

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

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

Cortico-cancellous block
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

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

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

ORDER INFORMATION*

Blocks

DESCRIPTION	ITEM NUMBER	L [mm]	W [mm]	H [mm]
Cancellous block	ALO406	10	10	10
	ALO409	20	10	10
	ALO400	30	10	10
	ALO416	30	20	10
	ALO417	30	30	10
	ALO401	30	15	15
Unicortical cancellous block	ALO402	10	10	10
	ALO403	20	10	10
	ALO404	30	10	10

LxWxH

LxWxH

Cortico-cancellous block

Cancellous block

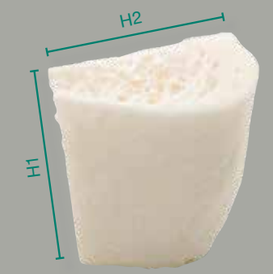
Tricortical block

DESCRIPTION	ITEM NUMBER	H1 x H2 [mm]
Tricortical block	ALO480	10 x 10
	ALO481	20 x 10
	ALO482	20 x 20
	ALO483	20 x 30
	ALO484	30 x 20
	ALO485	40 x 20

H1xH2

H1xH2

H1xH2



Tricortical block

** 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. SAL10^{-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. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Corrective osteotomy
Rehydration:	Min. 10 minutes

Cancellous wedge

ORDER INFORMATION*

DESCRIPTION	A	ITEM NUMBER	S	D [mm]	H [mm]
Cancellous wedge	7°	ALO462	S	<45	5,0
		ALO460	L	≥45	7,0
	10°	ALO465	S	<45	7,0
		ALO463	L	≥45	10,0
	13°	ALO468	S	<45	10,0
		ALO466	L	≥45	13,0
	16°	ALO470	S	<45	13,0
		ALO469	L	≥45	16,0
Cortico-cancellous wedge	15°	ALO410	-	n.a.	10,0

A, S

A

Cortico-cancellous wedge

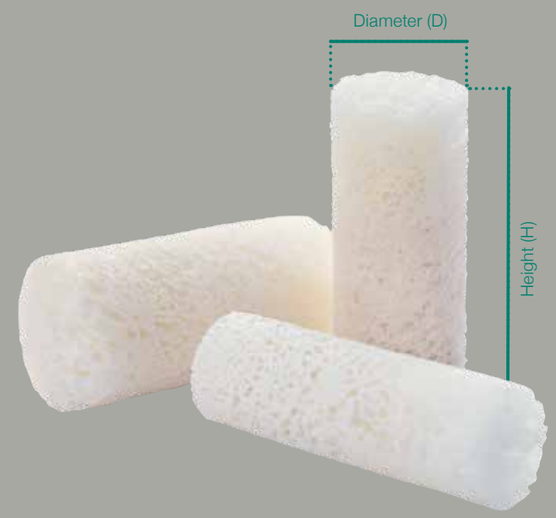
* *Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.*

CANCELLOUS CYLINDER

Cancellous bone cylinders are preferably used in sports medicine for filling drill channels in cruciate ligament revisions.

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



ORDER INFORMATION*

DESCRIPTION	ITEM NUMBER	D [mm]	H [mm]
Cancellous cylinder	ALO423	10	20
	ALO424	10	30
	ALO425	12	20
	ALO426	12	30
	ALO427	14	20
	ALO428	14	30

DxH

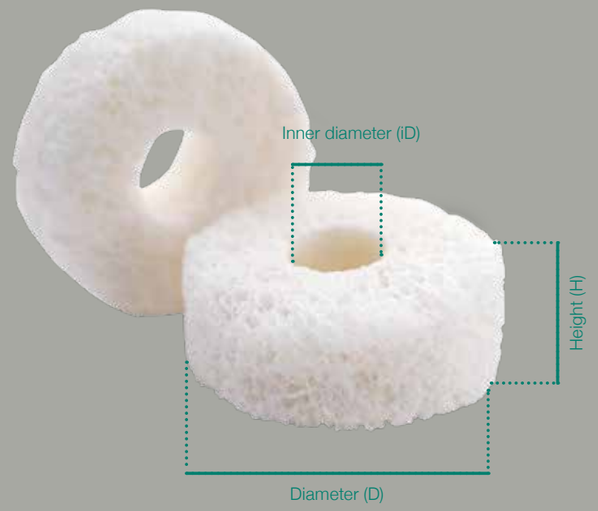
* *Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.*

CANCELLOUS RING

The cancellous ring was specially developed to simplify the reconstruction of the glenoid in a total shoulder prosthesis.

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*

DESCRIPTION	iD [mm]	ITEM NUMBER	D [mm]	H [mm]
Cancellous ring	1,5	ALO431	26	10
		ALO433	32	10
		ALO432	26	20
		ALO434	32	20
	7,7	ALO436	26	10
		ALO437	32	10
		ALO435	26	20
		ALO430	32	20

iD,DxH

iD,DxH

** 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

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

Halved diaphysis

ORDER INFORMATION*

DESCRIPTION	ITEM NUMBER	L [mm]
Halved diaphysis	ALO120	100
	ALO121	150
	ALO122	200

L

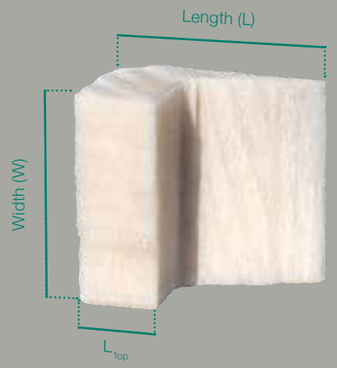
** Please note: Due to the nature of human bone tissue and the technical possibilities of shaping, slight deviations of the specified sizes may occur.*

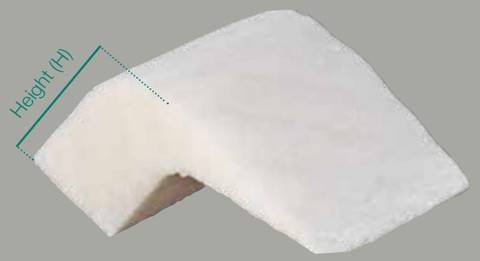
J-CHIP

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.

J-Chip

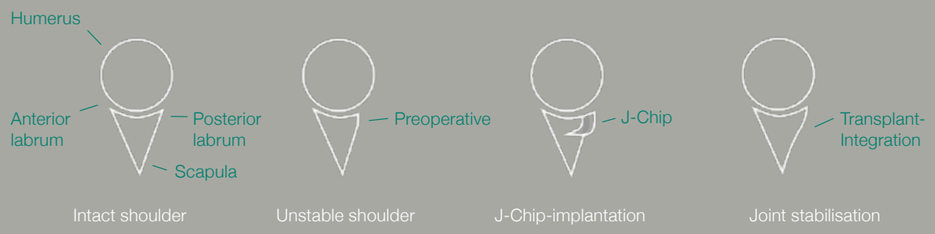
Origin:	Human
Tissue:	Cortical bone
Processing:	Allotec® purification procedure
Inactivation:	Min. SAL10^{-6} for viruses and bacteria
Sterilisation:	Gamma irradiaton
Application:	Shoulder instability
Rehydration:	Min. 10 minutes





J-Chip

Joint Stabilization



Intact shoulder | Unstable shoulder | J-Chip-implantation | Joint stabilisation

ORDER INFORMATION*

DESCRIPTION	ITEM NUMBER	L [mm]	W [mm]	H [mm]	L_{top} [mm]
J-Chip	ALO620	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.

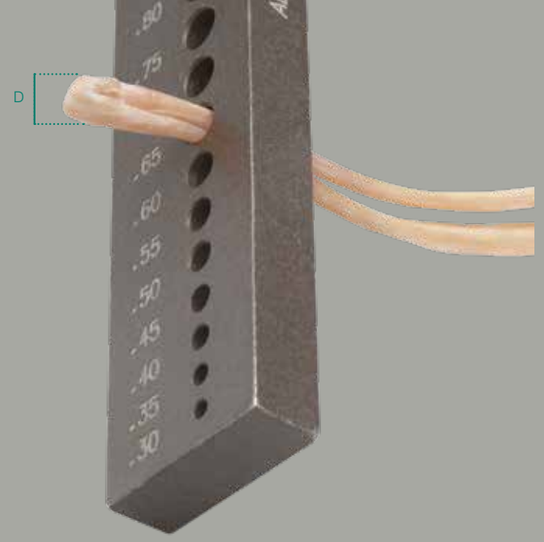
The cleansed soft tissues are offered without gamma irradiation after an obligatory sterility test.
All soft tissues are stored at ≤-40°C and delivered on dry ice.

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



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

Tendons & Ligaments with bone

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

LIGAMENTS AND TENDONS ARE ONLY AVAILBLE IN DENMARK!

* *Please note that the size information above does not reflect all available dimensions. Additional tendon sizes are available upon request. You can find the exact information about ordering on the next page.*

Soft Tissue

ORDER PROCESS

1 ENQUIRY

The responsible surgeon sends a request to BT Medicals.

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.btmedicals.com/request-form.

2 ORDER

BT Medicals either confirms the availability of the graft according to the enquiry or suggests alternatives if the required transplant is not available.

The responsible physician makes a decision based on the proposal of BT Medicals and submits 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.

Patellar ligament with bone, whole

Tunnel filling with bone cylinders

APPLICATION AID

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	2800120
Tray (without application aid) 1 piece	2800150

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

LITERATURE

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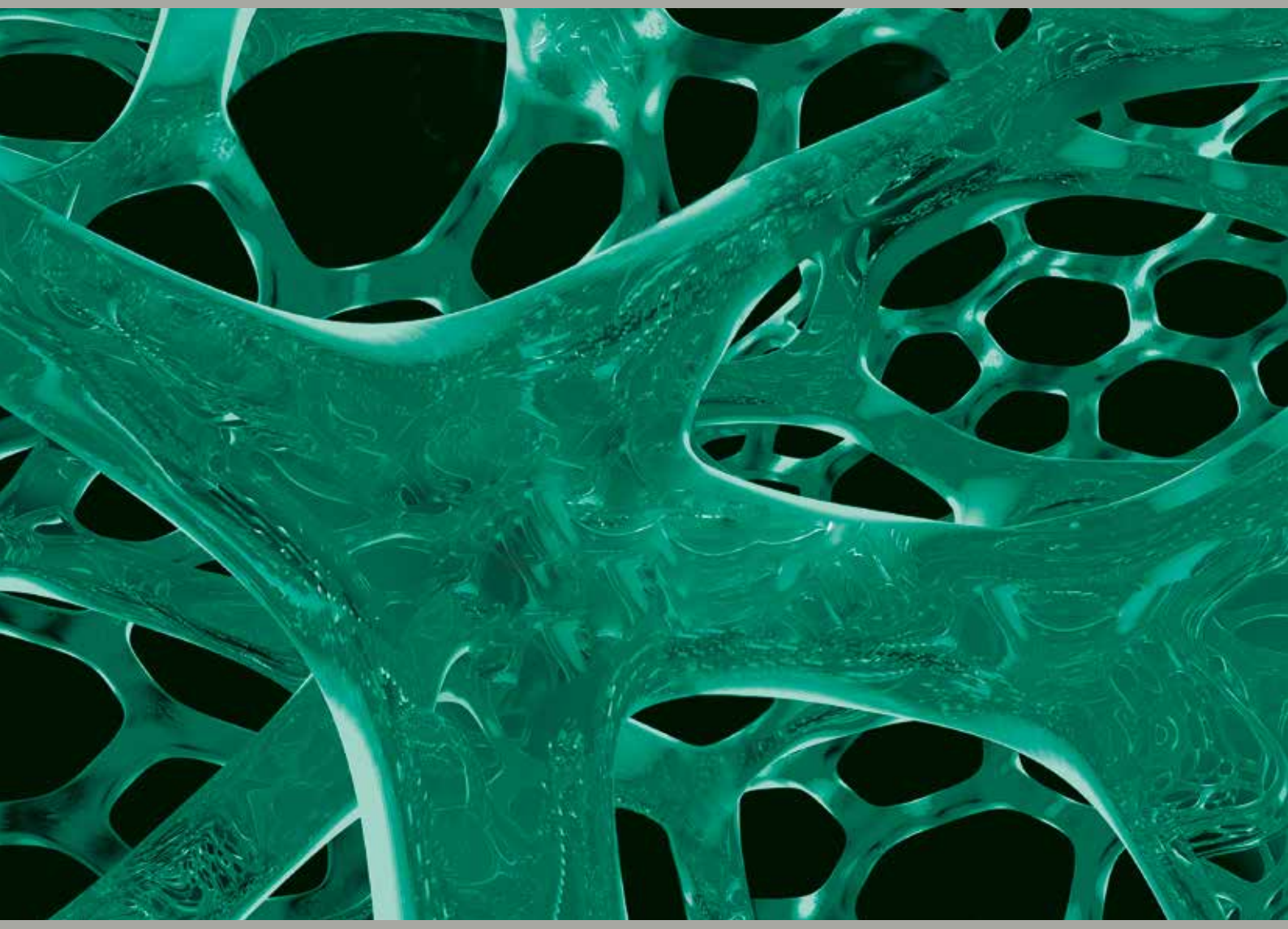

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