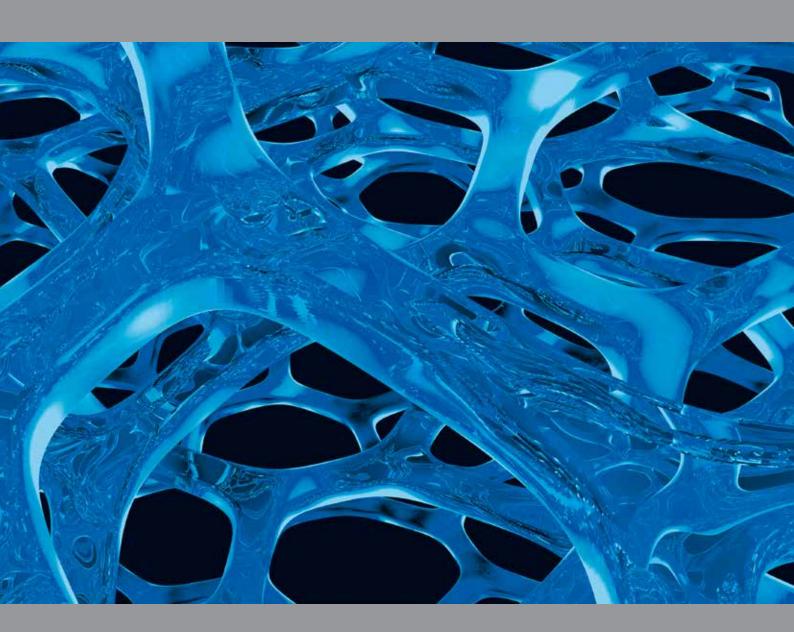


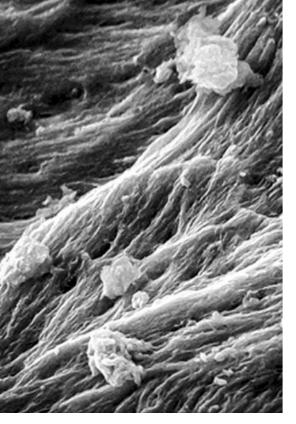


Overview and Order Information

# ALLOGENIC TISSUE







*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	Н
Diameter	D
Inner Diameter	iD
Size	S
Angle	А
Volume	V

## **CONTENT**

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### **CELLS+TISSUEBANK AUSTRIA**

The Cells+Tissuebank Austria (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. C+TBA accompanies and is responsible for the entire process of graft harvesting, from tissue donation to processing with the Allotec® purification procedure and the final distribution by local service partners.

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 safety and effectiveness of the bone transplants was the capacities are constantly being expanded.

Compliance with the highest quality and safety standards has top priority. C+TBA is certified for tissue donation, pro- As a full-service provider for human transplants, C+TBA curement, storage, distribution and import of tissue of the human musculoskeletal system by the Austrian Federal Office for Safety in Health Care (BASG).



confirmed by the Paul Ehrlich Institute as part of a drug approval in Germany.

also provides soft tissue and DBM. The supply in this area is guaranteed by the close cooperation with partner tissue banks in Europe and the USA.



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.<sup>8, 9</sup>

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

#### Recognize 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.¹¹¹ 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.¹¹²

#### 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.<sup>10, 11</sup>

#### 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.<sup>12, 13</sup>

#### 4 Oxidative treatment

The hydrogen peroxide denatures persistent soluble proteins, specifically inactivates uncoated viruses and bacterial endospores, and reduces antigenicity to a minimum.<sup>14</sup> The collagen matrix remains intact.

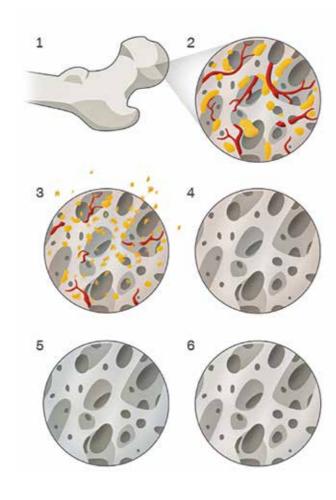
#### 5 Freeze drying

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  $\leq$ 10%, combined with the double packaging, guarantees a shelf life of five years at room temperature.

#### 6 Terminal sterilization

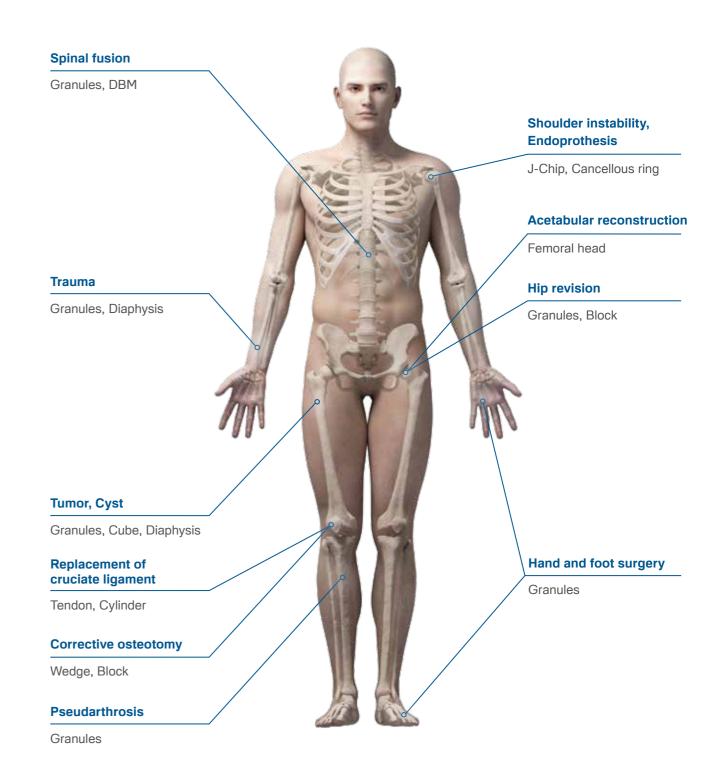
The final tissue-preserving irradiation at a controlled low temperature – together with the preceding cleaning steps – leads to a safety level SAL of  $\geq \! 10^{\text{-}6}.$   $^{15, \, 16}$ 



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.

Cells + Tissuebank Austria gemeinnützige GmbH

Overview - Allogenic Tissue

### **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		ALO319	5
		ALO315	15
		ALO309	30
		ALO317	45
	5-8	ALO326	5
		ALO316	15
		ALO310	30
		ALO331	45
		ALO305	5
		ALO306	15
		ALO307	30
		ALO308	45
	>8	ALO300	15
		ALO301	30
Cancellous Granules -	5-10	ALO350	30
Spierings	2-8	ALO351	10
		ALO352	15
		ALO353	30
Cortico-cancellous		ALO340	15
Granules		ALO341	30
Cancellous Cubes*	5x5x5	ALO325	10
		ALO314	20
Cancellous Granules	< 10	ALO370	5
sawn		ALO371	10
		ALO372	15
		ALO373	30

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

#### **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.



000





Granules saw



Granules Spierings 5-10 mm

# CANCELLOUS GRANULES IN THE APPLICATOR

### Cancellous Granules

Origin: Human

Tissue: Cancellous bone

Processing: Allotec® purification procedure
Inactivation: Min. SAL10-6 for viruses and bacteria

Sterilisation: Gamma irradiation: 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	
	ALO361	15
	ALO362	30

<sup>\*</sup> 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 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: Cancellous bone

Processing: Allotec® purification procedure Inactivation: Min. SAL10-6 for viruses and bacteria

Sterilisation: Gamma irradiation Rehydration: Min. 10 minutes

#### Femoral Head, Bisected

Origin:

Cortico-cancellous bone Allotec® purification procedure
Min. SAL10-6 for viruses and bacteria Processing:

Sterilisation: Gamma irradiation Application: Bone void filler Rehydration: Min. 10 minutes





### **ORDER INFORMATION\***

#### **Bisected Femoral Head**

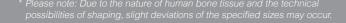
DESCRIPTION	ITEM NUMBER	SIZE
Bisected Femoral Head	ALO446	short
	ALO447	long





#### **Halved Femoral Head**

DESCRIPTION	ITEM NUMBER	D [mm]	H [mm]
Halved Femoral Head	ALO441	< 45	20
	ALO444	> 45	20





### **BLOCKS**

#### **Cancellous Block**

Origin: Cancellous bone

Allotec® purification procedure
Min. SAL10-6 for viruses and bacteria

Application: Bone void filler Rehydration: Min. 10 minutes

#### **Tricortical Block**

Origin:

Tissue: Cortical and cancellous bone Processing: Allotec® purification procedure
Inactivation: Min. SAL10<sup>-6</sup> for viruses and bacteria

Sterilisation: Gamma irradiaton Application: Bone replacement Rehydration: Min. 10 minutes

#### 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

#### **Tricortical Block**

DESCRIPTION	ITEM NUMBER	H1xH2 [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

#### Cortico-cancellous Block

Origin:

Cortico-cancellous bone Allotec® purification procedure Processing: Inactivation: Min. SAL10<sup>-6</sup> for viruses and bacteria

Application: Bone void filler Rehydration: Min. 10 minutes



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









### **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: Cancellous bone

Processing:

Allotec® purification procedure Min. SAL10-6 for viruses and bacteria

Sterilisation: Gamma irradiaton Rehydration: Min. 10 minutes

#### **Cortico-cancellous Wedge**

Origin:

Cortical and cancellous bone Allotec® purification procedure Min. SAL10-6 for viruses and bacteria Processing:

Gamma irradiaton Sterilisation: Application: Corrective osteotomy Rehydration: Min. 10 minutes



### **ORDER INFORMATION\***

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







### **CANCELLOUS CYLINDER**

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

#### **Cancellous Cylinder**

Origin:

Cancellous bone

Allotec® purification procedure Processing:

Min. SAL10<sup>-6</sup> for viruses and bacteria

Gamma irradiaton Application: Tunnel filling Rehydration: Min. 10 minutes

### **CANCELLOUS** RING

#### Cancellous Ring

Origin:

Cancellouse bone Processing:

Allotec® purification procedure Min. SAL10<sup>-6</sup> for viruses and bacteria

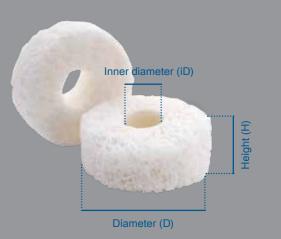
Sterilisation: Gamma irradiaton

Remodelling of the glenoid

in case of shoulder endoprosthesis

Rehydration: Min. 10 minutes





#### **ORDER INFORMATION\***

#### **Cancellous Cylinder**

DESCRIPTION	ITEM NUMBER	D [mm]	H [mm]
Cancellous Cylinder	ALO423	10	20
	ALO424	10	30
	ALO425	12	20
	ALO426	12	30
	ALO427	14	20
	AL 0429	1.4	20



#### **Cancellous Ring**





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

Cells + Tissuebank Austria gemeinnützige GmbH

Overview - Allogenic Tissue

### **J-CHIP**

better support. The round back provides a smooth surtures in combination with e.g. plates. face for soft tissue.

**HALVED DIAPHYSIS** 

Developed in the 1980s, the J-Chip operation is a tech- Cortical bone grafts derived from the femoral or tibial nique used to treat patients with recurrent shoulder dis- diaphysis are used in case additional structural stability is locations after trauma. 18, 19 The J-Chip consists entirely of required, but only if the function is not weight-bearing. An cortical bone, leading to high stability during insertion and application example is the splinting of periprosthetic frac-

#### J-Chip

Origin: Cortical bone

Processing: Allotec® purification procedure Min. SAL10<sup>-6</sup> for viruses and bacteria

Application: Shoulder instability Rehydration: Min. 10 minutes

#### **Halved Diaphysis**

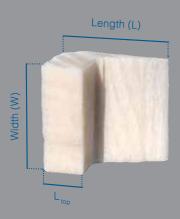
Origin: Cortical bone

Processing:

Allotec® purification procedure Min. SAL10<sup>-6</sup> for viruses and bacteria

Application: Bone replacement Rehydration: Min. 10 minutes







#### **ORDER INFORMATION\***

#### J-Chip

DESCRIPTION	ITEM NUMBER	L [mm]	W [mm]	H [mm]	L <sub>top</sub>
J-Chip	ALO620	15	15	10	5

### **Halved Diaphysis**

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

#### 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.

according to the specifications of C+TBA. A medical history, a donor test for hepatitis B & C, HIV, HTLV, and *Trepo*The cleansed soft tissues are offered without gamma
nema pallidum as well as a PCR test for HBV, HCV, HIV irradiation after an obligatory sterility test. are carried out. The tests are conducted in specially certi- All soft tissues are stored at ≤-40°C and delivered on dry ice.

approved processes, which have been proven to have a depletion potential for infectious agents, but impair the Voluntary and unpaid tissue donations are checked physical properties of the soft tissues as little as possible.



Fresh Frozen

### **TENDONS & LIGAMENTS**

**Tendons & Ligaments** Origin: Human

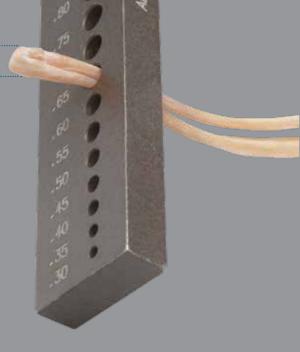
Tissue: Allogenic soft tissue

Processing: Offically approved cleansing procedure

Preservation: Froze

Application: Replacement of tendons

and ligaments



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

#### **ORDER INFORMATION**

#### **Non-bone Tendons**

14

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		230-255	6-8
	AL0771	≥260	6-8
		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				
Patellar ligament with Bone, whole	ALO776		upon request	
Achilles tendon		≥ 150 < 160		
	ALO778	≥ 160		

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.

Soft Tissue

### **ORDER PROCESS**

1	2	3
ENQUIRY	ORDER	SHIPPING

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.

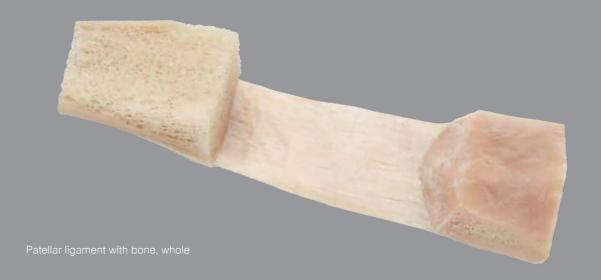
The request form is provided by a local service partner or can be downloaded from www.ctba.at/st-request.pdf.

The C\*TBA 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 C\*TBA and submits the binding order.

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.



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.<sup>20</sup> The current gold standard for tunnel filling is autologous corticocancellous iliac crest graft harvesting.<sup>21</sup> But, the iliac crest donor site is associated with a significant number of complications causing the quest for alternative tunnel filling materials.<sup>22</sup>

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

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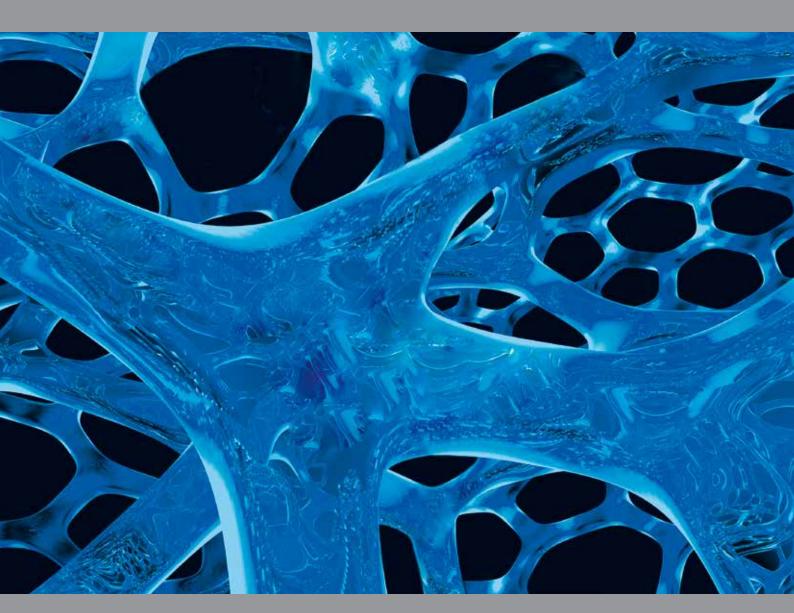
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