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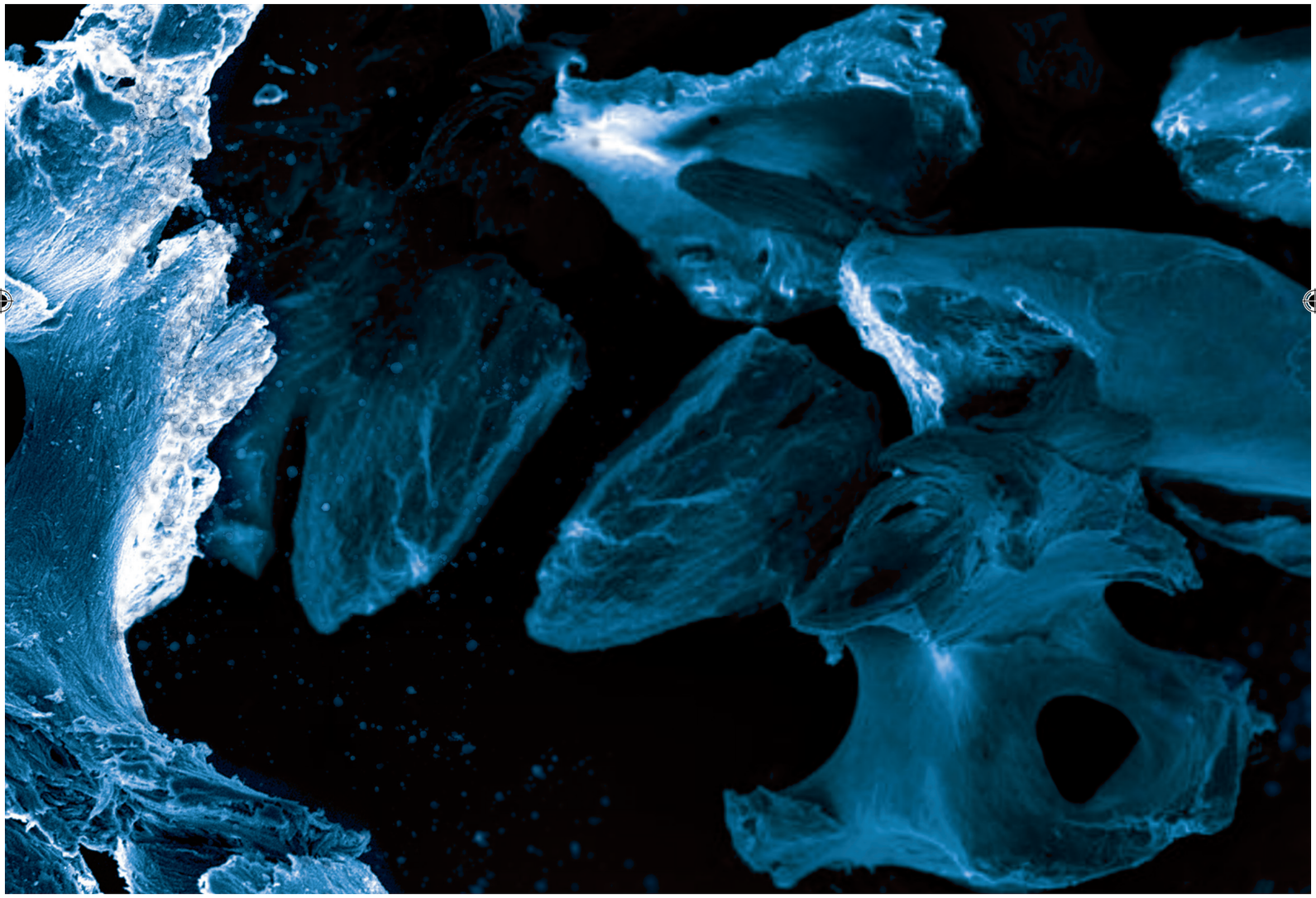
C+TBA
austria

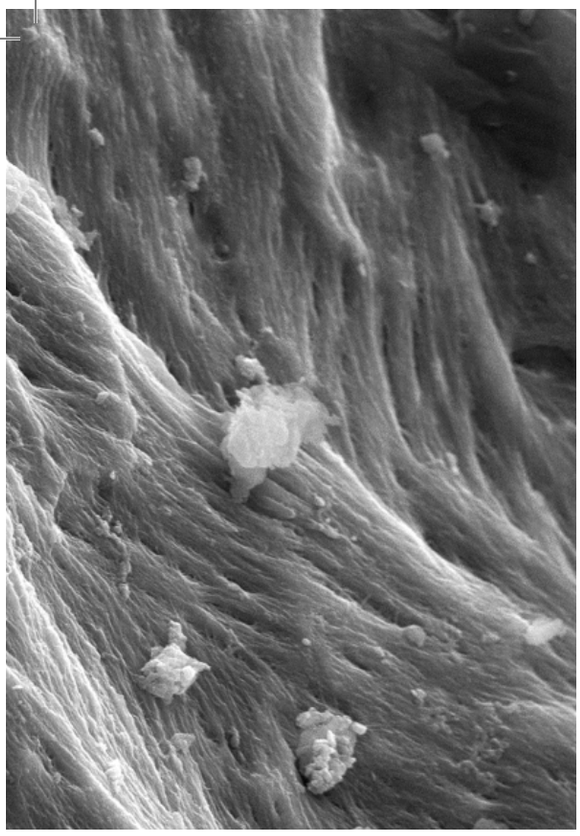
Comprehensive Overview

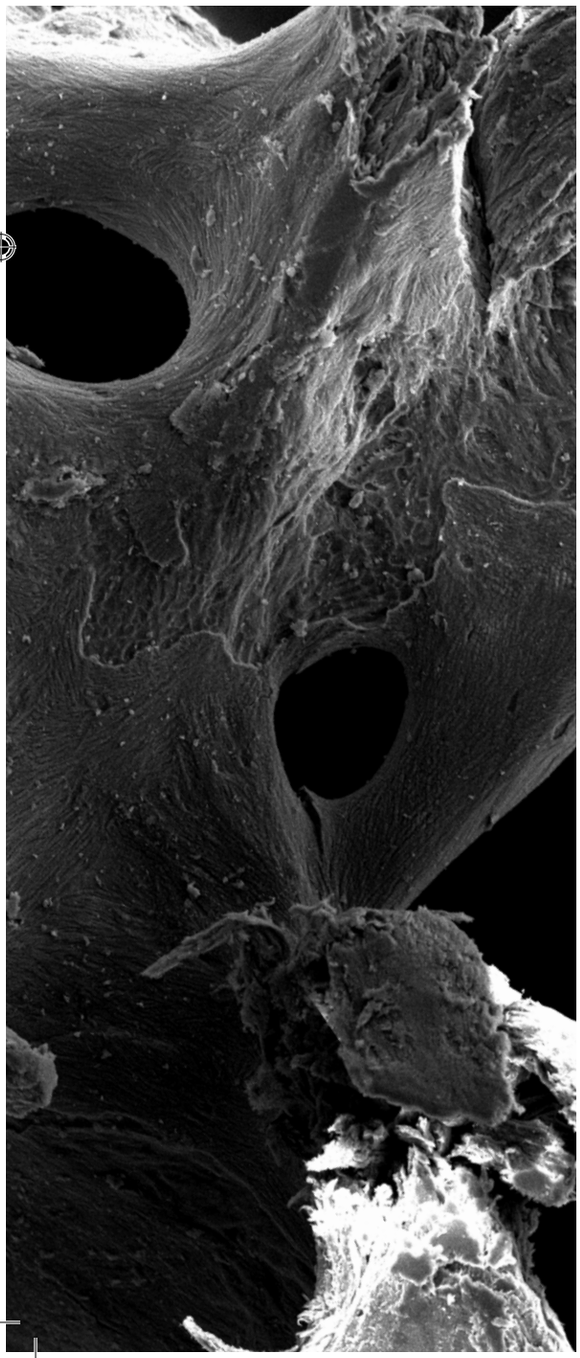
# ALLOGENIC TISSUE



**Cells+Tissuebank Austria**
gemeinnützige GmbH

2019





*Top, bottom:* Scanning Electron Microscopy (SEM) images of C⁺TBA allogenic granules reveal the interconnecting macropores similar to natural bone. Due to the AlloTec purification process, the allografts retain their natural collagen matrix. Higher magnifications show mineralized collagen fibers.

# CONTENT

# ABOUT C+TBA

**Cells+Tissuebank Austria (C+TBA)** is a non-profit tissue bank aiming to meet the continuously growing medical demand for allogenic tissue.

Specialized on human bone grafts, C+TBA is one of only a few tissue banks in Europe controling the entire life cycle of their transplants: from the donation of tissue to the allograft processing with its proprietary AlloTec® purification procedure and finally the distribution *via* competent partners.

At C+TBA, the number one priority is to achieve the highest quality and safety standards for all products. The C+TBA is inspected by the Austrian Federal Office for Safety in Health Care (BASG), follows and implements the European directives (as certified by the Austrian Tissue Safety Act, GSG 2009) and works in compliance with the GMP.

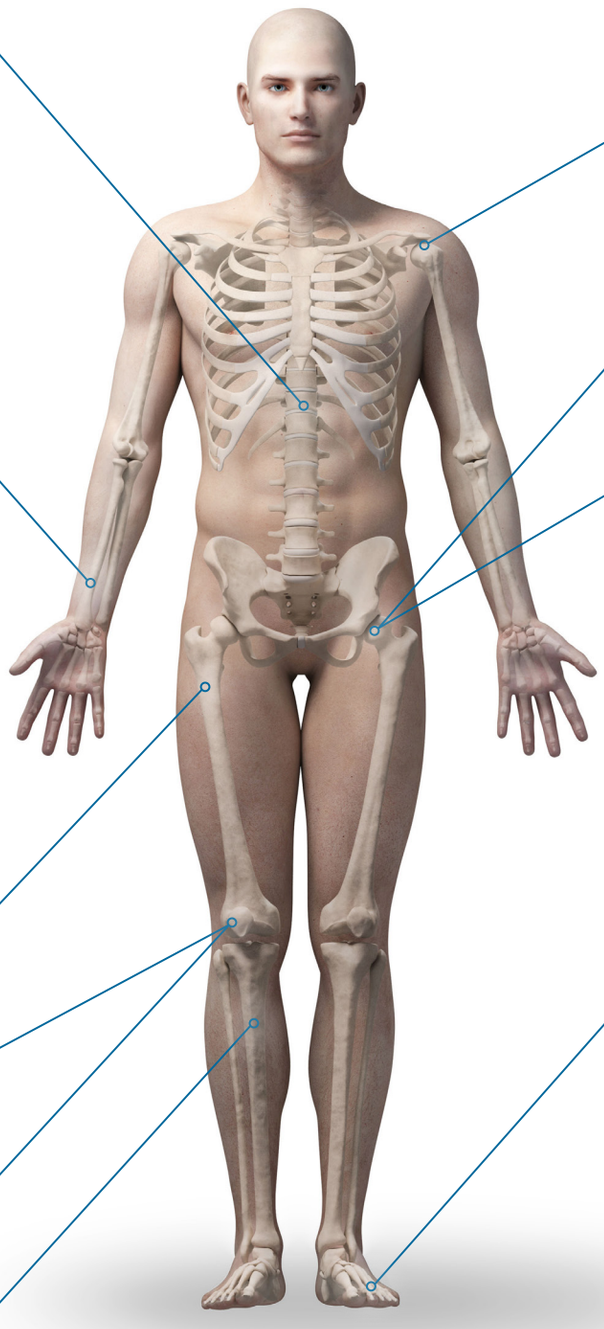
The C+TBA bone was implanted far more than 150,000 times without any documented adverse event. No signs of rejection in any orthopedic implantation procedure have been reported.


*Left, right:* The C+TBA processing facility. The refinement process of the donated tissue is subject to a strictly validated procedure.

Indications &

# ALLOGRAFT USE

*It is advised that the attending physician is solely responsible to decide on the most suitable treatment.*



**Spinal Fusion**

Granules, Struts

**Shoulder Instability**

J-Chip

**Acetabular Reconstruction**

Femoral Head

**Fracture**

Granules, Struts

**Hip Revision**

Granules, Blocks

**Tumor, Cyst**

Granules, Cubes

**Cruciate Ligament Rupture**

Tendons, Cylinders

**Hand or Foot Surgery**

Granules, Struts

**Displacement Osteotomy**

Wedges, Blocks

**Pseudarthrosis**

Granules

# QUALITY & SAFETY

## Allogenic Tissue

A variety of materials is available for the regeneration of lost tissue following trauma, inflammation or tumor removal. Autologous tissue grafts carry no risk of an immunological response and remain the golden standard due to their superior biological properties. However, the availability of autologous bone grafts is limited and its harvest is frequently associated with pain and donor site morbidity.[1-3]

The use of processed allogenic tissue constitutes an excellent alternative to autologous transplants. Vatious studies show that processed allogenic bone and autologous bone do not differ in their immunological compatibility in that no circulating antibodies could be detected in patients who received allografts.[4] Furthermore, it was confirmed that allografts and autografts were radiographically, histologically and morphologically equal in their final incorporation.[5-7]

## Tissue donation and procurement

C+TBA bone allografts are derived from donor tissue and harvested according to quality and safety standards as specified within the European directives.

The cancellous bone graft materials originate from femoral heads of living donors resected during total hip arthroplasty; cortical and cortico-cancellous allografts could also be derived from the femur or distal tibiae of donors within 24 hours post mortem. The bone tissue is then processed individually.

The procurement, standardized by a predefined protocol, is carried out by certified procurement centers. All tissue donations are based on highly selective exclusion criteria with regards to the donor's state of health and performed with their written informed consent.

## Donor Testing

The donated tissue is only released for processing after having passed a thorough inspection, including a strict serological screening protocol to exclude potential infection risks. In addition to antibody (Ab) screening, nucleic acid tests (NAT) are executed to ensure safety.

| Pathogen | Test | Specification |
|---|---|---|
| hepatitis B virus (HBV) | HBsAg, HBcAb, NAT | negative |
| hepatitis C virus (HCV) | Ab, NAT | negative |
| human immunodeficiency virus (HIV 1/2, Ag p-24) | Ab, NAT | negative |
| Treponema pallidum | Ab | negative |

## Viral inactivation

In addition to donor testing, critical viral inactivation steps are implemented during processing, namely dynamic immersion in ethanol, hydrogen peroxide treatment, and gamma irradiation. The viral inactivation steps have been validated for reliability and reproducibility by an independent test facility according to international guidelines.[8, 9]

During the validation, suspensions of model viruses for coated and uncoated DNA viruses (HBV, HAV), and coated RNA viruses (HIV, HCV) have been applied. The process showed an overall efficacy in inactivating all test viruses globally $\geq 6.0$ $\log_{10}$ levels (reference value for efficient viral inactivation $> 4.0$ $\log_{10}$ levels) and may, therefore, be considered effective in removing potential viral contaminants.

Bone purification process

# C⁺TBA ALLOTEC®

C⁺TBA AlloTec® is a multi-level cleansing process developed to achieve a maximum level of safety while preserving the natural integrity of the supporting and connective tissue in a bone graft. Due to the preservation of natural collagen, the graft material retains its biomechanical properties[10] and supports the physiological bone formation and subsequent remodeling (osteoconduction), creating reliable scaffolds for revascularization and migration of osteoblasts and progenitor cells.[17]

### 1 Shaping

After crude removal of surrounding soft tissue, fat and cartilage, the donated bone is shaped into its final form (e.g. blocks, wedges, granules).

### 2 Ultrasonic bath

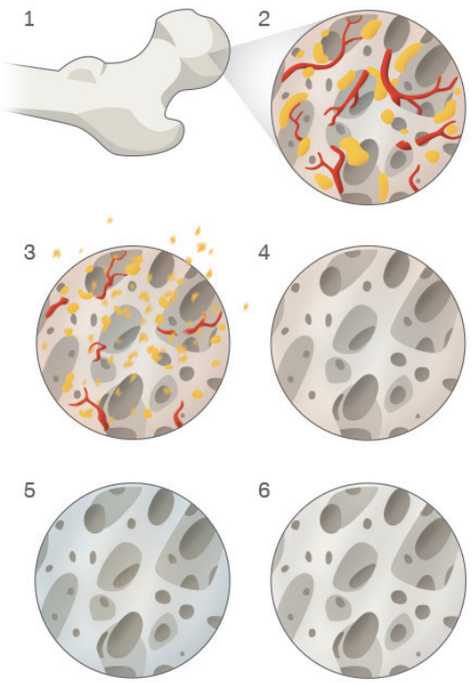
A thorough ultrasound cleaning step removes blood, as well as cell and tissue components. During this step, also fat is detached from the spongy bone, reducing the immunogenic potential and facilitating the successive penetration of reagents during the further process.[10, 11]

### 3 Chemical purification

Alternate rinsing with diethyl ether and ethanol leaches out cellular components and denatures non-collagenous proteins, thereby inactivates potential viruses and destroyes remaining bacteria.[12, 13]

### 4 Oxidative treatment

Hydrogen peroxide denatures persistent soluble proteins, specifically inactivates uncoated viruses and bacterial endospores and reduces antigenicity to a minimum.[14] Insoluble collagen remains intact.



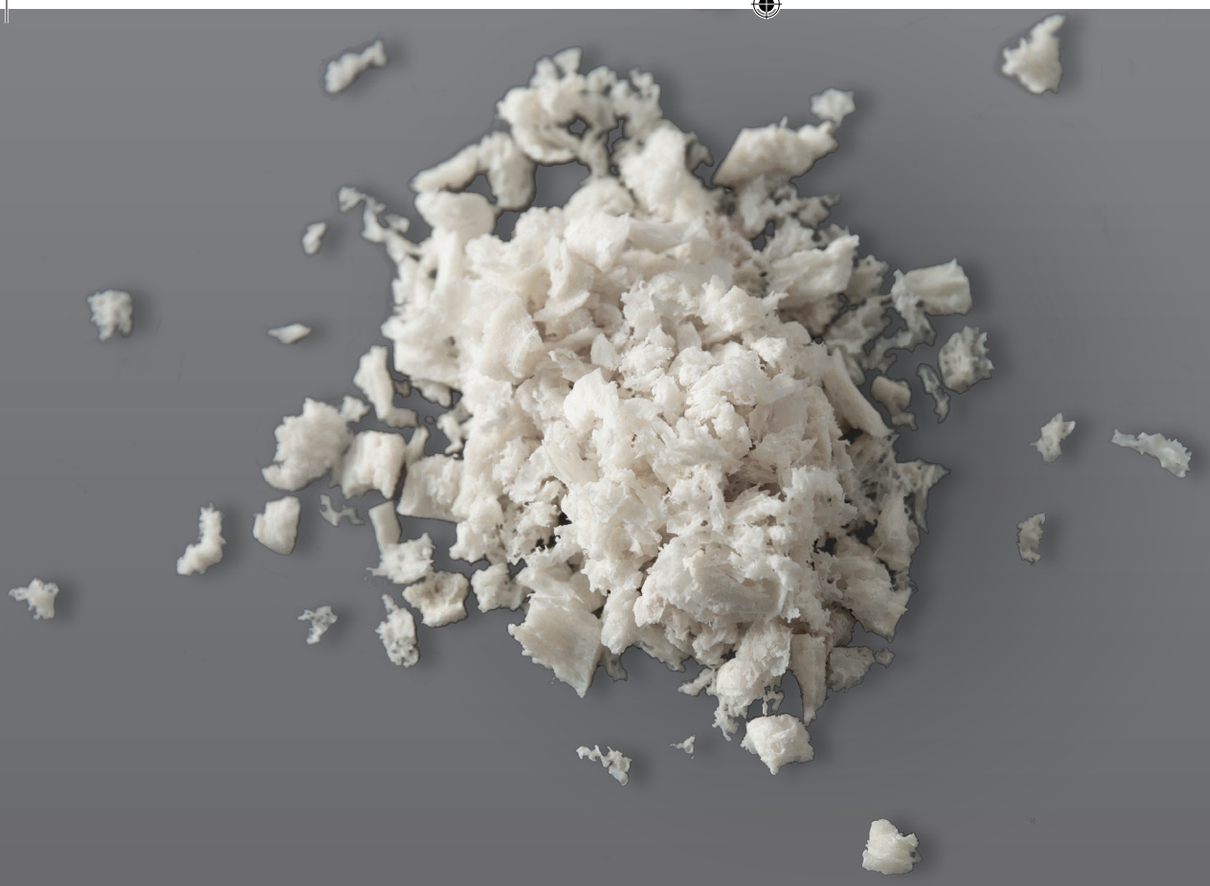

*AlloTec® processing:* 1 - shaping, 2 - ulatrasonic bath, 3 - chemical purification, 4 - oxidative treatment, 5 - lyophilization, 6 - gamma irradiation.

### 5 Lyophylization

Freeze-drying by lyophilization allows a gentle and tissue-preserving removal of water. Due to the lyophilization process, the structural integrity of the material remains unaltered, supporting a fast incorporation of the bone graft. The residual moisture of ≤ 10% facilitates rapid rehydration and product handling.

### 6 Gamma irradiation

The final gamma irradiation at 25 – 35 kGy warrants a sterility assurance level (SAL) of $10^{-6}$. Double packaging ensures a reliable sterility of the product and the packaging while preserving the structural integrity of the graft, and guarantees a five-year shelf life at room temperature.[15, 16]



# GRANULES

## Overview

C+TBA Granules are available as cortico-cancellous granules (containing up to 30% cortical components) and pure cancellous granules. The cancellous structure is always maintained and grants quick incorporation. The applications of cortico-cancellous granules are the same as for cancellous granules, but due to the cortical components, cortico-cancellous granules provide an increased stability in case of impaction.

The particle sizes are chosen according to the purpose of the application and the defect size. Examples of use are cysts as well as defects after endoprosthesis loosening.

| Description | Size | Unit of Measure |
|---|---|---|
| Cancellous granules | 2 - 5 mm | 5 ml |
| | | 15 ml |
| | | 30 ml |
| | | 45 ml |
| | 2 - 8 mm | 5 ml |
| | | 15 ml |
| | | 30 ml |
| | | 45 ml |
| | 5 - 8 mm | 5 ml |
| | | 15 ml |
| | | 30 ml |
| | | 45 ml |
| Cortico-cancellous granules | 2 - 8 mm | 15 ml |
| | | 30 ml |

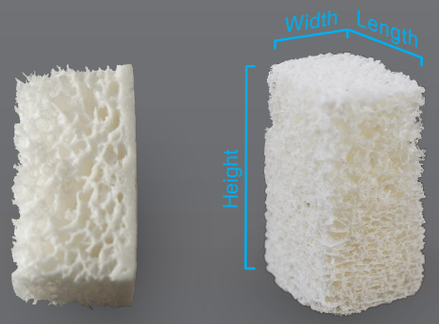
# STRUCTURAL GRAFTS

## Overview

Primary anchorage and good incorporation. Structural grafts are, alone or in combination with granules, suited for one void filling.

## Block

| Description | Size (WxLxH) | Unit of Measure |
|---|---|---|
| Cancellous block | 10 x 10 x 10 mm | 1 pce |
| | 10 x 10 x 20 mm | |
| | 10 x 10 x 30 mm | |
| | 15 x 15 x 30 mm | |
| Unicortical cancellous block | 10 x 10 x 10 mm | 1 pce |
| | 10 x 10 x 20 mm | |
| | 10 x 10 x 30 mm | |




## Cubes

| Description | Size (WxLxH) | Unit of Measure |
|---|---|---|
| Cancellous cubes | 5 x 5 x 5 mm | 10 ml |
| | | 20 ml |

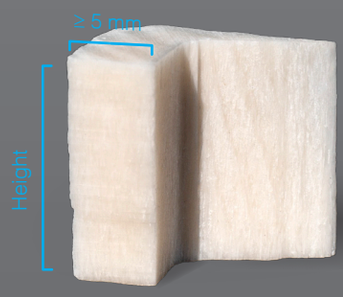
## Cylinder

| Size | Unit of Measure |
|---|---|
| 20 mm, Ø 10 mm | 1 pce |
| 30 mm, Ø 10 mm | 1 pce |

# J-CHIP

## Overview

The J-Chip consists entirely of cortical bone, leading to higher stability during insertion and better support. A round back provides a smooth surface for soft tissue.



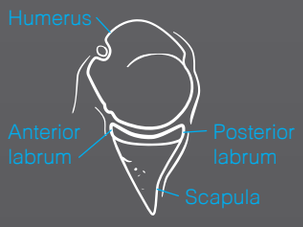

## J-chip surgery

The J-Chip surgery is a technique developed in the 1980s for the treatment of patients with repeated shoulder dislocations after trauma.

The shoulder joint consists, in simple terms, of a large ball and a small socket. The cause of shoulder instability is often a bony defect in the already naturally small joint socket. Similarly to glenoid osteoplasty, the goal of the J-Chip surgery is to compensate for this defect, anatomically reconstruct the joint socket, and thereby stabilize the shoulder again.

The advantage of the J-Chip surgery over other techniques is fixation without the need for any additional attachment by foreign matter (e.g. screws).

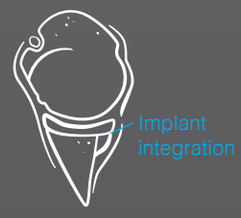
| Size | Unit of Measure |
|---|---|
| 15 x 15 mm | 1 pce |




*Intact shoulder*


*Before surgery*


*J-Chip implantation*




*Healed implant*

# FEMORAL HEAD

## Overview

A specific kind of block, mostly used in the case of acetabular reconstruction, alone or in combination with granules. Halved femoral heads are available in two different diameters (<45mm and >45mm). The height is 20 mm.


*Halved femoral head*

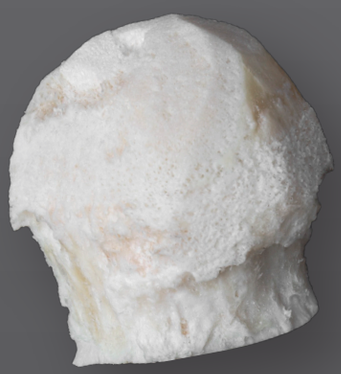
## Halved femoral head

| Size | Unit of Measure |
|---|---|
| Ø < 45 mm | 1 pce |
| Ø > 45 mm | 1 pce |

## Bisected femoral head

| Description | Size | Unit of Measure |
|---|---|---|
| Short | Ø < 45 mm | 1 pce |
| Long | Ø > 45 mm | 1 pce |

*Bisected femoral head - short*



*Bisected femoral head - long*

# TENDONS & LIGAMENTS

## Non-bone tendons

| Description* | Size |
|---|---|
| Semitendinosus | 230 - 255 mm |
| | ≥ 260 mm |
| Gracilis | 230-255 mm |
| | ≥ 260 mm |
| Tibialis, anterior | 230-255 mm, Ø: 6-8 mm |
| | ≥ 260 mm, Ø: 6-8 mm |
| | 230-255 mm, Ø: ≥ 9 mm |
| | ≥ 260 mm, Ø: ≥ 9 mm |
| Tibialis, posterior | 230-255 mm, Ø: 6-8 mm |
| | ≥ 260 mm, Ø: 6-8 mm |
| | 230-255 mm, Ø: ≥ 9 mm |
| | ≥ 260 mm, Ø: ≥ 9 mm |

**Unit of measure:* 1 pce


## Achilles tendon

| Size | Unit of Measure |
|---|---|
| ≥ 150 < 160 mm | 1 pce |
| ≥ 160 mm | 1 pce |

## Patellar ligament

| Description | Unit of Measure |
|---|---|
| Patellar ligament with bone, whole | 1 pce |
| Patellar ligament with bone, bisected | 1 pce |

*Images top to bottom:* non-bone tendon; non-bone tendon - diameter measurement; achilles tendon; patellar ligament - with bone, whole and bisected.

## How to order

First a request of the attending surgeon, including particular information regarding the patient (eg. weight, gender), the precise specification of the favored graft, and the delivery, has to be submitted to C⁺TBA or a distribution partner of C⁺TBA. A respective order form could be downloaded from the C⁺TBA website or will be supplied by the local partner of C⁺TBA.

Based on the availability C⁺TBA will simply return a confirmation or - in case the favored transplant would not be exactly available - C⁺TBA will suggest alternative grafts.

The attending surgeon will make his concluding decision along the proposal of C⁺TBA and send the final order. The transport of the transplant will be conducted in a validated shipping box. Storage in the box is possible for up to five days, including the days of shipment. With respect to transportation issues, the preferred days for surgery are Tuesday to Thursday. Finally, the datalogger, optionally added to the shipping box to record the temperature during the transportation, has to be returned to C⁺TBA.

## Our partners

In the field of soft tissue transplants, C⁺TBA cooperates with the National Cell and Tissue Centre in the Czech Republic and Community Tissue Services in the USA.

Community Tissue Services®

**Community Tissue Services (USA)**
is registered with the Food and Drug Administration (FDA), accredited by the American Association of Tissue Banks (AATB) and maintains all applicable state licenses. The basis for Community Tissue Services' research and development operations is to be on the forefront of technology, while ensuring that he available allografts have the highest quality of performance for patient recovery and effectiveness.

All Community Tissue Services donors are tested for transmissible diseases using FDA-licensed, approved, or cleared donor screening test kits.

Additionally, each individually recovered tissue undergoes pre-processing microbiological cultures to ensure pathogenic organisms are not introduced to the processing environment.

www.communitytissue.org

národní centrum tkání a buněk

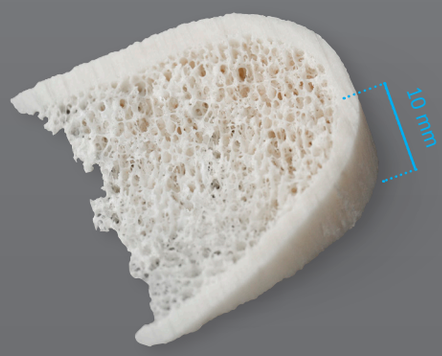
**The National Cell and Tissue Centre (Czechia)**
is an innovative company focused on the development and production of Advanced Therapy Medicinal Products (ATMPs) and tissue and cell processing in highest quality according to the Good Manufacturing Practice (GMP) system. The processing is carried out in compliance with the valid legislation of the Czech Republic and the European Union.

The mission of the National Tissue Centre is to help physicians return patients to a full, active life.

www.natic.cz/en

# WEDGE

**Overview**
Wedges are a specific kind of cortico-cancellous block, mainly used in displacement osteotomy. C+TBA wedges are 10 mm high at the cortical side and preshaped at an 15° angle.




| Angle | Unit of Measure |
|---|---|
| 15° | 1 pce |

# HALVED DIAPHYSIS

**Overview**
Cortical struts produced from the femoral diaphysis contain the most cortical part of the bone. Struts are used where stability is required. Examples of use are the splinting of periprosthetic fractures or augmentations of stress shielding zones.

| Size | Unit of Measure |
|---|---|
| 100 mm | 1 pce |
| 150 mm | 1 pce |
| 200 mm | 1 pce |

# LITERATURE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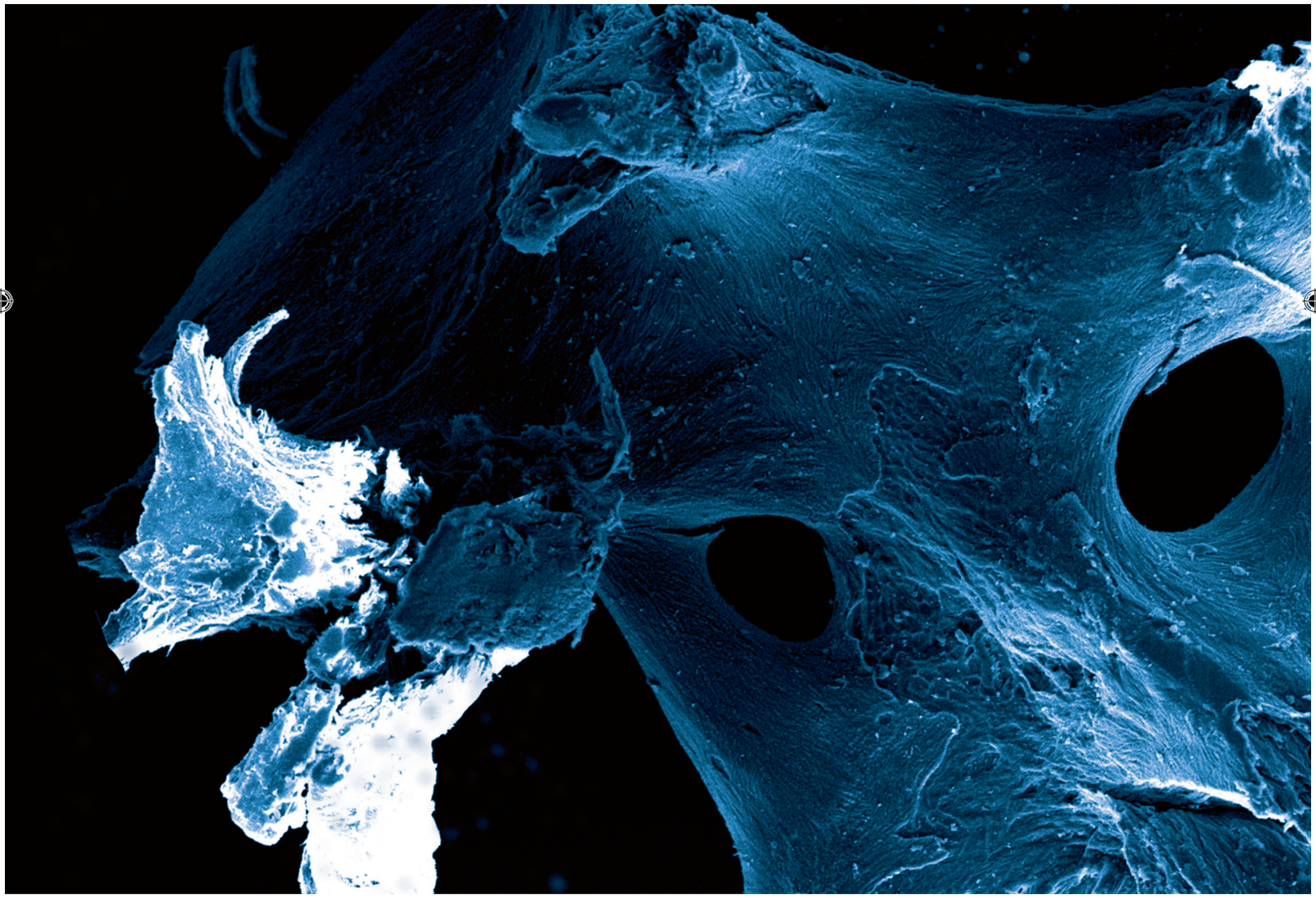

Overview V 2.0 / 09.2018

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