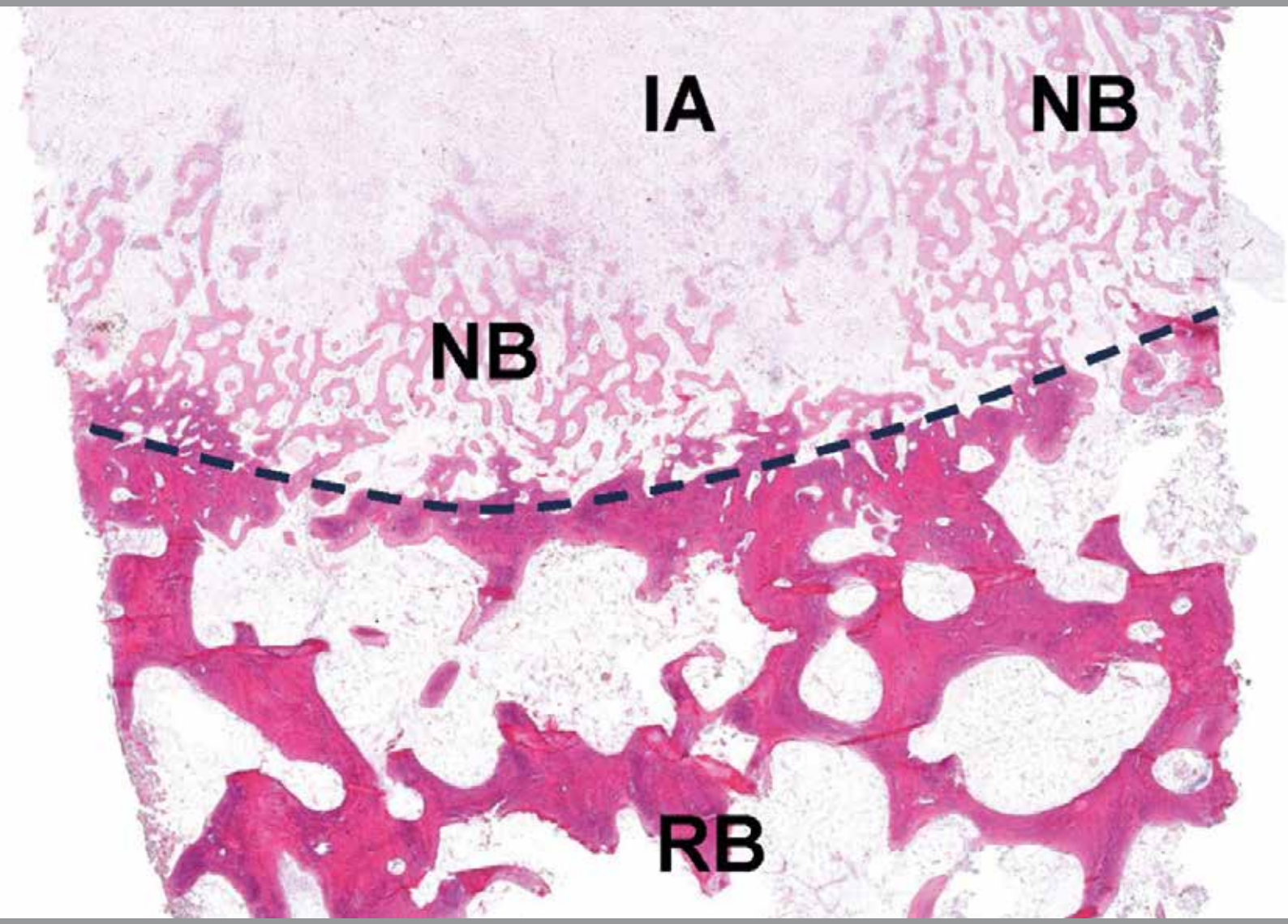
JOINTLY
BUILDING BRIDGES

C+TBA
austria

Overview and Order Information

ALLOGRAFT C+TBA GRANULES+HyA



Sticky Bone

Take Initiative

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 path of the allogenic grafts, from tissue donation to processing with the Allotec® purification procedure and the final distribution.

C⁺TBA grafts are safe, indication-based and easy to use. As a full-service tisseu establishment in the area of the musculoskeletal system C⁺TBA also provides soft tissue grafts and DBM.

Allograft C⁺TBA+HyA

INTRODUCTION

Allograft C⁺TBA Granules+HyA consists of 60 % allogenic bone granules and 40 % sodium hyaluronate powder (HyA). By adding WFI or 0.9 % NaCl solution, the sodium hyaluronate develops pasty properties and connects the bone particles. The allogenic bone granules are easier to handle in the paste and stay in situ after application.

Allograft C⁺TBA Granules+HyA

Allograft C⁺TBA Granules+HyA is composed of allogenic bone granules and sodium hyaluronate.

The bone granules can consist of cortical, cortico-cancellous, or cancellous bone tissue, which is lyophilised before the grinding process.

Hyaluronate is one of the most hygroscopic molecules. The hydrophilicity of hyaluronate is the fundamental property for controlling tissue hydration and osmotic balance. Hyaluronate can bind up to 1000 times its own weight in water.[1]

Application

Allograft C⁺TBA Granules+HyA is used to fill bone defects and is applied in spinal surgery, orthopaedics and trauma surgery as well as in the dental field.

Allograft C⁺TBA Granules+HyA must be hydrated before use. Mixing with liquid isconducted directly befor application and can take place in the primary packaging. The addition of WFI or 0.9 % NaCl solution results in a pasty consistence. This facilitates the application of the bone particles and keeps the graft in situ.
The amount of liquid required depends on the product volume is defined in the instructions for use.

Recognize Potentials

PROPERTIES

Consistence | Can be varied by the user depending on the amount of liquid added – mouldable to pasty

Safety | Donor history, validated serological and microbiological tests and validated inactivation of viruses and germs during the Allotec® purification procedure

Storage | The shelf life of the product is three years when stored between 5 °C and 25 °C.

Implant stability | Resistant to flushing out by body fluids and resistant to body temperature

Usage | Ready for use immediately after mixing and easy to apply

Water retention | Hyaluronic acid can bind large quantities of fluids.

Mixture with WFI or 0.9 % NaCl solution in primary packaging

Consistence: mouldable

Easy application

Consistence: pasty

Take Responsibility

QUALITY & SAFETY

Certification

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

Processing

To produce Allograft C⁺TBA Granules+HyA, the allogenic bone tissue is first prepared using the Allotec® purification procedure (see “Safety”).

The cleaned bone granules are mixed with 40 % sodium hyaluronate powder. Sodium hyaluronate has - as a matrix component - the potential to trigger a change in cell behaviour, which can lead to faster new bone formation.[2]

To achieve the paste-like consistency of the product, liquid (WFI, 0.9 % NaCl solution) must be added before application. The amount of liquid required for different volumes can be found in the instructions for use.

Safety

The donated tissue is selected according to the strictest criteria and will only be released for processing after prescribed tests to minimise potential infection risks.

The allogenic bone tissue is processed using the Allotec® purification procedure to ensure the highest level of safety. C⁺TBA’s Allotec® purification procedure is multi-stage and based on highly volatile reagents.

The depletion potential of the Allotec® purification procedure was validated by an independent laboratory. This showed a reduction of all test viruses and bacteria of at least 6.0 Log10, which corresponds to pharmaceutical safety standards.[3]

Quality

The final, tissue-protecting irradiation at a controlled low temperature guarantees the sterility of Allograft C⁺TBA Granules+HyA (safety level SAL of $\geq 10^{-6}$).[4,5]

Allograft C⁺TBA Granules+HyA can be stored at room temperature and therefore does not require any refrigeration capacity.

Centrifugation of blood samples in preparation for serological testing

Optical in-process control

Gain Insights

PRECLINICAL INVESTIGATION

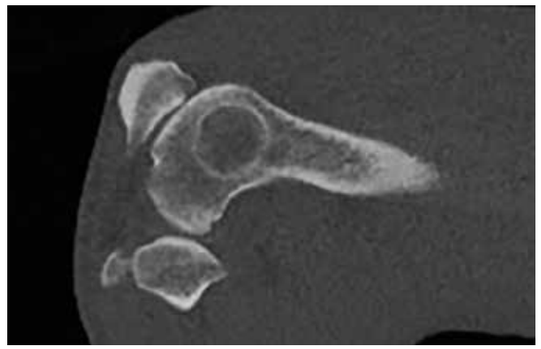
An in vivo study was conducted with Allograft C⁺TBA+HyA in accordance with DIN EN ISO 10993-2:2006/ILAR guidelines at the University of Graz.[6] The aim of the study was to investigate the biocompatibility and regeneration potential of Allograft C⁺TBA+HyA.

The study comprised 12 female sheep, each of which had 7–10 ml of Allograft C⁺TBA Granules+HyA implanted into a defect in the femoral head. After a period of 6 weeks, the femoral head was removed for histopathological evaluation.

The histological examination showed no excessive inflammation within the implantation areas. The values are comparable with other biodegradable bone substitutes or biomaterials known to be biocompatible.[7, 8, 9, 10]

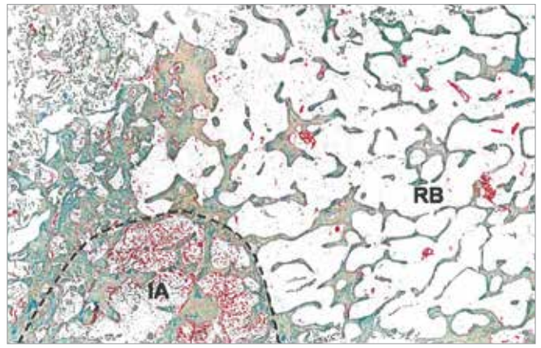
In the biopsies shown below, there is clearly pronounced new bone formation. The results of this preclinical study suggest that the application of the bone substitute material supports the potential for secondary bone healing.

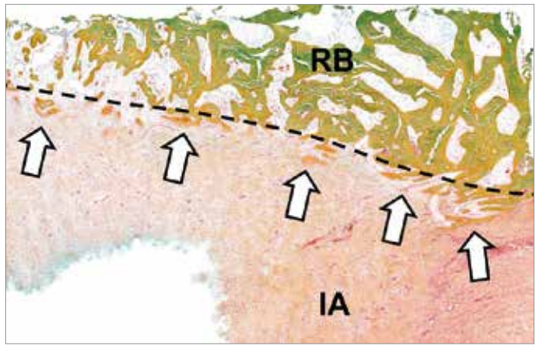
The in vivo study has shown that the application of Allograft C⁺TBA Granules+HyA does not cause any inflammatory tissue reactions, is biocompatible and supports the bone healing process.



Femoral head with the filled defect p.op.

Native graft site after 6 weeks. Early phase of secondary bone healing





Overview of the biopsies. IA and dashed line = implantation area, RB = residual bone, arrows = ingrowing bone tissue (Movat’s Pentachrome staining, 100x magnification)

ORDER INFORMATION

Allograft C+TBA Granules+HyA
Tissue Origin: Human
Composition: Allogenic bone tissue and sodium hyaluronate
Processing: Allotec® purification procedure
Inactivation: Min. SAL 10^{-6} for viruses and bacteria
Sterilisation: Gamma irradiation
Application: Bone void filler
Rehydration: Mixing with WFI or NaCl solution.

DESCRIPTION	GRAIN SIZE [mm]	ITEM NUMBER	VOLUME [cc/ml]
Cancellous Granules 0,25–1 mm (S) +HyA	0,25 – 1	ALO535	1,0
		ALO536	2,0
		ALO537	5,0
		ALO538	10,0
Cortico-cancellous Granules 0,25–1 mm (S) +HyA	0,25 – 1	ALO530	1,0
		ALO531	2,0
		ALO532	5,0
		ALO533	10,0
Granules <0,25 mm (XS) +HyA	< 0,25	ALO540	1,0
		ALO541	2,0
		ALO542	5,0
		ALO543	10,0

Gr. Size

Gr. Size

LITERATURE

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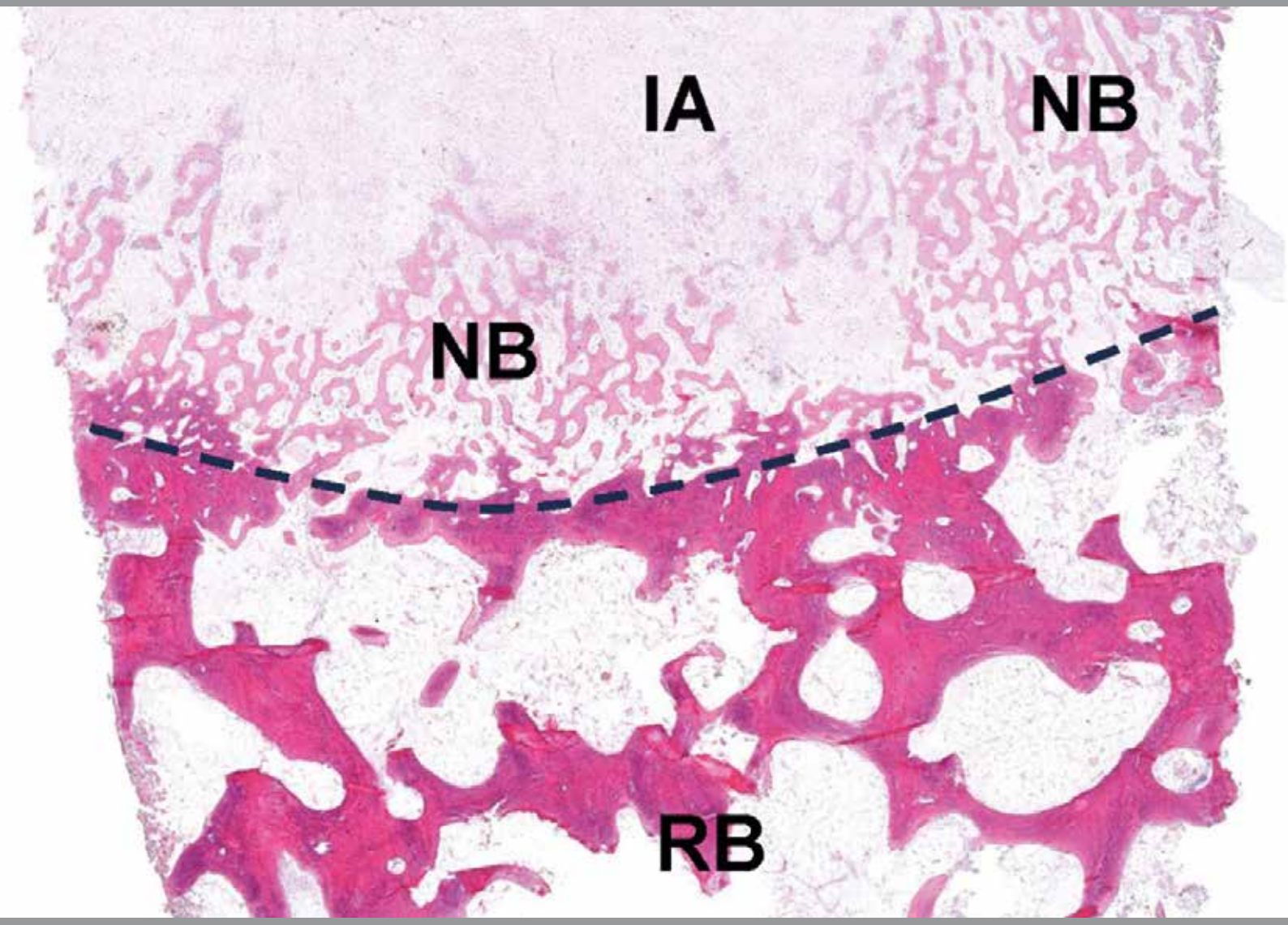

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