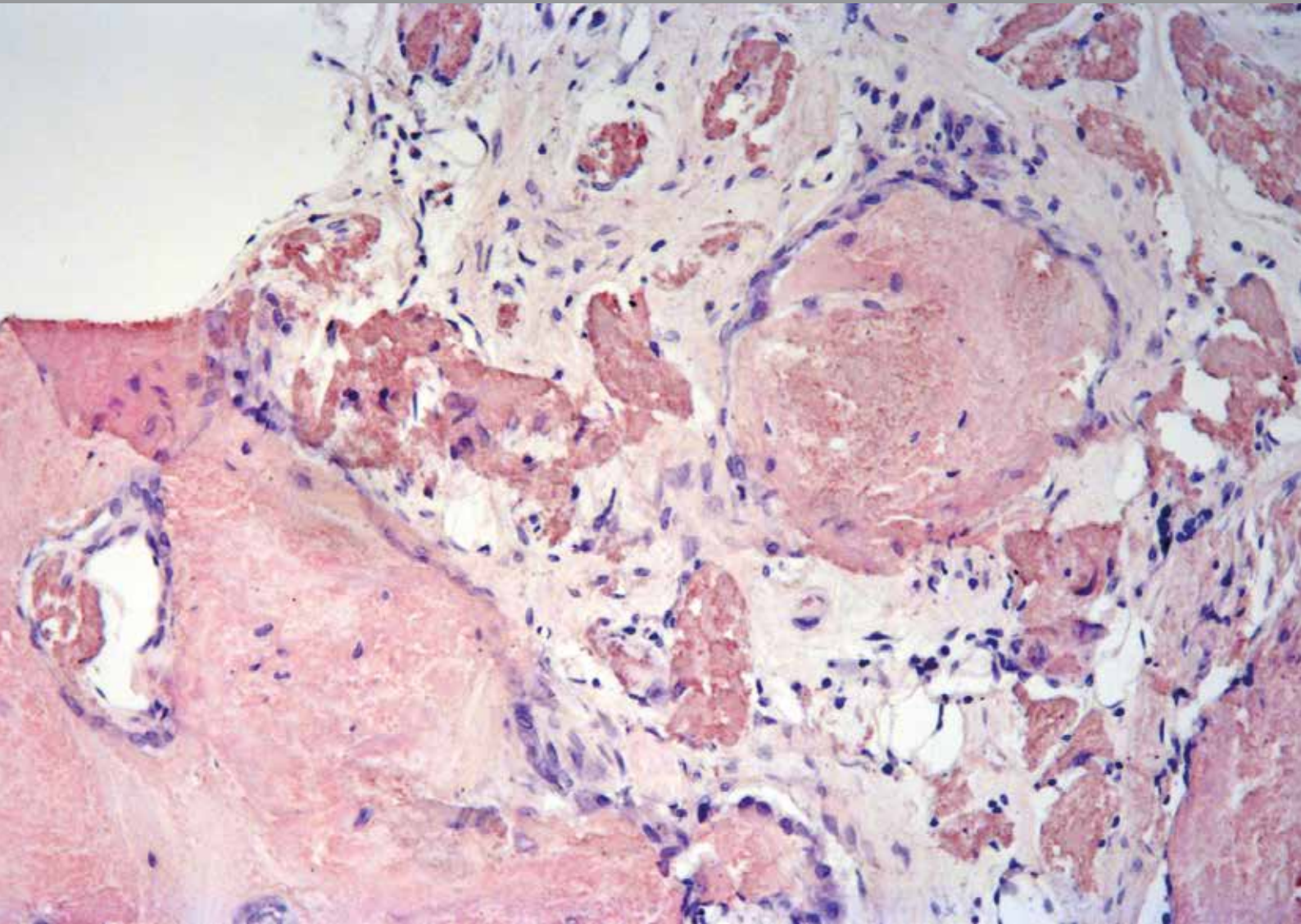


AlloHeal® C+TBA

DBM PUTTY



Demineralised Bone Matrix

INTRODUCTION

AlloHeal® C+TBA DBM Putty consists of 100% demineralised, allogenic bone of human origin with no carrier substances. AlloHeal® C+TBA DBM Putty is proven to be osteoinductive, meaning it promotes bone growth, and thereby contributes to rapid bone healing.

Demineralised Bone Matrix (DBM)

Bones are composed of about 70% mineral and 30% organic components. The mineral part consists primarily of calcium phosphate in the form of hydroxyapatite. The organic part is composed of 90% Type I collagen and 10% non-collagenous proteins and fat. The bone marrow consists of haematopoietic cells, bone marrow fatty tissue and supporting stroma cells.^{1,2}

The demineralisation process reduces the calcium content of the bone, making both the collagen and the non-collagenous proteins, such as BMPs, readily accessible. The latter give the transplant its osteoinductive property.³

Transplants made of demineralised bone matrix can consist of cortical or cancellous bone or a combination of the two.

Applications

AlloHeal® C+TBA DBM Putty is intended for use in remodeling small to medium-sized bone defects in orthopaedic, trauma and spinal surgery as well as in sports medicine. It is also used in dental and maxillofacial surgery.⁴ Biocompatibility and osteoinductivity promote rapid bone remodeling.⁵

The paste-like consistency of the putty makes it easy to manipulate and create a form-fit application in the defect. The transplant retains its stable shape in the event of bleeding or during gentle lavage.

Demineralised bone matrix (DBM) contains an abundance of biologically active bone morphogenic proteins (BMPs) that give rise to DBM's osteoinductive properties. Thus far, many different BMPs have been identified in human bone tissue, of which four possess known osteogenic properties.⁶

Fields of application for AlloHeal® C+TBA DBM Putty include:

- Remodeling bone defects
- Vertebral fusion
- Malunion



PROPERTIES

100% Allogenic Bone Tissue | Processed bone tissue with no carrier material used

Safety | Donor medical history, serological and microbiological testing, as well as validated inactivation of viruses and germs during the Allotec® purification procedure

Ready-to-use | No mixing required, immediately ready for use as a mouldable tissue graft from the applicator

Stable for Implantation | Resistant to erosion by bodily fluids and stable at body temperature

High Regenerative Potential | Preservation of the natural structure and properties of the collagen through a gentle purification process

Easy Storage | At room temperature



Conical luer slip for precise application



A range of volumes: 1 ml, 2.5 ml, 5 ml, 10 ml - READY TO USE



Mouldable



Stable for implantation

QUALITY & SAFETY

Certification

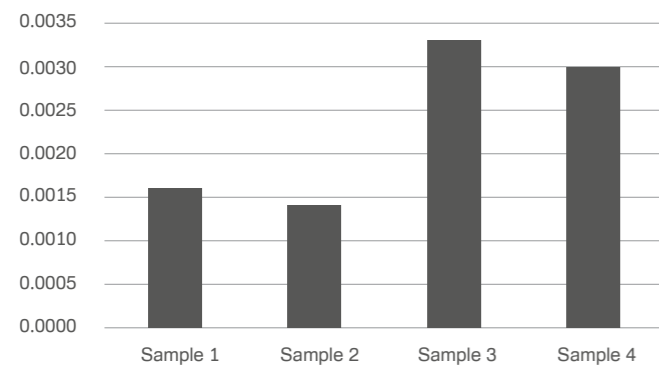
C+TBA is certified by the Austrian Federal Office for Safety in Health Care (BASG) for the donation, procurement, storage, distribution and import of tissue from the human musculoskeletal system.

Manufacture

The meticulous manufacture of AlloHeal® C+TBA DBM Putty serves as the foundation for the highest quality and safety of the transplant.

The allogenic bone tissue is prepared using the Allotec® purification procedure (see Safety). The demineralisation process is then carried out on the bone tissue. To preserve the osteoinductive properties of the bone tissue, gentle demineralisation is conducted with low-molar hydrochloric acid. The organic matrix therefore remains intact and the risk of transmitting pathogens is reduced.⁷

The EDQM Guideline prescribes a maximum calcium content of 5% after demineralisation.⁸ AlloHeal® C+TBA DBM Putty has a residual calcium content of less than 0.1%. The graph below shows the calcium content of the AlloHeal® C+TBA DBM Putty after the demineralisation process.



Calcium content [%] after demineralisation

Safety

Stringent inspections throughout the entire manufacturing process ensure the consistent quality and functionality of AlloHeal® C+TBA DBM Putty. The required inspections cover various parameters, including microbiological tests, the final calcium content and osteoinduction testing.⁸

A cytotoxicity test was conducted in accordance with ISO standard 10933-5.

The allogenic bone tissue is prepared using the Allotec® purification procedure to ensure the highest level of safety. The Allotec® purification procedure of C+TBA has multiple stages and employs volatile reagents.

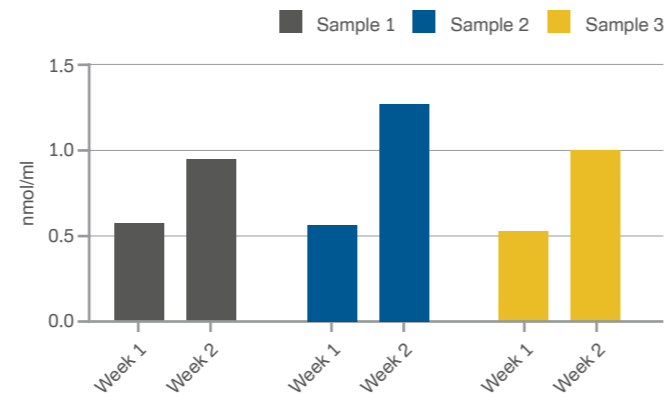
The depletion potential of the Allotec® purification procedure has been validated by an independent laboratory. The results demonstrated a reduction in all test viruses and bacteria of at least 6.0 log₁₀. This complies with pharmaceutical safety standards.

The Allotec® purification procedure from C+TBA is therefore proven to be effective.^{9,10}

The Austrian Agency for Health and Food Safety (AGES) evaluates the bioburden of each batch.

Quality

Osteoinductivity of AlloHeal® C+TBA DBM Putty is verified using alkaline phosphatase, a marker protein for bone growth.



Osteoinductivity of the AlloHeal® C+TBA DBM Putty

The concluding, tissue-preserving irradiation conducted at a controlled low temperature ensures the sterility of the AlloHeal® C+TBA DBM Putty (SAL safety level of $\geq 10^{-6}$).^{11,12}

DBM Putty can be stored at room temperature and therefore does not occupy any refrigeration capacity.

PRECLINICAL INVESTIGATION

In order to demonstrate the regenerative potential of AlloHeal® C+TBA DBM Putty, a calvaria model was conducted in an independent laboratory with 5 Wistar rats in accordance with DIN EN ISO 10993-6:2017.¹³ The study investigated the biocompatibility and the ingrowth behaviour of AlloHeal® C+TBA DBM Putty.

In this model, 2 defects were induced in each rat. The induced defects were repaired with AlloHeal® C+TBA DBM Putty and the wounds were closed. The histopathological evaluation of the tissue reaction was carried out after 30 days.

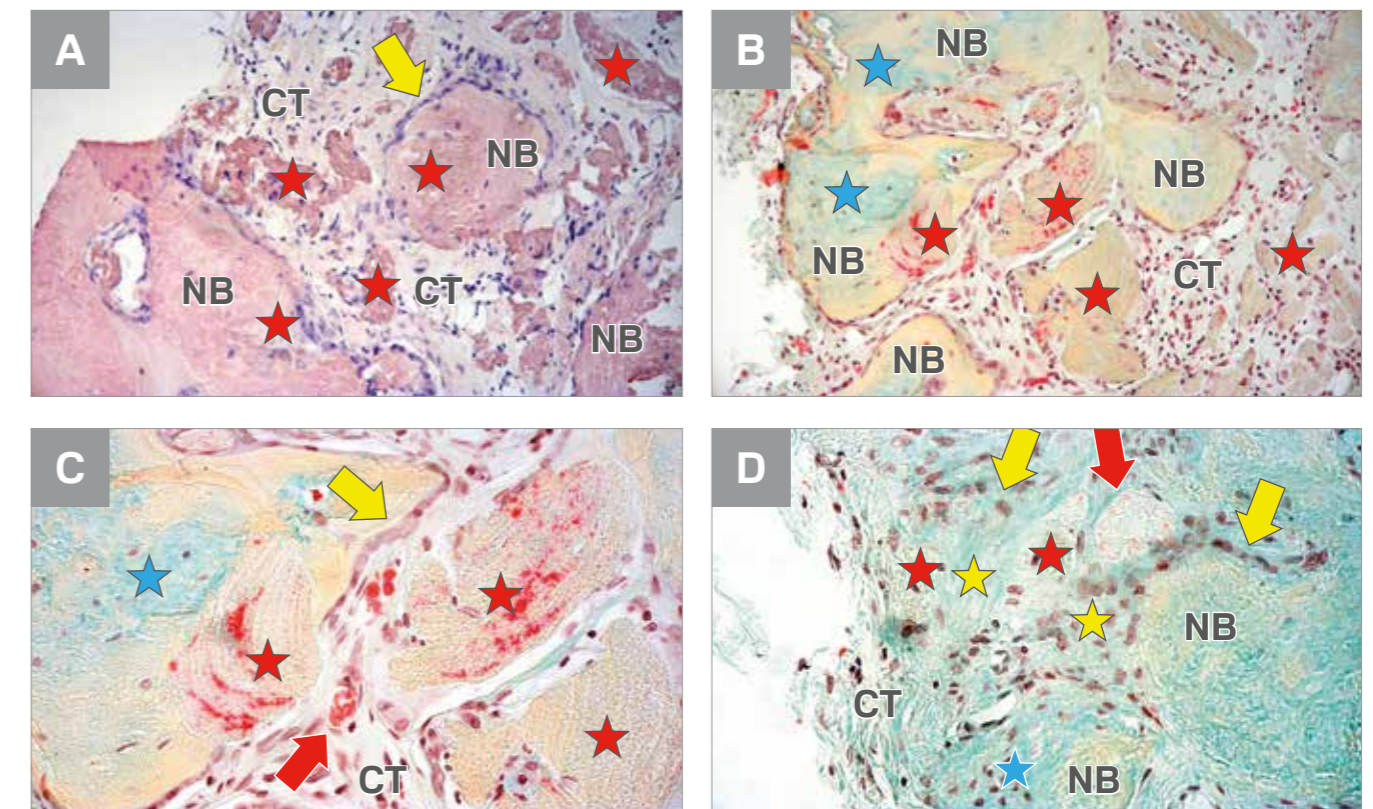
The histological examination showed no signs of any material-induced unwanted cell or tissue reaction. Likewise, no material failure was observed.

Newly formed bone is visible in the implantation regions (Figures A–D). The newly formed bone tissue shows

clear signs of ongoing regenerative growth, which is also substantiated by the number of osteoblasts present and the extensive osteoid formation.

In light of the proven early bone matrix formation, osteoinductive and osteoconductive defect remodeling can be assumed.

The transplant is biocompatible. The present study supports the conclusion that AlloHeal® C+TBA DBM Putty contributes to rapid remodeling of the bone.



(A)–(C) Representative histological images of the bony integration of the DBM Putty (red stars). NB = new calcified bone tissue, blue stars = newly formed, not completely calcified bone tissue, CT = connective tissue, yellow arrows = osteoblast sutures, red arrows = blood vessels (A: H&E staining, 200x magnification; B: Movat's Pentachrome staining, 200x magnification, C: Movat's Pentachrome staining, 400x magnification). (D) Enclosure of the DBM putty (red stars) in early, non-calcified bone tissue/osteoid (yellow stars).

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. As a full-service for human transplants C+TBA also provides soft tissue and bone grafts.



AlloHeal® C+TBA DBM Putty

Source: Human
 Tissue: 100% allogenic bone tissue
 Preparation: Allotec® purification procedure & demineralisation
 Inactivation: Min. SAL 10⁶ for viruses and bacteria
 Sterilisation: Gamma irradiation
 Preservation: Ready to use
 Application: Repairing bone defects

ORDERING INFORMATION

DESCRIPTION	ITEM NUMBER	GTIN	V [cc]
AlloHeal® C+TBA DBM Putty	81010	9009808006505	1.0
	81025	9009808006512	2.5
	81050	9009808006529	5.0
	81100	9009808006536	10.0



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