DIZG

DEUTSCHES INSTITUT FÜR
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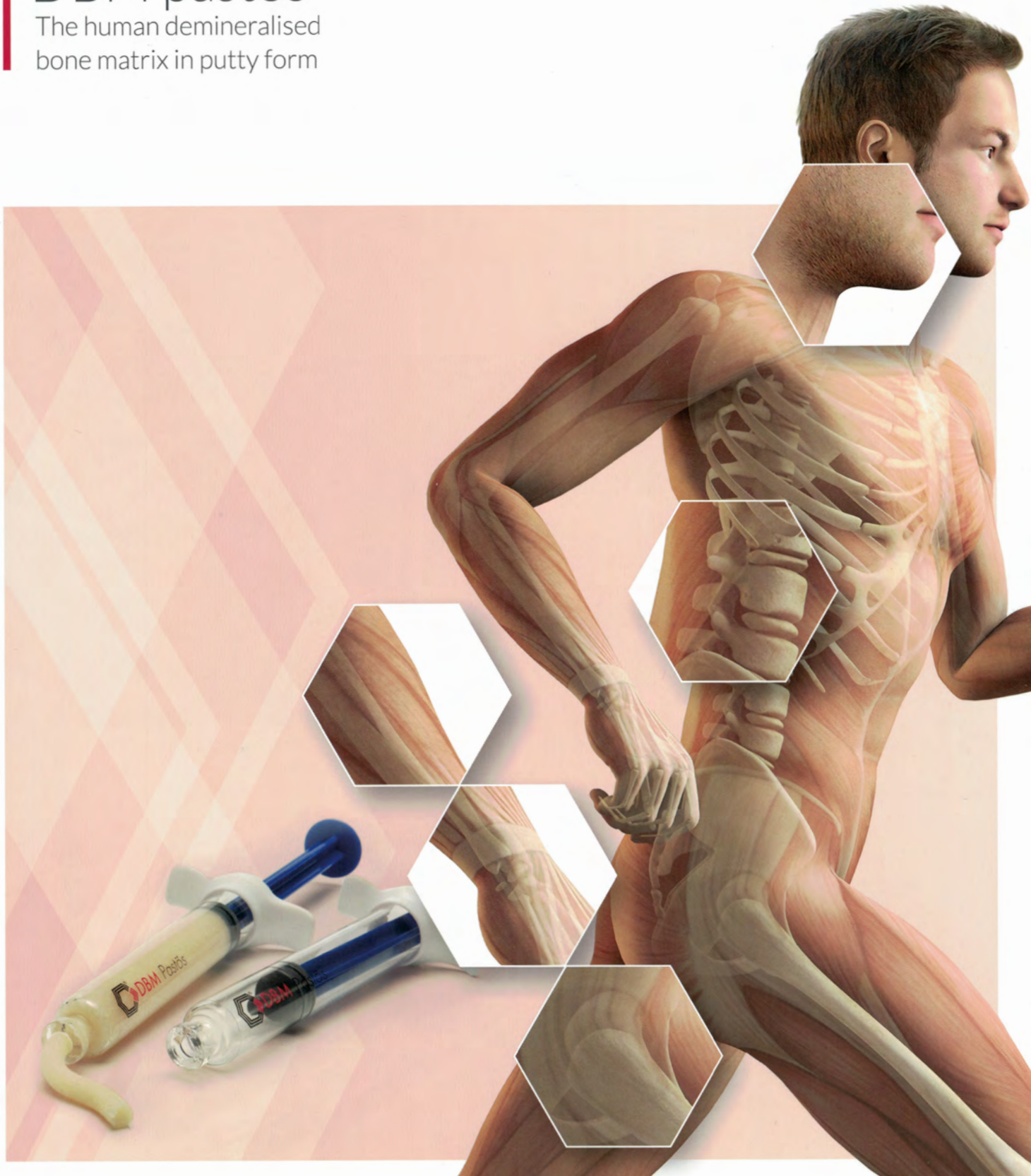
Gemeinnützige Gesellschaft mbH

DBM pastös

The human demineralised bone matrix in putty form



DBM pastös – the human demineralised bone matrix in putty form

DBM pastös is an allograft for the treatment of bone defects. The putty is fully converted into new bone after approximately six to twelve months following treatment.

WHAT DOES DBM PASTÖS CONSIST OF?

DBM pastös consists of demineralised bone matrix (DBM) gained from human donors, and a biocompatible carrier substance. During the production process, the mineral components are first removed from cortical bone. The thus gained demineralised bone matrix is then mixed with a biocompatible substance, a sodium hyaluronate solution.

Hyaluronic acid is present in human tissue such as skin, muscles and bone and lends the bone matrix a user-friendly putty form.

Since 2007, DIZG has provided over 35,000 units to physicians and so helped tens of thousands of patients to improved bone healing.

CORTICAL BONE

DBM

CARRIER SUBSTANCE

High quality sodium hyaluronate in pharmacopoeial quality in dibasic phosphate buffer

> Biocompatible

> Manufactured in compliance with GMP

DBM pastös

DBM pastös is approved as a medicinal product in Germany*

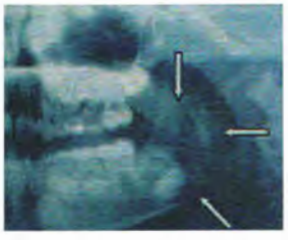
SCOPE OF APPLICATIONS

Orthopaedics/traumatology
> Treatment of fractures in all extremities
> Filling of defects (ideal for the treatment of solitary bone cysts)
> Pseudarthrosis

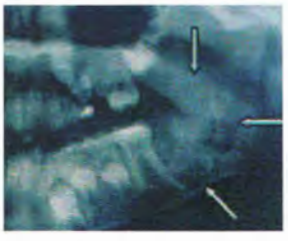
Spinal column
> Vertebral fusion
> Cage filling
> Treatment of fractures

Oromaxillofacial surgery
> Filling of cysts

Fig 1:
Treatment of bone cysts in OMF surgery



Preoperative X-ray of a follicular cyst



6 months postoperative X-ray

3 years postoperative X-ray

A study from the Charité shows: DBM pastös significantly improves bone regeneration after the removal of cysts in the maxillary region. A total of 90 patients were included in the study, with the cysts showing an average area of 11.2 cm^2 on the X-ray. The cysts were removed by surgery in all study subjects. In 50 patients, the resulting bone cavities were filled with human demineralised bone matrix, 40 patients did not receive a filling. The radiological follow-up for a period of up to ten years showed clearly faster new bone formation in the DBM pastös group. The scientists at the Charité explained this effect with the excellent osteoneogenetic properties due to the demineralisation of the bone matrix of DBM pastös.[9]

*Marketing authorisation number: PEI.H.03358.01.1

Properties

- Human demineralised bone matrix
- Volume ratio of demineralised bone matrix at approx. 76% (v/v)
- Cell-free[5]
- Sterile, safe
- Putty, excellent mouldability (offers perfect sealing with defect margins, can be applied to every form of defect)
- Bonds in situ, even under exuding conditions
- Ideal structure and pore size for the recolonisation with cells and revascularisation[6,7]
- Full remodelling according to natural bone metabolism
- High tolerability
- No impairment of biomechanical properties due to thermal effects
- Not γ-irradiated[1,8]
- Free of α-Gal
- Biocompatible carrier
- Osteoconductive (guided bone regeneration)[10]
- Free of antibiotics
- Free of preservatives
- Can be mixed with autologous bone, blood, bone marrow and/or antibiotics[4]
- Biocompatible carrier
- Approved as medicinal product according to German Law on Therapeutic Products (§ 21)
- Presentation form: putty, in glass syringe
- Long storability of 5 years at room temperature

EXCELLENT INTRAOPERATIVE HANDLING:

- Ready-to-use and can therefore be applied directly
- No rehydration required
- No thawing required
- No mixing/stirring required
- Does not stick to gloves

Advantage of allogeneic (human) materials

> Allogeneic DBM demonstrates better properties than xenogeneic and synthetic materials in cell colonisation studies[6,7]

> Comparably high fusion rates as for the use of an autologous bone graft[2]

Fractures in the region of the spinal column **93.8 %** fusion rate[3]

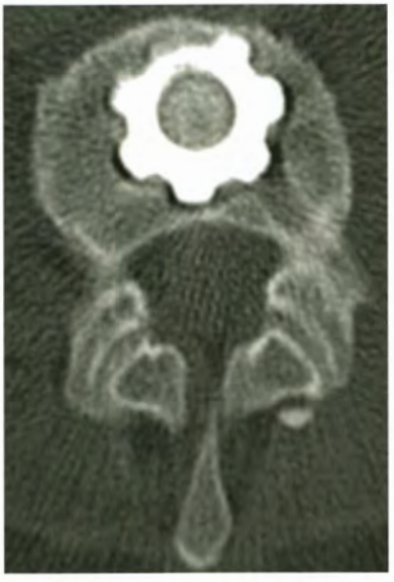
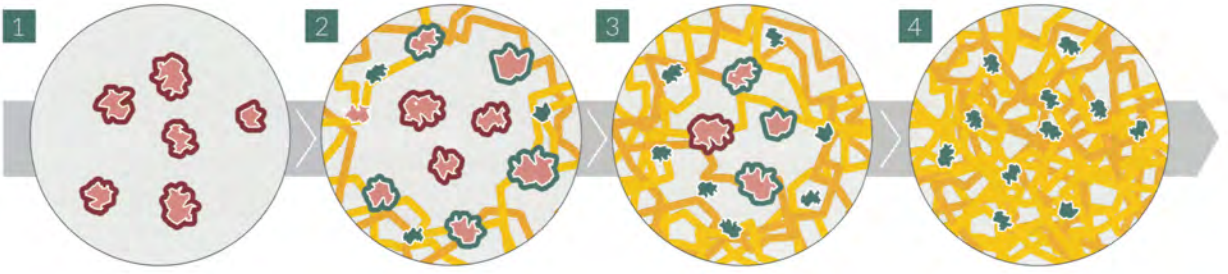


Fig 2:
Example of a posterior lateral fusion with DBM pastös in an L2 fracture (10 months after stabilisation)[3]

DBM pastös is suitable as bone graft for PLF in traumatic thoracolumbar fractures. The use of DBM pastös in posterior lumbar fusion (PLF) prevents site morbidity. Simultaneously, the time for surgery is reduced by approximately 19 minutes[11]. This makes DBM pastös largely cost-neutral.*

*According to a paper by Fleischer et al. in the Deutsches Ärzteblatt in 2012, every minute of surgery costs an average of EUR 45. At an inflation rate of 2.5 per cent per annum, we can therefore assume a minimum cost of EUR 50 per minute for 2017. If one multiplies this value with the minutes of surgery saved, this shows DBM pastös to be absolutely cost-neutral.

Degradation and conversion of DBM during the course of healing



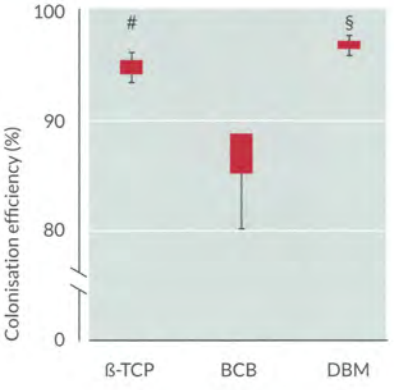
Formation of new bone from the edge of the drill hole to the centre of the defect

- DBM occupied with osteoclasts (resorption)
- DBM occupied with osteoblasts (inclusion)
- DBM residue after inclusion (resorption)
- Bone trabeculae

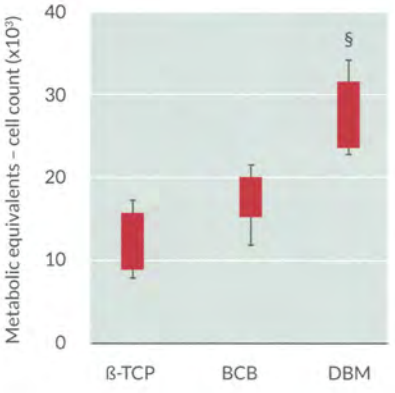
The times given apply to the sheep model

1	0 weeks	DBM particles inserted into the defect are occupied by osteoclasts. The particles are degraded and utilised for new bone formation.
2	3 weeks	New bone is created at the defect margins, the first DBM particles are now occupied by osteoblasts. The particles are integrated into the new bone network.
3	6 weeks	During the further course, parallel bone formation and degradation (remodelling).
4	9 weeks	The defect has healed. The new bone matrix includes partly well integrated DBM particles.

HIGHER CELL COLONISATION WITH HUMAN DBM



Bone marrow cells adhere significantly better to human DBM than to bovine cancellous bone.[6]



After 21 days of culture, the cell count and metabolic activity on colonised DBM were significantly higher than on bovine cancellous bone and β-TCP.[6]

A safe and biocompatible carrier

Carrier properties
> Hyaluronic acid is a polysaccharide which is formed in the human body from plasma membrane proteins.
> Hyaluronic acid plays an important role in cell proliferation, migration, adhesion and angiogenesis.
> Sodium hyaluronate improves the storage stability of the tissue graft.
> DBM pastös exclusively contains high quality sodium hyaluronate pharmacopoeial quality, manufactured by fermentation in compliance with the GMP Guideline, Annex 1
> The sodium hyaluronate used for DIZG DBM pastös is not of animal raw materials.

DBM pastös pack sizes

Article number	Grain size	Pack size
OL3550	0.212 - 0.85 mm	0.5 cm^3
OL3551	0.212 - 0.85 mm	1.0 cm^3
OL3552	0.212 - 0.85 mm	2.5 cm^3
OL3553	0.212 - 0.85 mm	5.0 cm^3
OL3554	0.212 - 0.85 mm	10.0 cm^3

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Name of the medicinal product:	Demineralised human bone matrix, lyophilised, DIZG
Marketing authorisation number:	PEI.H.03358.01.1
Composition:	Parts of decalcified human bone tissues. DBM pastös contains: 30% demineralised bone matrix (DBM) in a mixture of sodium hyaluronate, sodium chloride, sodium monophosphate and sodium diphosphate in water for injection.
Pharmaceutical forms:	in putty form
Therapeutic indications:	for implantation. For filling bone defects in various surgical specialist disciplines.
Contraindications:	Use in necrotic host sites is contraindicated. Should be used only when strictly indicated in poorly perfused or infected host sites, due to the poorer healing rate.
Undesirable effects:	None known
Sales limitations:	prescription only

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