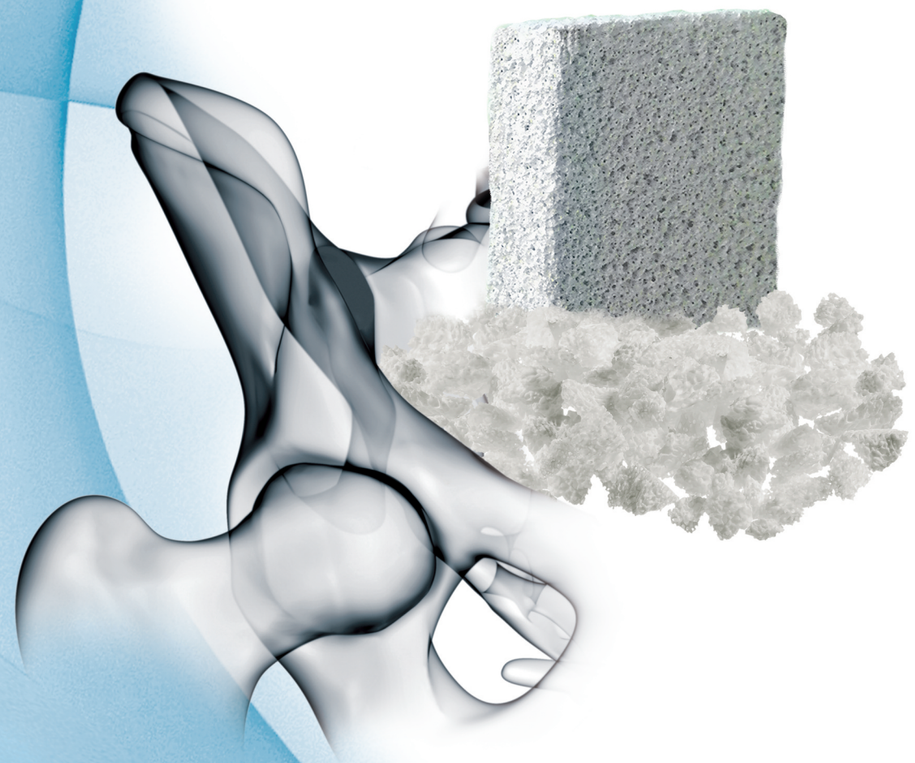
Artosal® Blocks

SIZE	QUANTITY	ART.-NO.
10 x 10 x 10 mm	1	248022
10 x 10 x 20 mm	1	248023
10 x 30 x 30 mm	1	248029
20 x 20 x 20 mm	1	248030

Artosal® Granules

GRAIN SIZE	ART.-NO.
5 cc (1-4 mm)	248011
10 cc (1-4 mm)	248012
15 cc (1-4 mm)	248013
20 cc (1-4 mm)	248014
30 cc (1-4 mm)	248016



aap Implantate AG
Lorenzweg 5 • 12099 Berlin
Germany

Phone +49 30 75019-0
Fax +49 30 75019-111

customer.service@aap.de
www.aap.de

responsible manufacturer:

European Medical
Contract Manufacturing B.V.
Middenkampweg 17 • 6545 CH Nijmegen
The Netherlands

Phone +31 24 371 5252
Fax +31 24 371 5253

customerservice@emcm.com
www.emcm.com

(01)04042409335006(10)1511
WP 3F0010 EN / 1511

Artosal®
• Resorbable Synthetic Bone Substitute

Artosal®

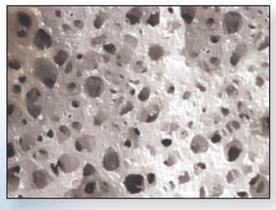
Artosal® is a fully synthetic osteoconductive bone substitute for reconstruction of aseptic bone defects that shows a controlled resorption. Due to its ultra porous and highly interconnected pore matrix it offers a similar strength to cancellous bone and supports the remodelling of the new natural bone.

Benefits

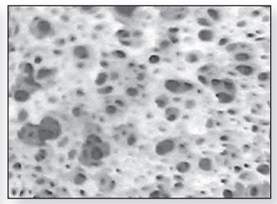
- Osteoconductive and fully biocompatible
- Very similar to the mineral component of human bone due to composition of 60 % hydroxyapatite (HA) and 40 % β-tricalcium phosphate (β-TCP)
- Ultra porous, 200-800 µm pore size range (average 250 – 400 µm)
- Ultra highly interconnected pores are similar to cancellous bone for rapid and unrestricted bone ingrowth
- Microporosity allows nutrient transfer
- Controlled resorption after 1-2 years (depending upon patient and defect location)
- Resorption byproducts encourage osteoblast formation & ingrowth
- Easy to use, no chemical mixing of components
- Adjustable to defect size with standard surgical instruments
- Synthetic and fully reproducible, reliable and consistent performance to reduce / eliminate need for autograft
- Can be mixed with bone marrow aspirate or platelet concentrate to provide an additional biological boost from associated growth factors
- Compositions of HA and TCP are successfully used in more than 25 years

Resorbable synthetic bone substitute with almost identical set-up and structure of the human bone

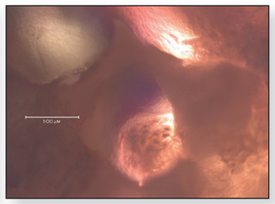
The fully interconnected pore structure is nearly identical with the human cancellous bone and provides an ideal environment for the ingrowth of new bone. Over 80 % porosity allows rapid bone ingrowth throughout the interconnected pore system.
Artosal® provides support without significantly limiting natural bone density. The microporosity within the Artosal® structure assists the supply of the new bone with essential nutrients.



Human cancellous bone



Artosal®



Osteoconduction with bone radiating through pores to the centre of the implant

Indications

Artosal® can be used for many not load bearing indications of aseptic bone reconstruction in the fields of traumatology, orthopaedics, spine and neurosurgery by supporting the ingrowth of adjacent viable bone in defects that are not intrinsic to the stability of the bone structure. These indications can be:

- Filling of defects of pelvis, long bones and extremities
- Filling of bone defects in epiphyseal and diaphyseal simple and comminuted fractures
- Filling of bone defects of the acetabulum on change of prosthesis
- Filling after removal of osteosynthesis materials
- Filing of bone defects with delayed or non-union pseudarthrosis, arthrodesis and osteotomies
- Filling of defects caused by excision of benign bones
- Filling of bone cysts
- Lumbar spinal fusion

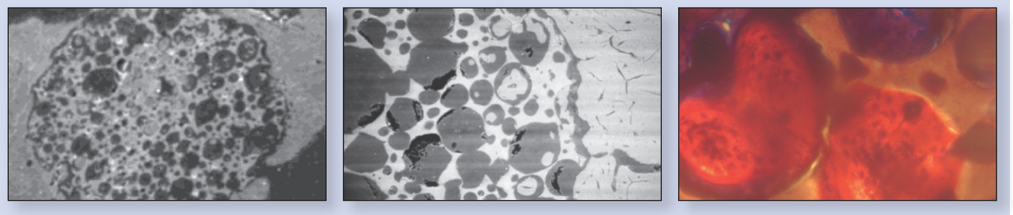
Publications / Clinical Studies

The biocompatibility and clinical efficacy of HA and TCP as bone substitute materials is supported by over 3,000 publications and over 500 clinical studies with more then 25 years of successful use.
Artosal® has proven biocompatibility and osteoconductivity. Studies show that Artosal® implanted both in cancellous bone and cortical bone gives excellent osseointegration with rapid bone penetration through the core of the implant.

Animal Results

In vivo determination of the biocompatibility of calcium phosphate bioceramics implanted in a non-healing mandibular ramus model:

The aim of this consultancy was to investigate the response of bone to porous ceramic material HA/TCP (Artosal®) in vivo using a non-healing model. The jaw model in the rat mandible has been well documented, consisting of a full thickness defect in the ramus of the mandible. A standardised full thickness 'non-healing' defect was created from an extra-oral approach in the left mandibular ramus of 21 male Wister Rats, aged between 3 and 4 months (weight 450 to 500 g). The animals were divided equally into groups according to the treatment they received; defects were left to heal unaided (control) or received implantation of HA+bTCP (Artosal®) discs.



Detail from two different specimens showing new bone infiltrating into pores.

Conclusions

New bone failed to develop in the control defects. The HA/bTCP (Artosal®) was osteoconductive with clear evidence of new bone formation in the larger pores of both materials. There was evidence of good osseointegration of HA/bTCP (Artosal®). Qualitatively at 6 weeks healing there was good bone infiltration into HA/bTCP (Artosal®). The hard and soft tissues accepted the presence of HA/bTCP (Artosal®) with no evidence of any adverse effect. There was no evidence of any fibrous encapsulation of HA/bTCP (Artosal®).