APPLICATION

Orthopaedic

EXTREMITIES

ReproBone™ granules and blocks for the filling of voids in trauma and joint surgery. Wedges for osteotomy procedures.

SPINE

Spinal fusion procedures. ReproBone™ granules, blocks and cylinders act as a bone graft scaffold within a rigid hollow spinal fusion cage.

HIP & KNEE

ReproBone™ granules and blocks for the filling of voids during hip and knee, primary and revision surgery.

FEMUR, TIBIA & HUMERUS

ReproBone™ granules and blocks for the filling of voids from fracture, trauma or tumour resection.

Dental

DENTAL PERIODONTAL & MAXILLOFACIAL

ReproBone™ dental granules specially designed for small volume applications such as root socket filling, ridge augmentation, sinus lift procedures.

PROPERTIES

ReproBone™ BLOCKS/GRANULES/DISCS/WEDGES	
COMPOSITION	60% HA, 40% ß-TCP
POROSITY	83%
MACROPOROSITY	200 - 800um
FULLY INTERCONNECTED	Yes
MICROPOROSITY	1.0 - 10um
STERILITY	Gamma irradiated

CERAMISYS

Ceramisys is located in Sheffield, England, and focuses on manufacturing innovative biomaterials and medical implants. Ceramisys has developed a portfolio of implantable products for bone grafting and oculoplastic surgery.

Working closely with research institutions such as the Centre for Biomaterials and Tissue Engineering, and the School of Clinical Dentistry, at the nearby University of Sheffield, along with several other UK and European institutions, Ceramisys is able to rapidly develop it's innovative products and processes.

PRODUCT RANGE
& ORDERING INFORMATION

CYLINDERS	BLOCKS	WEDGES WxLxH¹xH²		GRANULES (1–4mm)
RB5D5 D=5mm H=5mm	RB0511 5mm x 10mm x 10mm	RWG101 15 x 20 x 6 x 4	RWG304 20 x 25 x 12 x 6	RBG2.5 2.5cc
RB5D10 D=5mm H=10mm	RB0512 5mm x 10mm x 20mm	RWG102 15 x 20 x 8 x 6	RWG305 20 x 25 x 14 x 7	RBG5 5cc
RB6D15 D=6mm H=15mm	RB0513 5mm x 10mm x 30mm	RWG103 15 x 20 x 10 x 8	RWG401 30 x 30 x 6 x 3	RBG10 10cc
RB7.5D15 D=7.5mm H=15mm	RB0514 5mm x 10mm x 40mm	RWG104 15 x 20 x 12 x 9	RWG402 30 x 30 x 8 x 4	RBG15 15cc
RB9D25 D=9mm H=25mm	RB111 10mm x 10mm x 10mm	RWG105 15 x 20 x 14 x 10	RWG403 30 x 30 x 10 x 5	RBG20 20cc
RB10D5 D=10mm H=5mm	RB112 10mm x 10mm x 20mm	RWG201 20 x 20 x 10 x 5	RWG404 30 x 30 x 12 x 6	RBG25 25cc
RB10D10 D=10mm H=10mm	RB113 10mm x 10mm x 30mm	RWG202 20 x 20 x 12 x 6	RWG405 30 x 30 x 14 x 7	RBG30 30cc
RB10D15 D=10mm H=15mm	RB114 10mm x 10mm x 40mm	RWG203 20 x 20 x 14 x 7	RWG501 30 x 35 x 8 x 4	
RB15D5 D=15mm H=5mm	RB122 10mm x 20mm x 20mm	RWG204 20 x 20 x 16 x 8	RWG502 30 x 35 x 10 x 5	
RB15D10 D=15mm H=10mm	RB123 10mm x 20mm x 30mm	RWG301 20 x 25 x 6 x 3	RWG503 30 x 35 x 12 x 6	
RB15D15 D=15mm H=15mm	RB124 10mm x 20mm x 40mm	RWG302 20 x 25 x 8 x 4	RWG504 30 x 35 x 14 x 7	
RB15D20 D=15mm H=20mm	RB133 10mm x 30mm x 30mm	RWG303 20 x 25 x 10 x 5	RWG601 35 x 15 x 8 x 6	
RB20D5 D=20mm H=5mm	RB222 20mm x 20mm x 20mm			
RB20D10 D=20mm H=10mm	3RB041045 (3 pack) 4mm x 10mm x 45mm			
RB20D15 D=20mm H=15mm				
RB20D20 D=20mm H=20mm				

Please contact us for details of 0.5 –1.0mm and 0.8-1.5mm granules which are specifically designed for use in dental and periodontal procedures.

Other sizes and customised shapes are available upon request.

QUALITY

Ceramisys employs a total Quality Management System and is BSI Registered to BS EN ISO 13485 with Full Quality Assurance. ReproBone™ carries the CE Mark (Class III).

Distributed by:

CE 0086

BSI FM 97418

For more information about ReproBone™ or other Ceramisys products, please contact your local distributor.

ceramisys

CERAMISYS LTD 101 Leigh Street Sheffield S9 2PR England
TEL +44 (0)114 242 7630 FAX +44 (0)114 242 7631
EMAIL enquiries@ceramisys.com www.ceramisys.com

BONE GRAFT SUBSTITUTE
BLOCKS/GRANULES/DISCS/WEDGES

ReproBone™

_SAFE
_RELIABLE
_PROVEN
_UNLIMITED

ReproBone's™ unique structure, porosity and strength closely match the properties of real bone.

ceramisys

ReproBone™ BONE GRAFT SUBSTITUTE

ReproBone™ bone graft substitutes are manufactured in block and granular forms. The chemical composition and fully interconnected resorbable, macroporous structure of the matrix is very similar to that found in human cancellous bone and acts as an ideal scaffold for bone support and regeneration.

SYNTHETIC

Innovative product that offers a sterile, reliable alternative to cancellous autograft or allograft in unlimited quantities.

RESORBABLE

60% HA, 40% ß-TCP composition is similar to the mineral component of human bone and undergoes complete resorption at a controlled rate.

ULTRA HIGH POROSITY

Over 80% porosity allows rapid bone ingrowth throughout the pores. ReproBone™ provides support without significantly limiting natural bone density. Microporosity within the HA/ß-TCP structure assists the transfer of essential nutrients.

OSTEOCONDUCTIVE

Osteoconductive scaffold. Vascularisation and fast bone regeneration throughout the implant occurs within a few months.

SAFE AND RELIABLE

A gamma sterilised product, available in unlimited quantities. The biocompatibility and clinical efficacy of HA and ß-TCP as bone substitute materials is supported by over 3000 publications and over 500 clinical studies with 25 years of successful use.

REDUCED MORBIDITY

With healing times comparable to that of autogeneous bone grafts, ReproBone™ is the natural alternative to bone grafts, in many cases eliminating the need for a second operation site, reducing blood loss and lowering patient morbidity.

PROVEN TECHNOLOGY THE WORLD OVER

Over the last 20 years, hundreds of successful clinical studies have been performed on the ability of porous HA and ß-TCP to provide an osteoconductive environment assisting in the regeneration of a bony defect. A biphasic HA/ß-TCP composition with a highly interconnected structure provides an optimal osteoconductive environment and is resorbable in a controlled way.

Due to its similarity with human bone, no adverse reactions have ever been reported. The calcium and phosphate resorption products are beneficial in assisting local osteoblast activity at the site.

P.V. Hatton, M. Ehdi, C. Gillingham, I. Brook, Evaluation of the in-vitro biocompatibility of novel porous hydroxyadatite bone substitutes / scaffolds – in print.

N. Passuti, S. Martin, G. Daculsi, S. Legeros, R.S. Raher Macroporous calcium phosphate ceramic for long bone surgery in humans & dogs: Clinical & histological Suudy J. Biomed. Mat. Rex. 1990, Vol 24, 379–396.

C. Schwartz, P. Liss, B. Jacquemaire, P. Lecestre Biphasic synthetic bone substitute use in orthopaedic & trauma surgery: clinical, radiological and histological results J. Mat Sci: Mat. in Med. issue: 1999 Vol 10. No. 12 821–825.

P. Frayssinet, J.L. Trouillet. N. Rouquet, E. Azimus, A. Autofage Effects of the Chemical Composition of calcium phosphate ceramics on their osseointegration. Orthopaedics Int'l. Ed. 1993, Vol 1, No. 4.

ReproBone™
BLOCKS/GRANULES/DISCS/WEDGES

Ready to use

Pre-shaped in standard sizes, sterile and easy to handle.

Easy application

ReproBone™ blocks can be soaked with blood, or bone marrow aspirate e.g. for spinal fusion procedures, and can easily be cut and shaped to fit the defect. ReproBone™ granules when mixed with blood, bone marrow aspirate or platelet concentrate form a cohesive mixture that is easily handled. Can be mixed with autograft as a bone graft extender if required.

Indications

ReproBone™ blocks and granules are indicated for use as a bone graft substitute for the repair of non-load bearing osseous defects. Standard fixation techniques must be used in load bearing applications.

ReproBone™ Granules

ReproBone™ Blocks
Available in a variety of sizes and shapes.

CLINICAL PERFORMANCE

ReproBone™ has proven biocompatibility and osteoconductivity. Studies show that ReproBone™ implanted both in cancellous bone and cortical bone provides excellent osseointegration with rapid bone penetration through to the core of the implant.

1. OSTEOCONDUCTION
Bone radiating through pores to the centre of the implant.

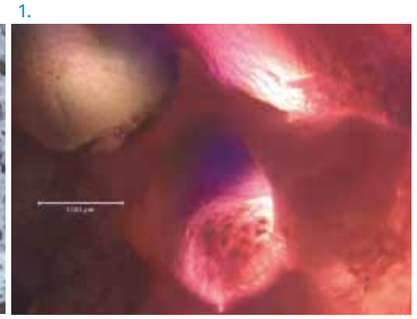
2. INTEGRATION
At 12 weeks complete integration with new bone, implant is now embedded within new bone forming bicontinuous matrix.

3. CONSOLIDATION & MATURATION
Osteoclastic resorption and phagocytosis, releases calcium and phosphate ions locally, which in turn encourages osteoblastic activity and the deposition of new bone. Bone remodelling transforms initially woven bone into lamellar bone.

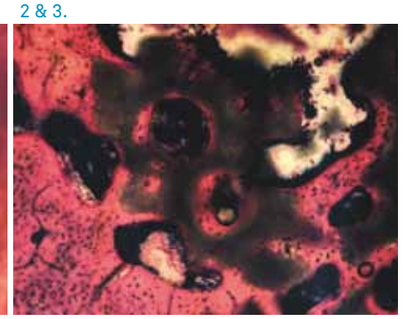
4. RESORPTION
At 12 weeks osteoclastic resorption can be clearly observed, the implant has a distinctly blurred outline with highly microporous surface. Bone remodelling continues until the implant is completely resorbed.

ReproBone™ 'Cancellous like' structure

1.



2 & 3.



4.