

APPLICATION

Orthopaedic

EXTREMITIES

ReproBone *novo*TM for the filling of voids in trauma and joint surgery.

SPINE

Spinal fusion procedures. ReproBone *novo*TM acts as a bone graft scaffold within a rigid hollow spinal fusion cage enabling fusion of adjacent segments.

HIP & KNEE

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

FEMUR, TIBIA & HUMERUS

ReproBone *novo*TM for the filling of voids from fracture, trauma or tumour resection.

Dental

DENTAL PERIODONTAL & MAXILLOFACIAL

ReproBone *novo*TM is convenient for application into small volume defects such as root socket filling, periodontal pocket filling and sinus lift procedures.

PROPERTIES

ReproBone *novo*TM PASTE

HIGH SURFACE AREA	Approx 100M ² /g
HYDROXYAPATITE CONTENT	Nominal 38%
HA NANOTECHNOLOGY	30-50nm particles
PRODUCT VOLUME	Various 0.5cc to 15cc
STERILITY	Gamma irradiated

CERAMISYS

Ceramisy is located in Sheffield, England, and focuses on manufacturing innovative biomaterials and medical implants. Ceramisy 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, Ceramisy is able to rapidly develop it's innovative products and processes.

PRODUCT RANGE & ORDERING INFORMATION

PASTE

PAS05
0.5cc

PAS1
1cc

PAS2
2cc

PAS2.5
2.5cc

PAS5
5cc

2PAS5
10cc

3PAS5
15cc



QUALITY

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

Distributed by:



0086



FM 97418

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



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BONE GRAFT SUBSTITUTE PASTE

ReproBone *novo*TM

_SAFE
_RELIABLE
_PROVEN
_UNLIMITED

ReproBone *novo*'sTM unique composition provides an effective, easy to apply, bone graft substitute.



BONE GRAFT SUBSTITUTE

ReproBone *novo*TM bone graft substitute is manufactured in paste form. The product is an aqueous composition of nano hydroxyapatite and is chemically similar to that found in human bone. The material acts as a temporary scaffold for bone support and regeneration.

SYNTHETIC

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

RESORBABLE

The nano HA composition undergoes complete resorption over a period of months.

AQUEOUS PASTE

The sticky aqueous composition of nano HA and water does not form a barrier to vascularisation or bone colonisation and allows rapid bone ingrowth throughout the material. The product provides support without significantly limiting natural bone density.

POSITIVE OSTEOSTIMULATIVE EFFECT

The high molecular surface area attracts natural bone growth promoters to adsorb onto the surface and contributes towards the osteostimulative effect. The dissolution byproducts contribute to locally elevated Ca and P ions encouraging remineralisation.

Early vascularisation takes place 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 as a bone substitute material is well established with over 25 years of successful use.

REDUCED MORBIDITY

With healing times comparable to that of autogenous bone grafts, ReproBone *novo*TM 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 HA to provide a supportive environment assisting in the regeneration of a bony defect. A nano-HA paste composition with water provides an effective, stimulative environment for bone regeneration that is resorbable in a controlled way.

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

A.S. Pankratov, V.P. Zuyev, et al. Use of ultra highly dispersed hydroxyapatite in the complex treatment of patients with mandibular fractures, *Stomatologija*, 1995, 74(4) 22-25.

F.X. Huber, I. Berger et al. Clinical evaluation of nanocrystalline hydroxyapatite paste in the treatment of human periodontal bony defects – a randomized controlled clinical trial: 6 month results. *J. Periodontology*, 2008, 79(3) 394-400.

F.X. Huber, J. Hillmeier et al. The use of nanocrystalline hydroxyapatite for the reconstruction of calcaneal fractures: preliminary results. *J. Foot ankle surg.* 45(5) 322-328.

F.X. Huber, J. Hillmeier et al. Open reduction and palmer plate osteosynthesis in combination with a nanocrystalline hydroxyapatite spacer in the treatment of comminuted fractures of the distal radius. *J. Hand Surg.* 2006 31(3) 298-303.

ReproBone *novo*TM PASTE



ReproBone *novo*TM nanocrystalline synthetic bone graft paste

Ready to use

Easy to use with no pre-mixing or preparation required. Remove cap and apply directly from the applicator.

Sticky mouldable paste consistency

Sticky viscosity allows easy positioning, adapts easily to the shape of the defect. Sticks to the bone surface maximising the bone-implant interface.

Volume stable

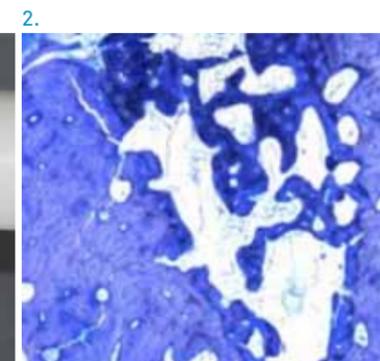
Stays inside the defect and resists irrigation. Blood will eventually impregnate the implant and resettle the growth factors essential for bone regeneration. Vascularisation will impregnate the implant, laying the foundation support essential for bone regeneration.

Nano technology

With a high molecular surface area of the Hydroxyapatite approx 100M² per cc for ReproBone *novo*TM it is 50-100 times greater than typical bone graft technologies.

CLINICAL PERFORMANCE

ReproBone *novo*TM has proven biocompatibility and bone regenerative properties. Studies show that ReproBone *novo*TM implanted in cancellous bone provides excellent osseointegration with rapid vascularisation and bone penetration through to the core of the implant.



1. APPLICATION & PRIMARY STAGES

The non-hardening mouldable paste does not form a barrier to adjacent healthy bone cells, the sticky paste ensures good contact and cells readily migrate inwards. Blood passively infiltrates, bringing with it

the growth factors needed for bone regeneration, and early vascularisation takes place.

2. BONE FORMATION

ReproBone *novo*TM stimulates bone healing by accelerating the rate at which bone-forming cells proliferate, resulting in a rapid building of new bone.

The bone defect is regenerated with new woven bone after several weeks. In parallel the graft has been almost completely resorbed by macrophages and osteoclasts. Remodelling and maturation of the bone continues as normal.