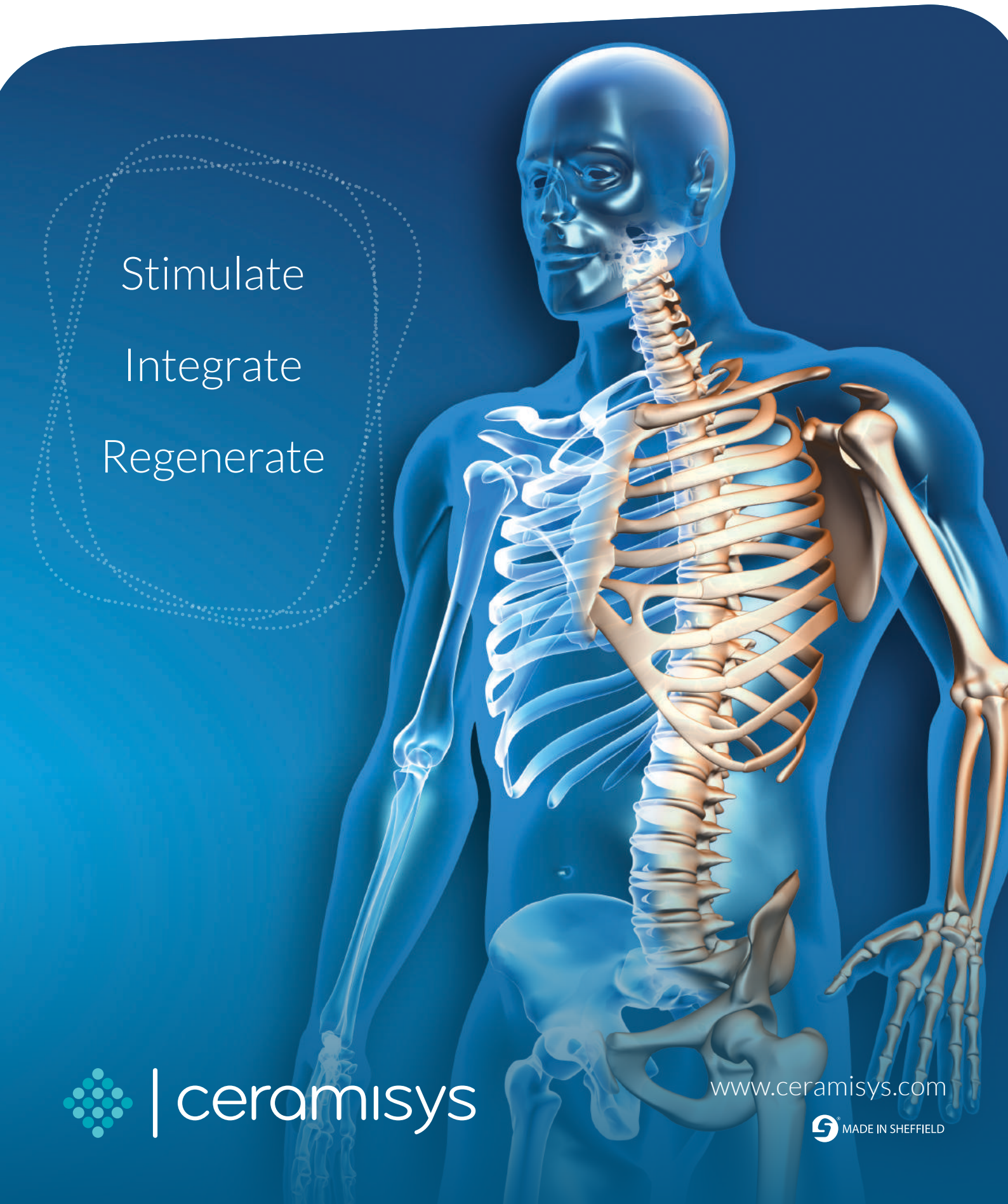
ReproBone®

Synthetic Bone Graft Substitutes for **Orthopaedic Applications**



Stimulate

Integrate

Regenerate

ceramisys

www.ceramisys.com

MADE IN SHEFFIELD

ReproBone®'s advanced properties provide the ideal supporting matrices for the regeneration of bone.

ReproBone® is an innovative range of synthetic bone grafts that support bone integration and regeneration. With a composition very similar to that of human cancellous bone **ReproBone®** acts as an ideal scaffold.

ReproBone® is available in a variety of convenient forms to suit the challenges that surgeons face in orthopaedic and trauma surgery.

Synthetic

Innovative products that offer sterile alternatives to allograft or xenograft with no risk of disease transmission or limited supply. Additionally, **ReproBone®** can be used as an extender of autograft.

Reduced morbidity

ReproBone® in many cases reduces the need for bone harvesting and therefore eliminates donor site morbidity.

Safe and reliable

Manufacturing to international standards ensures high quality and reliable products. A composition similar to human bone provides confidence in safety and efficacy.

Stimulate

Integrate

Regenerate

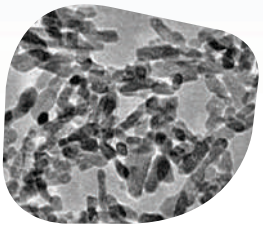
ReproBone® *fusion*

Unique innovative injectable matrix combining an osteostimulative* carrier with the longer term support of porous micro-scaffolds.

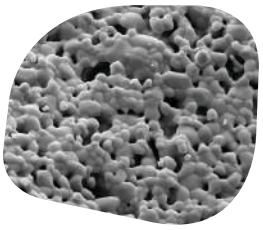
Ready to use

Easy to inject with no pre-mixing or preparation required. Simply remove the cap and apply directly into the defect. Optional cannulas are provided.

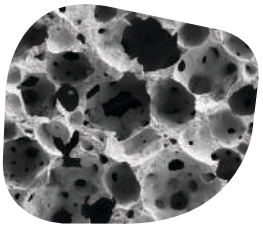
ReproBone® *fusion* can also be mixed with bone marrow aspirate and/or autologous bone prior to application.



High surface area of nano-hydroxyapatite adsorbs the biomolecules essential for the stimulation of the regenerative process.



Micro-porous topography assists capillary action for the flow of biological fluids and the adsorption of proteins supporting cell attachment.



Macro-porous structure provides an optimal osteoconductive environment supporting bone formation and maintaining bone volume until full regeneration is achieved.

* non-osteoinductive

Indications

ReproBone® *fusion* is indicated for use as a bone graft substitute for the repair of non-load bearing aseptic osseous defects of long bones and extremeties. Its mouldable and firm texture is especially suitable for the filling of bone defects that require longer term support and volume stability.

Injectable granulated paste

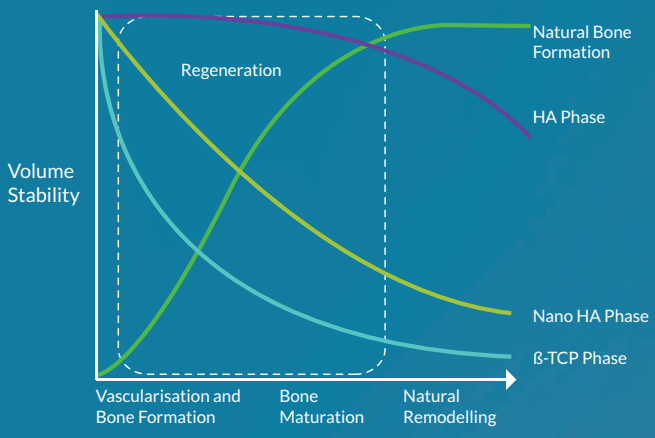
The putty-like volume stable viscosity allows easy and accurate application of the granulated paste. Excellent contact with the viable bone surface maximises the bone implant interface. The sticky non-setting formula supports bone regeneration by facilitating rapid cell ingrowth throughout the healing process.

Multiphasic regenerative activity

An advanced biomaterial with a unique multiphase composition of nano, micro and macro structured material that supports the formation of new bone whilst maintaining volume. Over time the material is gradually replaced by mature bone.

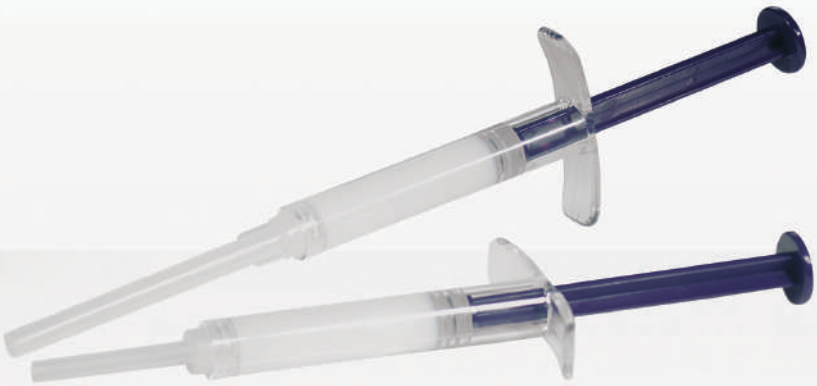
Osteostimulative*

ReproBone® *fusion* supports bone repair and regeneration. Its high surface area adsorbs the biomolecules essential for the repair of bone. The nano-hydroxyapatite has been shown to increase cell viability and the expression of markers for osteoblast differentiation[1].



ReproBone® *novo*

Injectable osteostimulative* bone graft paste.



Ready to use

Easy to inject with no pre-mixing or preparation required. Simply remove the cap and apply directly into defect. Optional cannulas are provided.

ReproBone® *novo* can also be mixed with bone marrow aspirate and/or autologous bone prior to application.

* non-osteoinductive

Mouldable consistency

Paste-like consistency allows easy positioning and fully adapts to the shape of the defect. Excellent contact with the viable bone surface maximising the bone implant interface.

Osteostimulative* effect

The nano-hydroxyapatite has been shown to increase cell viability and the expression of markers for osteoblast differentiation.[1] Additionally, the high molecular surface area adsorbs the biomolecules essential for the regenerative process.

Indications

ReproBone® *novo* is indicated for use as a bone graft substitute for the repair of non-load bearing aseptic osseous defects. Its mouldable and injectable texture is especially suitable for the filling of small or difficult to access bone defects.

Nano technology

The high molecular surface area of the hydroxyapatite (approx. 100 m^2/g) is 50-100 times greater than typical bone graft technologies.

Resorbable

Cell mediated resorption of **ReproBone® *novo*** occurs over several months alongside the formation of mature bone.

Cohesive texture

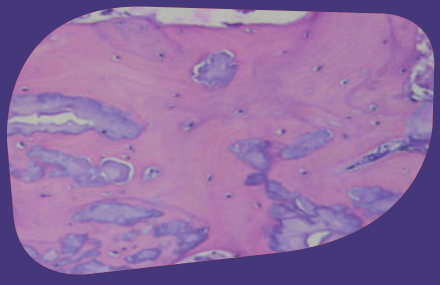
Bridges the gaps between bone surfaces and resists wash-out from bleeding of bone defects.

Clinical Performance

ReproBone® *novo* has proven biocompatibility as demonstrated by pre-clinical testing [1]. The efficacy of **ReproBone® *novo*** to support bone regeneration has been demonstrated over a number of years of clinical use in a variety of indications with no adverse reactions. Studies show that **ReproBone® *novo*** implanted into bone defects provides an excellent environment to allow new bone formation [2]. Integration of bone and vascularisation occurs throughout the implant and **ReproBone® *novo*** is fully resorbed over time.

Activity

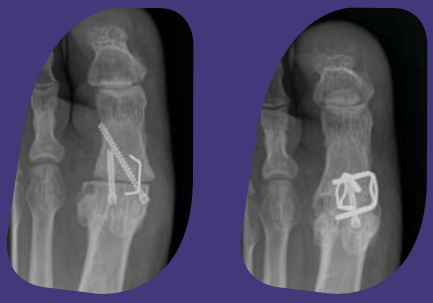
ReproBone® *novo* adsorbs biomolecules and along with the dissolution of ions facilitates the proliferation and differentiation of healthy progenitor cells.



Histological evaluation of human bone biopsy showing **ReproBone® *novo*** surrounded by new bone [3].

Bone formation

Osteoblasts lay down new bone throughout the graft matrix. Cell mediated resorption of **ReproBone® *novo*** occurs over time alongside the formation of mature bone.



Pre-op **6 months post-op**

x-ray showing fusion of the metatarsophalangeal joint [4].

ReproBone®

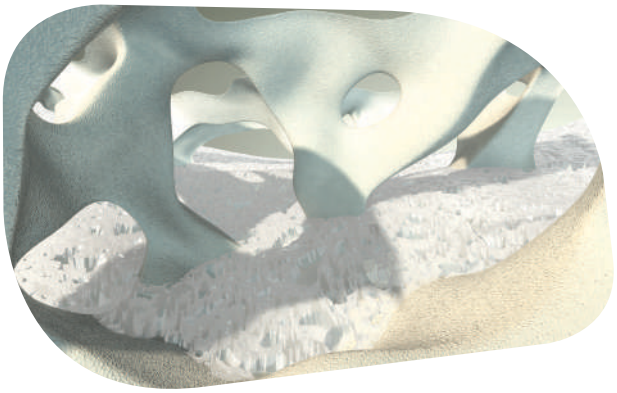
Resorbable, synthetic bone graft granules and blocks with a highly interconnected porous matrix.

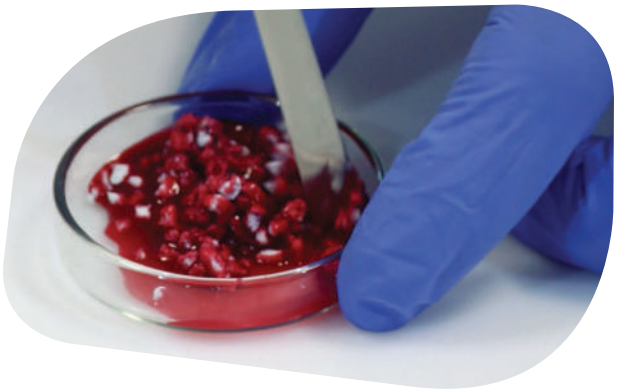
Ultra high porosity

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

Osteoconductive

Osteoconductive scaffold supports early vascularisation and bone regeneration throughout the implant.





Easy application

ReproBone® granules when mixed with blood, bone marrow aspirate or platelet concentrate form a cohesive mixture that is easily handled. Granules can be mixed with autograft as a bone graft extender if required. Blocks can be easily shaped to more closely fit the bone defect.

Indications

ReproBone® Granules and Blocks are indicated for use as bone graft substitutes for the repair of non-load bearing aseptic osseous defects.

Resorbable

With a composition similar to the mineral component of human bone **ReproBone®** undergoes complete resorption at a controlled rate.

Volume stable

Maintains bone volume throughout the whole repair and regeneration process.

Wide variety

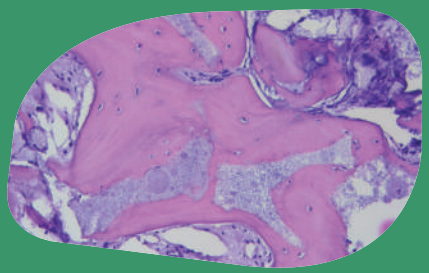
Granules, blocks, wedges, cylinders and discs available in a large range of convenient sizes.

Clinical Performance

ReproBone® has proven biocompatibility [1]. Its performance as a osteoconductive biomaterial has been demonstrated over many years of successful clinical use with no adverse reactions. Studies show that **ReproBone®** bone graft substitutes provide excellent osseointegration with rapid vascularisation and bone penetration through to the core of the implant [5].

Osteoconduction

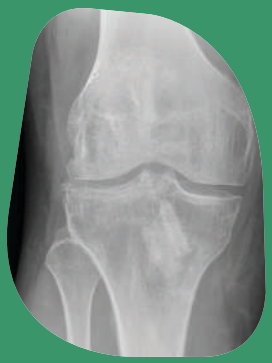
Biomolecules adsorb onto the porous surface supporting the regenerative process. Osteoblasts migrate throughout the fully interconnected structure laying down new bone resulting in complete integration of the implant and the formation of a bicontinuous matrix.



Histological evaluation of human bone biopsy showing **ReproBone®** surrounded by new bone. Complete integration of the implant was observed [6].

Resorption

Dissolution of **ReproBone®** occurs releasing ions locally which provides a nurturing environment for osteoblasts and supports the deposition of new bone. **ReproBone®** resorbs over time during which bone remodelling and maturation occurs.

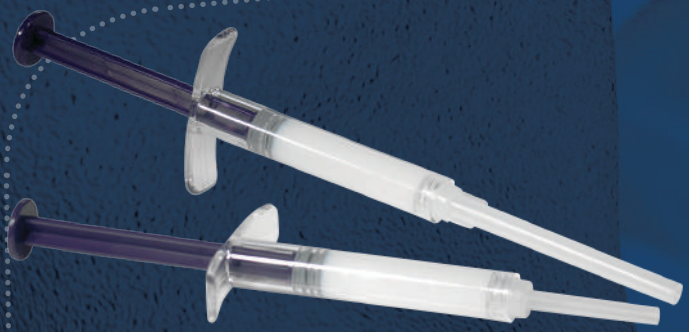


Two-stage ACL repair. Stage 1 involved screw removal from the tibia and filling of the tunnel with bone graft. After 3 months sufficient bone healing was achieved and stage 2 was performed - x-ray post op [7].

ReproBone® *fusion*

Granulated bone graft paste

- Osteostimulative*
- Multiphasic activity
- Mouldable consistency
- Maintains bone volume
- Ready to use
- Resorbable



ReproBone® *novo*

Nanocrystalline bone graft paste

- Nano-technology
- Osteostimulative*
- Mouldable consistency
- Ready to use
- Resorbable

ReproBone®

Porous bone graft -
granules / blocks / cylinders / wedges

- Osteoconductive
- Ultra-high porosity
- Maintains bone volume
- Easy to use
- Resorbable

* non-osteoinductive

ReproBone® products are indicated for the ingrowth of bone in defects that are not intrinsic to the stability of the bony structure. External fixation must be used where load is anticipated to be transferred to the device.

Metaphyseal Defects

Spinal Fusion (Cage Filling)

Iliac Crest Defects from Autograft Procedures

Distal Radius

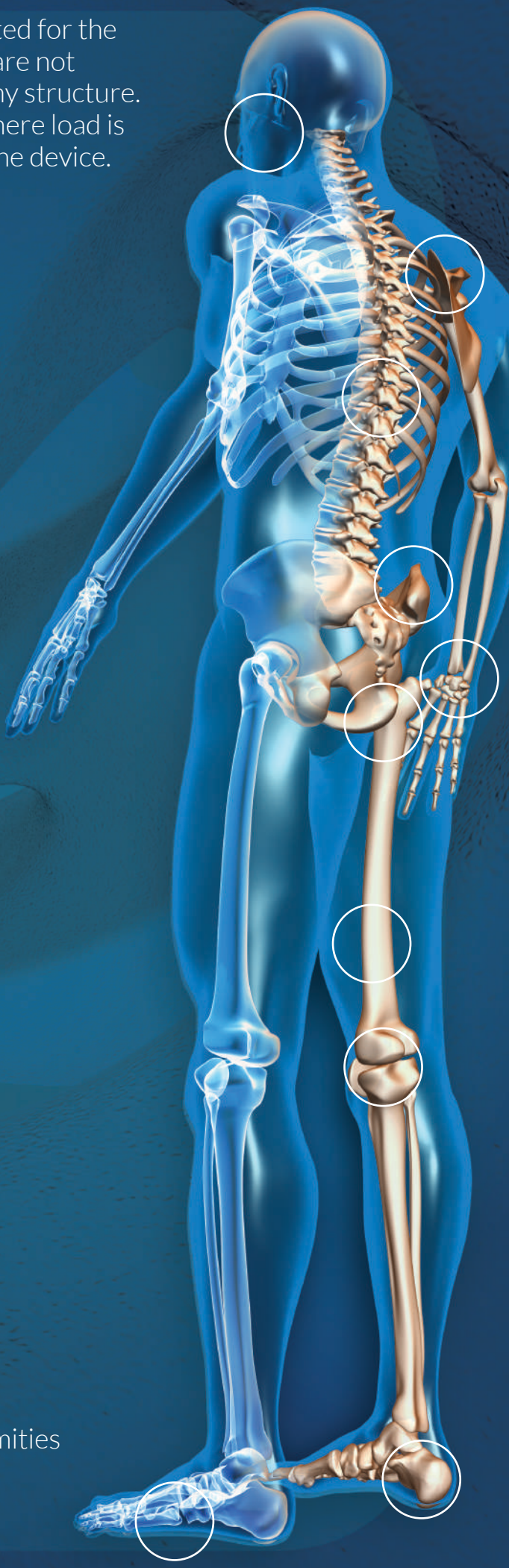
Revision Hip Surgery

Defects in Long Bones

Revision Knee Surgery

Osteotomy Procedures

Defects of the Extremities



Product Reference Guide

ReproBone® *fusion*

GNP1	1 cc
GNP2.5	2.5 cc
GNP5	5.0 cc
2GNP5	10 cc

ReproBone® Granules (1-4mm)

RBG5	5 cc
RBG10	10 cc
RBG15	15 cc
RBG20	20 cc
RBG30	30 cc

* Other sizes of granules available

ReproBone® *novo*

PAS1	1 cc
PAS2.5	2.5 cc
PAS5	5 cc
2PAS5	10 cc

ReproBone® Blocks/ Cylinders/Wedges

ReproBone® is available in a large variety of different shapes and sizes to suit individual bone defects.

For over 15 years **Ceramisys** has specialised in the manufacture and development of innovative synthetic biomaterials. At the forefront of the company's mission is a commitment to providing premium quality products which meet the requirements of surgeons. All of **Ceramisys'** products are manufactured in its state-of-the-art facility and are approved in the majority of international markets.

ReproBone® materials have clinically proven efficacy:

[1] Pre-clinical studies on file at Ceramisys
[2] Data on file at Ceramisys
[3] Ceramisys clinical case - 12-GB-CS-07/13
[4] Ceramisys clinical case - 32-GB-CS-06/14
[5] Data on file at Ceramisys
[6] Ceramisys clinical case - 08-GB-CS-07/13
[7] Ceramisys clinical case - 26-GB-CS-08/13

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