

NanoBone[®]

POWER TO REMODEL RAPIDLY



NanoBone can be placed in wet or dry sites and can be used in a variety of orthopaedic surgeries and in posterolateral spine¹

Ideal properties of bone graft

Easy to
prepare and
apply

Rapid and
reliable bone
formation

Completely
absorbs

NanoBone®

Perfect partner for remodelling bone defects rapidly

Reliable and convenient, NanoBone is a next generation, fully synthetic bone graft substitute.

Consisting of nanostructured hydroxyapatite (HA) embedded in a silica gel matrix - suspended in a hydrogel/polymer silica carrier - it provides the fullest support for bone regeneration at every stage of the healing process.

- ✓ Comparable healing rate to autograft without the costs and complications of harvesting¹
- ✓ Rapid absorption and reliable bone fusion¹
- ✓ Proven osteoinductive properties²
- ✓ Early osteogenesis - silica matrix exchanged for autologous proteins within 10 days³
- ✓ Patented nanostructure and optimised composition⁴
- ✓ Preloaded, versatile and ready-to-use⁴



Posterolateral spine | Depressed tibial plateau fracture | Radial fracture | Pathologic fracture
Pseudarthrosis | Acetabulum reconstruction | Displacement osteotomy | Bone necrosis
Defect fill after tumour or cyst removal

Patented nanostructure and optimised composition

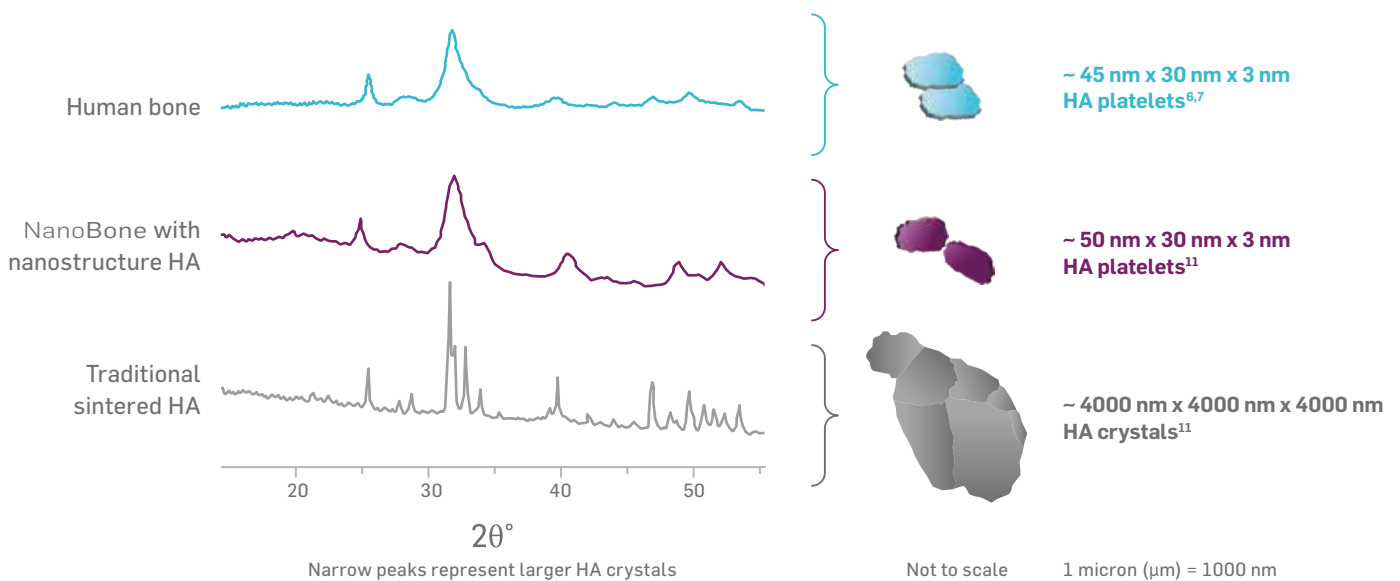
Unlike traditional synthetic HA scaffolds, the HA in NanoBone is precipitated and unsintered to preserve its highly porous and permeable nanoarchitecture and degradation properties. When combined with the high porosity silica gel matrix, NanoBone offers distinct design properties for successful bone healing:⁵

- Nanostructure of HA platelets is identical in morphology to HA in bone^{6,7,8}
- Nanostructure increases autologous protein enrichment^{3,9}
- Proven osteoinductive properties²

Nanostructure of HA platelets is identical in morphology to HA in bone

NanoBone is precipitated to achieve a HA morphology that mimics the HA in natural bone and ensures that complete natural bone remodelling takes place. Traditional sintered HA consists of larger connected crystals which lower porosity and its ability to degrade.^{10,11}

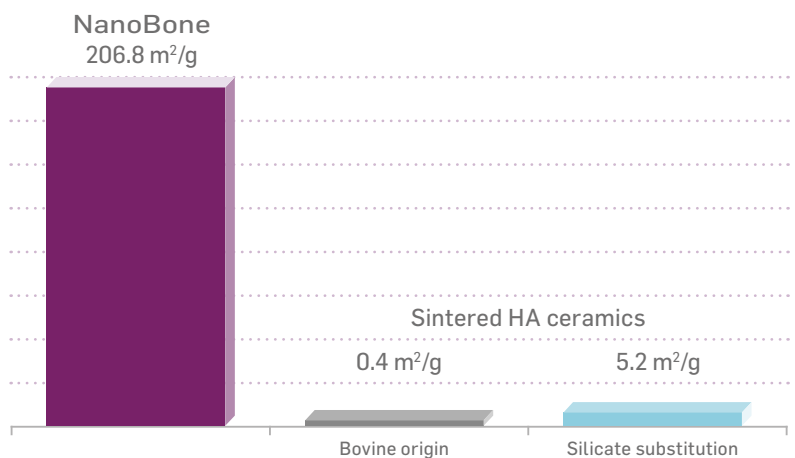
HA diffraction patterns⁸



Nanostructure increases autologous protein enrichment

High inner surface area is key to biological efficiency. Increasing the interaction between NanoBone and serum increases autologous protein enrichment and formation of an extracellular matrix to start bone healing.^{3,9,11}

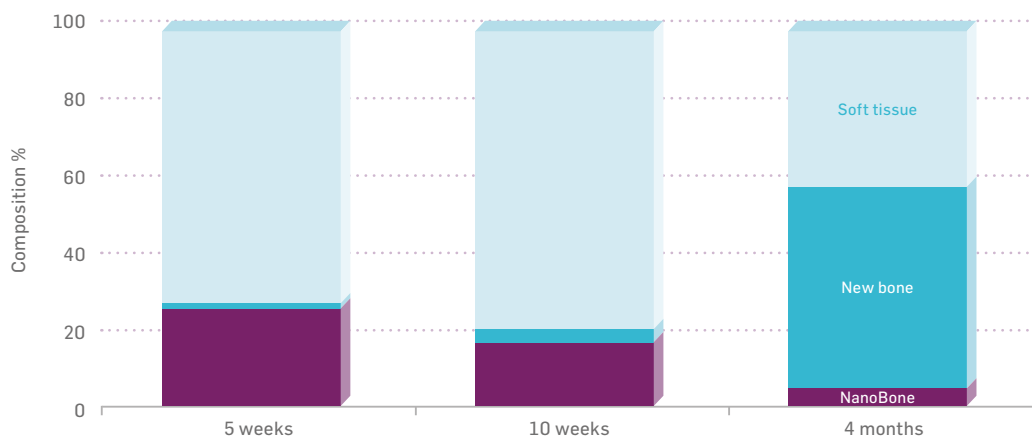
Specific surface area^{9,11,12}



Proven osteoinductive properties

Exchange of the silica gel for autologous proteins, in combination with nanostructured HA, provides a compound very similar to that of skeletal bone and promotes bone remodelling.^{2,11}

Histomorphometric findings in subcutaneous tissue²



In-vivo study - osteoinduction in mini pig model

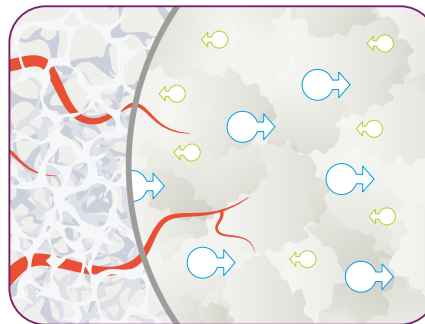
Reliable, early osteogenesis and bone formation





Bone healing is a multi-dimensional process. The silica gel matrix in NanoBone is quickly transformed by the body into a biomimetic organic matrix that enables physiological bone turnover at a very early stage.^{3,10}

Phase 1 approx. 10 days

Neovascularisation of the defect and attraction of autologous proteins

Silica from the carrier and the granules is released to accelerate neovascularisation and is then exchanged for an organic matrix of autologous proteins: inc. BMPs, osteocalcin, osteopontin, glycoproteins.^{3,10,13}

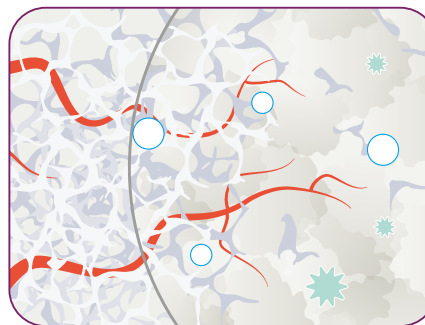






-  NanoBone
-  Vasculature
-  Autologous protein migration through NanoBone
-  Silica molecules released from NanoBone

Phase 2 approx. 100 days

Remodelling – absorption of nanostructured hydroxyapatite and proteins

Combination of nanostructured hydroxyapatite and organic matrix of autologous proteins promotes rapid bone remodelling and formation of woven bone.^{3,10,13}

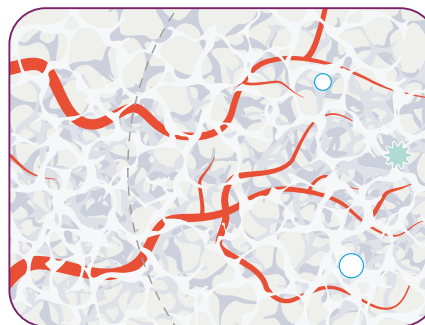






-  Woven bone
-  Vasculature
-  Osteoblast forms woven bone
-  Osteoclasts degrade biomaterial

Phase 3 beyond 100 days

Completion – absorption of woven bone and formation of lamellar bone

Remaining nanostructured hydroxyapatite and organic matrix of autologous proteins are biodegraded by osteoclasts, and osteoblasts form new lamellar bone.^{10,13}



-  Lamellar bone
-  Vasculature
-  Osteoblast forms lamellar bone
-  Osteoclasts absorb woven bone

Save procedure time and resource

NanoBone is preloaded and ready-to-use in a wide variety of applications to maximise flexibility and efficiency during procedures.

- ✓ No mixing or preparation time needed
- ✓ Versatile, ergonomic handling and placement
- ✓ Holds form when moulded and adheres to surfaces

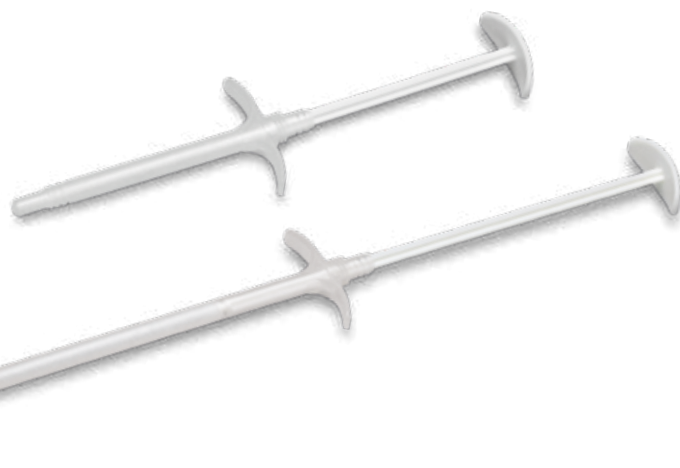
NanoBone SBX Putty

High extrusion volume for placement into larger open wounds



NanoBone QD

Slender profile for placement into deep cavities and minimally invasive procedures



Order number	Product	Volume	Outer diameter	Length
200049	NanoBone SBX Putty	1.0 ml	11 mm	70 mm
200051	NanoBone SBX Putty	2.5 ml	11 mm	70 mm
200052	NanoBone SBX Putty	5.0 ml	18 mm	100 mm
200053	NanoBone SBX Putty	10.0 ml	18 mm	100 mm

Order number	Product	Volume	Outer diameter	Length
200070	NanoBone QD	1.0 ml	8 mm	100 mm
200071	NanoBone QD	2.5 ml	8 mm	100 mm
200072	NanoBone QD	5.0 ml	8 mm	185 mm
200073	NanoBone QD	10.0 ml	8 mm	185 mm

NanoBone[®]

Define success on a different scale

In clinical studies, NanoBone achieved rapid, reliable fusion with complications and healing rates at least comparable with autograft.¹

- ✓ Rapid and reliable fusion
- ✓ No need for biological bone graft
- but can be easily added
- ✓ No foreign body reaction

NanoBone has been used successfully in **over 100,000** clinical cases.

NanoBone ALIF study¹⁴



92% fusion rate reached at **3 months** in the NanoBone group.
No foreign body reaction.

NanoBone PLIF study¹⁵



90% fusion rate reached at **9 months** in the NanoBone group.
28% improvement in overall Oswestry Disability Index (ODI) score.
47% improvement in pain on Visual Analogue Scores (VAS).
No foreign body reaction.

NanoBone benign bone tumour study¹⁶

98 patients with benign bone tumours

Implantation sites included:

- proximal humerus
- distal radius
- femur
- tibia
- hand
- foot

Rapid

4-12 week healing time:
with remodelling like natural bone
– with or without use of cryosurgery
(radiologically confirmed)

At week

12 **all patients:**
fully active and weightbearing.
Bony incorporation with early
remodelling, new bone growth and
reintroduction of trabecular bone

No post-operative infections

or fracture with long-term follow-up



NanoBone immediately post-op in the femur, at 3 months in the humerus, and at 6 months in the calcaneus, illustrating stages of remodelling and healing.

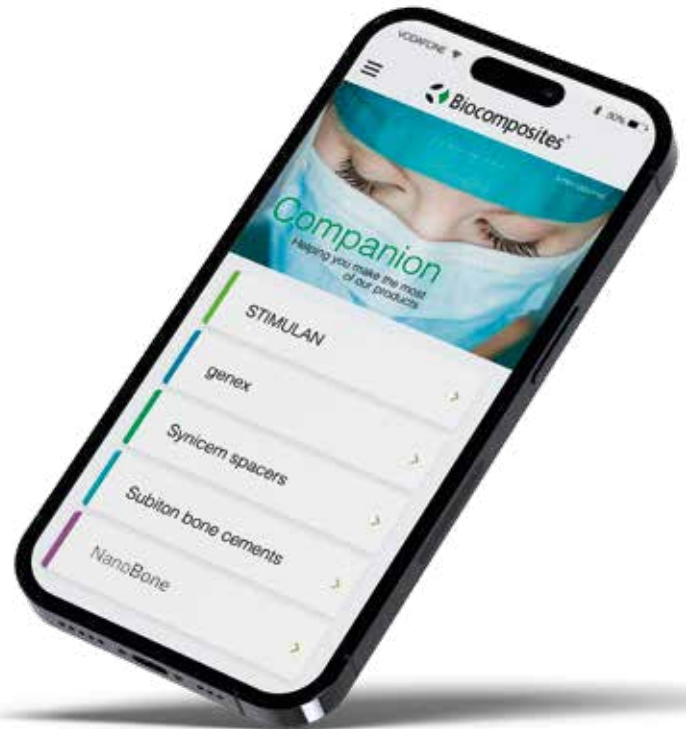


The Biocomposites Companion

Your essential guide to making the most of NanoBone – all in one straightforward app.

- ✓ Why NanoBone: benefits
- ✓ Top tips: tried and tested advice for surgeons
- ✓ FAQs: common questions answered
- ✓ Product range: what's available

To download your Biocomposites Companion, simply scan the QR code.



References

1. Kienast B et al. (2016). Nanostrukturiertes synthetisches Knochenersatzmaterial zur Behandlung von Knochendefekten, Trauma und Berufskrankheit, 4(18), 308-18. **2.** Götz W et al. (2010). A preliminary study in osteoinduction by a nano-crystalline hydroxyapatite in the mini pig. *Folia histochemica et cytobiologica*, 48(4), 589-596. **3.** Xu W (2011). Evaluation of injectable silica-embedded nanohydroxyapatite bone substitute in a rat tibia defect model. *Int J Nanomedicine*, 6, 1543-52. **4.** NanoBone® Summary of product characteristics. **5.** Meier J et al. (2008). Application of the synthetic nanostructured bone grafting material NanoBone® in sinus floor elevation, *Implantologie*, 16, 301-14. **6.** Fratzl, P., et al., (1991). Nucleation and Growth of Mineral Crystals in Bone Studied by Small-Angle-X-Ray Scattering, *Calcif Tissue Int.*, 48, 407-413. **7.** Weiner, S., et al., (1986). Disaggregation of Bone Into Crystals, *Calcif Tissue Int.*, 39, 365-375. **8.** Scherrer P., (1918). Bestimmung der Größe und der inneren Struktur von Kolloidteilchen mittels Röntgenstrahlen, *Nachrichten von der Gesellschaft der Wissenschaften zu Göttingen, Mathematisch-Physikalische Klasse*, 98-100. **9.** Kirchhoff M et al. (2011). Lateral augmentation of the mandible in minipigs with a synthetic nanostructured hydroxyapatite block. *Journal of biomedical materials research. Part B, Applied biomaterials*, 96(2), 342-350. **10.** Götz W et al. (2008). Immunohistochemical characterization of nanocrystalline hydroxyapatite silica gel (NanoBone) osteogenesis: a study on biopsies from human jaws. *Clinical oral implants research*, 19(10), 1016-1026. **11.** Gerber T et al. (2012). Nanostructured bone grafting substitutes – A pathway to osteoinductivity. In *Key Engineering Materials*, 493, 147-152. **12.** Data on file, External testing: Specific surface area, 2010. **13.** Abshagen K et al. (2009). In vivo analysis of biocompatibility and vascularization of the synthetic bone grafting substitute NanoBone®. *Journal of Biomedical Materials Research Part A: An Official Journal of The Society for Biomaterials, The Japanese Society for Biomaterials, and The Australian Society for Biomaterials and the Korean Society for Biomaterials*, 91(2), 557-566. **14.** Rickert M et al. (2019). Clinical Outcome After Anterior Lumbar Interbody Fusion with a New Osteoinductive Bone Substitute Material: A Randomized Clinical Pilot Study. *Clinical spine surgery*, 32(7), E319-E325. **15.** Hebecker R et al. (2008, June 1). A new nanostructured bone substitute for use in neurosurgery – results of a prospective study in lumbar fusion and further applications. 59th Annual Meeting of the German Society of Neurosurgery (DGNC) 3rd Joint Meeting with the Italian Neurosurgical Society (SINch). **16.** Rosenthal H. (2022). Evaluating a Nanocrystalline Hydroxyapatite Bone Graft Substitute for the Treatment of Benign Bone Tumors. *The Internet Journal of Orthopedic Surgery*, 30(1).

©2024, Biocomposites is a trademark/registered trademark of Biocomposites Ltd. NanoBone is a trademark/registered trademark of Biocomposites GmbH. All rights reserved. No unauthorised copying, reproduction, distributing or republication is allowed unless prior written permission is granted by the owner, Biocomposites Ltd.

Patents granted: EP 1 624 904 B1, US 8,715,744 B2, JP4764821B2, 284158, CA2537620C, RU2354408C2, ZL200480020915.3, DE 50 2004 002 554.4, ES2280969T3, AU 2004241740 B2, HK1080766A1, EP 3 600 464 B1, US 11,324,859 B2, JP7118132B2, CN110650754B, DE 50 2018 009 567.7, ES2917406T3, MX2019011659A, RU2768695C2, 386769, AU2018246310A1, BR112019020029A2, CA3058253A1

MA0443R2

NanoBone[®]

POWER TO REMODEL RAPIDLY

- ✓ Rapid absorption and reliable bone fusion¹

- ✓ Comparable healing rate to autograft¹

- ✓ Proven osteoinductive properties²

- ✓ Silica matrix exchanged for autologous proteins within 10 days³

- ✓ Patented nanostructure and optimised composition⁴

- ✓ Preloaded, versatile and ready-to-use⁴

Innovation is at the heart of what we do

Biocomposites' innovative calcium compound and polymer products range from bone grafts to implants that aid in the treatment of infection. Possessing unique characteristics for regenerating bone and managing infected sites, our products are opening new possibilities for surgeons around the world.

Find out more at biocomposites.com