PATIENT INFORMATION LEAFLET

NanoBone®

Bone Graft Substitutes

NanoBone® Products:

NanoBone® | granulate
NanoBone® | block S39
NanoBone® SBX Putty
NanoBone® QD

Product description of NanoBone®

NanoBone® is a synthetic, fully resorbable, bone graft substitute. It is composed of calcium phosphate (hydroxyapatite), which is structurally identical to the mineral in human bone, embedded in a silica gel (non-crystalline silicon dioxide) matrix.

NanoBone® SBX Putty and QD additionally contain a hydrogel carrier, which consists of water, a polymer (poloxamer), and also silica. NanoBone® does not contain any components of animal or human origin, eliminating the risk of disease transmission. Additionally, all NanoBone® products are sterilised by gamma irradiation as a final production step. NanoBone® products do not harden following implantation. Instead, all NanoBone® products are resorbed during the bone healing process, while new bone is formed in their place. NanoBone® leaves no residual material once the bone healing process is completed, and has therefore no risks of long-term complications.

All NanoBone® products function in the same way. The products differ in handling and applicator characteristics. Granulate and block do not include an applicator and have to be mixed with blood (preferable) or saline solution prior to implantation. SBX Putty and QD are provided in an applicator, ready to use, and do not have to be prepared prior to surgery. In their case, the hydrogel carrier serves in a comparable function as blood or saline.

Intended purpose of NanoBone®

All NanoBone® products are intended for the same indications: regeneration of bony gaps and defects and augmentation in dental, oral, maxillofacial, orthopaedic and spinal surgeries. These defects can be due to injury or surgically created.

Intended patient population for NanoBone®

There is no restriction in the use of NanoBone® with regard to sex or age in adults. There is no information available regarding the use of NanoBone® in children. There is no information available on the use of NanoBone® during pregnancy or nursing.

Operating instructions for the use of NanoBone®

NanoBone® | granulate and block have to be prepared with saline or blood prior to surgery. NanoBone® SBX Putty and QD can be used directly without additional preparation. All NanoBone® products must not be used in load bearing defects without the use of additional stabilising measures. Immediately after surgery, avoid mechanical stress to the operated site. Visit your physician for follow-up appointments to assess the recovery and healing of the treated site. In the event of post-operative discomfort or symptoms such as pain, infection, persisting swelling or other unusual symptoms, please contact your physician immediately. Your compliance is crucial for a successful outcome of the surgical procedure.

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Any serious incident that occurs in relation to the device should be reported directly to the manufacturer and the corresponding local representative at the email addresses listed below, as well as the Therapeutic Goods Administration at www.tga.gov.au.

Intended performance of NanoBone®

NanoBone® acts as a scaffold for new bone to grow on and improves growth of blood vessels in the defect area. Visibility of NanoBone® in X-rays immediately after implantation is poor due to the unique structure of NanoBone® and absence of any contrast enhancing agents. The carrier material in some products, as well as the blood clot, if prepared with blood, is degraded within the first few days after implantation. Thereafter, proteins and cells slowly replace the silica matrix surrounding hydroxyapatite. Some cells form new bone while other cells simultaneously degrade hydroxyapatite. This process occurs in the same way healthy bone is gradually renewed. No residual NanoBone® material remains once the defect healing is completed. The duration of the healing process is largely dependent on the defect size and location. Your physician will inform you about approximate healing times for your specific surgery.

Undesirable side effects of NanoBone®

Your physician will educate you about possible contraindications, side-effects and necessary precautions. Possible complications that can occur with any surgery include infection, swelling, pain, wound healing disturbances or complications associated with the use of anaesthesia or antibiotics. Improper implantation can lead to material migration with the associated risk of irritation.

Australian Sponsor

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