NanoBone® FLO

Synthetic, biodegradable bone graft material

Biocomposites GmbH
Fischerweg 421 | 18069 Rostock | Germany
Tel +49 (0) 381 806 99 40
Fax +49 (0) 381 806 99 49 9
Email: infogermany@biocomposites.com
Web: www.biocomposites.com

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex Street, Sydney NSW 2000 Australia

Swiss Authorized Representative
MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug, Switzerland

Indication

NanoBone® FLO is a resorbable implant for filling bone defects that are not essential for the stability of the bone structure and for augmentation. NanoBone® FLO can be used wherever the use of autologous cancellous bone would be possible.
NanoBone® FLO is resorbed and replaced by bone during the healing process.

Properties

NanoBone® FLO consists of nanoporous microparticles and a water-soluble carrier containing poloxamer. The nanoporous microparticles are nanocrystalline hydroxyapatite (HA) embedded in silica gel (amorphous SiO_2).
Due to the completely synthetic production, a transmission of infections or diseases of animal or human origin is excluded. NanoBone® FLO does not harden after implantation.

Application

NanoBone® FLO may only be used by qualified personnel with experience in the required surgical techniques. The principles of sterile working and patient medication applicable to the surgical procedure must be observed.
Preparation:
Bone debris and soft tissue located in the defect should be removed from the bone defect to be treated.
Depending on the type and location of the bone defect, additional osteosynthetic measures may be required to stabilize the bone augmentation material.
Cannula:
The enclosed cannula (inner Ø 2.55 mm, length 50 mm) should be used for the application of NanoBone® FLO. Approved blunt medical cannulas with the required minimum dimensions can also be used. The used cannula must be sterile.
Assembling the cannula and applicator:
To ensure safe use of NanoBone® FLO, it is important that the cannula is correctly attached to the applicator. Only use cannulas whose hub fits onto the Luer lock connector so that the applicator and cannula can be firmly connected. Remove the protective cap from the applicator. Grasp the cannula at the base. Press the cannula against the applicator and turn it clockwise to tighten. Make sure that the cannula hub is seated as tightly as possible on the luer lock connector. The point at which the connection closes tightly depends on the cannula attachment type.
Implantation:
NanoBone® FLO can be used alone or in any mixing ratio with autologous cancellous bone.
The implantation site of NanoBone® FLO may need to be properly secured by rigid fixation.
Maximum contact between the patient's bone and NanoBone® FLO is required to ensure bone regeneration.
NanoBone® FLO does not harden in-situ after implantation.
The bone defect must be completely filled with NanoBone® FLO. Overfilling must be avoided, as must compaction of the bone augmentation material in the bone defect.
The filled bone defect must be closed with a primary wound closure, whereby the defect should be covered by the periosteum.

Information

Successful bone regeneration requires the creation of a suitable bone bed (cavity) to prevent dislocation of the NanoBone® FLO and immobilization of the bone augmentation material. Micromovements may limit bone regeneration and must be avoided by appropriate surgical techniques (e.g. use of membranes).
Due to its structure, NanoBone® FLO exhibits a very low X-ray contrast directly after insertion. In the course of healing, this allows the newly forming bone to be detected in the X-ray image.
NanoBone® FLO must not be used after the expiry date.

Warnings

NanoBone® FLO is not suitable for load-bearing defects. No data are available on the use of NanoBone® FLO in pregnant women or children.
To avoid contamination, the sterile bone augmentation material must only be removed from the packaging immediately before use and must be used in a sterile working environment.
Reprocessing of unused NanoBone® FLO is not possible, as destruction of the nanostructure and a change in properties cannot be ruled out during reprocessing. For single use only. Reuse and/or re-sterilization of unused NanoBone® FLO is not permitted.

Interactions

Interactions of NanoBone® FLO with other medical devices or drugs are not known.

Side-effects
Side effects due to the use of NanoBone® FLO are not known.

Contraindications
- Acute and chronic infections in the surgical area (soft tissue infections, inflammatory, bacterial bone diseases, osteomyelitis), in the case of antibiotic therapy, the user must decide on the use of NanoBone® FLO based on the risk-benefit assessment
- Uncontrolled metabolic diseases (e.g. diabetes mellitus)
- Systemic diseases that negatively impact bone regeneration
- Use of medication known to negatively impact bone regeneration
- Immunosuppressive therapy
- Malignant tumors
- Application in the area of the open epiphyseal joint
- Do not use in mechanically unstable defects (after stabilization of the defect, e.g. with an osteosynthesis plate, it is possible to use NanoBone® FLO
- In the irradiated area or before a planned irradiation treatment
- Bone defects with absent or deficient vascular supply

Type and content of the package
NanoBone® FLO is available for application as needed in a sterile applicator. This is packaged in a sterile aluminium protective pouch (peel-off pack). The inner pouch is contained in an outer protective aluminium pouch (peel-off pack). Once the inner aluminium protective bag has been opened, NanoBone® FLO must no longer be stored.

Sterility
NanoBone® FLO is sterilized by gamma radiation. The expiry date and the integrity of the sterile packaging must be checked before provision.

A copy of the summary of safety and clinical performance (SSCP) can be requested at infogermany@biocomposites.com.