NanoBone® SBX Putty

Bone Graft Substitute

Product Description

NanoBone® SBX Putty contains NanoBone®, a synthetic, biodegradable bone grafting material that is composed of non-sintered nanocrystalline hydroxyapatite (HA) which is embedded in a silica gel matrix (amorphous SiO_2). The ratio of HA / SiO_2 has been chosen to optimize the rate of biodegradation for treatment of osseous defects in human bone.
NanoBone® SBX Putty does not contain any components of animal or human origin, eliminating the possibility of transmission of infection or disease.
NanoBone® SBX Putty is supplied in a sterile polycarbonate applicator and contains NanoBone® granules (0.6-2.0 mm) mixed with a silica gel matrix.
NanoBone® SBX Putty does not set in-situ following implantation.

Indications for Use

NanoBone® SBX Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. NanoBone® SBX Putty resorbs and is replaced with bone during the healing process.

Contraindications

NanoBone® SBX Putty is not designed or sold for any use except as indicated. Do not use Nano-Bone® SBX Putty in the presence of any contraindication. NanoBone® SBX Putty is contraindicated where the device is intended as structural support in the skeletal system.

Other conditions for which Nano-Bone® SBX Putty is contraindicated include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative disease
- Severely impaired renal function
- Hypercalcemia, abnormal calcium metabolism
- Existing acute or chronic infections, especially at the site of the operation
- Inflammatory bone disease such as osteomyelitis
- Malignant tumors
- Uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol

Application

NanoBone® SBX Putty may only be used by qualified professionals with experience in the required surgical techniques. The principles of sterile work and patient medication valid for surgical procedures must be observed. NanoBone® SBX Putty is not intended for load-bearing applications. The area where NanoBone® is implanted must be properly secured with rigid fixation. Maximize the contact between the patient's bone and NanoBone® SBX Putty to ensure bone regeneration. NanoBone® SBX Putty does not set in-situ following implantation.
The bone defect must be completely filled with NanoBone® SBX Putty. Avoid overfilling as well as compaction of the bone grafting material in the bone defect. The filled bone defect should be closed with a primary wound closure ensuring that the defect is covered by the periosteum. NanoBone® SBX Putty may appear radiopaque in x-rays, similar to cancellous bone.Do not overfill or attempt to pressurize the bony defect site, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues, or may lead to fat embolization or embolization of the product into the bloodstream.

Instructions for Use

1. Open outer (non-sterile) and inner (sterile) packaging.
2. NanoBone® SBX Putty is designed to be used alone.
3. Implant NanoBone® SBX Putty. Secure the surgical site after implantation to prevent micromotion and/or implant migration. If NanoBone® SBX Putty material is not positioned properly, remove the material and begin again with a new package of material.

Warnings

NanoBone® SBX Putty is not intended for load-bearing uses.There is no data available on the use of NanoBone® SBX Putty with pregnant women or children.Single use only. Do not attempt to reuse and/or resterilize unused NanoBone® SBX Putty.

Sterility

Contents are STERILE by exposure to gamma radiation unless opened or damaged. Do not use if sterile packaging has been damaged. Do not use if expiration date has been exceeded. Do not resterilize.

Storage, Shelf Life and Disposal

Product should be stored between 5-32°C (40-90˚F). The expiration date is printed on the label. DO NOT USE NanoBone® SBX Putty AFTER THE EXPIRATION DATE. NanoBone® SBX Putty is environmentally friendly. No special disposal is necessary.

Caution

U.S. Federal Law restricts this device to sale by or on the order of a physician or hospital. Responsibility for proper selection of patients, for adequate training, for experience in the selection and placement of NanoBone® SBX Putty and for the selection of post-operative protocols rests entirely with the physician.

Glossary

Symbol	Description	Source
	Manufactured by.	AAMI/ANSI/ISO 15223-1: 2016, section 5, reference no. 5.1.1
STERILE R	Contents are STERILE by exposure to gamma radiation.	AAMI/ANSI/ISO 15223-1: 2016, section 5, reference no. 5.2.4
	Do not use if package is damaged.	AAMI/ANSI/ISO 15223-1: 2016, section 5, reference no. 5.2.8
STERILIZE	Do not resterilize.	AAMI/ANSI/ISO 15223-1: 2016, section 5, reference no. 5.2.6
	Single use. Do not reuse.	AAMI/ANSI/ISO 15223-1: 2016, section 5, reference no. 5.4.2
40°F 90°F	Store between 40-90 °F.	AAMI/ANSI/ISO 15223-1: 2016, section 5, reference no. 5.3.7
	Consult instructions for use.	AAMI/ANSI/ISO 15223-1: 2016, section 5, reference no. 5.4.3
Rx Only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.	21 U.S. Code § 353, paragraph (b)(4)(A)

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