NanoBone® QD

Bone Graft Substitute

Instructions for Use

Product Description

NanoBone® QD contains NanoBone® SBX Putty, 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® QD does not contain any components of animal or human origin, eliminating the possibility of transmission of infection or disease.

NanoBone® QD is supplied in a sterile polymer cartridge with a separate sterile plunger. The cartridge contains NanoBone® granules (0.6-2.0 mm) mixed with a silica gel matrix.

NanoBone® QD does not set in-situ following implantation.

Indications for Use

NanoBone® QD 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® QD Putty resorbs and is replaced with bone during the healing process.

Contraindications

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

Other conditions for which NanoBone® QD 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® QD 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® QD is not intended for load-bearing applications. The area where NanoBone® QD is implanted must be properly secured with rigid fixation. Maximize the contact between the patient's bone and NanoBone® QD to ensure bone regeneration. NanoBone® QD does not set in-situ following implantation. The bone defect must be completely filled with NanoBone® QD. 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® QD 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. Remove the two wing nuts by turning counterclockwise (Fig. 1).
3. Insert the plunger into the cartridge (Fig. 2).
4. Push the biomaterial out of the cartridge into the bone void (Fig. 3).
5. NanoBone® QD is designed to be used alone.
6. Secure the surgical site after implantation to prevent micromotion and/or implant migration. If NanoBone® QD material is not positioned properly, remove the material and begin again with a new package of material.

Warnings

NanoBone® QD is not intended for load-bearing uses.

There is no data available on the use of NanoBone® QD with pregnant women or children.

Single use only. Do not attempt to reuse and/or resterilize unused NanoBone® QD.

Sterility

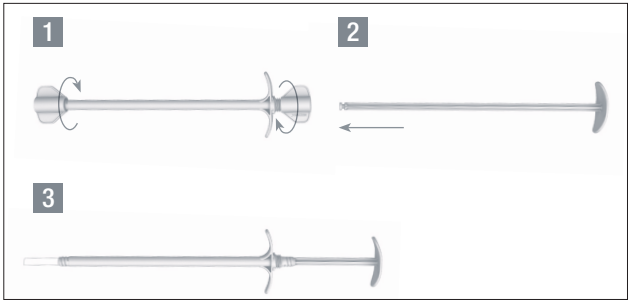
Contents are STERILE by exposure to gamma radiation unless opened or damaged. Do not use if sterile packaging has been damaged. Do not use if expiration date has been exceeded. Do not resterilize.

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® QD AFTER THE EXPIRATION DATE. NanoBone® QD 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. Responsibility for proper selection of patients, for adequate training, for experience in the selection and placement of NanoBone® QD 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
	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
	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
	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
	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)

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