EN – INSTRUCTIONS FOR USE – Bioactive Bone substitute

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AktiBone™ Granules

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THE BIOGLASS® COMPANY

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References	Granule size	Volume
XAK-GM0.5	0.5-1 mm	0.5 cc
XAK-GM1.0	0.5-1 mm	1 cc
XAK-GM5	0.5-1 mm	5 cc
XAK-GL1.0	1-3 mm	1 cc
XAK-GL5	1-3 mm	5 cc
XAK-GL10	1-3 mm	10 cc
XAK-GL16	1-3 mm	16 cc

List of symbols

	Do not use if package is damaged and consult instruction for use
	Manufacturer
2026/04	Last update
REF	Reference
LOT	Batch number
	Use-by date
	Caution - Instruction for Use
	Keep in a dry place
	Store away from sunlight
25°C 15°C	Temperature limit 15-25°C (storage)
	Do not reuse
STERILE R	Sterile, Gamma irradiation
2 STERILIZE	Do not resterilize
	Manufacturing date
MR	MR safe
VOL	Volume (cc / cm^3)
MD	Medical Device
	Granule size (mm)
	Single sterile barrier system with protective packaging inside
eifu.noraker.com	Consult electronic instruction for use
UDI	Unique Device Identifier
Rx Only	For provision and use only at a licensed physician's direction and under medical supervision

Indications for use

AktiBone Granules is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. AktiBone Granules resorbs and is replaced with bone during the healing process.

Rx Only

Description of the device

AktiBone Granules is a synthetic, biocompatible bone substitute device (bioactive glass 45S5) and osteoconductive bioactive material used either separately or in conjunction with autogenous bone for grafting. AktiBone Granules is composed of elements that exist naturally in bone or surrounding tissues (45%w silicon dioxide (SiO_2), 24.5%w calcium oxide (CaO), 24.5%w sodium oxide (Na_2O) and 6%w phosphate pentoxide (P_2O_5)).

During its implantation, AktiBone Granules is in contact with bone and biological fluids. The release of ions during resorption induces a surface reaction resulting in the formation of a calcium phosphate layer (carbonated hydroxyapatite) that is substantially equivalent in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer gives AktiBone Granules its osteoconduction property and creates a strong link between the granules and living tissue and provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect.

AktiBone Granules must be used by qualified surgeons trained in bone grafting and fixation techniques and who have read these instructions for use.

Contraindications

Warning against use in infected sites: AktiBone Granules should not be used in case of chronic or acute infection not treated with appropriate therapy.

AktiBone Granules should also not be used:

- In patients who have suffered serious trauma with external wounds open near the defect, which could become infected.
- In patients with known allergy to bioactive glass or its constituents (Ca^{2+}, PO_4^{3-} , Na^+ and $Si(OH)_4$).
- In patients with pre-existing conditions or disease that may interfere with the good healing of tissues
- In the irradiated bone (according to radiological criteria indicating osteonecrosis)
- To replace structures subject to high mechanical stresses
- During severe renal and hepatic infections.
- In conjunction with a treatment known to affect the skeleton.
- In case of unsutured meningeal breach in cranio-spinal surgery.
- In neonatology service

To date, we do not have any studies conducted in pregnant women or data related to use during breastfeeding. As a safety measure, the implantation of AktiBone Granules is not recommended during the periods of pregnancy and lactation. In addition, a warning is required for patients treated in special clinical situations (tumor, ongoing chemotherapy and radiation therapy, immunodeficiency).

Composition of AktiBone Granules

AktiBone granules (45S5) consist only of 45%w silicon dioxide (SiO_2), 24.5%w calcium oxide (CaO), 24.5%w sodium oxide (Na_2O) and 6%w phosphate pentoxide (P_2O_5).

Instructions for use

- Check the expiry date. Do not use the product if it is exceeded.
- Do not use if the sterile packaging (external blister) is damaged, opened prematurely or exposed to environmental conditions other than those specified.
Check each device before use to detect any deterioration. If deterioration is present, do not use the implant.
- Eliminate all soft and/or pathological tissue from the implantation site (debridement).
- Refresh the surface of the bone.
- Open the outer blister (sterile barrier) and remove the inner blister on the sterile field.
- Once the surgical site has been prepared, open the inner blister.
- Mix the substitute in a sterile cup with a saline solution (in a roughly 4:1 ratio) or patient blood (in a 2:1 ratio), depending on the clinical context, surgical specialty and surgeon practice. From a therapeutic point of view, there is no difference between the use of these mixtures compared to AktiBone Granules used alone whatever the situation: the choice depends on the surgeon's practice, the patient's disease, and the available constituents.
- Do not mix into the inner blister containing the granules as hemocompatibility nor compatibility of the blister with other constituents has not been tested.
- Using a sterile instrument, fill in the defect. Do not compress the material in the site or blot away the blood/moisture in the positioned graft.

After placement of AktiBone Granules, ensure the primary closure of the soft tissues at the graft site. Resorbable or non-resorbable membranes can also be used for closure.

- This device is MR safe.

Warnings and precautions for use

Caution: Federal law restricts this device to sale by or on the order of a physician.

Regarding the surgical procedure
- The general principles of asepsis and patient medication must be observed when using AktiBone Granules.
- AktiBone Granules does not substitute antibiotic therapy treatment during infection.
- Interaction of AktiBone Granules with drug has not been tested. The combination of any drug substance with AktiBone Granules during implantation is the responsibility of the surgeon.
- Manipulate AktiBone Granules with a surgical instrument to avoid piercing surgical gloves.
- Instructions for proper placement and containment in the desired treatment area: Completely fill the defect with Granules.
- Precaution against over-filling the defect site: Avoid placing granules outside of the bone defect. Remove them if necessary.
- It is possible to perform the application of AktiBone Granules if the defect has sufficient bone wall.
- Avoid direct contact of AktiBone Granules with the skin.

If it moves/migrates, the bioactive glass can cause wear of the joints and interfere with movement. Prevention of movement and granule migration is essential for proper bone formation.

- Instructions on the need for adequate fixation: AktiBone Granules does not have sufficient mechanical strength to withstand load bearing before hard tissue is formed. When used in load bearing areas, standard internal or external stabilization techniques should be followed to achieve rigid stabilization in all planes.
- Do not apply excessive pressure to the defect. Excessive pressure may cause embolization of fat in the bloodstream.
- AktiBone Granules maintains its volume: it does not shrink or expand.
- It is necessary to follow the usual post-operative treatment and rehabilitation procedures associated with bone grafts.

- The closure of the operative site depends on the surgery performed and the surgical site (membrane, sutures, etc.). An adequate closure of the graft site is mandatory (e.g., with cortical bone window, collagen membrane, mucosal-periosteum flap, fascia or muscle flap).

Regarding the medical device

- AktiBone Granules is a device that resorbs over time to make way for regenerated bone. There is currently no clinical study available that demonstrates complete resorption of the granules.
- This device does not harden like cement.
- AktiBone Granules is a sterile disposable device and must never be re-sterilized or reused. Reuse may cause contamination and impairment of bone substitute performance.

Adverse effects

An unknown allergy to one of the constituents of the product may be possible. Possible complications are the general complications due to surgery or anesthesia: Post-surgical symptoms (pain, redness, inflammation, oedema, hematomas, seroma, swelling, bleeding), postoperative infection, recurrence/residual disease, otorrhea, pulmonary embolism, vein thrombosis, wound leakage, nerve palsy or paresthesia, mechanical failure, delay in consolidation, loss of fracture reduction, fusion failure, fracture, loss of bone graft, protrusion of the graft.

These complications are the same as those that can occur with autologous bone grafting. Possible adverse events are not more severe than those expected of similar products if the instructions are followed correctly by a qualified surgeon familiar with bone grafting techniques.

Information for the patient

- The patient must be informed by the surgeon of the potential risks and adverse effects of implantation and agree to the proposed procedure.
- The surgeon should inform the patient who is the recipient of this device that the success of implantation depends on their behavior and good compliance with post-operative hygiene instructions.
- The patient must report any incident to the surgeon that could compromise the proper integration of the implant and undergo postoperative checks.

After surgery, an implant card is filled out by the medical staff and given to the patient. The patient should keep it for life.

Sterilization

AktiBone Granules is a single-use device, sterilized with gamma irradiation (sterile barrier ensured by external blister). Sterility is guaranteed until the expiration date if the sterile barrier has not been opened or damaged.

Storage & Disposal

The device must be stored in its original unopened packaging in a clean, dry place, away from direct sunlight and at a recommended temperature between 15°C and 25°C.
Disposal of the device should be carried out in accordance with local regulations and practices, at the risk of exposing users and patients to pathogens and contaminating the waste circuit.

Document update

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