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# KINEX® BIOACTIVE

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**IMPORTANT INFORMATION ON KINEX® BIOACTIVE**


**GLOBUS MEDICAL, INC.**
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA
Customer Service:
Phone 1-866-GLOBUS1 (OR)
1-866-456-2871
Fax 1-866-GLOBUS3 (OR)
1-866-456-2873


**ENGLISH**

## IMPORTANT INFORMATION ON KINEX® BIOACTIVE

### DESCRIPTION

KINEX® Bioactive is a resorbable bone void filler for the repair of bony defects. It is an osteoconductive and osteostimulative material that guides bone regeneration. When KINEX® is placed in direct contact with host bone, new bone grows in apposition to the surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by KINEX®.

KINEX® implants consist of bioglass (per ASTM F1538), collagen (per ASTM F2212), and hyaluronic acid, and are available in putty, gel, and strip forms to accommodate surgical and anatomical needs.

### INDICATIONS

KINEX® Bioactive is intended for use as a bone void filler and autograft extender for voids or gaps that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. KINEX® Plus Putty and KINEX® Plus Gel are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and spine) and should be combined with bone marrow aspirate. KINEX® Strip, KINEX® Plus Strip, KINEX® Putty and KINEX® Gel are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis) and should be combined with bone marrow aspirate. KINEX® resorbs and is replaced with bone during the healing process.

### WARNINGS

KINEX® is not designed with sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation methods are recommended as needed to ensure stabilization of the defect. Complete postoperative wound closure is essential.

KINEX® Putty is intended for manual application and is not intended for injection through a constrained opening or under high pressure. KINEX® Gel may be injected into the desired location. High pressure injection of KINEX® should not be conducted as pressurization in closed cavities can lead to device extrusion beyond the intended application site, which could damage surrounding tissues, or to embolization of fat or the device into the bloodstream.

Packaging should be intact up on receipt. Damaged packages and/or contaminated products should not be used and should be returned to Globus Medical.

### PRECAUTIONS

KINEX® Bioactive is intended for use by surgeons familiar with bone grafting techniques. If fixation is used, the labeling for the use of the fixation system chosen should be followed and the fixation must gain purchase in the host bone. Standard postoperative practices for the treatment and rehabilitation associated with bone grafting must be strictly followed.

Mental or physical impairment that compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

A successful result is not always achieved in every surgical case. This is particularly true in spinal surgery where many extenuating circumstances may compromise the results.

As with any surgical procedure, care should be demonstrated in treating patients with preexisting conditions that may impact the success of the surgical procedure. This includes patients with bleeding disorders of any etiology, long-term steroid therapy, or immunosuppressive therapy, or high dose radiation therapy.

Use this device as supplied and in accordance with the handling and use information provided below.

### CONTRAINDICATIONS

KINEX® must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen or who are being treated for desensitization to meat products because this product contains bovine collagen.

Conditions representing relative contraindications include:

1. Severe neurological or vascular disease
2. Hypercalcemia
3. Pregnancy
4. Cases of fracture fixation or where load support is required, unless standard internal or external stabilization techniques are followed to obtain rigid stabilization in all planes.
5. Systemic and/or metabolic disorders that affect the bone or wound healing
6. Conditions in which general bone grafting is not advisable
7. Local infection
8. Any patient unwilling to follow postoperative instructions
9. Vertebroplasty or kyphoplasty procedures
10. To gain screw purchase or to stabilize screw placement
11. Any case not described in the indications

## POTENTIAL ADVERSE EVENTS

Possible complications are the same as to be expected of autogenous bone grafting procedures and include but are not limited to:

1. Deformity of the bone at the surgical site
2. Fracture or extrusion of the KINEX® implant(s), with or without generation of particulate debris
3. Wound complications including hematoma, site damage, infection (superficial, deep or deep with osteomyelitis), bone fracture, and other complications common to any surgical procedure
4. Incomplete, or lack of, osseous ingrowth into bone void, as possible with any bone void filler
5. Delayed union or failure of fusion
6. Transient hypercalcemia
7. Loss of bone graft, graft protrusion and/or dislodgement, which could damage surrounding tissue
8. General complications that may arise from anesthesia and/or surgery

Localized immunological reactions consisting of transient localized edema, swelling, and rash have been reported to occur with bone void fillers containing collagen. Although there is no evidence that the device will be unsafe or ineffective in such patients, the safety and effectiveness of the device in these patients has not been established.

Occurrence of one or more of these conditions may require an additional surgical procedure and may also require removal of the bone void filler.

## OSTEOSTIMULATION

KINEX® is an osteostimulative and osteoconductive device. Osteostimulation is defined as an accelerated bone formation process, characterized by the active stimulation of osteoblast proliferation and differentiation in an osseous defect. This stimulatory action has been demonstrated during *in vivo* tests of Bioglass particulate to be more rapid than simple osteoconduction.[1,2] These tests have been supported by *in vitro* cell culture tests, which demonstrate the mechanisms of cell stimulation as being the result of cellular interaction with the ionic dissolution products released from Bioglass particulate during its absorption.[3-6] Clinical data on this acceleration of bone formation in the human has not been established.

KINEX® has only been demonstrated to form bone in osseous defects. KINEX® therefore is not osteoinductive. Such osteoinductive devices can be characterized by their ability to form new bone tissue in non-osseous (soft-tissue) sites.


1. Oonishi H, Kushitani S, Yasukawa E, Iwaki H, Hench LL, Wilson J, Tsuji E, Sugihara T: *Particulate Bioglass Compared with Hydroxyapatite as a Bone Graft Substitute.* Clin Orthop 334:316-325, 1997.
2. Fujishiro Y, Hench LL, Oonishi H: *Quantitative Rates of In vivo Bone Generation for Bioglass and Hydroxyapatite Particles as Bone Graft Substitute.* J Mater Sci Mat Med 8:649-652, 1997.
3. Vrouwenvelder WCA, Groot CG, de Groot K: *Histological and Biochemical Evaluation of Osteoblasts Cultured on Bioactive Glass, Hydroxyapatite, Titanium Alloy and Stainless Steel.* J. Biomed Res 27:465-475, 1993.
4. Xynos ID, Hukkanen MVJ, Batten JJ, Buttery LD, Hench LL, Polak, JM: *Bioglass 45S5 Stimulates Osteoblast Turnover and Enhances Bone Formation In vitro: Implications and Applications for Bone Tissue Engineering.* Calcif Tissue Int 67:321–329, 2000.
5. Xynos ID, Edgar AJ, Buttery LDK, Hench LL, Polak JM: *Ionic Products of Bioactive Glass Dissolution Increase Proliferation of Human Osteoblasts and Induce Insulin-Like Growth Factor II mRNA Expression and Protein Synthesis.* Biochem Biophys Res Comm 276:461-465, 2000.
6. Bosetti M, Cannas M: *The Effect of Bioactive Glasses on Bone Marrow Stromal Cells Differentiation.* Biomaterials 26(18):3873-3879, 2005.


## HANDLING & USE

KINEX® implants should be combined with autogenous bone marrow aspirate at a ratio of 1:1 (KINEX®:BMA). KINEX® should not be used alone.

KINEX® should be implanted into bony defects according to the following technique. Prepare the wall of the defect that will contact the KINEX® product, as needed. Mix or saturate the KINEX® product with autogenous bone marrow aspirate. Gently pack the site but avoid overfilling the bone void or compressing the treatment site. Remove excess material from the treatment site. Close the site using standard closure techniques and discard any unused KINEX® product.

## STORAGE

Do not freeze or expose to extreme heat. Store between 5°C (41°F) and 25°C (77°F).

## CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

## STERILIZATION

KINEX® Bioactive is provided sterile in an unopened and undamaged package. This product must be used on or before the expiration date that is provided on the package label. This device is for single patient use and should never be reused.

**CAUTION:** Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

| SYMBOL TRANSLATION | | | |
|---|---|---|---|
| REF | CATALOGUE NUMBER | STERILE R | STERILIZED BY IRRADIATION |
| LOT | LOT NUMBER | EC REP | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
| ⚠ | CAUTION | | MANUFACTURER |
| | SINGLE USE ONLY | | USE BY (YYYY-MM-DD) |
| QTY | QUANTITY | STERILE EO | STERILIZED BY EXPOSURE TO ETHYLENE OXIDE |
| | PRODUCT MUST BE STORED BETWEEN 5° C (41° F) AND 25° C (77° F) | | |