GLOBUS MEDICAL

KINEX® and KINEX® PLUS

Bioactive Bone Void Filler

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM | *Life moves us*

GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

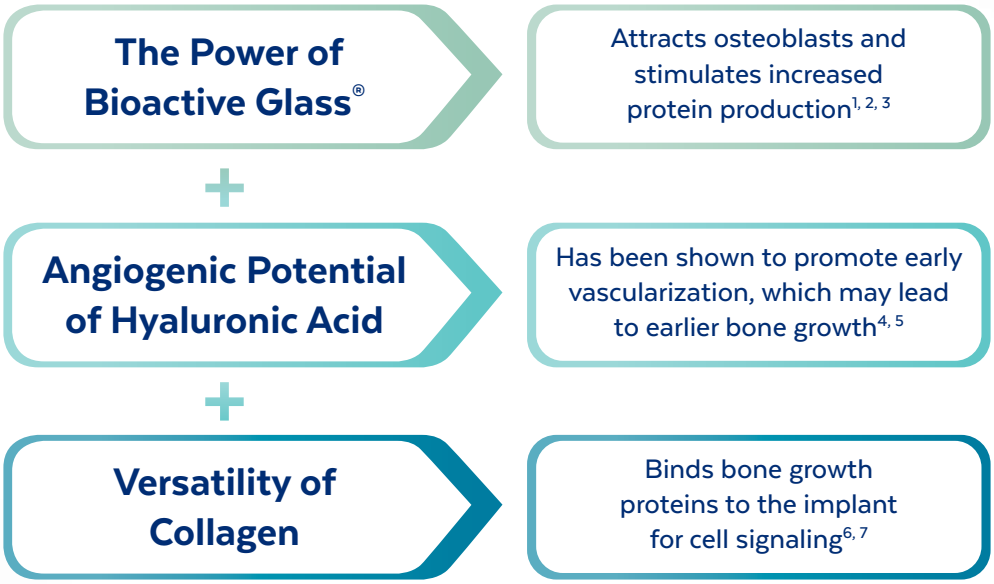
SURGICAL TECHNIQUE GUIDE

KINEX® and KINEX® PLUS

KINEX® and KINEX® PLUS

Bioactive Bone Void Filler

KINEX® and KINEX® PLUS components are designed to recruit and signal osteoblasts, promote early vascular development, and bind proteins necessary for bone regeneration. KINEX® and KINEX® PLUS use The Power of Bioactive Glass® to help promote bone formation and healing.



PRODUCT SPECIFICATIONS

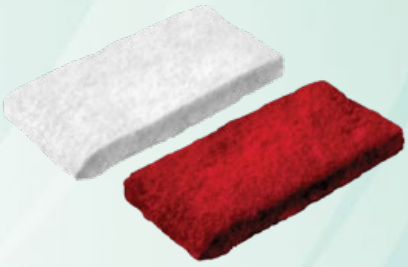
KINEX® Putty and KINEX® PLUS Putty

- Composition: Bioglass, collagen, and hyaluronic acid
- Packaged sterile in a tray
- KINEX® Putty Bioglass content: 80%
- KINEX® PLUS Putty Bioglass content: 84%
- Available in three sizes: 2, 5, and 10cc

KINEX® Gel and KINEX® PLUS Gel

- Composition: Bioglass, collagen, hyaluronic acid
- Packaged sterile in a luer lock syringe
- KINEX® Gel Bioglass content: 80%
- KINEX® PLUS Gel Bioglass content: 84%
- Available in three sizes: 2, 5, and 10cc

KINEX® Strip



- Composition: Bioglass, collagen, and hyaluronic acid
- Packaged sterile in a tray
- KINEX® Strip Bioglass content: 80%
- Available in three sizes: 5, 10, and 20cc

CLINICAL APPLICATIONS

SPINE

Posterolateral Fusion

KINEX® PLUS Putty

KINEX® PLUS Gel

PELVIS

Filling Defects

KINEX® Putty

KINEX® PLUS Putty

KINEX® Gel

KINEX® PLUS Gel

KINEX® Strip

EXTREMITIES

Filling Defects

KINEX® Putty

KINEX® PLUS Putty

KINEX® Gel

KINEX® PLUS Gel

KINEX® Strip

SURGICAL TECHNIQUE

KINEX® and KINEX® PLUS

Please refer to the product insert reprinted in the back of this manual for a complete description, indications, contraindications, and warnings associated with these products.

STEP 1 PREOPERATIVE PLANNING

The approximate defect size or volume should be determined prior to surgery using an MRI, CT, or X-ray. Select the KINEX® or KINEX® PLUS implant to completely fill the void.

STEP 2 SITE PREPARATION

Proper positioning of the patient is determined by the surgical approach. Clean the defect of debris. The surfaces of the defect may be smoothed using an instrument such as a burr. Prepare the walls of the defect that contact the KINEX® or KINEX® PLUS so that bleeding bone is exposed. Determine the amount of KINEX® or KINEX® PLUS to be used based on the size or volume of the defect to be filled.

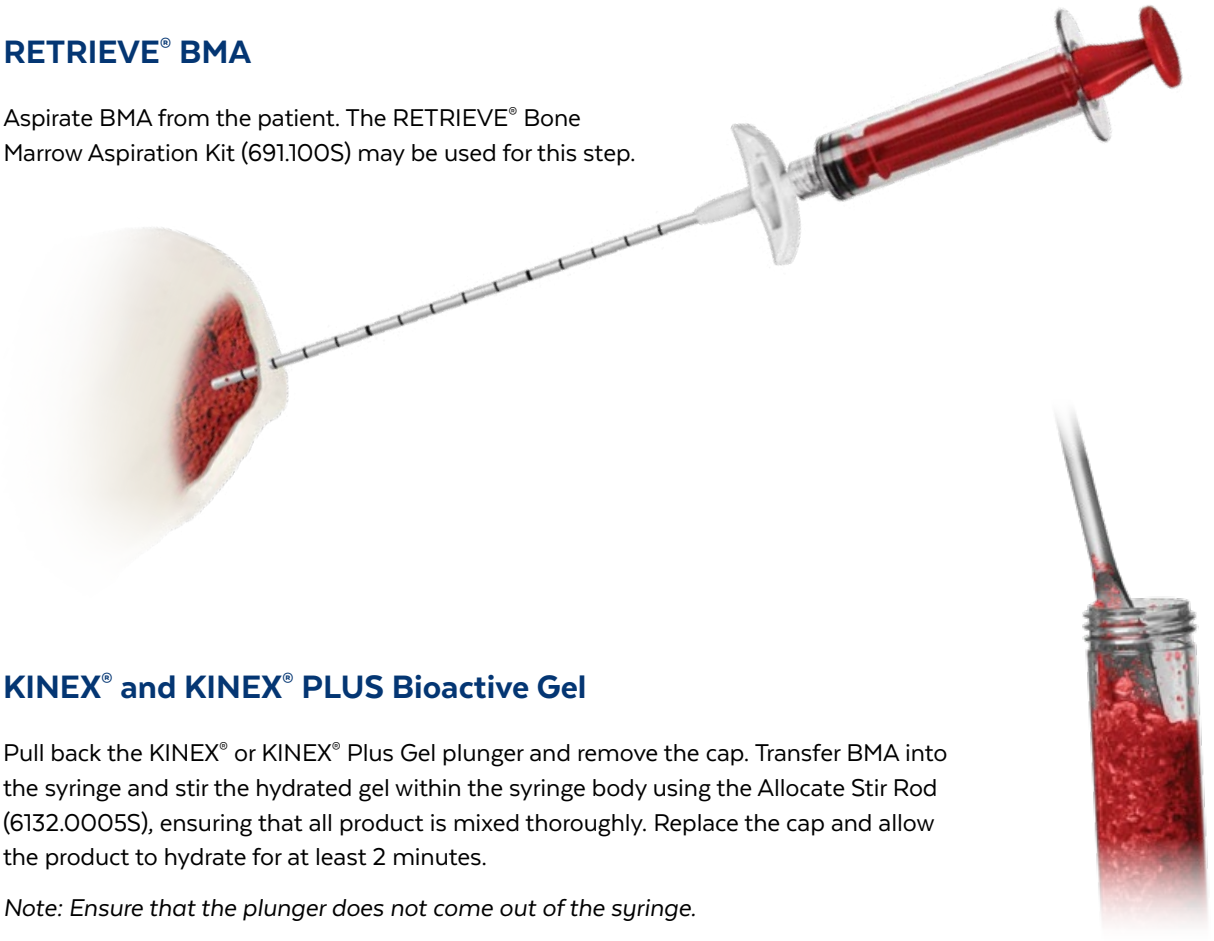
STEP 3 IMPLANT PREPARATION

KINEX® and KINEX® PLUS are provided sterile. Open the sterile packaging.

KINEX® and KINEX® PLUS implants should be combined with autogenous bone marrow aspirate (BMA) in a ratio of 1:1 (KINEX® PLUS : BMA; or KINEX® : BMA).

RETRIEVE® BMA

Aspirate BMA from the patient. The RETRIEVE® Bone Marrow Aspiration Kit (691.100S) may be used for this step.



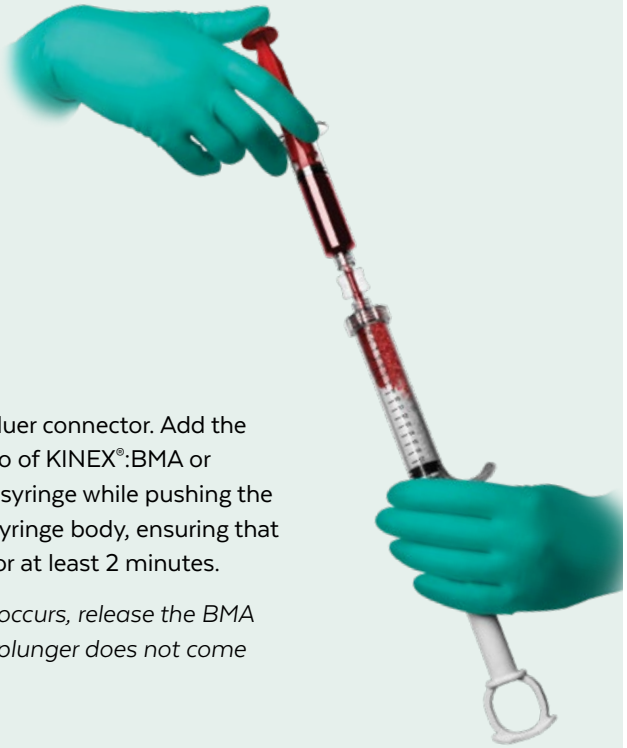
KINEX® and KINEX® PLUS Bioactive Gel

Pull back the KINEX® or KINEX® Plus Gel plunger and remove the cap. Transfer BMA into the syringe and stir the hydrated gel within the syringe body using the Allocate Stir Rod (6132.0005S), ensuring that all product is mixed thoroughly. Replace the cap and allow the product to hydrate for at least 2 minutes.

Note: Ensure that the plunger does not come out of the syringe.

Alternate Technique

Attach the luer connector to the KINEX® or KINEX® PLUS Gel syringe (provided in packaging).



Attach the syringe containing the BMA to the other end of the luer connector. Add the BMA to the KINEX® or KINEX® PLUS Gel syringe (using a 1:1 ratio of KINEX®:BMA or KINEX® PLUS:BMA), slowly pulling back the plunger on the gel syringe while pushing the plunger into the BMA syringe. Stir the hydrated gel within the syringe body, ensuring that all product is mixed thoroughly. Allow the product to hydrate for at least 2 minutes.

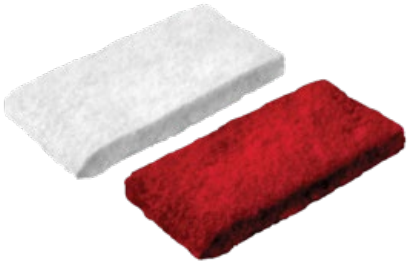
Note: Pressure may build in the syringe during transfer. If this occurs, release the BMA plunger to relieve pressure before proceeding. Ensure that the plunger does not come out of either syringe.

IMPLANT PREPARATION (CONT'D)

KINEX® and KINEX® PLUS Bioactive Putty and KINEX® Bioactive Strip

Aspirate BMA.

Hydrate KINEX® or KINEX® PLUS (using a 1:1 ratio of KINEX®:BMA or KINEX® PLUS:BMA).



For KINEX® Strip, allow the product to rest in the tray until needed.

For KINEX® Putty and KINEX® PLUS Putty, knead the product for approximately 30 seconds until a putty-like consistency is obtained. Allow the putty to rest in the tray until needed.

KINEX® and ALLOCATE™

Attach KINEX® or KINEX® PLUS Gel syringe to ALLOCATE™ Cannula (6132.1001S) for controlled delivery if necessary.

STEP 4 IMPLANT INSERTION

Gently pack the defect, avoiding overfilling or compressing the treatment site.

KINEX® Strips are used to fill shallow defects in the extremities or pelvis. Strips can also be cut to a custom size as desired.

KINEX® PLUS Putty and KINEX® PLUS Gel are used to fill various size defects or may be used in the posterolateral spine.

KINEX® Putty and KINEX® Gel are used to fill various size defects.

KINEX® Putty and KINEX® PLUS Putty can be molded and contoured into a custom shape to fill defects as desired. KINEX® Gel and KINEX® PLUS Gel are provided within a syringe, which when hydrated becomes an extrudable gel that can be delivered to small defects and confined spaces.

KINEX® Gel
KINEX® PLUS Gel

KINEX® Putty
KINEX® PLUS Putty

KINEX® Strip

STEP 5 CLOSURE

Remove any excess KINEX® material. Close the site using standard closure techniques and discard any unused KINEX® product.

KINEX® implants are not intended to provide structural support. Rigid fixation methods are required to ensure stabilization of the defect.

KINEX®
IMPLANT LIST

PART NO.	DESCRIPTION
8115.0005S	KINEX® Bioactive Strip, 25mm x 50mm x 4mm
8115.0010S	KINEX® Bioactive Strip, 25mm x 50mm x 8mm
8115.0110S	KINEX® Bioactive Strip, 25mm x 100mm x 4mm
8115.0120S	KINEX® Bioactive Strip, 25mm x 100mm x 8mm
8115.0202S	KINEX® Bioactive Gel, 2cc
8115.0205S	KINEX® Bioactive Gel, 5cc
8115.0210S	KINEX® Bioactive Gel, 10cc
8115.0302S	KINEX® Bioactive Putty, 2cc
8115.0305S	KINEX® Bioactive Putty, 5cc
8115.0310S	KINEX® Bioactive Putty, 10cc

KINEX® PLUS
IMPLANT LIST

PART NO.	DESCRIPTION
8115.5202S	KINEX® PLUS Bioactive Gel, 2cc
8115.5205S	KINEX® PLUS Bioactive Gel, 5cc
8115.5210S	KINEX® PLUS Bioactive Gel, 10cc
8115.5302S	KINEX® PLUS Bioactive Putty, 2cc
8115.5305S	KINEX® PLUS Bioactive Putty, 5cc
8115.5310S	KINEX® PLUS Bioactive Putty, 10cc

REFERENCES

1. 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. Commun.*, 2000; 276: 461–465.
2. Xynos ID, Hukkanen MV, 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.*, 2000; 67: 321–329.
3. Ducheyne P, Qiu Q. Bioactive ceramics: the effect of surface reactivity on bone formation and bone cell function. *Biomaterials*, 1999; 20: 2287–2303.
4. Sasaki T, Watanabe C. Stimulation of osteoinduction in bone wound healing by high-molecular weight hyaluronic acid. *Bone*, 1995; 16: 9–15.
5. West DC, Hampson IN, Arnold F, Kumar S. Angiogenesis induced by degradation products of hyaluronic acid. *Science*, 1985; 14: 1324–1326.
6. Morin R, Kaplan D, Perez-Ramirez B. Bone morphogenetic protein-2 binds as multilayers to a collagen delivery matrix: an equilibrium thermodynamic analysis. *Biomacromolecules*, 2006; 7(1): 131–138.
7. Geiger M, Li RH, Friess W. Collagen sponges for bone regeneration with rhBMP-2. *Adv. Drug Deliv. Rev.*, 2003, 55: 1613–1629.

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 AND 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,

IMPORTANT INFORMATION ON KINEX® BIOACTIVE

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			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		STERILIZED BY EXPOSURE TO ETHYLENE OXIDE
	PRODUCT MUST BE STORED BETWEEN 5° C (41° F) AND 25° C (77° F)		

DI171A
REV D

NOTES

NOTES

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

©2020 Globus Medical. All rights reserved. Patent www.globusmedical.com/patents.
Life moves us is a registered trademark of Globus Medical. Please refer to package insert for description, indications, contraindications, warnings, precautions and other important information.

GMTGD231
06.20 Rev A