

# genex<sup>®</sup> Bone Graft Substitute

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

## Important Information for the Operating Surgeon

Instructions for Use  
Number I.039 Rev 031902



## **Synthetic resorbable bone graft**

### **DESCRIPTION**

geneX® is a simple to use synthetic resorbable material designed to promote regeneration of bone in osseous defects. It degrades into component elements normally found in the body and is highly biocompatible.

The kit contains a powder and mixing solution which, when combined, provides a mouldable cohesive paste for introduction into a syringe. When injected the mixture sets to form geneX®, a hard but resorbable matrix. geneX® is supplied sterile.

### **STORAGE**

Store in a cool, dry place out of direct sunlight.

### **INTENDED USE**

geneX® injectable paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

### **INDICATIONS FOR USE**

- geneX® is indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure
- geneX® is indicated to be gently packed into voids or defects of the skeletal system (ie long bones, extremities, spine and pelvis)
- geneX® resultant paste can be injected, digitally packed into the bone void to cure in situ or moulded into solid implants that are to be gently packed into the defect
- The bony defects or cavities may be surgically created or the result of traumatic injury. geneX® provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

### **CONTRAINDICATIONS**

- filling of defects which are intrinsic to the stability of the bony structure
- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative bone disease
- pregnancy
- uncooperative patient who can't or won't follow post-operative instructions including individuals who abuse drugs or alcohol
- hypercalcaemia

### **WARNINGS AND PRECAUTIONS**

The device is for single use only and must not be reused. Do not resterilise the device. Do not use beyond expiration date on the label. Do not use if product package shows signs of tampering or damage.

Do not add other substances to the device. Adding other substances may alter the safety and effectiveness of this product. The device must be implanted where surrounding bone is healthy and vascular but not actively bleeding at time of insertion. Do not use for bony voids in the cranium, due to the potential risk of contact with cerebrospinal fluid (CSF) or dura mater. Do not irrigate the site prior to, or following, implantation. Avoid overfilling the bone void or pressurising the treatment site. Incomplete or inadequate soft tissue coverage may result in device migration and/or effusion or serous exudate. Do not implant unless adequate tissue coverage and/or containment can be achieved. The patient should be advised to report any related pain, swelling, fever or unusual incidences. The patient is to be cautioned to govern activities and protect the surgical site from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment. The patient is to be warned of surgical risks and made aware of possible adverse effects.

### **ADVERSE EFFECTS**

Injection of the paste material is associated with the potential to pressurise material in a closed void, which could result in fat embolisation and/or embolisation of the device material into the blood stream. Peripheral neuropathies have been reported following surgery. Sub-clinical nerve damage occurs more frequently, possibly the result of surgical trauma. Material sensitivity/allergic reactions in patients following surgery have been rarely reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to, or during the healing process. Infections, both deep and superficial, can lead to failure/removal of the device. Wound complications including haematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery, are unlikely but may occur.

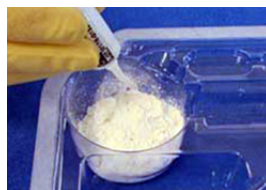
### **STERILISATION**

Unless opened or damaged, geneX® is supplied sterile within a double pack. Sterilisation is by gamma radiation to achieve a Sterility Assurance Level (SAL) of  $10^{-6}$ . Resterilisation by steam autoclave or ethylene oxide gas is prohibited. Non-aseptic personnel may open the outer pack. Aseptic personnel must retrieve the inner pack.

## INSTRUCTIONS FOR USE

### Mixing

1. Open outer packaging using standard aseptic "non touch" technique to avoid contact with the contents. Aseptic personnel must retrieve the inner pack. **Do not add any additional substances to the paste. Use only the mixing solution provided. Using alternative mixing solutions and/or adding other substances to the mixture may alter the setting time significantly. Some substances such as bone marrow and blood will prevent the paste from setting.**
2. Screw extension tip onto the syringe
3. Empty the powder into the sterile mixing Bowl.
4. Add the pre-measured sterile mixing solution.  
Allow to stand (soak out) for 30 seconds
5. Mix thoroughly until a paste is formed (approximately 30 seconds). **DO NOT over mix.**
6. Introduce into the syringe quickly.  
geneX® is now ready to place into the bony void. The material is injectable up to 3 minutes from the addition of the mixing solution.
7. Allow the product to harden for at least 15 minutes after mixing and prior to closure.



### Surgical Technique

1. Accurate diagnosis of any bone cyst is an essential pre-requisite.
2. Expose the bone defect. Raise a window of cortical bone with attached muscle or soft tissue where possible. Alternatively raise periosteum without dissection in the extraperiosteal plane. Decortication is to be preferred by sharp osteotome to raise small slivers of bone attached to the deep surface of periosteum.
3. In the case of a cyst, evacuate by curette or preferably a high-speed burr. A dental mirror or arthroscope improves clearance of all unwanted tissue by improving visualisation.
4. Lavage the prepared bone graft site with a saline solution until a healthy vascular surface is developed on all sides. Determine the size of the bone void by filling from a syringe of saline. The bone defect should then be gently packed with geneX® paste.
5. Avoid overfilling the bone void or compressing the defect site. Remove any excess paste from the defect site while the material is still workable prior to setting. Do not disrupt the paste while it is curing.
6. The material is injectable up to 3 minutes from the addition of the mixing solution. It will set approximately 15 minutes after mixing. When implanting the paste, the operating surgeon must ensure a dry (bloodless) field.
7. Cover the opening of the bone void with the preserved cortical bone window and/or healthy periosteum or other soft tissues.
8. It is of benefit to create a separate micro environment deep to the periosteum. Clean the wound in layers without tension, using standard closure techniques.
9. Discard any unused geneX® material and mixing tools.

genex<sup>®</sup> Bone Graft Substitute

is manufactured by



Biocomposites Ltd, Keele Science Park, Keele, Staffordshire, ST5 5NL, England  
Tel +44 (0) 1782 338580 Fax +44 (0) 1782 338599  
Email: [info@biocomposites.com](mailto:info@biocomposites.com) Web: [www.biocomposites.com](http://www.biocomposites.com)

Biocomposites Inc, PO Box 2692, Wilmington, NC 28402, USA  
Tel +1 (910) 350 8015 Fax +1 (910) 350 8072  
Email: [infous@biocomposites.com](mailto:infous@biocomposites.com) Web: [www.biocomposites.com](http://www.biocomposites.com)

Biocomposites (Shanghai)Ltd, 上海市恒丰路436号环智国际大厦 704室  
电话: +86 (0) 21 6380 2385 电传: +86 (0) 21 6380 5827  
电子信箱: [infochina@biocomposites.com](mailto:infochina@biocomposites.com) [www.biocomposites.com](http://www.biocomposites.com)

Australian Sponsor.  
Emergo Australia, Level 20, Tower II, Darling Park  
201 Sussex Street, Sydney, NSW 2000, Australia