genex® 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 062004

(EN) ENGLISH

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.

genex®, accessories and packaging are not made from natural rubber latex.

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.

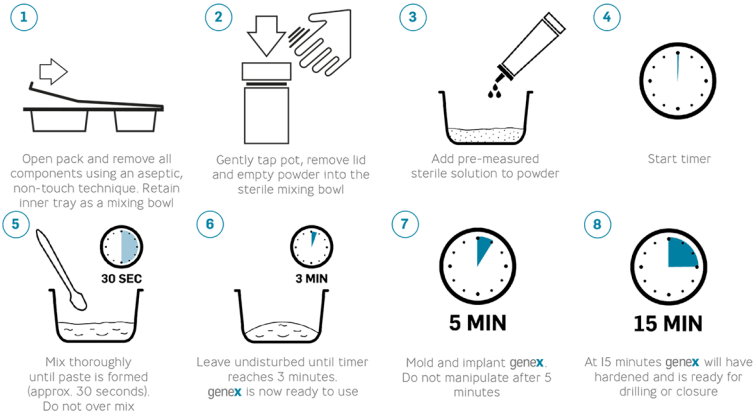
Wound complications including haematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery, are unlikely but may occur.

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.

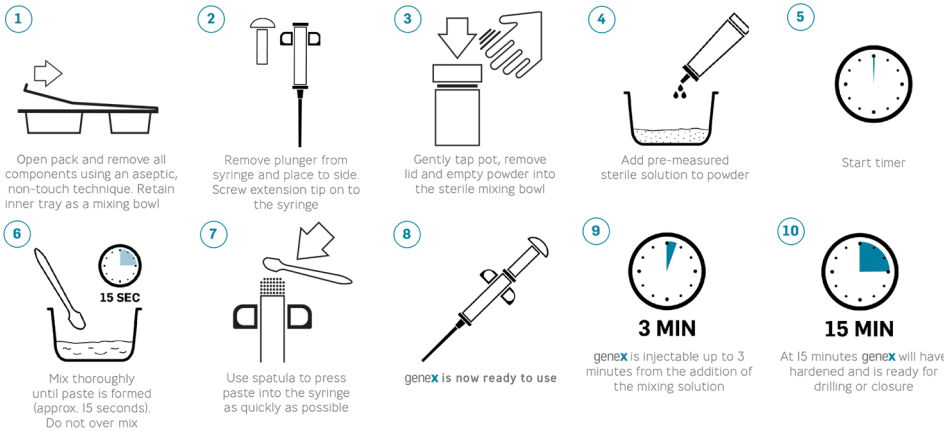
Preparation guide for manual implantation

Preparation of genex takes only a few careful moments. Use only the mixing solution provided. Do not add any additional substances to the paste. All times stated are measured from the start of the timer.



Preparation guide for injection

Preparation of genex takes only a few careful moments. Use only the mixing solution provided. Do not add any additional substances to the paste. All times stated are measured from the start of the timer.



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 extraperiostial 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® Bone Graft Substitute

is manufactured by

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