Frequently Asked Questions

for Distributors (EU)

November 2020

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FAQs

What is genex indicated for?[1]

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 (i.e. long bones, extremities, spine and pelvis). genex bone graft substitute 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.

What is genex contraindicated for?[1]

- 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

What supporting data do you have for genex?

Biocomposites has a variety of data ranging from pre-clinical laboratory testing, animal model data and clinical data. Biocomposites also has a growing number of case studies available that provide an overview of the use of genex in various clinical applications. Biocomposites would be happy to provide you with case studies for the clinical applications that you are most interested in.

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How long does genex take to absorb in bone?

genex is completely absorbed within 12 months.

What are the working and setting times of genex?

genex is injectable up to 5 minutes from the addition of the mixing solution. genex should be allowed to harden for at least 15 minutes after mixing and prior to closure.

What is the compressive strength of genex?[2]

genex has been shown to have a compressive strength approximately 3x stronger than cancellous bone when fully set (15 MPa). The compressive strength reduces as genex is absorbed.

Who is using genex and in which hospitals?

genex is used in over 10,000 cases per year in a wide range of different indications. Biocomposites would be happy to introduce you to an appropriate surgeon if you would like to have a peer-to-peer conversation.

Can I mix genex with antibiotics?

The mixing of antibiotics with genex has not been assessed by a European medicines Competent Authority and is considered off-label usage of the medicinal product. To do so is at the professional risk of the surgeon/healthcare professional. Concurrent use of locally administered antibiotics may affect the setting time. The treating physician is responsible for deciding the type and quantity of antibiotic used.

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Can I substitute other mixing solutions or add additional solution when preparing genex?

You should only use the mixing solution provided. Using alternative mixing solutions and/or adding other substances to the mixture may alter the setting time significantly. Some substance such as bone marrow and blood will prevent the paste from setting.

What should I do if my surgeon requires technical or clinical information or peer-to-peer communication?

Information requested by the surgeon or their medical team should be directed to your Biocomposites' Account Manager.

How does genex compare to CERAMENT®|BONE VOID FILLER?

genex is a precisely balanced ß-tricalcium phosphate/calcium sulfate hemihydrate compound. It contains no hydroxyapatite and is completely absorbed and replaced by bone within 12 months. genex is simple to prepare and does not go through a viscous stage when setting. It therefore does not require additional time to achieve optimum injectability and sets consistently in 15 minutes. genex can be digitally implanted.

CERAMENT|BONE VOID FILLER contains 40% hydroxyapatite (HA) and 60% α-calcium sulfate hemihydrate. When it is implanted and after the calcium sulfate has resorbed, new bone will completely surround and embed the HA particles[3]. The IFU states CERAMENT BVF be avoided in intra-articular use and it is contraindicated for use where there is local infection at the site of implantation.[3]

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How is setting time affected if I forget to soak out for 1 minute during preparation?

The purpose of the 1 minute ‘soak out’ step is to allow the mixing solution to soak through the powder ensuring a more efficient and thorough mixing process.

If the ‘soak out’ step is missed it is highly likely the mix may become dry and crumbly in consistency. This may result in genex becoming blocked in the syringe.

Is genex drillable?

Yes. 15 minutes after the addition of the mixing solution, genex will have hardened and is ready for drilling.

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For any other questions please contact: Ian Pass, Senior Marketing Manager, Content - ijp@biocomposites.com

References:
1. Biocomposites Ltd, genex Instructions for Use (EU).
2. Biocomposites Ltd, Data on File.
3. BONESUPPORT® AB, Instructions for Use CERAMENT|BONE VOID FILLER - A 0210 - Document No. IFU 0007-08 en 2014-06

For indications, contraindications, warnings and precautions see Instructions for Use.

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