

genex[®] Frequently Asked Questions for Distributors (USA)

May 2020

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 resultant paste can be injected, digitally packed into the bone void to cure in situ or molded 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.

FAQs

How long does genex take to absorb in bone?

genex is completely absorbed within 12 months.

How long do I have to inject or manually implant genex?

genex is injectable for up to 3 minutes from the addition of the mixing solution. If manually implanting, genex is moldable and implantable from minute 3 to 5 after the addition of the mixing solution.

Is genex drillable?

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

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?

genex is not currently FDA cleared/approved to be mixed with antibiotics. Specific questions relating to off label/physician directed use should be sent to the Biocomposites' Compliance Department via the Unsolicited Request Process.

FAQs

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' Field Marketing Specialist (FMS) or Regional Manager (RM).

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

genex is a precisely balanced β -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, does not require additional time to achieve optimum injectability and sets consistently in 15 minutes. genex can also 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 particles³. 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

FAQs

For any other questions please contact your Biocomposites Representative.

References:

1. Biocomposites Limited, genex Instructions for Use (USA).
2. Biocomposites Limited, 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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