

Competitor Fact Sheet: Cerament®



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| Feature | genex® | Cerament® Bonesupport® AB |
|----------------------------------|---|--|
| Composition | Powder: 50% β -tricalcium phosphate, 50% CaSO_4 hemihydrate Mixing solution: Sterile water ¹ | Powder: 60% CaSO_4 , 40% Hydroxyapatite (HA) Mixing solution: Liquid containing iohexol ^{4,5} |
| Scaffold type | Osteoconductive with negative surface charge for accelerated bone restoration ² | Osteoconductive ⁵ |
| Available sizes | 5cc, 10cc | 5cc, 10cc, 18cc |
| Wait time before injection | No | 3 minutes ⁶ |
| Setting time | 15 minutes ¹ | 15 minutes ⁶ |
| Temperature sensitive setting | No ¹ | No ⁵ |
| Drillable when fully set | Yes ¹ | Yes ⁵ |
| Versatility | Moldable, packable, injectable ¹ | 3 bead sizes, Injectable, moldable ^{4,5,7} |
| Injection flexibility | <ul style="list-style-type: none"> Luer Lock syringe with narrow plastic cannula included for hard-to-reach defects OsteoPrecision™ Graft Delivery Device available to withstand insertion pressure | <ul style="list-style-type: none"> Injection device with 2 tip extenders included |
| Impurities | No ¹ | Unknown |

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|-----------------------------------|--|--|
| Claimed absorption rate | Up to 12 months ³ | 6-12 months ⁵ |
| Fully absorbs | Yes ¹ | No ¹ |
| Dry compressive strength | 15 MPa ¹ | 40-60 MPa ⁸ |
| Radiopaque | Yes ¹ | Yes ⁵ |
| Key selling points and weaknesses | (+) Precisely balanced β -tricalcium phosphate/calcium sulfate hemihydrate ¹ (+) Contains no HA or insoluble impurities ¹ (+) Fully absorbed within 12 months ³ (+) No waiting period required before injection (+) Provides options for injection flexibility (+) Drillable when fully set ¹ (+) Radiopaque ¹ (+) No precaution against use in articulating surfaces ¹ (+) Negatively charged surface chemistry accelerates bone growth up to 5x normal levels ² (+) Restores bone to normal trabecular structure in 36 weeks ³ (+) Comprehensive support network for our customers and hospitals | (+) Radiopaque during injection ⁵ (+) Drillable ⁵ (+) Optional bead tray available for order ⁷ (-) Contains HA, which has a slow and incomplete absorption rate ¹ (-) HA can cause a long-term nidus for infection ¹ (-) Contraindicated for infected sites ^{4,8} (-) Contraindicated for patients with a history of serious reaction to iodine based radio contrast agents (iohexol component) ^{4,8} (-) Precaution to avoid intra-articular use ⁴ (-) Requires 3 minute wait time before injection |
| | | * (+) = competitor selling points (-) = competitor weaknesses |

References:

1. Biocomposites, Data on file.
2. Cooper, J.J., J.A. Hunt, and F. Pu, Enhancing the Osteogenic Potential of Bioabsorbable Implants through Control of Surface Charge. Presented at the Society for Biomaterials 2007 Annual Meeting. 2007: Chicago, Illinois, USA.
3. Yang HL et al. Bone healing response to a synthetic calcium sulfate/beta-tricalcium phosphate graft material in a sheep vertebral body defect model. J Biomed Mater Res B Appl Biomater. 2012;100B(7):1911-21.
4. BONESUPPORT® AB Instructions for use CERAMENT™ Bone Void Filler – A 0210. Document No. IFU 0007-08 en 2014-06.
5. BONESUPPORT® AB CERAMENT™ Bone Void Filler Brochure. PR 0346-03 en US.
6. BONESUPPORT® AB CERAMENT™ Bone Void Filler Mixing Guide. PR 0647-01 en EU/US.
7. BONESUPPORT® AB CERAMENT™ Bone Void Filler Bead Tray Product Fact Sheet. PR 0836-01 en US.
8. BONESUPPORT® AB CERAMENT™ Bone Void Filler Product Fact Sheet. PR 0649-01 en EU/US.

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

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