Competitor Fact Sheet: PRO-DENSE™

Biocomposites

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Feature	genex®	PRO-DENSE™ Wright Medical Group
Composition	Powder: 50% β-tricalcium phosphate, 50% $CaSO_4$ hemihydrate Mixing solution: Sterile water[1]	Powder: 75% mined $CaSO_4$ hemihydrate (OSTEOSET®), 25% brushite + granular β-tricalcium phosphate Mixing solution: Neutralized glycolic acid[1,4,5]
Scaffold type	Osteoconductive with negative surface charge for accelerated bone restoration[2]	Osteoconductive[5]
Available sizes	5cc, 10cc	2cc, 5cc, 7cc, 10cc, 12cc, 15cc, 40cc 15cc Core Decompression Kit[5,6]
Setting time	15 minutes[1]	20-30 minutes[5]
Temperature sensitive setting	No[1]	No[5]
Drillable when fully set	Yes[1]	Yes[5,6]
Versatility	Moldable, packable, injectable[1]	Packable, injectable[6]
Injection flexibility	• Luer Lock syringe with narrow plastic cannula included for hard-to-reach defects • OsteoPrecision™ Graft Delivery Device available to withstand insertion pressure	• Delivery syringe with two cannula sizes included • Disposable syringe only kit available
Impurities	No[1]	Contains non-absorbable impurities due to mined $CaSO_4$ (OSTEOSET®) component[1,7]

Feature	genex®	PRO-DENSE™ Wright Medical Group
Claimed absorption rate	Up to 12 months[3]	6-12 months[5]
Fully absorbs	Yes[1]	May not fully absorb[1]
Dry compressive strength	15 MPa[1]	25 MPa[1]
Radiopaque	Yes[1]	Yes[5]
pH	Physiologic[1]	Acidic[1]
Key selling points and weaknesses	(+) Precisely balanced β-tricalcium phosphate/calcium sulfate hemihydrate[1] (+) 100% Pharmaceutical-grade $CaSO_4$ component (+) Contains no Hydroxyapatite (HA) or insoluble impurities[1] (+) Fully absorbed within 12 months[3] (+) No contraindication against use in articulating surfaces[1] (+) Physiologic pH[1] (+) Hydrophilic[1] (+) Radiopaque[1] (+) Provides options for injection flexibility (+) Drillable when fully set[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	(+) Indicated for use in benign bone cysts and tumors in children ages 6+[6] (+) Available in a core decompression kit for avascular necrosis[5,6] (+) Radiopaque[5] (+) Drillable when fully set[5,6] (-) Mined $CaSO_4$ component (OSTEOSET®)[1,4,5] (-) $CaSO_4$ (OSTEOSET®) contains 1.1% insoluble impurities[7] (-) Brushite component converts to Hydroxyapatite (HA) after implantation[1] (-) HA has a slow and incomplete absorption rate[1] (-) HA can cause a long-term nidus for infection[1] (-) Contraindicated in articulating surfaces[6] (-) Acidic pH[1] (-) Hydrophobic[1] (-) Long setting time

* (+) = competitor selling points
(-) = competitor weaknesses

References:

1. Biocomposites, Data on file.
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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. Pro-Dense™ Injectable Regenerative Graft Technical Monograph. 2019 Wright Medical Group N.V. or its affiliates. AP-010805A 19-Nov-2018.
5. Pro-Dense™ Injectable Regenerative Graft Competitive Guide. 2018 Wright Medical Group N.V. or its affiliates. AP-002461B_21-Nov-2018.
6. Pro-Dense™ Injectable Regenerative Graft Comprehensive Surgical Technique Booklet. 2019 Wright Medical Group N.V. or its affiliates. AP-010792A_16-Nov-2018.
7. Wright Medical Technology OSTEOSET® Bone Graft Substitute Technical Monograph. 010662A_21-Jul-2014.

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

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