Competitor Fact Sheet: **MONTAGE®**

Biocomposites

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Feature	genex®	MONTAGE® ABYRX®
Composition	Powder: 50% β-tricalcium phosphate, 50% $CaSO_4$ hemihydrate Mixing solution: Sterile water[1]	Two putty-like components: Granular calcium phosphate (Hydroxyapatite & β-tricalcium phosphate), calcium stearate, vitamin E acetate, triacetin, 1,4 butanediol, lactide-diester and caprolactone polymers[5]
Device type & code	Bone void filler (MQV)[2]	Bone wax (MTJ)[5]
Intended use	Bone void filler	Bone hemostasis[5]
Scaffold type	Osteoconductive with negative surface charge for accelerated bone restoration[3]	Osteoconductive with up to 10% expansion from porosity that develops during hardening phase[6]
Available sizes	5cc, l0cc	2cc, 5cc
Setting time	15 minutes	Within minutes[6]
Drillable when fully set	Yes[1]	Yes
Versatility	Moldable, packable, injectable[1]	Manually applied, spreadable[5]
Injection flexibility	• Luer Lock syringe with narrow plastic cannula included for hard-to-reach defects • OsteoPrecision™ Graft Delivery Device available to withstand insertion pressure	• Not injectable

Feature	genex®	MONTAGE® ABYRX®
Impurities	No[1]	Unknown
Claimed absorption rate	Up to 12 months[3]	Not specified. Expected to be >6 months[1]
Fully absorbs	Yes[1]	May not fully absorb[1]
Radiopaque	Yes[1]	Yes[5]
Key selling points and weaknesses	(+) Indicated for use as a bone void filler[1,2] (+) Precisely balanced β-tricalcium phosphate/calcium sulfate hemihydrate[1] (+) Contains no Hydroxyapatite (HA) or insoluble impurities[1] (+) Fully absorbed within 12 months[4] (+) Provides options for injection flexibility (+) Drillable when fully set[1] (+) Radiopaque[1] (+) Negatively charged surface chemistry accelerates bone growth up to 5x normal levels[3] (+) Restores bone to normal trabecular structure in 36 weeks[4] (+) Comprehensive support network for our customers and hospitals	(+) Adheres to bleeding bone surfaces[6] (+) Instantly shapeable and spreadable[6] (+) Radiopaque[5] (-) Not indicated for use as a bone void filler[5] (-) Categorized as a bone wax[5] (-) Contains HA, which has a slow and incomplete absorption rate[1] (-) HA can cause a long-term nidus for infection[1] (-) Bone wax has no active hemostatic properties and does not activate the blood clotting cascade[1] (-) Potential issue if implanted into bony voids as product can expand up to 10% due to porosity that develops during hardening phase[1]

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

References:

1. Biocomposites, Data on file.
2. U.S. Food and Drug Administration, Department of Health and Human Services, Center for Devices and Radiological Health. Genex® 510(k) K082381 approval letter, November 14, 2008.
3. 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.
4. 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.
5. U.S. Food and Drug Administration, Department of Health and Human Services, Center for Devices and Radiological Health. Montage™ Settable, Resorbable Hemostatic Bone Putty 510(k) K152005 approval letter, October 15, 2015.
6. https://www.abyrx.com/products.montage.asp.

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

Patents granted: EP 1390086 BI, US 8632796, CN ZL02809194.9, US 8496955

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