

# Competitor Fact Sheet: Norian® Drillable products



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Feature	genex®	Norian® Drillable Fast Set Putty Norian® Drillable Inject DePuy Synthes
Composition	Powder: 50% $\beta$ -tricalcium phosphate, 50% $\text{CaSO}_4$ hemihydrate Mixing solution: Sterile water <sup>1</sup>	Powder: Calcium phosphate with polylactide/glycolide copolymer fibers Mixing solution: Dilute sodium phosphate with sodium hyaluronate <sup>4,5</sup>
Scaffold type	Osteoconductive with negative surface charge for accelerated bone restoration <sup>2</sup>	Osteoconductive
Available sizes	5cc, 10cc	3cc, 5cc, 10cc <sup>4,5</sup>
Setting time	15 minutes	<ul style="list-style-type: none"> <li>Putty: Within 9 min 30 sec of adding mixing solution<sup>4</sup></li> <li>Inject: Within 16 min 10 sec of adding mixing solution<sup>5</sup></li> </ul>
Temperature sensitive setting	No <sup>1</sup>	Yes <sup>4,5</sup>
Drillable when fully set	Yes <sup>1</sup>	Yes - during or after setting <sup>4,5</sup>
Versatility	Moldable, packable, injectable <sup>1</sup>	Moldable, packable, injectable <sup>4</sup>
Injection flexibility	<ul style="list-style-type: none"> <li>Luer Lock syringe with narrow plastic cannula included for hard-to-reach defects</li> <li>OsteoPrecision™ Graft Delivery Device available to withstand insertion pressure</li> </ul>	<ul style="list-style-type: none"> <li>Putty: Graft delivery device available<sup>4</sup></li> <li>Inject: Delivery syringe included<sup>5</sup></li> <li>Variety of delivery needles available<sup>4,5</sup></li> </ul>
Impurities	No <sup>1</sup>	Unknown

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Claimed absorption rate	Up to 12 months <sup>3</sup>	Slowly absorbed over a period of years <sup>6</sup>
Fully absorbs	Yes <sup>1</sup>	May not fully absorb <sup>1</sup>
Dry compressive strength	15MPa <sup>1</sup>	<ul style="list-style-type: none"> <li>Putty: 25 MPa<sup>4</sup></li> <li>Inject: 35 MPa<sup>5</sup></li> </ul>
Radiopaque	Yes <sup>1</sup>	Yes <sup>4,5</sup>
Key selling points and weaknesses	<ul style="list-style-type: none"> <li>(+) Precisely balanced <math>\beta</math>-tricalcium phosphate/calcium sulfate hemihydrate<sup>1</sup></li> <li>(+) Contains no Hydroxyapatite (HA) or insoluble impurities<sup>1</sup></li> <li>(+) Fully absorbed within 12 months<sup>3</sup></li> <li>(+) No contraindication against use in the spine<sup>1</sup></li> <li>(+) No contraindication against use in articulating surfaces<sup>1</sup></li> <li>(+) Not temperature sensitive<sup>1</sup></li> <li>(+) Provides options for injection flexibility</li> <li>(+) Drillable when fully set<sup>1</sup></li> <li>(+) Radiopaque<sup>1</sup></li> <li>(+) Negatively charged surface chemistry accelerates bone growth up to 5x normal levels<sup>2</sup></li> <li>(+) Restores bone to normal trabecular structure in 36 weeks<sup>3</sup></li> <li>(+) Comprehensive support network for our customers and hospitals</li> </ul>	<ul style="list-style-type: none"> <li>(+) Reinforced with fibers for added toughness<sup>4,5</sup></li> <li>(+) Can be drilled during or after setting<sup>4,5</sup></li> <li>(+) Radiopaque<sup>4,5</sup></li> <li>(-) Calcium phosphate converts to carbonated apatite after implantation (similar to HA)<sup>4,5</sup></li> <li>(-) HA has a slow and incomplete absorption rate<sup>1</sup></li> <li>(-) HA can cause a long-term nidus for infection<sup>1</sup></li> <li>(-) Contraindicated for infected sites<sup>4,5</sup></li> <li>(-) Contraindicated for use in the spine<sup>4,5</sup></li> <li>(-) Contraindicated for the intra-articular space<sup>4,5</sup></li> <li>(-) Temperature sensitive<sup>4,5</sup></li> <li>(-) Components should be equilibrated to room temperature prior to mixing<sup>4,5</sup></li> <li>(-) Setting time can extend if implanted below body temperature<sup>4,5</sup></li> <li>(-) Inject has a complex preparation technique (~11 steps) and requires separate rotary mixer<sup>5</sup></li> </ul>
		<p>* (+) = competitor selling points          (-) = competitor weaknesses</p>

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. DePuy Synthes Norian® Drillable Fast Set Putty Fiber Reinforced Calcium Phosphate Bone Void Filler Surgical Technique. DSUS/MOC/0914/0105(2) 7/17 DV. 2017.
5. DePuy Synthes Norian® Drillable Inject Fiber Reinforced Calcium Phosphate Bone Void Filler Surgical Technique. DSUS/MOC/0914/0104(1) 12/16 DV. 2016.
6. U.S. Food and Drug Administration, Department of Health and Human Services, Center for Devices and Radiological Health. Norian Drillable™ Inject and Norian Drillable™ Fast Set Putty™ 510(k) K102722 Summary. January 27, 2011. <https://www.accessdata.fda.gov/CDRH510K/K102722.pdf>

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

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