



Warren, NJ, 11/16/2016: NJ-based Prosidyan® (www.prosidyan.com), developer of proprietary fiber-based bioactive glass products, announced today that it has received FDA 510(k) clearance of FIBERGRAFT® BG Morsels for Postero-lateral Spinal Fusion. FIBERGRAFT® BG Morsels is an ultra-porous Bone Graft Substitute, made entirely from 45S5 Bioactive Glass microfibers and microspheres, engineered for optimal biological response.

FIBERGRAFT® BG Morsels - Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. FIBERGRAFT® BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., postero-lateral spine, extremities and pelvis). These defects may be surgically-created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. FIBERGRAFT® BG Morsels must be used with autogenous bone marrow aspirate and autograft in the postero-lateral spine.

Dr. Hyun Bae, MD, Chief Medical Officer of Prosidyan®, commented, “ *With FIBERGRAFT® we now finally have the next generation of synthetic bone grafting for spine. Synthetic bone grafts have been stagnant for twenty years using the same porous technology. FIBERGRAFT® is the exclusive synthetic bone graft which uses bioactive glass fibers to provide direct connectivity. This is a paradigm shift in synthetic bone grafting.* “

Prosidyan®’s President and CEO, Charanpreet Bagga, elaborates on the importance of this latest clearance: “*The spine is where the majority of bone grafting is done and where there is an unmet clinical need. There are very few synthetic bone grafts with FDA clearance for postero-lateral spinal fusion. We believe that FIBERGRAFT®, mixed with autograft and Bone Marrow Aspirate will be a great option for the spine surgeons.*”

Prosidyan® was founded in 2009 to develop a family of synthetic bioactive bone graft substitutes based on microscopic fibers of bioactive glass. Prosidyan®’s flagship product, FIBERGRAFT® BG Morsels, a synthetic bone graft substitute, has been in the market for over 18 months. The product’s first FDA clearance was received in March 2014, and the first surgery utilizing this innovative bone substitute was performed in May 2014. The firm’s second product in the line, FIBERGRAFT® BG Putty, is FIBERGRAFT® BG Morsels delivered through Prosidyan®’s proprietary bioactive carrier, OSSIGLIDE.™

Distribution Opportunities are still available. Contact Sales@prosidyan.com

ABOUT Prosidyan®: Prosidyan® is the creator and supplier of the next generation in synthetic bone grafting through its proprietary manufacturing process utilizing microscopic fibers of bioactive glass. For more information about the company and its products, please visit www.prosidyan.com, or call 908.517.3666.