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FIBERGRAFT® BG MORSELS AND PUTTY – BIOACTIVE GLASS BONE GRAFT SUBSTITUTE

FIBERGRAFT® BG Morsels is a purely synthetic bone graft substitute made entirely from crystalline 45S5 bioactive glass. Each granule of FIBERGRAFT® BG Morsels is created from a matrix of bioactive glass fibers and microspheres that are engineered to create an ultra-porous granular structure, which is designed to have adequate structural integrity for its application as a bone graft substitute material, while

optimizing radiopacity and
resorption.



BIOACTIVE GLASS WATCH THE ANIMATION

FIBERGRAFT® BG (BONE GRAFT) MORSELS AND PUTTY – HISTORY

WHAT IS BIOACTIVE GLASS?

Bioactive glass is defined as a group of glasses which has a compositional range that allows the formation of hydroxyapatite (HA) as a surface layer when exposed to an aqueous phosphate containing solution

such as simulated body fluid. The HA layer that forms in an aqueous phosphate containing solution plays a significant role in forming a strong bond with natural bone.

Bioactive glass has an established history of bone bonding that occurs as a result of a rapid sequence of reactions on its surface when implanted into living tissues. When hydrated, a layer of silica gel forms on the surface of the bioactive glass. The adhesion of amorphous calcium, phosphate, and carbonate ions to the silica surface leads to an eventual crystallization of a bone-like hydroxyapatite (HA)- as early as 24 hours. Bone-forming cells migrate and colonize the surface of the bioactive glass and promote the production of a new bone like matrix.

*High magnification image of
FIBERGRAFT® BG Morsel*

**FIBERGRAFT® BG PUTTY IS
FIBERGRAFT® BG MORSELS
DELIVERED THROUGH A**

PROPRIETARY BIOACTIVE CARRIER, OSSIGLIDE™

FIBERGRAFT® BG (BONE GRAFT) MORSELS AND PUTTY – WHY FIBERGRAFT?

FIBERGRAFT® is designed to have adequate structural integrity for its application as a bone graft substitute material, while optimizing radiopacity and resorption.

CONTINUOUS POROSITY

The porosity created by the fibers is continuous and completely interconnected and there are no physical interruptions. The amount and range of porosity in FIBERGRAFT® BG Morsels has been engineered by controlling the size and quantities of fibers and microspheres, and by the optimized design of its porous outer shell.

CONNECTIVITY

Bioactive glass fibers in FIBERGRAFT® BG Morsels provide a unique and exclusive direct connectivity inside a bone void defect. Unlike traditional bone

grafts, the connectivity of the fibers provides an uninterrupted corridor for cell growth along their length.

INCREASED SURFACE AREA

FIBERGRAFT® proprietary design creates a mechanical and biomechanical environment providing maximized surface area for HA deposition and controlled resorption. Utilizing solid or porous structures, the concentrated fibers inside FIBERGRAFT® BG Morsels offer vastly increased surface area.

DIFFERENTIAL RATE OF RESORPTION

Each BG Morsel is comprised of a range of fibers and microspheres. The smaller fibers and microspheres resorb quicker, while the larger structures resorb over an extended period of time. This optimized mode of differential resorption creates a favorable environment during all phases of bone healing.

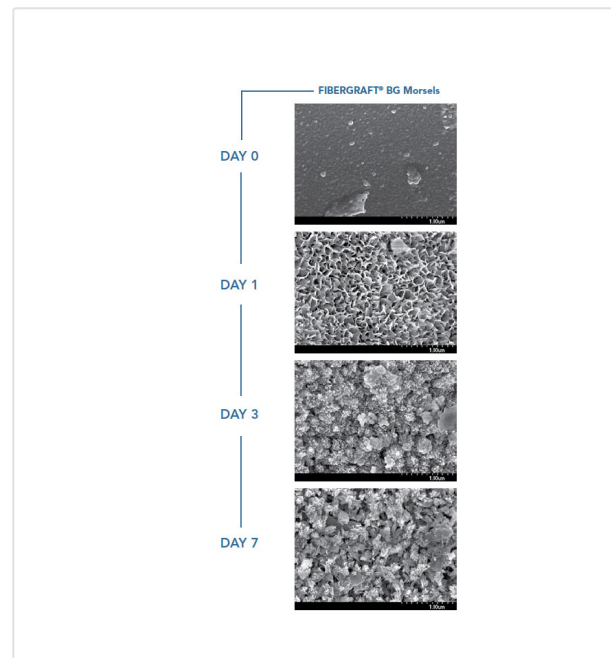
APPLYING THE POWER OF MICROSCOPIC FIBERS TO DEVELOP AN ULTRA POROUS BIOACTIVE BONE GRAFT MATRIX.

PRE-CLINICAL DATA

EARLY HA DEPOSITION

In an in-vitro test, FIBERGRAFT® was immersed in Simulated Body Fluids at 37°C to test for HA deposition on its surface.

Crystallites of HA were observed on the FIBERGRAFT® surface within 24 hours of immersion.



GLP SHEEP DISTAL FEMORAL CRITICAL SIZED DEFECT STUDY

In a 58 Sheep GLP study, FIBERGRAFT® BG Morsels was tested against a competitive bioactive glass bone graft, as well

as an empty Sham, in a critical sized distal femoral defect. Sheep study results show bone formation in the FIBERGRAFT® group that covered most of the implant by 8 weeks, and increased bone formation in the defect up to 12 weeks with FIBERGRAFT® BG Morsels.

Un-decalcified histology – Goldener’s Trichrome Stain. Green represents new bone formation. Mature lamellar bone was formed as early as 8 weeks in the Sheep defect sites treated with FIBERGRAFT® BG Morsels.

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