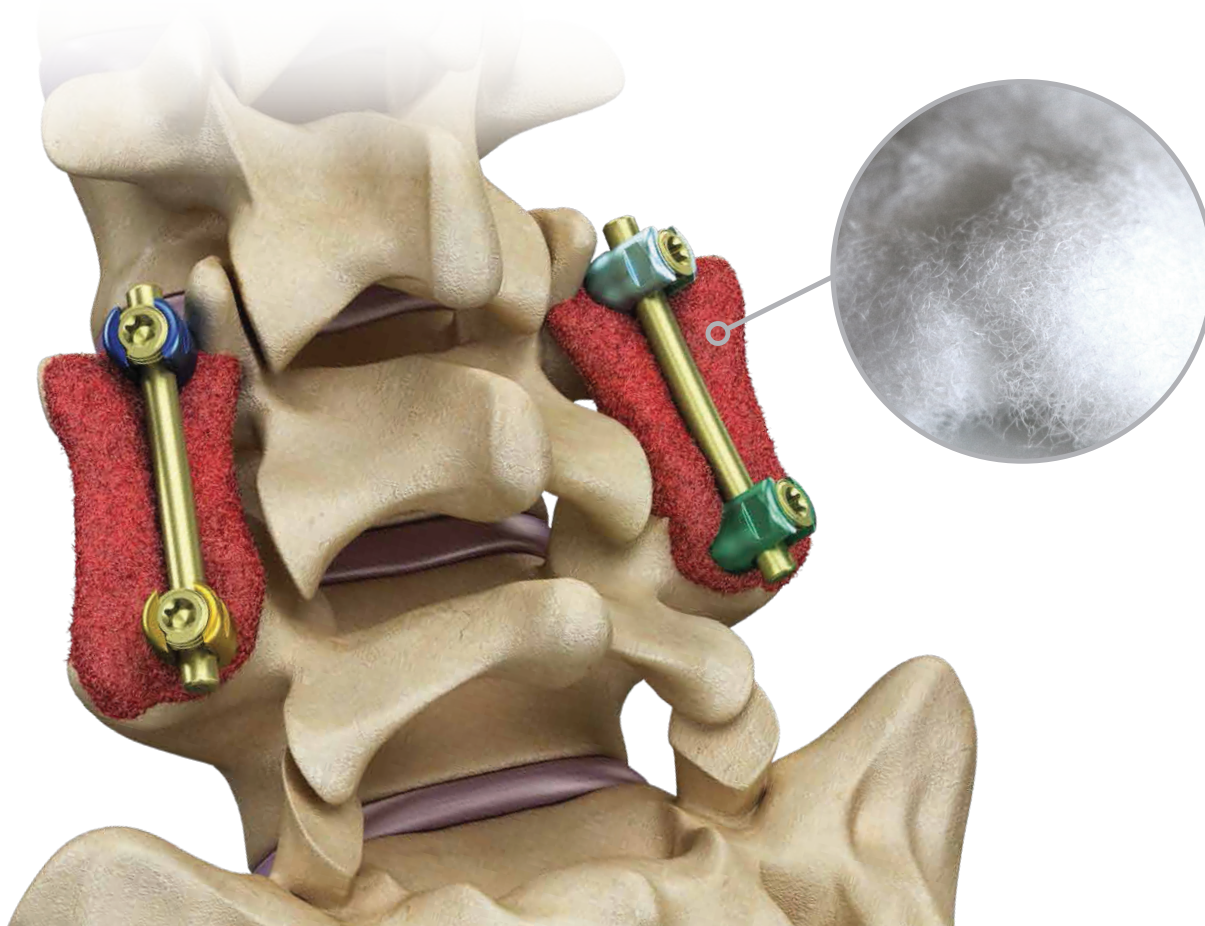




KYOCERA Medical Technologies, Inc.

BIOCERATM FIBERS

**The only biosynthetic scaffold with
electrospun microfiber construction**



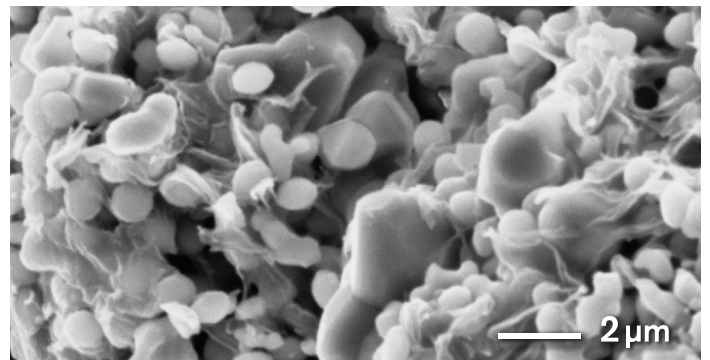
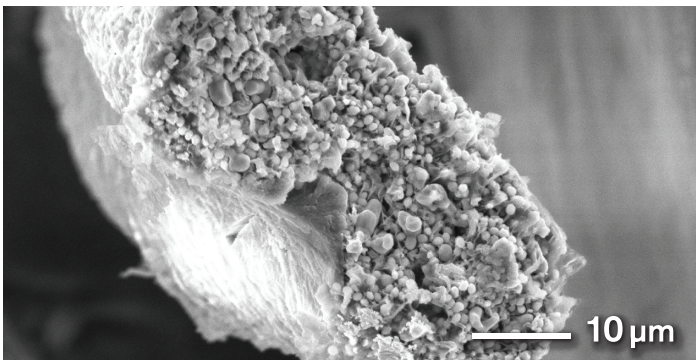
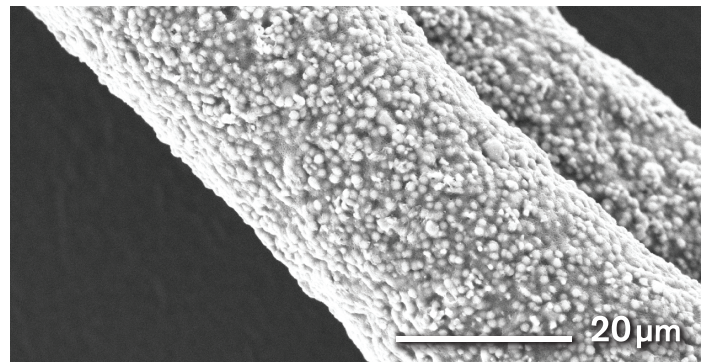
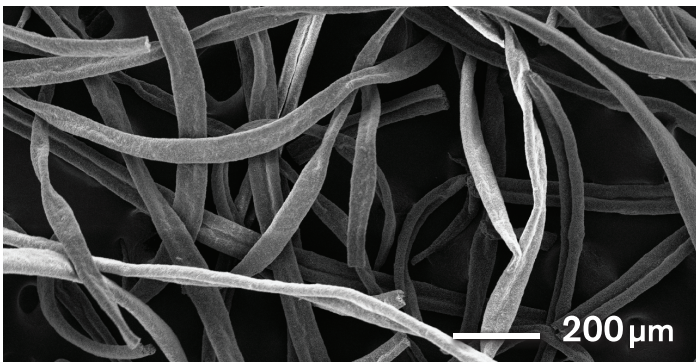


- Proven to support cell activation, retention, and proliferation
- Superior handling characteristics
- Optimal fit and fill:
 - BioCera FIBERS offers up to 54% compression recovery
 - Maintains integrity during and after placement

About BioCera FIBERS

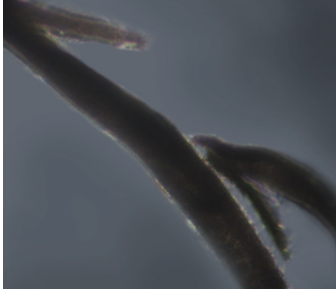
BioCera FIBERS is the only biosynthetic bone scaffold with electrospun microfiber construction. Composed of β TCP, CaCO_3 , silicon, and PLGA, the special formula contains 0.5% to 1% silicon by weight, which is comparable to the level found in natural bone.

The interconnected network of microporous fibers in BioCera FIBERS is created by a unique and proprietary electrospinning process that produces an absorbent, biodegradable scaffold. BioCera FIBERS is known for its moldable properties, as well as for its ability to retain bioactive fluids, which enhances its osteoinductive potential.

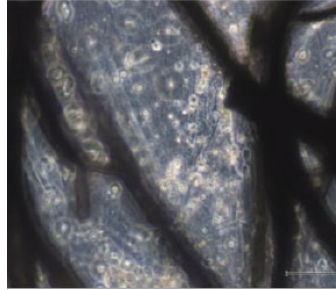


Demonstrated Effectiveness

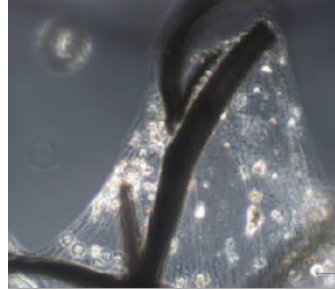
In a recent test by Dr. George Muschler, MD at the Cleveland Clinic Lerner Research Institute, osteoprogenitor cells were separated from bone marrow and were applied to BioCera Fibers. The resulting cultures were carefully scrutinized at various stages. Staining and microscopic analysis showed robust cell growth migration and proliferation of cells on the fiber scaffold, indicating that cell colonies were growing and expanding on the microfibers—an early sign of bone formation. This test demonstrated that BioCera Fibers functions as an effective bone graft that supports cell vitality and adherence.



De novo BioCera Fibers prior to infiltration & attachment



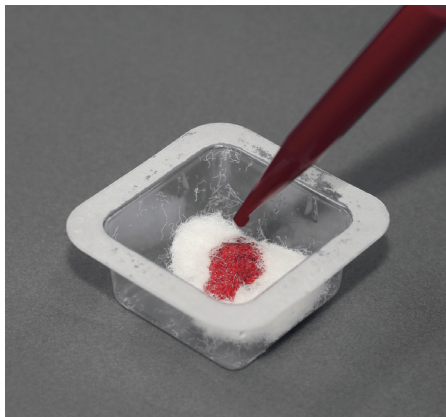
ECM formation - 3 days



Cell colonization & attachment -11 days

Products

Product Number	Pre-Hydration Volume	Fluid Absorption
ORB-0304C	10mL	3.5mL
ORB-0307C	18mL	6mL
ORB-0310C	25mL	8mL
ORB-0320C	50mL	16mL



*The volume of BioCera Fibers decreases if the product is hydrated (optional).
Change in volume depends on specimen and hydration material.



ELECTROSPUN MATRIX

Composed of β -TCP, CaCO₃, silicon and PLGA.
Contains 0.5% to 1% silicon by weight, which is
comparable to the level found in natural bone.

INDICATIONS FOR USE

BioCera Fibers are intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. BioCera Fibers are indicated to be packed gently into bony voids or gaps of the skeletal system (extremities, pelvis, and posterolateral spine). In the extremities and pelvis BioCera Fibers may be used without hydration or hydrated with blood. In the posterolateral spine BioCera Fibers are to be used hydrated with bone marrow aspirate and mixed with autograft bone. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.



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