MASTERGRAFT®
Family of Products

MASTERGRAFT® Granules
MASTERGRAFT® Mini Granules
MASTERGRAFT® Putty

15% HYDROXYAPATITE
85% BETA-TRICALCIUM PHOSPHATE
Introduction

The MASTERGRAFT® Family of Products are biphasic, resorbable ceramics composed of hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP), either in granule form or distributed evenly throughout a Type I collagen in putty form. The biphasic blend of HA/β-TCP throughout the products provides a purely osteoconductive graft made of materials similar to the mineral found inherently in bone.1,2 The uniform mixture of hydroxyapatite and beta-tricalcium phosphate provides the surgeon with characteristics that balance long-term stability with a natural cell-mediated (osteoclastic) resorption process.2

Bone is composed of organic and inorganic, or mineral, elements. The weight of dry bone is made up of an inorganic calcium phosphate and an organic matrix of fibrous protein and collagen. The inorganic portion of bone can be further broken into minerals including calcium phosphate, calcium carbonate, and small quantities of magnesium, fluoride, and sodium.1,2
Resorption Mechanism

The 15% hydroxyapatite, 85% beta-tricalcium phosphate blend which makes up the MASTERGRAFT® Products results in a unique material which balances long-term stability with resorption. Hydroxyapatite alone remains without remodeling for long periods of time allowing bone to encapsulate the graft and preventing resorption. Pure tricalcium phosphate tends to remodel too quickly eliminating the scaffolding and allowing for soft tissue to collapse into the defect. The biphasic blend of the MASTERGRAFT® Products provides the surgeon with a space maintaining product that resorbs through natural, cell-mediated creeping substitution, replacing the scaffold with new host bone.

Biocompatibility and Sterilization

The MASTERGRAFT® Family of Products has demonstrated no inflammatory or pathologic response. The use of MASTERGRAFT® Products eliminates the risk associated with products that contain tissues of human origin.

MASTERGRAFT® Granules and MASTERGRAFT® Mini Granules are tested using:

- Preclinical studies
- Sterility tests
- Biocompatibility tests
- *in vitro* biodegradation testing

MASTERGRAFT® Putty is tested using:

- Preclinical studies
- Biocompatibility tests
- Sterility tests
MASTERGRAFT® Granules and MASTERGRAFT® Mini Granules

Composition, Structure, and Handling

MASTERGRAFT® Granules and MASTERGRAFT® Mini Granules are biphasic, resorbable, ceramic granules composed of 15% hydroxyapatite (HA) and 85% beta-tricalcium phosphate (β-TCP). The granules have a natural, interconnected, porous structure which mimics the natural structure of bone and allows for rapid, homogenous bone ingrowth throughout each granule.2 Each granule is 80% porous with an average pore size of 500 microns and 125 microns interconnected diameter. MASTERGRAFT® Granules have an average diameter of 1.6mm – 3.2mm. MASTERGRAFT® Mini Granules have an average diameter of 0.5mm – 1.6mm.

Through a highly porous granular structure and the 15% HA/85% β-TCP chemical composition, MASTERGRAFT® Granules and MASTERGRAFT® Mini Granules facilitates rapid, homogenous osseointegration, which supports the bone healing process by acting as a scaffold over which bone can grow. The porosity of the material provides an excellent basis for vascularization and penetration of associated cells, which support integration of the substitute materials required for healing while preserving the bony architecture and attached gingiva.4

Summary of Indications

MASTERGRAFT® Granules can be used alone or in combination with autogenous bone in oral/maxillofacial augmentation or reconstruction and other larger bony defects. MASTERGRAFT® Mini Granules are ideal for smaller defects such as extraction site preservation and periodontal defects, or in combination with autogenous bone in larger defects such as sinus augmentation and cystic defects.
**MASTERGRAFT® Putty**

Composition, Structure, and Handling

MASTERGRAFT® Putty is composed of resorbable ceramic granules uniformly distributed through a highly purified resorbable Type I bovine collagen. The resorbable ceramic granules of 15% HA, 85% β-TCP balance long-term stability with complete resorption. The granules range in size from 0.5mm-1.6mm in diameter and are 80% porous. The Type I bovine collagen used is composed of two formulations of collagen: 70% insoluble fibrous collagen and 30% soluble collagen. The collagen allows the graft materials to be malleable and resistant to water solubility while still maintaining the graft’s integrity. MASTERGRAFT® Putty is an osteoconductive scaffold that resorbs by cell-mediated creeping substitution, and is gradually replaced with new, homogenous bone growth throughout the site. MASTERGRAFT® Putty also enables the user to perform radiographic assessment of the graft after implantation.

MASTERGRAFT® Putty was designed for easy hydration using sterile water or blood. Once hydrated, it can be mixed with autogenous bone to increase the volume of graft material while providing a small level of osteogenic potential due to the presence of autograft. The putty structure allows for retention of biological factors at the site of implantation.
Proven Bone Formation

MASTERGRAFT® Granules Bone Formation and Mechanism of Action

Using MASTERGRAFT® Granules, a seven-patient study was conducted to evaluate the implant survival and changes in alveolar bone histology and morphology following post-extraction socket augmentation.

In seven patients, between the ages of 35 and 82, MASTERGRAFT® Granules were used to graft an extraction socket defect to preserve ridge form after tooth extraction. Bone core samples were taken from the grafted sites for histologic and radiographic evaluation. Intraoperative and postoperative images using MASTERGRAFT® Granules can be seen below.4

Nonrestorable tooth #9

MASTERGRAFT® Granules placed in extraction socket

Implant placement at 4 months post-extraction

Final restoration at 6 months post implant placement

Trephine core biopsy taken at time of implant placement

H & E histological analysis of core samples taken from MASTERGRAFT® Granules augmented extraction site bone. New bone formation is seen around MASTERGRAFT® Granules.
Proven Bone Formation in Pre-clinical Studies

MASTERGRAFT® Putty Bone Formation and Mechanism of Action

MASTERGRAFT® Putty has been evaluated for osteoconductivity and bone forming potential when combined with autograft in a challenging preclinical model. Results from this model can be seen below.

Autograft alone and MASTERGRAFT® Putty plus autograft (in either a 50:50 or 25:75 percent composition) were used in a single level, bilateral, posterolateral intertransverse process fusion in 30 rabbits. Results shown below were determined at 8 weeks post surgery.

<table>
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<th>Graft Type</th>
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<th>Radiographic Fusion Rate</th>
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<td>Autograft</td>
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<td>Putty 50% (1.5cc) + Autograft 50% (1.5cc)</td>
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Results show that MASTERGRAFT® Putty can be effectively combined with autograft as an extender to produce new bone bridging the space between the bony segment.

Histological evaluation indicated that bone formed directly on the putty’s ceramic particles, that remodeling was ongoing, and that there was no evidence of inflammatory reactions.

Animal studies are not necessarily predictive of human clinical outcomes.
MASTERGRAFT® Granules and MASTERGRAFT® Mini Granules Applications

- MASTERGRAFT® Mini Granules with sterile water for extraction site preservation
- MASTERGRAFT® Mini Granules with blood for extraction site preservation
- MASTERGRAFT® Mini Granules with sterile water for sinus augmentation
- MASTERGRAFT® Mini Granules with blood for sinus augmentation
MASTERGRAFT® Putty Applications

MASTERGRAFT® Putty hydrated with sterile water for extraction site preservation

MASTERGRAFT® Putty hydrated with blood for extraction site preservation

MASTERGRAFT® Putty with autograft for sinus augmentation

MASTERGRAFT® Putty with autograft for sinus augmentation

Mandibular ridge deficiency

Mandibular ridge augmentation using MASTERGRAFT® Putty with autograft and a titanium mesh for space maintenance
MASTERGRAFT® Family of Products Summary

Proven Bone Formation via osteoconduction

» 15% HA, 85% β-TCP, biphasic blend
» Balances long-term stability with resorption
» Cell-mediated resorption process
» 80% interconnected porosity
» Resorbable

Handling

» Moldable putty form
» Packable putty form
» Radiopaque in putty and granular form
» Space maintaining in granular form
» Can be mixed with autograft in putty or granular form
» Resists migration in putty form
» Granules are hydrophilic in nature

Biocompatibility

» No inflammatory or pathologic response
» Sterile

References

Product Ordering Information

**MASTERGRAFT® Mini Granules**

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