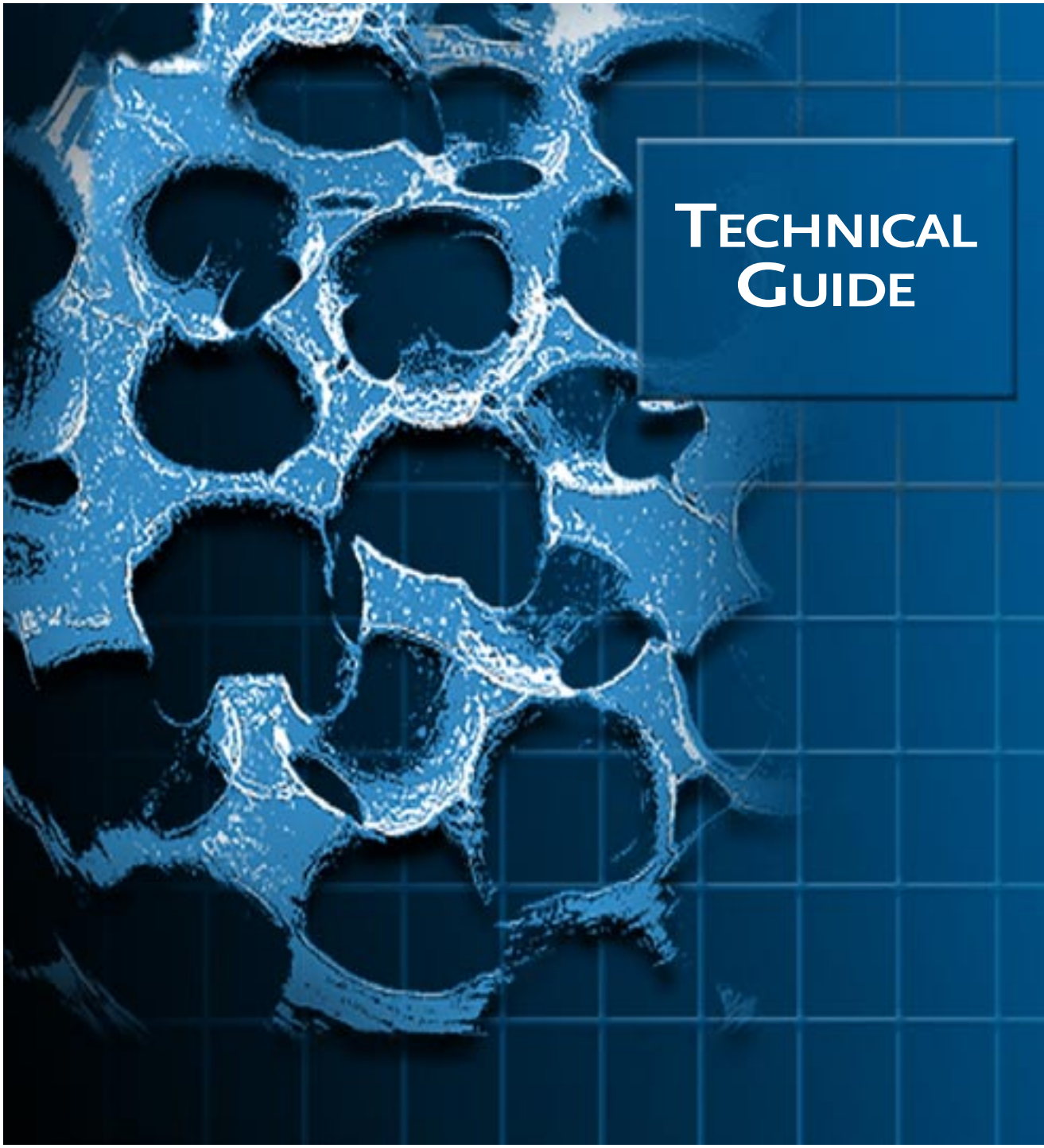
Medtronic
SOFAMOR DANEK

MASTERGRAFT™

Resorbable Ceramic Granules



MasterGraft™
Resorbable Ceramic Granules

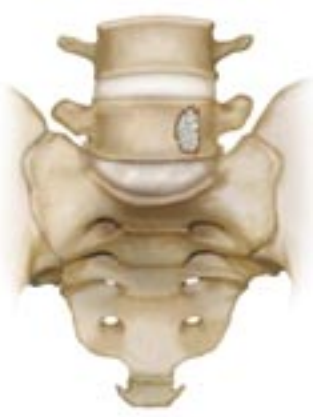
Medtronic Sofamor Danek's commitment to our customers has allowed us to focus our energies, talents and resources in developing the latest state-of-the-art bone void filler technology on the market: MasterGraft™ Resorbable Ceramic Granules.

MasterGraft™ Resorbable Ceramic Granules are a medical-grade, polyporous resorbable ceramic hybrid composed of 15% hydroxyapatite (HA) and 85% beta-tricalcium phosphate (β-TCP). The combination of these natural bone materials provides surgeons with an osteoconductive, porous implant, that improves osteointegration by allowing for the colonization of cells throughout the implant and optimizing the bone healing process.

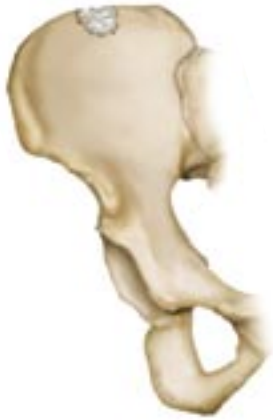
The innovative MasterGraft™ Resorbable Ceramic Granule technology is enhanced even further by its natural cell-mediated resorption process. By improving osteointegration, each granule increases its exposure to the natural osteogenic elements. Consequently, the exposure optimizes the bone healing process and allows the MasterGraft™ granules to resorb as bone grows.

To ensure that this optimal cellular environment exists in each MasterGraft™ Resorbable Ceramic Granule, Medtronic Sofamor Danek has developed a patented, solution-based, chemical process. The patented process provides excellent control over pore size, a consistent porous architecture, and prevents variations in phase, porosity, and density caused by high heat and long firing cycles.

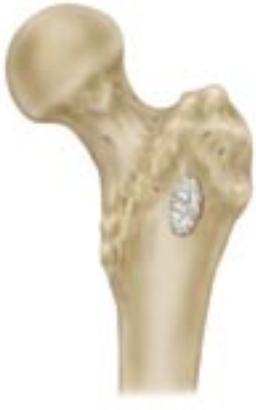
The result of Medtronic Sofamor Danek's commitment to our customers' needs is a highly porous, resorbable ceramic hybrid whose efficacy is unparalleled.



SPINE



PELVIS



EXTREMITY

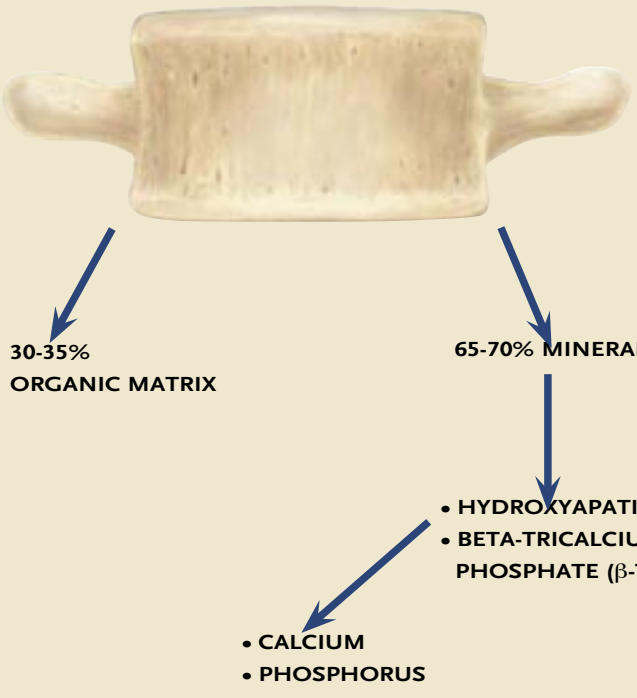
What are MasterGraft™ Resorbable Ceramic Granules?

- Medical-grade polyporous resorbable ceramic granules
  - Each granule is composed of:
    - 15% hydroxyapatite (HA)
    - 85% beta-tricalcium phosphate (β-TCP)

Why are the granules composed of 15% HA & 85% β-TCP?

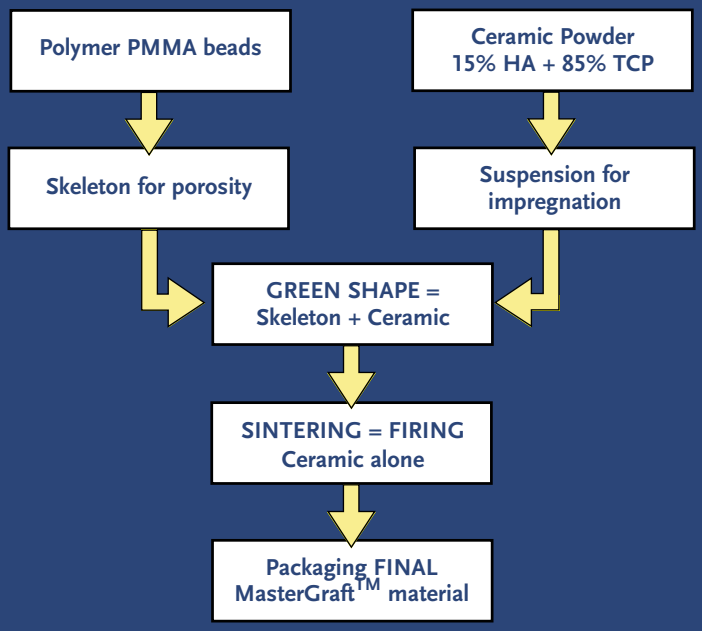
- To provide an osteoconductive porous scaffold composed of minerals similar to those found in bone
  - Both HA & β-TCP contain calcium and phosphate – the principal constituents of bone
  - Hydroxyapatite is the primary mineral found in bone matrix
- HA & β-TCP are the two most widely studied ceramics used for bone void filling applications, supported by more than 20 years of clinical experience
- The combination of HA & β-TCP provides an engineered combination of the desired bioactivity characteristics:
  1) Long-term stability
  2) Resorption rate

Composition of Bone

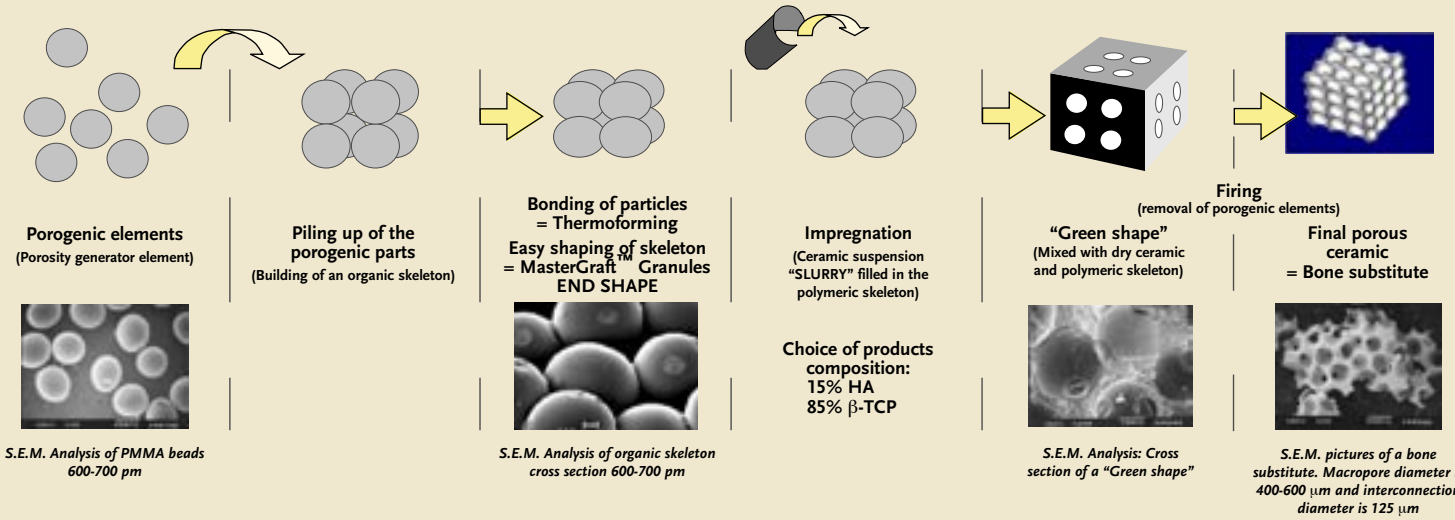


How are MasterGraft™ granules produced?

Patented solution-based chemical process



- Provides accurate control over the chemical composition of each granule
- Consistently produces granules with a highly porous architecture
- Prevents variations in phase, porosity, and density due to high heat and long firing cycles in the manufacturing process
- Consistently provides a highly porous scaffold with predictable resorption behavior



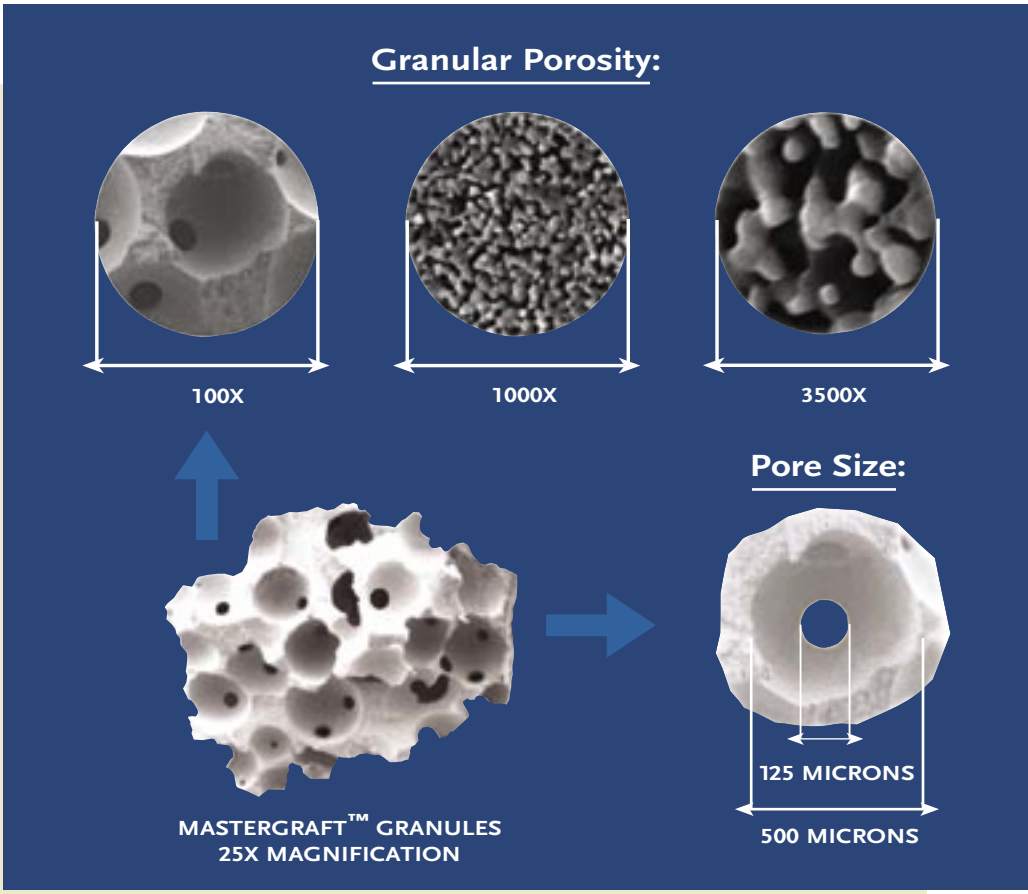
S.E.M. Analysis of PMMA beads 600-700 pm

S.E.M. Analysis of organic skeleton cross section 600-700 pm

S.E.M. Analysis: Cross section of a "Green shape"

S.E.M. pictures of a bone substitute. Macropore diameter is 400-600 µm and interconnection diameter is 125 µm

The Porosity Advantage

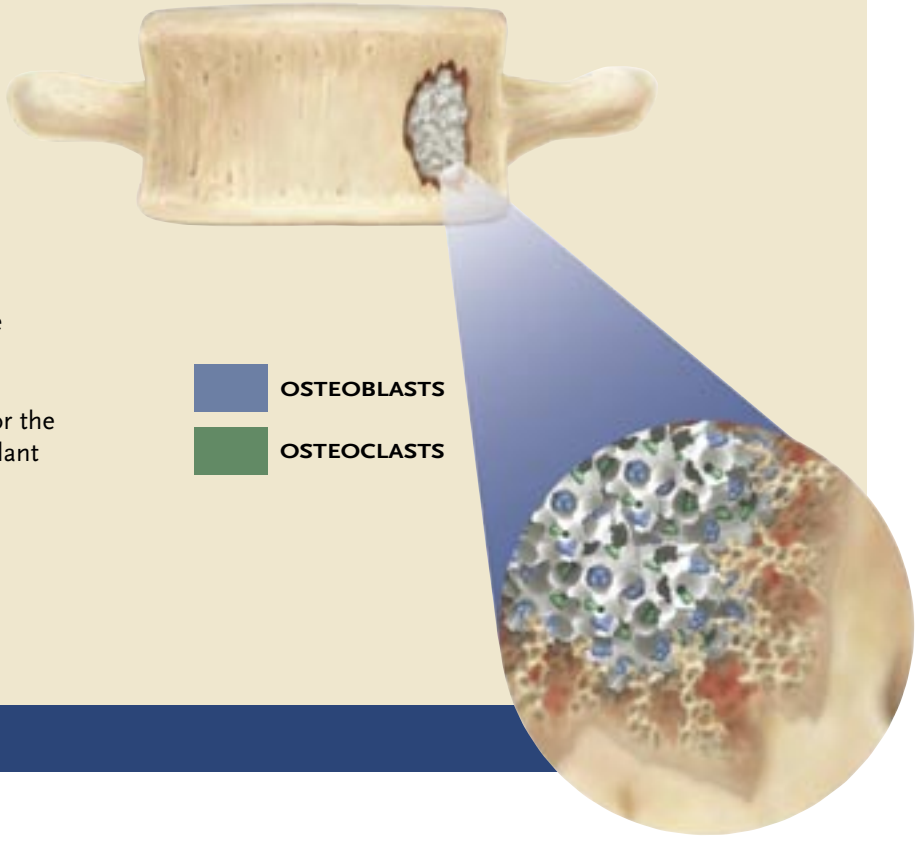


Features

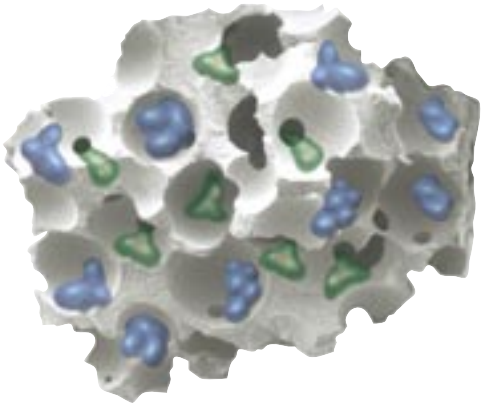
- 80% granular porosity
- 500 micron average pore size
- 125 micron average interconnected diameter

Benefits

- Emulates the highly osteoconductive porous structure of human cancellous bone (500mm pore size)
  - Mimics defect filling capabilities of autograft bone
- Optimizes blood flow throughout the 3-dimensional interconnected macroporous structure
  - Allows rapid and homogeneous bone ingrowth throughout the implant
- Improves osteointegration by allowing for the colonization of cells throughout the implant



The Resorbability Advantage



OSTEOBLASTS

OSTEOCLASTS

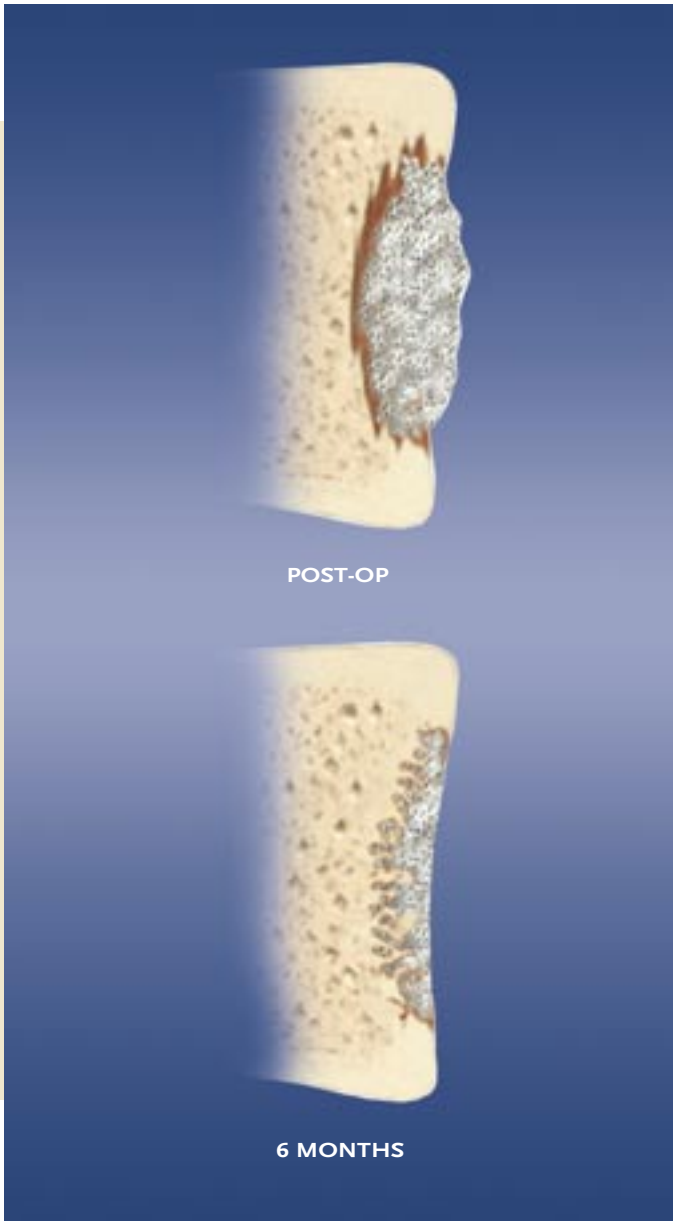
Feature

- Excellent osteointegration
  - Natural cell-mediated resorption process
  - Natural dissolution process
  - Resorbs in approximately 6 months*

Potential Benefits

- Promotes rapid and homogeneous osteointegration
  - Optimizes the bone healing process by acting as a scaffold for new bone formation
  - Allows creeping substitution to gradually replace the MasterGraft™ granules with new host bone
- Encourages growth of mature bone throughout the entire defect site
  - Forms strong bonds between MasterGraft™ granules and natural bone surrounding the defect
  - Residual granules are disbursed throughout the defect site and are in direct contact with woven bone and osteoid
- Masters the challenge of bone regeneration prior to complete resorption
  - Allows for bony ingrowth
  - Biphasic composition avoids complete resorption prior to bone regeneration

*From animal study on file.



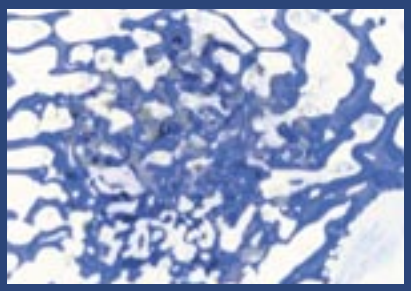
The Biocompatibility Advantage

Feature

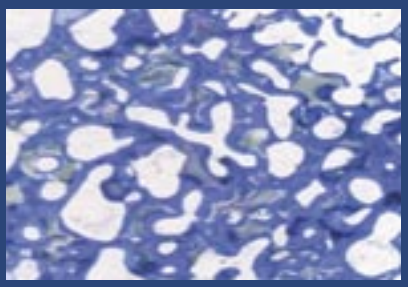
- Excellent biocompatibility
- Proven to be safe and effective
- Testing by North American Science Associates Inc. and Texas Health Research Institute includes:
  - Pre-clinical studies
  - Cytotoxicity tests
  - Sterilization tests
  - Biocompatibility tests
  - Biodegradation in consideration with ISO TR 10993-9

Benefit

- No inflammatory or pathologic responses



HISTOLOGY: 12 WEEKS



HISTOLOGY: 26 WEEKS

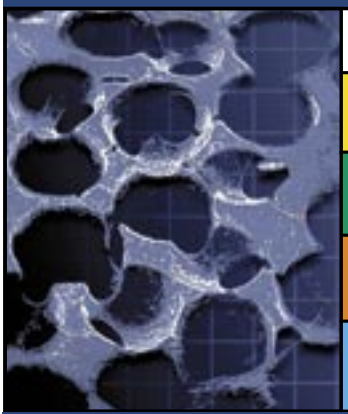
NEW BONE GROWTH

MASTERGRAFT™ GRANULES (RESORBING)

The Standards

- Conforms to European harmonized norm EN 30993 specifications
- Pre-manufacturing β-TCP materials conform to ASTM-F 1088-87 specifications for β-TCP for surgical implantation
- Pre-manufacturing hydroxyapatite materials conform to ASTM-F 1185-88 specifications for composition of ceramic hydroxyapatite for surgical implants

Product Offering



Part Number	Vial Size
7600105	5cc vial
7600110	10cc vial
7600115	15cc vial
7600130	30cc vial

Important Information on the Medtronic Sofamor Danek MasterGraft™ Resorbable Ceramic Granules

PURPOSE:
MasterGraft™ Resorbable Ceramic Granules is intended to help fill voids or gaps in bone which may be surgically created osseous defects, or osseous defects caused by traumatic injury to the bone. MasterGraft™ Resorbable Ceramic Granules provides a bone void filler that resorbs and is replaced with bone during the healing process.

DESCRIPTION:
MasterGraft™ Resorbable Ceramic Granules is made of medical grade combination of hydroxyapatite and β-tricalcium phosphate. MasterGraft™ is provided in a 60 percent hydroxyapatite and 40 percent β-tricalcium phosphate formulation. Alternatively, MasterGraft™ may be provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. The product is supplied sterile for single patient use. MasterGraft™ is an osteoconductive porous implant. Medtronic Sofamor Danek expressly warrants that this product is fabricated from hydroxyapatite and β-tricalcium phosphate conforming to recognized standards ASTM F1185-88 and ASTM F1088-87. No other warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:
MasterGraft™ Resorbable Ceramic Granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MasterGraft™ Resorbable Ceramic Granules is to be gently packed into bony voids or gaps of the skeletal system (e.g., the spine, pelvis, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MasterGraft™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS:
This product is not intended to provide structural support during the healing process, therefore, MasterGraft™ is contraindicated where the device is intended as structural support in the skeletal system.
Conditions representing relative contraindications include:
1. Severe neurological or vascular disease.
2. Uncontrolled diabetes.
3. Hypercalcemia.
4. Pregnancy.
5. Where stabilization of fracture is not possible.
6. Segmental defects.
7. Where there is significant vascular impairment proximal to the graft site.
8. When there are systemic and/or metabolic disorders that affect the bone or wound healing.
9. Any patient unwilling to follow postoperative instructions.
10. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS
A list-ing of potential adverse events includes, but is not limited to:
1. Deformity of the bone at the surgical site.
2. Fracture or extrusion of the MasterGraft™ Resorbable Ceramic Granules, with or without generation of particulate debris.
3. Wound complications including hematoma, site damage, infection, bone fracture, and other complications common to any surgical procedure.
4. Incomplete, or lack of, osseous ingrowth into bone void, as possible with any bone filler.

WARNING AND PRECAUTIONS:
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.
As with any surgical procedure, care should be demonstrated in treating patients with preexisting conditions that may impact the success of the surgical procedure. This includes patients with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy, or high dosage radiation therapy.
MasterGraft™ Resorbable Ceramic Granules does not possess sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation methods are recommended as needed to ensure stabilization of the defect. Complete postoperative wound closure is essential.
Use this device as supplied and in accordance with the handling and use information provided.
Warning: Never use this device if the vial is cracked or broken.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

HANDLING AND USE:
MasterGraft™ is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product is never to be resterilized. This device is for single patient use and should never be reused. Use MasterGraft™ Resorbable Ceramic Granules according to the following technique:
Implant MasterGraft™ Resorbable Ceramic Granules preferably in contact with spongy autologous bone. Freshen the bone wall being in contact with MasterGraft™ Resorbable Ceramic Granules. Impregnate MasterGraft™ Resorbable Ceramic Granules with blood or marrow from the patient. Gently pack the site, but avoid overfilling the bone void, or compressing the treatment site. Remove excess material from the treatment site. Close the site using standard closure techniques and discard any unused MasterGraft™ Resorbable Ceramic Granules.

PACKAGING:
Packages for MasterGraft™ Resorbable Ceramic Granules should be intact upon receipt. Damaged packages or products should not be used, and should be returned to Medtronic Sofamor Danek.

PRODUCT COMPLAINTS:
Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or Medtronic Sofamor Danek. Further, if any of the implanted bone void filler ever “malfunctions”. (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic Sofamor Danek product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek products, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.

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