MASTERGRAFT® Putty is a malleable-cohesive, osteoconductive scaffold composed of collagen that is physically mixed with resorbable ceramic granules.
MASTERGRAFT® Putty

**Design Rationale**

Designed to provide surgeons with a malleable implant that localizes biologic components and allows the implant to be shaped based on surgical environment and patient anatomy.

**Indications**

MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Putty is to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically-created osseous defects or osseous defects created from traumatic injury to the bone. MASTERGRAFT® Putty is resorbed and is replaced with bone during the healing process.
MASTERGRAFT® Putty Components

Resorbable Ceramic Granules

» 15% HA is uniformly distributed through the 85% β-TCP.
  - Hydroxyapatite (HA) is a slow resorbing mineral that allows time for the remodeling process to occur.
  - Beta-tricalcium phosphate (β-TCP) is a quicker resorbing mineral.

» Formulated to balance bony ingrowth and resorption of the scaffold structure.*

15% HA/85% β-TCP (Long-term Stability and Resorption)

» Physical structure emulates the highly osteoconductive porous structure of human cancellous bone.
  - 80% porous vs. 55% to 90% for human cancellous bone.
  - 500 micron average pore size vs. 500 microns for human cancellous bone.

Collagen

» Highly purified resorbable bovine Type I that is composed of two formulations of collagen.
  - 70% insoluble fibrous collagen.
  - 30% soluble collagen.

» Allows the material to be malleable, non-water soluble, and maintain its integrity.

*Data on file.
Resorption Mechanism

» Osteoconductive graft that resorbs by a natural cell-mediated process of creeping substitution to gradually replace the scaffold structure with new host bone.

» Chemical composition dictates the resorption rate of synthetic bone grafts.
  - If it resorbs too quickly, scaffold disappears prior to full osteointegration.
  - If it resorbs too slowly, bone encapsulates the structure, making it a permanent implant.

6 Months Postoperative

- Resorbs Too Quickly
- Resorbs Too Slowly
Cellular Localization Effects

Absorption Capabilities

» Readily absorbs bone marrow aspirate and delivers cells to site of implantation.
» Aids in the localization of cellular elements.

Fill interior depression with BMA and allow 5 minutes for absorption.

Cellular Environment

» Three-dimensional interconnected porous structure.
  – Helps blood flow through the implant.
  – Creates a favourable environment for rapid and homogenous bony ingrowth.

MASTERGRAFT® Putty Saturated with BMA

3-D Scaffold

» Scaffold allows for attachment of cells to the collagen-ceramic matrix.
  – Allows cells to colonize and grow.
» Accurate placement and retention of biological factors at the site of implantation.
  – Allows for mixing and delivery of autogenous bone and bone marrow aspirate at the site of implantation.
  – Reduces handling waste.

Cell Attachment to MASTERGRAFT® Putty Structure

BMA Retained in Graft Material
Moldable, Interconnected Structure

Intraoperative Malleability

- Allows graft to be shaped based on surgical environment and patient anatomy (no shape constraints).
  - Retains malleability throughout entire surgical procedure.

**Note**

*Before proceeding, allow hydrated putty to stand for a minimum of 5 minutes. Use within 2 hours.*

Can be Shaped and Molded into a Variety of Forms

- Strip
- Cylinder
- Irregular Shapes

Interconnected Structure

- Allows homogenous bone growth throughout the implant.
  - Minimizes interruptions/resistance to the bone-forming process.
Handling Characteristics

Easy Hydration

- Shaped to retain bone marrow aspirate or sterile water as it hydrates the putty.

Hydrated with Bone Marrow Aspirate (BMA)

Hydrated with Sterile Water

Shape Preservation

- Maintains fabricated shape to allow cellular proliferation and bony ingrowth.

MASTERGRAFT® Putty Placed in Bony Defect and Molded to Patient Anatomy

Adhesive

- Allows homogeneous mixing with autologous bone graft.

Radiopaque

- Provides radiographic assessment of graft material location.

MASTERGRAFT® Putty with Sterile Water
Stays In Place

Maintains Graft Integrity

» Allows for irrigation prior to surgical closure.
» Resists postoperative graft migration.

Fluid Retention

» Retains BMA within the graft material and at the site of implantation.
  – Bone marrow does not leach or defuse from the graft.
Important Product Information on MASTERGRAFT® Matrix and MASTERGRAFT® Putty

PURPOSE
MASTERGRAFT® Matrix and MASTERGRAFT® Putty are 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® Matrix and MASTERGRAFT® Putty provide bone void fillers that resorb and are replaced with bone during the natural healing process.

DESCRIPTION
MASTERGRAFT® Matrix and MASTERGRAFT® Putty are made from a combination of medical grade purified collagen and biphasic calcium phosphate ceramic. In the MASTERGRAFT® Matrix device, the collagen is a highly purified (>95%) Type I bovine-derived lyophilized collagen. The collagen component in the MASTERGRAFT® Putty device is Type I bovine collagen. The biphasic ceramic portion of both MASTERGRAFT® Matrix and MASTERGRAFT® Putty is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. MASTERGRAFT® Matrix product is supplied sterile in a premixed strip form for single patient use. MASTERGRAFT® Putty is supplied as a sterile, dry, solid, construct that is hydrated for single patient use and is a moldable form of bone void filler. Both devices are osteoconductive, porous implants that allow for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The products are biocompatible. Both MASTERGRAFT® Matrix and MASTERGRAFT® Putty readily absorb bone marrow aspirate and have been shown to heal bone defects.

Medtronic Sofamor Daneck expressly warrants that these products are fabricated from hydroxyapatite and β-tricalcium phosphate. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS
MASTERGRAFT® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps that are not intrinsically to the stability of the bony structure. Additionally, MASTERGRAFT® Putty can be used with autograft as a bone graft extender. MASTERGRAFT® Matrix is to be combined with autogenous bone marrow and is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Both devices are to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ilium, and/ or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Both devices resorb 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® Matrix and MASTERGRAFT® Putty are 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.
5. Where stabilization of fracture is not possible.
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 listing of potential adverse events includes, but is not limited to:

1. Deformity of the bone at the surgical site.
2. Fracture or extrusion of MASTERGRAFT® Matrix or MASTERGRAFT® Putty, 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® Matrix and MASTERGRAFT® Putty do 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 packaging is compromised.

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.

[USA] For US Audiences Only

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

HANDLING AND USE
MASTERGRAFT® Matrix and MASTERGRAFT® Putty are provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. These products are never to be resterilized. These devices are for single patient use and should never be reused.

MASTERGRAFT® MATRIX
Implant MASTERGRAFT® Matrix preferably in contact with spongy autologous bone. Freshen the bone wall being in contact with MASTERGRAFT® Matrix. Saturate MASTERGRAFT® Matrix with blood or marrow from the patient. (Note: It is mandatory that MASTERGRAFT® Matrix be mixed with bone marrow aspirate.) Bone marrow should be obtained immediately prior to implantation and should be aspirated in a minimum 1:1 ratio of marrow to material (ex. 5mL of bone marrow for each 5cc of material). Once bone marrow aspirate is applied to MASTERGRAFT® Matrix allow the scaffold structure to soak for 1-3 minutes prior to implantation. Adequate soaking has occurred once bone marrow aspirate coats all surfaces. 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® Matrix.

MASTERGRAFT® PUTTY
Use MASTERGRAFT® Putty according to the following techniques:

A. Bone Marrow Aspirate (BMA) plus MASTERGRAFT® Putty

Aspirate Bone Marrow

Bone marrow aspirate (BMA) should be obtained immediately prior to implantation and should be aspirated in a 1:1 ratio of bone marrow to MASTERGRAFT® Putty (ex. 1mL of bone marrow for each 1cc of MASTERGRAFT® Putty)

Step 1 - Based on size/volume of defect, determine the amount of material (cc/mL) needed to completely fill the bony void.

Step 2 - Locate the posterior or anterior superior iliac crest. Using sterile technique, prepare surgical site.

Step 3 - Percutaneously introduce the aspiration needle into the iliac crest. To stabilize the needle and enhance user control, hold the proximal end of the T-handle in palm and place the index finger against the shaft of the needle near the crown.

Step 4 - Use gentle, but firm pressure to advance the needle. Rotate needle 45° in alternating clockwise — counter clockwise motion. Decreased resistance is experienced upon entrance into the marrow cavity. If the needle is advanced beyond the marrow cavity, aspiration of marrow will be prevented. Should this occur, slowly withdraw the needle from the opposing iliac crest wall while rotating the needle 45° in alternating clockwise — counter clockwise motion until marrow can be aspirated.

Step 5 - Remove stylet from the cannula of the needle.

Step 6 - Attach a 10mL syringe with a Luer™ Lok or Lee™ Lok taper to the hub of the aspiration needle.

Step 7 - Aspirate the desired amount of marrow by retracting the syringe plunger. To maintain the highest quality marrow, a maximum of 3mL of marrow should be withdrawn from any one aspiration site. If more marrow is needed, move the needle 1cm along the iliac crest and repeat steps 3 through 6 as needed. Aspiration of peripheral (venous) blood should be avoided.

METHODS
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HANDLING AND USE
MASTERGRAFT® Matrix and MASTERGRAFT® Putty are provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. These products are never to be resterilized. These devices are for single patient use and should never be reused.

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Implant MASTERGRAFT® Matrix preferably in contact with spongy autologous bone. Freshen the bone wall being in contact with MASTERGRAFT® Matrix. Saturate MASTERGRAFT® Matrix with blood or marrow from the patient. (Note: It is mandatory that MASTERGRAFT® Matrix be mixed with bone marrow aspirate.) Bone marrow should be obtained immediately prior to implantation and should be aspirated in a minimum 1:1 ratio of marrow to material (ex. 5mL of bone marrow for each 5cc of material). Once bone marrow aspirate is applied to MASTERGRAFT® Matrix allow the scaffold structure to soak for 1-3 minutes prior to implantation. Adequate soaking has occurred once bone marrow aspirate coats all surfaces. 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® Matrix.

MASTERGRAFT® PUTTY
Use MASTERGRAFT® Putty according to the following techniques:

A. Bone Marrow Aspirate (BMA) plus MASTERGRAFT® Putty

Aspirate Bone Marrow

Bone marrow aspirate (BMA) should be obtained immediately prior to implantation and should be aspirated in a 1:1 ratio of bone marrow to MASTERGRAFT® Putty (ex. 1mL of bone marrow for each 1cc of MASTERGRAFT® Putty)

Step 1 - Based on size/volume of defect, determine the amount of material (cc/mL) needed to completely fill the bony void.

Step 2 - Locate the posterior or anterior superior iliac crest. Using sterile technique, prepare surgical site.

Step 3 - Percutaneously introduce the aspiration needle into the iliac crest. To stabilize the needle and enhance user control, hold the proximal end of the T-handle in palm and place the index finger against the shaft of the needle near the crown.

Step 4 - Use gentle, but firm pressure to advance the needle. Rotate needle 45° in alternating clockwise — counter clockwise motion. Decreased resistance is experienced upon entrance into the marrow cavity. If the needle is advanced beyond the marrow cavity, aspiration of marrow will be prevented. Should this occur, slowly withdraw the needle from the opposing iliac crest wall while rotating the needle 45° in alternating clockwise — counter clockwise motion until marrow can be aspirated.

Step 5 - Remove stylet from the cannula of the needle.

Step 6 - Attach a 10mL syringe with a Luer™ Lok or Lee™ Lok taper to the hub of the aspiration needle.

Step 7 - Aspirate the desired amount of marrow by retracting the syringe plunger. To maintain the highest quality marrow, a maximum of 3mL of marrow should be withdrawn from any one aspiration site. If more marrow is needed, move the needle 1cm along the iliac crest and repeat steps 3 through 6 as needed. Aspiration of peripheral (venous) blood should be avoided.
Important Product Information on MASTERGRAFT® Matrix and MASTERGRAFT® Putty continued

Step 8 - Once the desired volume of marrow has been collected, remove the needle from the syringe.

Step 9 - Remove needle from wound and close wound using standard surgical technique.

MASTERGRAFT® Putty Preparation
- Uniformly apply BMA in a 1:1 ratio to MASTERGRAFT® Putty (ex. 1mL of bone marrow for each 1cc of MASTERGRAFT® Putty).
- Let set for a minimum of 5 minutes to allow for full hydration.
- Mold MASTERGRAFT® Putty using kneading technique.
- Implant MASTERGRAFT® Putty/BMA material.

B. Bone Marrow Aspirate (BMA) plus Autograft plus MASTERGRAFT® Putty

Aspirate Bone Marrow
Bone marrow aspirate (BMA) should be obtained immediately prior to implantation and should be aspirated in a 1:1 ratio of bone marrow to MASTERGRAFT® Putty (ex. 1mL of bone marrow for each 1cc of MASTERGRAFT® Putty).

Step 1 - Based on size/ volume of defect, determine the amount of material (cc/mL) needed to completely fill the bony void.

Step 2 - Locate the posterior or anterior superior iliac crest. Using sterile technique, prepare surgical site.

Step 3 - Percutaneously introduce the aspiration needle into the iliac crest. To stabilize the needle and enhance user control, hold the proximal end of the 1-handle in palm and place the index finger against the shaft of the needle near the crown.

Step 4 - Use gentle, but firm pressure to advance the needle. Rotate needle 45° in alternating clockwise — counter clockwise motion. Decreased resistance is experienced upon entrance into the marrow cavity. If the needle is advanced beyond the marrow cavity, aspiration of marrow will be prevented. Should this occur, slowly withdraw the needle from the opposing iliac crest wall while rotating the needle 45° in alternating clockwise — counter clockwise motion until marrow can be aspirated.

Step 5 - Remove stylet from the cannula of the needle.

Step 6 - Attach a 10mL syringe with a Luer™ Lok or Lee™ Lok taper to the hub of the aspiration needle.

Step 7 - Aspirate the desired amount of marrow by retracting the syringe plunger. To maintain the highest quality marrow, a maximum of 3mL of marrow should be withdrawn from any one aspiration site. If more marrow is needed, move the needle 1cm along the iliac crest and repeat steps 3 through 6 as needed. Aspiration of peripheral (venous) blood should be avoided.

Step 8 - Once the desired volume of marrow has been collected, remove the needle from the syringe.

Step 9 - Remove needle from wound and close wound using standard surgical technique.

MASTERGRAFT® Putty Preparation
- Uniformly apply BMA in a 1:1 ratio to MASTERGRAFT® Putty (ex. 1mL of bone marrow for each 1cc of MASTERGRAFT® Putty).
- Let set for a minimum of 5 minutes to allow for full hydration.
- Add autograft to the MASTERGRAFT® Putty, with a lower limit of 25% MASTERGRAFT® Putty to 75% autograft or with an upper limit 50% of MASTERGRAFT® Putty to 50% autograft bone.

C. Sterile Water plus MASTERGRAFT® Putty plus Autograft

MASTERGRAFT® Putty Preparation
- Uniformly apply sterile water in a 1:1 ratio to MASTERGRAFT® Putty (ex. 1mL of sterile water for each 1cc of MASTERGRAFT® Putty).
- Let set for a minimum of 5 minutes to allow for full hydration.
- Add autograft to the MASTERGRAFT® Putty, with a lower limit of 25% MASTERGRAFT® Putty to 75% autograft or with an upper limit 50% of MASTERGRAFT® Putty to 50% autograft bone.
- Mold MASTERGRAFT® Putty/sterile water/autograft mixture using kneading technique.
- Implant MASTERGRAFT® Putty/sterile water/autograft material.

PACKAGING
Packages for MASTERGRAFT® Matrix and MASTERGRAFT® Putty 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 complaints 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 spiral system component(s) ever “malfunction,” (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 and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION
Recommended directions for use of this system (surgical operative techniques) are available at no change upon request. If further information is needed or required, please contact MEDTRONIC SOFAMOR DANEK.

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Contact customer service or your sales representative for the most up-to-date version of the package insert and surgical technique.
Notes
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.