MASTERGRAFT® Strip’s broad geometric design maximizes bony surface area contact and allows for continuous bone growth over large bony gaps.
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Introduction

Design Rationale

Designed to provide surgeons with a flexible, compression-resistant, osteoconductive implant that localizes cells and maximizes contact with bony surfaces to allow for a continuous fusion over large bony gaps (i.e., multiple level fusions, segmental defects).

Indications

MASTERGRAFT® Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and for use as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., 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.

The device resorbs and is replaced with bone during the healing process.
**Components**

MASTERGRAFT® Strip is a resorbable, osteoconductive scaffold composed of collagen physically mixed with resorbable ceramic granules.

**Physical Structure**

- Mimics the lattice-like structure of human cancellous bone: 89% porous vs. 55%-90% for human cancellous bone
- Provides a favorable environment for natural, uninterrupted bony ingrowth
- Allows penetration of bone marrow aspirate throughout the entire implant
- Accommodates bone growth in the center and throughout the entire implant

**MASTERGRAFT® Strip contains 96.5% ceramic/3.5% collagen by weight**

- Larger ceramic content provides more scaffolding for bone formation after resorption of the collagen component

**Resorbable Ceramic Granules Component**

**Chemical Composition**

- Polyporous resorbable ceramic granules composed of 15% hydroxyapatite (HA) and 85% beta-tricalcium phosphate (β-TCP)
- HA is a slow resorbing mineral that allows time for the remodeling process to occur
- β-TCP is a quicker resorbing mineral that aids in the remodeling of the scaffold structure

**Did You Know?**

Composition dictates the resorption rate of synthetic bone grafts

- Ceramic in MASTERGRAFT® Strip balances bony ingrowth and resorption of the scaffold structure

**Absorbable Collagen Component**

- Highly purified collagen from bovine tendon
- Allows for the attachment of cells to the scaffold structure

**In Vitro Study of Ceramic Resorption Rates**

- Graph showing the percentage change from Week 0 over time for different ceramic granules and pellets.
Characteristics

Flexible, Interconnected Structure

» Allows graft to be shaped based on surgical environment and patient anatomy

» Retains intraoperative shape throughout the entire surgical procedure

Broad Geometric Design

» Allows for the localization of cells and maximizes bony surface area contact to allow for a continuous fusion over large bony gaps

Fluid Absorption and Retention

» Fluid absorption = 105% of dry volume (water)
  - Aids in the localization of cellular elements

» Accurate delivery and retention of cells at the site of implantation

Compression Resistant

» 797 Newton compression resistance preserves space for greater volume of bone formation*

*10cm strip wet with water at 50% strain

Note: No loss of fluid under compression
Pre-clinical Autograft Extender Data

Objective

To determine if MASTERGRAFT® Strip is a suitable autograft extender in a rabbit lumbar transverse process fusion model

Study Design

Thirty-four (34) New Zealand White rabbits underwent bilateral posterolateral fusions (L5 and L6)

**Animals were divided into three groups (n=12)**

» 50% MASTERGRAFT® Strip (1.5cc) soaked with 1.5cc BMA + 50% Autograft (1.5cc)

» 75% MASTERGRAFT® Strip (2.25cc) soaked with 2.25cc BMA + 25% Autograft (0.75cc)

» 100% Autograft (3.0cc)

Animals were sacrificed at eight weeks

**Fusion Assessment Methods**

» Radiographs:
  - AP plain films
  - Computerized tomography (CT) three dimensional scans

» Manual palpation

» Histology

**FAXITRON® Radiographs — Dorsal View at 8 weeks**

![Dorsal View at 8 weeks](image)
Pre-clinical Autograft Extender Data continued

Results and Conclusions

Radiographic fusion was judged by continuous trabecular continuity between the affected transverse processes.

Table 1 | Radiographic Fusion Assessment

<table>
<thead>
<tr>
<th>Group</th>
<th>Fusion Rate at Eight Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>75% MASTERGRAFT® Strip (2.25cc) soaked with 2.25cc BMA + 25% Autograft (0.75cc)</td>
<td>58% (7/12)</td>
</tr>
<tr>
<td>50% MASTERGRAFT® Strip (1.5cc) + 1.5cc BMA + 50% Autograft (1.5cc)</td>
<td>75% (9/12)</td>
</tr>
<tr>
<td>Autograft (3.0cc/side)</td>
<td>60% (6/10)</td>
</tr>
</tbody>
</table>

Computerized Tomography (CT) 3 Dimensional Scans — Dorsal View

50% MASTERGRAFT® Strip (1.5cc) + 1.5cc BMA + 50% Autograft (1.5cc)  
75% MASTERGRAFT® Strip (2.25cc) soaked with 2.25cc BMA + 25% Autograft (0.75cc)  
Autograft (3.0cc/side)
Pre-clinical Autograft Extender Data continued

Results and Conclusions continued

Table 2 | Manual Palpation Results

<table>
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<th>Group</th>
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</tr>
<tr>
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<td>75% (9/12)</td>
</tr>
<tr>
<td>Autograft (3.0cc/side)</td>
<td>50% (5/10)</td>
</tr>
</tbody>
</table>

The highest fusion rate was in the 50% MASTERGRAFT® Strip (1.5cc) soaked with 1.5cc BMA + 50% Autograft (1.5cc) group, in which 75% (9/12) were fused.

Table 3 | Histology Score Means For Each Group

<table>
<thead>
<tr>
<th>Group</th>
<th>New Bone Formation*</th>
<th>Inflammation**</th>
<th>Fusion***</th>
</tr>
</thead>
<tbody>
<tr>
<td>75% MASTERGRAFT® Strip (2.25cc) soaked with 2.25cc BMA + 25% Autograft (0.75cc)</td>
<td>2.17</td>
<td>4.00</td>
<td>7.00</td>
</tr>
<tr>
<td>50% MASTERGRAFT® Strip (1.5cc) + 1.5cc BMA + 50% Autograft (1.5cc)</td>
<td>2.33</td>
<td>3.83</td>
<td>7.00</td>
</tr>
<tr>
<td>Autograft (3.0cc/side)</td>
<td>2.17</td>
<td>3.67</td>
<td>6.50</td>
</tr>
</tbody>
</table>

The MASTERGRAFT® Strip treatment groups tended to have more histological evidence of mature/immature bone development across the inter-transverse process spaces than did the autograft controls.

* on a 0 – 3 scale where 0 indicated no bone formation detected
** on a 0 – 4 scale where 4 indicated no inflammatory response
*** on a 1 – 10 scale where 10 indicated complete bridging with mature bone

Conclusion

MASTERGRAFT® Strip + BMA used as an autograft extender in this commonly employed rabbit posterolateral fusion model produced physiologically and radiographically similar results to autograft fusion alone.

Results of animal studies are not necessarily predictive of human clinical outcomes.
Ordering Information

MASTERGRAFT™ Strip Product Offering

- **7800310**
  - 10cm (12cc)

- **7800320**
  - 2 x 10cm (24cc)

- **7800336**
  - 36cm (43cc)

Based on length/volume of defect, determine the amount of material (cm or cc) needed to fill the bony void completely.

Summary of Indications

MASTERGRAFT® Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure; MASTERGRAFT® Strip can also be used with autograft as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., 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.

The device resorbs and is replaced with bone during the healing process.
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 important medical information.