INDICATIONS FOR USE

INDUCTIGRAFT is an implant intended to be used in place of cortico-cancellous, or cancellous allograft or autograft bone to fill bony voids or gaps of the skeletal system (i.e., extremities, pelvis, spine, dental). INDUCTIGRAFT may be used in spinal fusion procedures, where pedicle screw fixation or an interbody cage relieve the graft site from physiological loads.

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Rx Only.

For safe and proper use please refer to full device Instructions for Use for Contraindications, Warnings, and Precautions.

References:

1. INDUCTIGRAFT Bioactive Bone Graft Instructions for Use.

For more information, please contact your local sales representative or call 1-888-229-0001.
Iliac crest autograft is the commonly utilized "gold standard" graft material in spine surgical techniques. In a pre-clinical posterolateral fusion model, INDUCTIGRAFT exhibited similar fusion rates to autograft. *Preclinical data. Results may not correlate to performance in humans.

Fusion rates were established by manual palpation.

<table>
<thead>
<tr>
<th>Fusion Rate (%)</th>
<th>ICBG: Illiac Crest Bone Graft</th>
<th>Si-CaP EP/BMA: AltaPore with bone marrow aspirate</th>
<th>Si-CaP EP/ICBG: AltaPore with iliac crest bone graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>70.0</td>
<td>(5/10)</td>
<td>(4/10)</td>
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<tr>
<td>60.0</td>
<td>(5/10)</td>
<td>(4/10)</td>
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<tr>
<td>50.0</td>
<td>(5/10)</td>
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<tr>
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<td>0.0</td>
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<td>(4/10)</td>
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Introducing the Next Generation Osteoinductive Silicified Substituted Bone Graft Substitute

INDUCTIGRAFT is an osteoinductive and osteoconductive silicate substituted calcium phosphate bone void filler. INDUCTIGRAFT contains microgranules, sized 1–2 mm, with 80–85% macro porosity and 31–47% micro porosity, suspended in an absorbable aqueous gel carrier. The interconnected and open porous structure is similar to human cancellous bone and is designed to promote osteogenesis.

Optimized Porosity to Enhance Bone Growth

**Earlier Vascularization**
The enhanced porosity of INDUCTIGRAFT promotes early vascularization, oxygen, nutrients, and growth factors that are vital for successful bone formation.

**Enhanced Cellular Activity**
The enhanced macro and micro porosity of INDUCTIGRAFT provides for increased surface area and topography, which facilitates increased proliferation and differentiation of osteoblasts along the surface of the graft and promotes increased new bone formation.

**Physiologically Balanced Bone Growth**
INDUCTIGRAFT promotes osteogenesis and enhances the body’s own remodeling response producing osteogenically high-quality bone throughout the graft.

**Versatility and Ease of Use**
This precise handling characteristic of INDUCTIGRAFT allows the putty to be molded into multiple shapes to adapt to various surgical needs, designed to instill confidence while handling without using assistive tools or equipment.

**Enhanced Performance**
INDUCTIGRAFT is designed for use as a standalone bone graft substitute or as an autograft extender (Autograft). It can be combined with autologous bone (Autograft) or with bone marrow aspirate (BMA).

**Versatility and Ease of Use**
Fusion was assessed by manual palpation of the treated segment by three blinded, independent reviewers. "Fusion" was determined if no motion was detected in flexion or extension. At 8 and 12 weeks, Si-CaP EP, ICBG+Si-CaP EP, and Si-CaP EP+BMA exhibited comparable fusion rates to ICBG.

**Enhanced Performance**
INDUCTIGRAFT is designed for use as a standalone bone graft substitute or as an autograft extender. While not necessary, it can be combined with autologous bone (Autograft) or bone marrow aspirate (BMA).
Comparable Results to Autograft\textsuperscript{6,7,8} Iliac crest autograft is the commonly utilized “gold standard” graft material in spine surgical techniques. In a pre-clinical posterolateral fusion model, INDUCTIGRAFT exhibited similar fusion rates to autograft.\textsuperscript{5}

*Preclinical data. Results may not correlate to performance in humans.

<table>
<thead>
<tr>
<th>Fusion Rate (%)</th>
<th>4 Weeks</th>
<th>8 Weeks</th>
<th>12 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Si-CaP EP</td>
<td>(5/10)</td>
<td>(4/10)</td>
<td>(4/10)</td>
</tr>
<tr>
<td>ICBG + Si-CaP EP</td>
<td>(5/9)</td>
<td>(4/10)</td>
<td>(5/9)</td>
</tr>
<tr>
<td>Si-CaP EP + BMA</td>
<td>(6/10)</td>
<td>(5/9)</td>
<td>(6/10)</td>
</tr>
</tbody>
</table>

ICBG: iliac crest bone graft
Si-CaP EP/BMA: AltaPore with bone marrow aspirate
Si-CaP EP/ICBG: AltaPore with iliac crest bone graft

Introducing the Next Generation Osteoinductive Silicated Substituted Bone Graft Substitute

INDUCTIGRAFT is an osteoinductive and osteoconductive silicate substituted calcium phosphate bone void filler. Its structure promotes mineralization, enhances differentiation, and supports angiogenesis, resulting in bone fusion. INDUCTIGRAFT contains microgranules, sized 1–2 mm, with 80-85% macro porosity and 31-47% micro porosity, suspended in an absorbable aqueous gel carrier. The interconnected and open porous structure is similar to human cancellous bone and is designed to promote osteogenesis.

Optimized Porosity to Enhance Bone Growth

Earlier Vascularization\textsuperscript{2} The enhanced porosity of INDUCTIGRAFT Bioactive Bone Graft promotes early vascularization, oxygen, nutrient, and growth factor delivery, which is critical for appropriate bone development.

Enhanced Cellular Activity\textsuperscript{2} The enhanced macro and micro porosity of INDUCTIGRAFT Bioactive Bone Graft provides for an increased surface area and topography, which facilitate the increased proliferation and differentiation of osteoblasts along the surface of the graft and promote increased new bone formation.

Physiologically Balanced Bone Growth\textsuperscript{2} INDUCTIGRAFT promotes osteogenesis and endosteal remodeling without the need for osteogenic supplements. The interconnected, natural porous structure allows for bone growth throughout the bone graft and not by creeping substitution.

Versatility and Ease of Use

The precise handling characteristics of INDUCTIGRAFT allow the putty to be molded into multiple shapes to adapt to various surgical needs, designed to instill confidence while allowing ease of use regardless of technique or operator.

Enhanced Performance

Fusion was assessed by manual palpation of the treated segment by three blinded, independent reviewers. “Fusion” was determined if no motion was detected in flexion or extension. At 8 and 12 weeks, SiCaP EP, ICBG+SiCaP EP, and SiCaP EP+BMA exhibited comparable fusion rates to ICBG.

INDUCTIGRAFT promotes osteogenesis and endosteal remodeling without the need for osteogenic supplements. INDUCTIGRAFT is designed for use as a standalone bone graft substitute or as an autograft extender. INDUCTIGRAFT can be combined with autologous bone (autograft) or bone marrow aspirate (BMA).

INDUCTIGRAFT as a standalone

Enhanced Performance

Composite Results Autograft vs.

Enhanced Performance

Fusion was assessed by manual palpation of the treated segment by three blinded, independent reviewers. “Fusion” was determined if no motion was detected in flexion or extension. At 8 and 12 weeks, SiCaP EP, ICBG+SiCaP EP, and SiCaP EP+BMA exhibited comparable fusion rates to ICBG.

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Fusion was assessed by manual palpation of the treated segment by three blinded, independent reviewers. “Fusion” was determined if no motion was detected in flexion or extension. At 8 and 12 weeks, SiCaP EP, ICBG+SiCaP EP, and SiCaP EP+BMA exhibited comparable fusion rates to ICBG.

INDUCTIGRAFT as a standalone bone graft substitute or as an autograft extender. INDUCTIGRAFT can be combined with autologous bone (autograft) or bone marrow aspirate (BMA).
**Compared Results to Autograft**

Iliac crest autograft is the commonly utilized “gold standard” graft material in spine surgical techniques. In a pre-clinical posterolateral fusion model, INDUCTIGRAFT exhibited similar fusion rates to autograft. *Preclinical data. Results may not correlate to performance in humans.*

<table>
<thead>
<tr>
<th>Fusion Rate (%)</th>
<th>0.0</th>
<th>10.0</th>
<th>20.0</th>
<th>30.0</th>
<th>40.0</th>
<th>50.0</th>
<th>60.0</th>
<th>70.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Weeks</td>
<td>0/10</td>
<td>2/10</td>
<td>2/10</td>
<td>4/10</td>
<td>5/10</td>
<td>5/10</td>
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<td>5/10</td>
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<tr>
<td>8 Weeks</td>
<td>0/9</td>
<td>2/9</td>
<td>2/9</td>
<td>4/10</td>
<td>5/9</td>
<td>5/9</td>
<td>5/10</td>
<td>5/10</td>
</tr>
<tr>
<td>12 Weeks</td>
<td>0/9</td>
<td>2/9</td>
<td>2/9</td>
<td>4/9</td>
<td>5/9</td>
<td>5/9</td>
<td>5/10</td>
<td>5/10</td>
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**Fusion Rates**

ICBG: iliac crest bone graft
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**Optimized Porosity to Enhance Bone Growth**

**Earlier Vascularization**

The enhanced porosity of INDUCTIGRAFT Bioactive Bone Graft promotes early vascularization, essential for bone formation, and provides oxygen, nutrients, and growth factors to facilitate bone development.

**Enhanced Cellular Activity**

The enhanced macro and micro porosity of INDUCTIGRAFT Bioactive Bone Graft provides for increased surface area and topography, which facilitate the increased proliferation and differentiation of osteoblasts along the surface of the graft and promote increased new bone formation.

**Physiologically Balanced Bone Growth**

INDUCTIGRAFT promotes osteogenesis and endochondral bone formation to enhance bone growth throughout the bone graft and not by creeping substitution.

**Versatility and Ease of Use**

The enhanced porosity of INDUCTIGRAFT allows for intramedullary shaping to adapt to various surgical needs, designed to instill confidence while handling and using as standalone with autograft, or in combination with ICBG.

**Enhanced Performance**

Fusion was assessed by manual palpation of the treated segment by three blinded, independent reviewers. “Fusion” was determined if no motion was detected in flexion or extension. At 8 and 12 weeks, SiCaP EP, ICBG+SiCaP EP, and SiCaP EP+BMA exhibited comparable fusion rates to ICBG.

**Versatility and Ease of Use**

The precise handling characteristics of INDUCTIGRAFT allow for ease of use and confidence in its application as a standalone, with autograft, or BMA.

**INDUCTIGRAFT** as a standalone

**INDUCTIGRAFT** vs. ICBG

**INDUCTIGRAFT** vs. Autograft

INDUCTIGRAFT is designed for use as a standalone bone graft substitute or as an autograft extender (BMA not necessary). It can be combined with autologous bone (taking up to a 2:1 ratio) or bone marrow aspirate (up to a 1:3 ratio).

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GLBL/87/18-0001   12/2018

For more information, contact your local sales representative or call 1-888-229-0001

**Micro-granule Characteristics:**

- INDUCTIGRAFT contains microgranules, sized 1–2 mm, suspended in an absorbable aqueous gel carrier.
- INDUCTIGRAFT contains 0.8% silicon by weight, which in preclinical studies was shown to be optimal for bone formation.

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*Preclinical data. Results may not correlate to performance in humans.*

**Enhance Bone Growth**

- 80-85% Macro Porosity
- 31-47% Micro Porosity
- 0.8 wt% Silicone Level

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**Product Name**

- Inductigraft Osteoinductive Bone Graft Substitute

**Product Size**

- 1.5 mL
- 2.5 mL
- 5 mL
- 10 mL
- 20 mL

**Order Code**

- Baxter Code
- Baxter Code
- Baxter Code
- Baxter Code
- Baxter Code

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Enhance Bone Growth™

Baxter

[Graphic and product images]
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