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nanOss Bioactive advanced bone graft combines a collagen-based biopolymer and nanocrystalline hydroxyapatite that mimic the structure of bone to give a natural bone growth solution.

The bioscaffold carrier provides an ideal cellular environment for bone repair. The advanced carrier in nanOss Bioactive utilizes a patented process to open collagen’s triple helical structure to form an open bioscaffold for tissue infiltration. Host cells interact with the open bioscaffold carrier that provides an ideal environment for bone formation.

### COMPARISON OF NANOSS BIOACTIVE AND HUMAN BONE: NANOSS BIOACTIVE IS SYNTHETIC BONE

<table>
<thead>
<tr>
<th>Human Bone</th>
<th>nanOss Bioactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contains Hydroxyapatite and Collagen</td>
<td>✔</td>
</tr>
<tr>
<td>Bone Composition: 60% hydroxyapatite 32% collagen 8% water</td>
<td></td>
</tr>
<tr>
<td>Contains interconnected porosity</td>
<td>✔</td>
</tr>
<tr>
<td>Equivalent crystal size and structure</td>
<td>25-500 nm</td>
</tr>
<tr>
<td>Optimal size for tissue interaction</td>
<td></td>
</tr>
<tr>
<td>High surface area</td>
<td>100 m²/g</td>
</tr>
</tbody>
</table>
CLINICAL APPLICATION

11 weeks post surgery x-ray of tibial plateau fracture repaired with nanOss Bioactive.

1-year CT image of patient treated with nanOss Bioactive combined with bone marrow aspirate and local bone graft across the transverse process.

NANOSS BIOACTIVE SPINAL FUSION STUDY

- L5-L6 Posterolateral Fusion in rabbit
- 12 Week Duration
- 3 Treatment Groups
  › nanOss Bioactive + Bone Marrow Aspirate + Autograft
  › Competitive Product + Bone Marrow Aspirate + Autograft
  › Bone Marrow Aspirate + Autograft

- RESULTS - nanOss Bioactive mixed with bone marrow aspirate and Autograft had:
  › Excellent handling properties
  › 2.5 times more new bone formation than Competitive Product
  › Statistically stronger fusions (peak load and stiffness) than the Competitive Product
  › Excellent histology results

*nanOss Bioactive resulted in a significantly higher peak load compared to the Competitive Product, (p<0.05), but was not different than Autograft. There was no significant difference between the Competitive Product and Autograft.
## SYSTEM OVERVIEW

### nanOss Bioactive

<table>
<thead>
<tr>
<th>Unit Size</th>
<th>Product</th>
<th>Catalog #</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1cc</td>
<td>nanOss Bioactive</td>
<td>90-100-01</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>2cc</td>
<td>nanOss Bioactive</td>
<td>90-100-02</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>5cc</td>
<td>nanOss Bioactive</td>
<td>90-100-05</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>10cc</td>
<td>nanOss Bioactive</td>
<td>90-100-10</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>20cc</td>
<td>nanOss Bioactive</td>
<td>90-100-20</td>
<td>Room Temperature</td>
</tr>
</tbody>
</table>

### nanOss Bioactive Loaded

<table>
<thead>
<tr>
<th>Unit Size</th>
<th>Product</th>
<th>Catalog #</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>10cc</td>
<td>nanOss Bioactive Loaded</td>
<td>90-200-10</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>10cc</td>
<td>nanOss Bioactive Loaded Kit (10cc unit, bone graft delivery syringe &amp; adapter)</td>
<td>90-200-1002</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>Each</td>
<td>nanOss Bioactive Loaded Accessory Kit (bone graft delivery syringe &amp; adapter)</td>
<td>90-900-02</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>Each</td>
<td>Bone graft delivery syringe</td>
<td>53-syringe-1</td>
<td>Room Temperature</td>
</tr>
<tr>
<td>10 pack</td>
<td>Bone graft delivery syringe</td>
<td>53-syringe</td>
<td>Room Temperature</td>
</tr>
</tbody>
</table>
**INDICATIONS**

nanOss Bioactive and nanOss Bioactive Loaded are both indicated for bony voids or gaps that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. These products are indicated to be used in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone. nanOss Bioactive and nanOss Bioactive Loaded are also indicated to be gently packed into the bony voids or gaps in the skeletal system (extremities, pelvis) in conjunction with autogenous blood and sterile saline. These products provide a bone void filler that resorbs and is replaced with bone during the healing process.

**CONTRAINDICATIONS**

Use of nanOss Bioactive or nanOss Bioactive Loaded is contraindicated in the presence of one or more of the following clinical situations:

- fractures of the epiphyseal plate.
- metabolic or systemic bone disorders that affect bone or wound healing.
- fractures for which stabilization of the fracture is not possible.
- significant vascular impairment proximal to the graft site.
- infected or contaminated wounds, or fractures for which intraoperative soft tissue coverage is not planned or possible.
- acute and chronic infections in the surgical area (soft tissue infections; inflammatory, bacterial bone disorders, osteomyelitis).
- impaired calcium metabolism.
- treatment with steroids and other drugs affecting calcium metabolism.
- immunosuppressant therapy.
- use in the area of the open epiphyseal growth plate.
- patients allergic to porcine collagen products.

**WARNINGS**

nanOss Bioactive and nanOss Bioactive Loaded do not possess sufficient mechanical strength to support the reduction of a fracture site prior to soft and hard tissue in-growth or to support a load. Standard internal fixation techniques such as the use of plates and/or screws must be followed to obtain rigid stabilization. External stabilization alone is not sufficient to achieve the rigidity necessary for bony in-growth of nanOss Bioactive. nanOss Bioactive and nanOss Bioactive Loaded material must not be used to gain screw purchase or to stabilize screw placement. All screws used in conjunction with this product and fixation devices must attain rigid fixation into the host bone. nanOss Bioactive must not be used to repair metaphyseal defects.

Complete postoperative wound closure is essential. nanOss Bioactive Loaded must not be used to repair metaphyseal defects where complete soft tissue coverage cannot be achieved.

- nanOss Bioactive Loaded must not be used to gain screw purchase or to stabilize screw placement. All screws used in conjunction with this product and fixation devices must attain rigid fixation into the host bone.
- never introduce nanOss Bioactive Loaded into closed cavities under pressure, as this may lead to fat embolization or embolization of device into blood stream; and avoid application of nanOss Bioactive Loaded beyond intended treatment site, as this may damage surrounding tissues. Avoid application of nanOss Bioactive Loaded beyond intended treatment site as this may damage surrounding tissue.

Clinical human data using nanOss Bioactive is limited.
**PRECAUTIONS**

nanOss Bioactive and nanOss Bioactive Loaded are intended for use only by surgeons familiar with bone grafting and rigid fixation techniques.

nanOss Bioactive and nanOss Bioactive Loaded granules are radiopaque and the radiopacity may mask underlying pathological conditions.

nanOss Bioactive and nanOss Bioactive Loaded are intended for single use only.

- do not apply nanOss Bioactive or nanOss Bioactive Loaded dry to the defect.
- do not re-sterilize nanOss Bioactive or nanOss Bioactive Loaded.
- discard any un-used nanOss Bioactive or nanOss Bioactive Loaded.
- nanOss Bioactive and nanOss Bioactive Loaded have no weight bearing function. Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.
- always follow recommended mixing instructions when rehydrating nanOss Bioactive.
- postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

**REFERENCES:**


*See product insert for complete labeling limitations related to this device.*