**Ionic® Spine Spacer System**

**DESCRIPTION**
The Ionic Spine Spacer System is a single component device with a solid center core that provides structural integrity and slotted platforms that allows for bone growth around the center core. The superior and inferior platforms are flared outward to allow greater surface contact. The platforms are also designed with fins, which grip into the endplates of the vertebral body to reduce implant migration.

The Ionic Spine Spacer device is available in height sizes from 9mm-56mm lordotic angles of 0° and 8°.

The Ionic Spine Spacer device is made from titanium alloy (Ti-6A1-4V ELI), conforming to ASTM Standard F136. Instruments designed for implantation of the device are made from stainless steel, conforming to ASTM Standard F899.

**INDICATIONS**
The Ionic Spine Spacer System is intended for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Ionic Spine Spacer System is also indicated for treating fractures of the thoracic and lumbar spine. The Ionic Spine Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged time. The system must be used in conjunction with the Biomet® Omega21™ Spinal System or the SpineLink® System.

**CONTRAINDICATIONS**
Ionic Spine Spacer devices should not be implanted in patients with an active infection at the operative site.

**PRECAUTIONS**
1. Ionic Spine Spacer device is to be implanted using an open anterior or anterior-lateral approach.
2. The surgeon should only implant the Ionic Spine Spacer device after adequate training and familiarity with the information provided in the Surgical Technique Manual.
3. **Single Use Only.** Never reimplant an explanted metal device, under any circumstances. Although the device appears to be undamaged, it may have small defects and internal stress patterns.

**STERILIZATION**
The Ionic Spine Spacer implant is provided nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

<table>
<thead>
<tr>
<th>Cycle:</th>
<th>High Vacuum</th>
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</thead>
<tbody>
<tr>
<td>Temperature:</td>
<td>270°F/132°C</td>
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<tr>
<td>Time:</td>
<td>8 minutes</td>
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<tr>
<td>Note:</td>
<td>Allow for Cooling</td>
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</tbody>
</table>

Individuals not using the recommended method temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

**ADVERSE EVENTS**
The potential risks associated with the use of the Ionic Spine Spacer device are similar to those reported for “implantable spinal fusion devices” and include the following:

1. Nonunion (pseudoarthrosis) or delayed union
2. Bending, fracture, loosening or migration of the implant
3. Metal sensitivity of foreign body reaction
4. Decrease in bone density due to stress shielding
5. Pain, discomfort, or abnormal sensations due to presence of the implant
6. Nerve, soft tissue, or blood vessel damage due to surgical trauma
7. Fracture of bony structures
8. Nerve root or spinal cord impingement
9. Dural leak
10. Bursitis
11. Necrosis of bone
12. Hemorrhage
13. Infection
14. Death

CAUTION
Federal Law (USA) restricts this device to sale by or on the order of a physician.

INFORMATION
For further information, please contact Customer Service Department at:
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U.S. Patent No. 6,296,665

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