The First New Lumbar Total Disc Replacement
FDA Approved in 10 Years

Indications for Use
The activL® Artificial Disc is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL® Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL® Artificial Disc should have failed at least six months of nonoperative treatment prior to implantation of the device.

Contraindications, Warnings and Precautions
The activL® Artificial Disc should not be implanted in patients with the following conditions:
- Active systemic infection or localized infection near the surgical site.
- Osteoporosis or osteopenia defined as dual-energy X-ray absorptiometry (DEXA) bone mineral density T-score less than or equal to -1.0
- Allergy or sensitivity to the implant materials (cobalt, chromium, polyethylene, titanium, tantalum, or calcium phosphate)
- Isolated radiculopathy, especially due to herniated disc
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year)
- Extruded disc material with sequestrum (i.e., free disc fragment)
- Myelopathy
- Spinal stenosis
- Spinal deformity such as scoliosis
- Spondylolysis/isthmic spondylolisthesis, degenerative spondylolisthesis > Grade I, or segmental instability
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., current or prior vertebral fracture) or disease (e.g., ankylosing spondylitis)
- Facet ankylosis or facet joint degeneration
- Preoperative remaining disc height < 3 mm
- Symptoms attributed to more than one vertebral level
- Abdominal pathology that would preclude an anterior retroperitoneal approach
- Involved vertebral endplates dimensionally smaller than 31 mm in the medial-lateral and/or 26 mm in the anterior-posterior directions

For a complete list of Warnings, Precautions and Risks please visit www.aesculapimplantsystems.com

Features
- Intelligent Motion Technology™ combines natural motion with mechanical stability allowing clinically-stable translational and rotational movement
- Single-step insertion may save up to 10 minutes per procedure*

Bone-Sparing Spike Endplates
- Coated with Plasmapore® μ-CaP, a microporous titanium coating and a thin bioactive calcium phosphate surface finish
- Endplate designs specific for anatomical variations between L4/L5 and L5/S1

Constructs available in total heights of 8.5, 10, 12 and 14 mm
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- Coated with Plasmapore® μ-CaP, a microporous titanium coating and a thin bioactive calcium phosphate surface finish for stability that starts at the surface
- Widest range of endplate configurations and construct heights to meet diverse anatomical needs

In the activL® IDE Trial, an 8.5 mm total construct height was chosen in 87% of cases as the best fit for the subjects' anatomy.

-Dr. Rolando Garcia
activL IDE Study Primary Investigator

Inferior endplate
Superior endplate
PE inlay
Ultra-high molecular weight polyethylene core

Ordering Information
The implants are delivered sterile packed.

ST0565 – activL Implant Bank/ST0566 – activL Instruments

<table>
<thead>
<tr>
<th>PE Inlay</th>
<th>Height (mm)</th>
<th>8.5</th>
<th>10</th>
<th>12</th>
<th>14</th>
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</thead>
<tbody>
<tr>
<td>PE inlay</td>
<td>SW965</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>SW966</td>
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</table>

The height shown corresponds to the height of the implant measured at the posterior end.

activL Spike Endplates

<table>
<thead>
<tr>
<th>Superior Plate</th>
<th>Angle</th>
<th>S (26x31)</th>
<th>M (28x34.5)</th>
<th>L (30x39)</th>
<th>XL (33x40)</th>
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</thead>
<tbody>
<tr>
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<td>SW981K</td>
<td>SW991K</td>
<td>SW891K</td>
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<tr>
<td>11°</td>
<td>SW972K</td>
<td>SW982K</td>
<td>SW992K</td>
<td>SW892K</td>
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<th>Inferior Plate</th>
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<th>XL (33x40)</th>
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<tbody>
<tr>
<td>0°</td>
<td>SW970K</td>
<td>SW980K</td>
<td>SW990K</td>
<td>SW890K</td>
<td></td>
</tr>
</tbody>
</table>

S1 Inferior Plate | 5° | SW976K | SW986K | SW996K | SW888K |

Four footprints, each available in total construct lordotic configurations of 6°, 11° and 16°

- S 26 mm x 31 mm, allows 1.5 mm translation
- M 28 mm x 34.5 mm, allows 2.0 mm translation
- L 30 mm x 39 mm, allows 2.0 mm translation
- XL 33 mm x 40 mm, allows 2.0 mm translation

*In the activL IDE Trial, activL patients showed on average a 10 minute improvement in operative time compared to the study's control.

Each surgeon must evaluate the appropriateness of the implant height for each patient.