

**Aesculap Announces Landmark Publication in *Spine* on the Disc-to-Disc activL® Artificial Disc Multi-Center, Randomized, Control Trial for 1-Level Lumbar Total Disc Replacement**

*Trial Finds activL Artificial Disc to be Highly Effective in the Treatment of Discogenic Low Back Pain*

**Center Valley, PA (January 11, 2016)** – Aesculap Implant Systems, LLC announced today that *Spine*, a peer-reviewed publication, has published the 24-month primary endpoint outcomes of the activL Artificial Disc in comparison to predicate lumbar total disc replacement designs.

The paper, Garcia, R. Jr., et al: “Lumbar Total Disc Replacement for Discogenic Low Back Pain: Two-year Outcomes of the activL Multicenter Randomized Controlled IDE Clinical Trial,” *Spine*, was published on December 15, 2015. The study, authored by many of the principal investigators from the activL Artificial Disc IDE Trial, was a non-inferiority trial comparing the activL device to predicate motion preservation devices. The objective of the trial was to determine if activL Artificial Disc was safe and effective for the treatment of degenerative disc disease.

Previous generation total disc replacement systems have typically been studied against fusion controls. This is the first FDA-approved disc with head-to-head evidence from an IDE study. Surgeons in the study were able to implant either ProDisc-L or Charité as the Control device based on technique preference. The previous lumbar total disc replacement IDE trials against fusion have shown favorable outcomes.

The trial found the activL Artificial Disc to be non-inferior to the Control devices in the primary composite endpoint ( $p < 0.001$ ). Also, in a protocol-defined analysis activL Artificial Disc was found superior ( $p = 0.02$ ) due largely in part of the range of motion component of the primary composite endpoint.

“It is exciting to have a high-impact journal like *Spine* recognize the significance of data like this and make it the lead article,” said Glenn Buttermann, MD, (Midwest Spine and Brain Institute, Stillwater, MN), an investigator on the activL Artificial Disc IDE trial and co-author of the publication. “Evidence like this is important to help motion preservation surgeons like myself defend our position with payers and increase our qualified patients’ access to motion preservation surgery.”

This publication is the first of the outcomes expected from the anticipated activL Artificial Disc IDE Trial, which will continue to seven-year follow-up.

**activL Artificial Disc**

activL Artificial Disc features cobalt chromium endplates which affix to the patient’s vertebrae with bone-sparing spikes for initial stabilization. This is the first lumbar artificial disc with a mobile ultra high molecular weight polyethylene core that supports both controlled translational and rotational movement similar to the movement of the healthy lumbar spine.



On June 11, 2015, Aesculap received a letter of approval from the U.S. Food and Drug Administration (FDA) allowing the commercial sale and distribution of the activL® Artificial Disc for the treatment of lumbar degenerative disc disease at one level in the United States.

The Aesculap Implant Systems 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 with no more than Grade I spondylolisthesis at the involved level.

For more information about Aesculap Implant Systems visit: [aesculapimplantsystems.com](http://aesculapimplantsystems.com)

#### **About Aesculap Implant Systems, LLC**

Aesculap Implant Systems, LLC, part of the B. Braun group of companies, is part of a 175-year-old global organization focused on meeting the needs of the changing healthcare environment. Through close collaboration with its customers, Aesculap Implant Systems develops advanced spine and orthopaedic implant technologies to treat complex disorders of the spine, hip and knee. Aesculap Implant Systems strives to deliver products and services that improve the quality of patients' lives. For more information, call 800-234-9179 or visit [aesculapimplantsystems.com](http://aesculapimplantsystems.com).

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