

## **FOR IMMEDIATE RELEASE**

### **SIMPLIFY MEDICAL COMPLETES ENROLLMENT IN IDE TRIAL STUDYING SIMPLIFY DISC IN ONE LEVEL OF SPINE FOR CERVICAL DISC REPLACEMENT**

**SUNNYVALE, Calif. – February 14, 2018** – [Simplify Medical Pty Ltd](#), maker of the [Simplify® cervical artificial disc](#), today announced completion of enrollment in its U.S. IDE trial studying the Simplify Disc used for one-level cervical implantation of the device between C3 to C7 compared with a historical control group. The trial enrolled 166 patients at 16 U.S. sites.

“We want to thank the surgeon investigators, their staffs and the patients participating in the Simplify trial for their time and tremendous support,” said David Hovda, chief executive officer of Simplify Medical. “Recognizing that most of the devices used in disc replacement today require patients to be exposed to substantial ionizing radiation from CT scans post-operatively, it’s important for patients and physicians to have an alternative that minimizes that risk.”

The trial’s national co-primary investigator Domagoj Coric, MD, with Carolina Neurosurgery and Spine Associates said, “The Simplify Disc is straightforward to implant, with materials designed to optimize biocompatibility and lower disc heights to better match cervical anatomy. We are pleased with the positive early clinical outcomes and look forward to seeing the longer-term study results, anticipating that they will validate the promise seen to date.”

Richard Guyer, MD, chairman of the Texas Back Institute Foundation and national co-primary investigator for the study said, “The Simplify Disc is made of materials designed to optimize MRI imaging of the disc space and adjacent spinal canal without artifact. This can minimize or eliminate the use of post-operative CT scans and their risk of radiation to patients, and we look forward to having this capability as an option for treating our patients with cervical disc disease.”

While magnetic resonance imaging (MRI) is widely used pre-operatively for surgical planning, spine surgeons often switch to CT scans post-operatively in order to accommodate metal components, which can make it difficult to view the devices, as well as the facets and adjacent disc levels. However, CT scans have been shown to expose patients to ionizing radiation that equates to 400 to 550 chest X-rays per scan.

Composed of primarily non-metal materials (PEEK-on-ceramic), the Simplify Disc is designed to be viewed on MRI in order to minimize patient exposure to radiation. With no metal in its articulating components, the disc is also designed for low levels of wear to optimize long-term durability. Implantation of the Simplify Disc is accomplished in a straightforward, three-step procedure. The Simplify Disc is also anatomically designed with low height implant options to

accommodate patients with smaller cervical disc spaces, making it ideal for women and certain regional populations. The device is considered MRI-conditional, posing no known hazard in an MRI environment within prescribed conditions of use.

The Simplify Disc used in two levels of the spine is being studied in a second IDE trial in the U.S., which is approximately 40 percent enrolled and enrollment is expected to be completed by the end of 2018. The prospective pivotal trial will encompass up to 200 patients at up to 18 centers, comparing cervical implantation of the device in two contiguous discs from C3 to C7 with two-level cervical fusion surgery. For information about eligibility or enrollment in the two-level clinical trial, please visit <http://www.simplifytrial.com/>.

The Simplify Disc has received the CE Mark and is commercially available in select European markets. Early clinical data has shown substantial improvement in patient pain scores and functional improvement after treatment.

#### **ABOUT SIMPLIFY MEDICAL**

Simplify Medical is focused on cervical spinal disc arthroplasty, using innovative, MRI-friendly materials designed to decrease the need for ionizing radiation and enhance patient options. Simplify Medical is located in Sunnyvale, California. To learn more, visit <http://www.simplifymedical.com/>.

*Caution: The Simplify Disc is an investigational device in the United States and is limited by law to investigational use.*

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