# Press Release

## FOR IMMEDIATE RELEASE

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## SAGICO Announces Market Release of Expandable Stand-Alone Cervical Technology

**Tampa, FL, USA, April 11, 2018:** Previously, the US FDA issued to SAGICO a 510(k) clearance for the SAGICO IBF (Inter-Body Fusion) System. Contained within the 510(k) was the clearance for the cervical appliance branded as the "ARION". Per the Indications for Use, "…the Arion Cervical implant is an interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from (C-2-T-1)." The Indications for Use also states that the Arion Cervical is to be filled with autogenous bone graft material, must be placed via an open anterior approach, and must be used with additional "internal" fixation.

The Arion Cervical is an expandable PEEK-Optima constructed cage with self-contained internal fixation. Once the blades are deployed, the Arion Cervical offers three points of fixation known as Tri-Fix™, the triple fixation cervical technology. The advanced clinical outcomes of the Arion Cervical are also attributed to the industry leading large grafting window, allowing for superior fusion and limited migration rates. During a presentation at a recent spine conference, James Gibson, President of SAGICO, stated, "The Arion Cervical by SAGICO, when clinically achievable, has a proven track record of success across thousands of implantations in multiple countries. It has been adopted globally as a stand-alone implant because of the unique Tri-Fix™ triple fixation cervical technology".

The initial 510(k) application that was submitted to the FDA by SAGICO was done so under the auspicious of a "bundled" submission. Per the US FDA Guidance for Industry and Food and Drug Administration Staff, "bundling" refers to the inclusion of multiple devices or multiple indications for use for a device in a single premarket submission, including products subject to the device and biologics license application (BLA) authorities. Multiple devices may include different models within a generic type of device[1] or devices that are of differing generic types, such as the Arion Cervical.

The US FDA has accepted submissions in which multiple indications for use were bundled when the indications presented issues that could be addressed during one review. Applicants like SAGICO are not required to bundle multiple devices or indications but may choose to do so when appropriate. As with any device requirement in a bundled submission, the Arion Cervical satisfied all the applicable statutory and regulatory premarket requirements associated with the product clearance.

The Arion Cervical was cleared by the FDA under the Product Code "OVE". The OVE Product Code is highly coveted because of its unique features as defined by the FDA. First, the OVE Product Code is unique to cervical appliances that offer "Intervertebral Fusion Devices With Integrated Fixation". The Arion Cervical achieves such benefit with its proprietary Tri-Fix™, triple fixation cervical technology.

Additionally, OVE products are intended to stabilize cervical spinal segments to promote fusion in order to restrict motion and decrease pain using bone graft with or without supplemental fixation. Because of the unique product code afforded this category, the FDA has clearly defined the "Technical Method" for these OVE products and it is stated that the cervical appliance "Acts as a disc spacer and holds bone graft; also includes some form of integrated fixation to maintain stability by direct purchase into the bony vertebral endplates." The Arion Cervical when fully expanded deploys into the endplates and offers integrated fixation in compliance with the OVE Product Code.

***MORE ABOUT SAGICO:*** Spinal Analytics & Geometrical Implant Co, (SAGICO) and its principals have many years of spinal industry success spanning multiple continents in more than 60 countries. SAGICO and its affiliates are privately held companies with global partners and shareholders and an aggressive pipeline that includes: novel artificial disk implants (TDR), Porous Titanium interbody technology, Expandable VBR options and unique Pedicle Screw Systems optimized for Complex & Pediatric surgery are just a few of the product lines SAGICO offers. SAGICO's USA corporate based operations are located in Tampa, Florida.

***DISCLOSURE*:** We at SAGICO are confident in our products and so should our professional surgeons. A surgeon must always rely on his or her own clinical judgment when deciding whether to use a particular medical appliance that may be applicable for a specific patient and adhere to the package insert, product label and/or instructions for use before using any SAGICO product. SAGICO does not diagnose nor does SAGICO offer medical advice on medical conditions and SAGICO requires that all surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the depth and future of all of SAGICO's product lines. Some products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact SAGICO prior to any medical procedures to learn more.

## Learn more @: www.SAGICO.co

To schedule an interview please contact SAGICO in the USA: Telephone: 813-830-3636

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