Press Release

FOR IMMEDIATE RELEASE

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SAGICO Announces 510(k) Pedicle Screw Clearance for its OSI Spinal System

Tampa, FL, USA, June 5, 2018: The USA FDA has issued SAGICO another 510(k) for its pedicle screw system, branded and marketed as the OSI Spinal System. The technology in the OSI Spinal System include constructs of monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking cap set screws, rods, hooks, monoaxial and multiaxial transverse connectors, and associated surgical instruments. The OSI Spinal System implants are available in a variety of sizes to accommodate individual patient anatomy and pathology conditions. SAGICO's OSI Spinal System implants are designed to adapt 5.5mm diameter rods; the implants are manufactured from Ti6A14V alloy and offered in a sterile package option.

Among the surgical usages for the OSI Spinal System, they are intended for use in the non-cervical spine. When used for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the SAGICO OSI Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Spinal stenosis;
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis);
- Pseudoarthrosis; and
- Failed previous fusion

SAGICO's OSI Spinal System were cleared to market by the FDA under a variety of Product Codes to include; Thoracolumbosacral Pedicle Screw System (NKB), Appliance, Fixation, Spinal Intervertebral Body (KWQ) and Appliance, Fixation, Spinal Interlaminal (KWP)

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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