The coflex-F™ is a spinous process fixation device that establishes the spinous process spinus to spinus contact necessary for the stabilization of the lumbar spine. The device is manufactured from wrought titanium alloy (Ti-6Al-4V). A set of two wings extend from the implant to attach to the proximal and distal spinous processes. The attachment to the spinous processes is through a unique design that allows the implant to self-tighten in any orientation. Due to its design, the device should never be re-implanted under any circumstances.

The fundamental suitability of the implants for any condition is decided by the manufacturer and/or by an independent accredited testing laboratory by application of the relevant ISO 5832 series of standards (ISO 5832-1 to ISO 5832-12). The manufacturer's declaration of compliance with the applicable ISO 5832™ series of standards shall be available to the user from the manufacturer or any authorized representative if further information on this product is needed.

For further information please refer to Paradigm Spine LLC – an authorized representative if further information on this product is needed.

INSTRUCTIONS FOR USE

The operating surgeon should review the operation protocol with the implant component(s) before their sterilization and implementation as per the package labeling instructions from his/her surgeon is very important. The operating surgeon must have a thorough understanding of the following information must be available at the workplace.

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