

WOVEN ORTHOPEDICS SECURES SECOND FDA SPINE CLEARANCE – OGMEND® NOW AVAILABLE FOR MOST PEDICLE SCREW DIAMETERS

MANCHESTER, Conn, February 28, 2024 -- Woven Orthopedic Technologies, developer of Ogmend®, a simple implantable sleeve that quickly and easily secures stable screw fixation, has received its second 510(k) clearance from the Food and Drug Administration (FDA) for the use of Ogmend® Implant Enhancement System in spine surgery.

“We are excited about this latest clearance of our Large-size Ogmend® because it provides surgeons with access to Ogmend® for a broader range of pedicle screw sizes, especially important for larger diameter screws used at the bottom of constructs, including the sacrum,” said Brandon Bendes, CEO of Woven.

Prominent industry groups and publications, including AO, the Journal of Neurosurgery, and the International Spine Study Group, have reported the complexities encountered in spinal surgeries, particularly in the lower lumbar and sacral segments. These areas are commonly stabilized with larger diameter screws given their larger bone structure and the greater forces endured. The resulting stresses placed on these screws can create challenges for surgeons that call for the use of special techniques and tools.

“The large Ogmend® provides surgeons with a unique and simple tool for a number of situations where larger size screws are more common, such as longer construct corrections, complex thoracolumbar revisions, and complex spinal deformities,” says Woven’s Commercial Director, Justin Loosvelt.

The Ogmend® LARGE joins the currently available Ogmend® MEDIUM to provide surgeons with a simple, off-the-shelf solution that ensures they are always prepared to quickly & easily secure stable fixation with screws ranging from 3.5mm – 10.5mm in diameter.

The Ogmend® Implant Enhancement System is the first interface enhancement device that efficiently secures the entire screw/bone interface and provides multidimensional fixation enhancement by counteracting peak focal stress, facilitating bone growth, and increasing resistance to foundational failure.

Both sizes of Ogmend® are now available in the United States and Europe.

For further details regarding Ogmend® or to inquire about obtaining it for your institution, please visit www.wovenorthopedics.com or reach out to us via email at sales@wovenorthopedics.com.

About Woven Orthopedic Technologies

Woven Orthopedic Technologies is a commercial stage medical device company focused on making neuromusculoskeletal treatments easier, better, and more affordable for surgeons and global health systems. The company is based in Manchester, Connecticut, USA.

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