



Innovasis Announces Successful FDA Clearance for the 'PEEK Box' VBR System

SALT LAKE CITY, Jan. 5 /PRNewswire/ -- Utah-based Innovasis, a research, development and manufacturer of spinal implant devices, has received 510(k) clearance of its "PEEK Box" System as a Vertebral Body Replacement (VBR) by the United States Food and Drug Administration after previously been cleared as a Cement Restrictor.

The "PEEK Box" System will be used as a Vertebral Body Replacement within the spine. The Innovasis "PEEK Box" System is manufactured from PolyEtherEtherKetone (PEEK) with Tantalum markers. PolyEtherEtherKetone (PEEK) is a material with an elasticity module (GPA) that is the closest to Cancellous Bone compared to Cortical Bone, Titanium or Stainless Steel implants.

Features and benefits of the "PEEK Box" system include: Variety of different shapes, proud angled tooth design on superior and inferior surfaces to resist migration, Bullet-shaped tip to assist in distraction, and parallel and lordotic-shaped with large central windows for placement of bone graft.

"This is good news for our company as we strive to be a recognized leader in the global spinal business by building intense customer loyalty and improving our products," said Martin Crous, Ph.D., Vice President of Sales and Marketing of Innovasis.

Other products already cleared by the FDA for Innovasis include the Le Forte Cranial Plating System, the Excella-M Pedical Screw System and the Optyryx Cervical Plate System.

Innovasis offers spinal product implants and instruments that address major pathologies and focus areas of traditional spinal surgery, including deformities, degenerative conditions; trauma and tumors, all of which can result in severe back pain and sometimes paralysis. Spinal implants are aimed at restoring mechanical and neurological function by readjusting vertebral positioning until bone fusion occurs. Founded in 2002, Innovasis is committed to providing surgeons with training, support and excellent customer service.

For information on Innovasis contact Martin Crous, Ph.D., at 801-261-2242 or mcrous@innovasis.com or visit the website at www.innovasis.com.