DePuy Receives Approval For Corrective Spinal Systems

DePuy Synthes Spine announced it has received 510(k) clearance from the U.S. Food and Drug Administration for use of its EXPEDIUM, VIPER, and VIPER2 Spine Systems on patients with adolescent idiopathic scoliosis, an abnormal curvature of the spine that typically affects children between the ages of 10 and 18. This expands the scoliosis indication for the pedicle screw systems, which now are indicated for both adolescents and adults.

The EXPEDIUM technology was first introduced in 2004. The VIPER and VIPER2 Spine Systems have been used in minimally invasive spine surgery for a wide range of pathologies since 2005 and 2008, respectively. The new indication, which was received last month, clears the way for the devices to be used in posterior non-cervical pedicle screw fixation in adolescent patients and for the company to provide training and education about its appropriate use.

Scoliosis can lead to chronic back pain, reduced respiratory function and impact quality of life by limiting activity. If the curvature of the spine is between 25 to 45 degrees, back bracing is generally recommended in an attempt to stop curve progression. If the curve progresses beyond 45 degrees, spinal fusion surgery is considered to strengthen and straighten the spine. Most patients do not progress to a degree needing surgical intervention.

According to the National Scoliosis Foundation, scoliosis patients make more than 600,000 visits to private physician offices, 38,000 children undergo spinal fusion surgeries and about 30,000 children are braced each year in the United States.