

A Rising Tide Lifts All Boats: Interbody Fusion and Instrumentation

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“A rising tide lifts all boats.” The tide is made up of over 30 million physician visits for back-related symptoms each year, and over a million spine-related surgical procedures performed annually. We estimated this translated into \$7.1 billion in spine-related revenues for medical device companies in 2007. The 800-pound gorillas are still instrumentation and interbody fusion devices. What’s driving this market? Later in this article, we’ll see what surgeons said in San Francisco at AAOS 2008. Also, it’s time to consult the PearlDiver database on posterior instrumented interbody fusions.

4th Quarter 2007 Earnings: It’s Still Spacers and Implants

While new technologies are on the horizon in spine, one takeaway from the 4Q is that while emerging technologies may displace traditional revenue drivers related to spine surgery, non-bone interbody fusion devices, cages, and instrumentation are still behind a significant portion of spine revenues. But don’t take our word for it...take it right from the conference calls.

- Speaking during Zimmer’s 4Q conference call, CFO Jim Crines said the 17.8% year-over-year advance in spine revenues “was lifted by sales of thoracolumbar outerbody fusion products, *interbody spacers*, and Dynesys.”
- Speaking on Stryker’s 4Q conference call, CFO Dean Bergy said of the company’s fifth straight quarter of spine growth north of 20%, “*Interbody spacers* led our U.S. spine growth, but growth was also extremely strong in the thoracolumbar and cervical categories.”

Overall, interbody spacers and fusion-related instrumentation drove growth in the quarter.

Interbody Fusion: Titanium to PEEK

Improved instrumentation, MIS (minimally invasive surgery) technology, innovative anatomical approaches, high fusion rates, and good clinical outcomes all drive interbody fusion volumes. Increasing revenues for companies marketing interbody fusion devices follow suit. Interbody fusion should remain a sweet spot in the spine market. Classic interbody devices include cylindrical threaded titanium cages such as the Zimmer BAK® cage and Stryker Spine’s Ray Threaded Fusion Cage™. There is also, of course, Medtronic’s LT Cage® approved for use with INFUSE®, which is available in both PEEK and titanium.

Overall usage of titanium and bone interbody fusion devices has declined. PEEK (polyetheretherketone) devices are on the move. Higher price points with respect to PEEK devices have shifted the revenue mix in the spacer market. The advantage of PEEK is that it is radiolucent, which allows the surgeon to better examine the progression of bone growth after a spine fusion is performed.

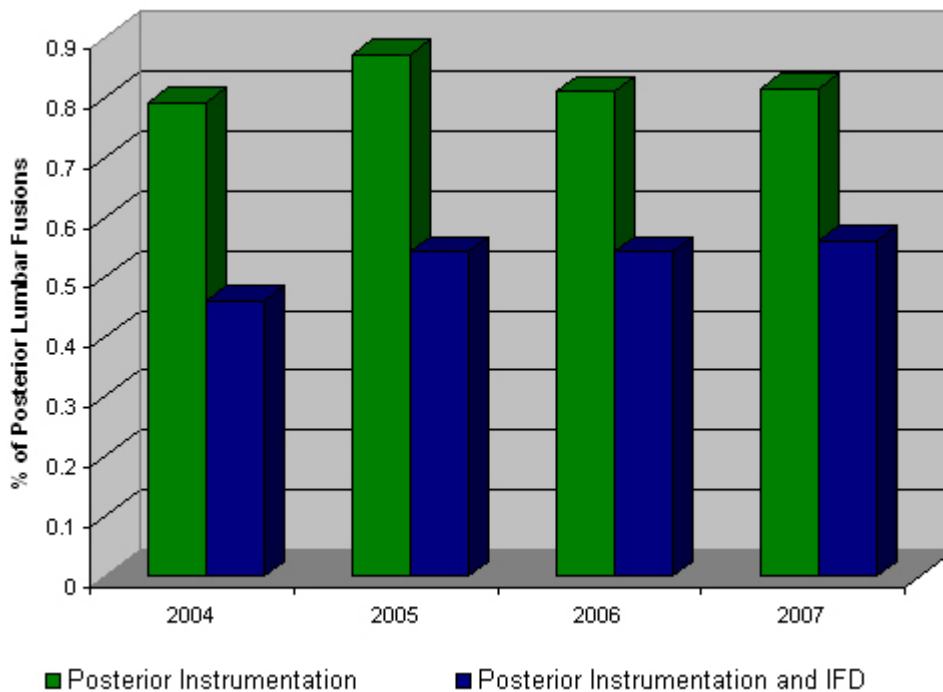
PearlDiver Data

To determine trends in the use of posterior instrumentation and interbody fusion devices, we consulted the PearlDiver Patient Records Database. By analyzing the CPT codes used for reimbursement, we can broadly track the usage of these devices in applicable surgeries. By using ICD-9 procedure codes in combination with CPT codes related to spine procedures, we can analyze trends in the usage of posterior instrumentation and interbody fusion devices in spine fusion.

Chart 1 below displays the use of posterior instrumentation and interbody fusion devices in lumbar spine fusions employing a posterior approach. As can be seen, posterior instrumentation is employed in 80% of posterior lumbar fusions. Beginning in 2005, the data show that over 50% of the time, an interbody fusion device was implanted in addition to the instrumentation. This is a trend that has grown from 2004-2007, according to PearlDiver data.

As one would expect, with this trend revenues have grown. In fact, fusion adjuncts and interbody devices make up close to 60% of spine industry revenues, which amounts to over \$3 billion! The pedicle screws and rods for a one-level fusion can cost from \$4,000 – \$6,000, while for a two-level construct their cost can range from \$8,000 – \$10,000.

Chart 1: Use of Posterior Instrumentation and Interbody Fusion Devices in Posterior Lumbar Fusion

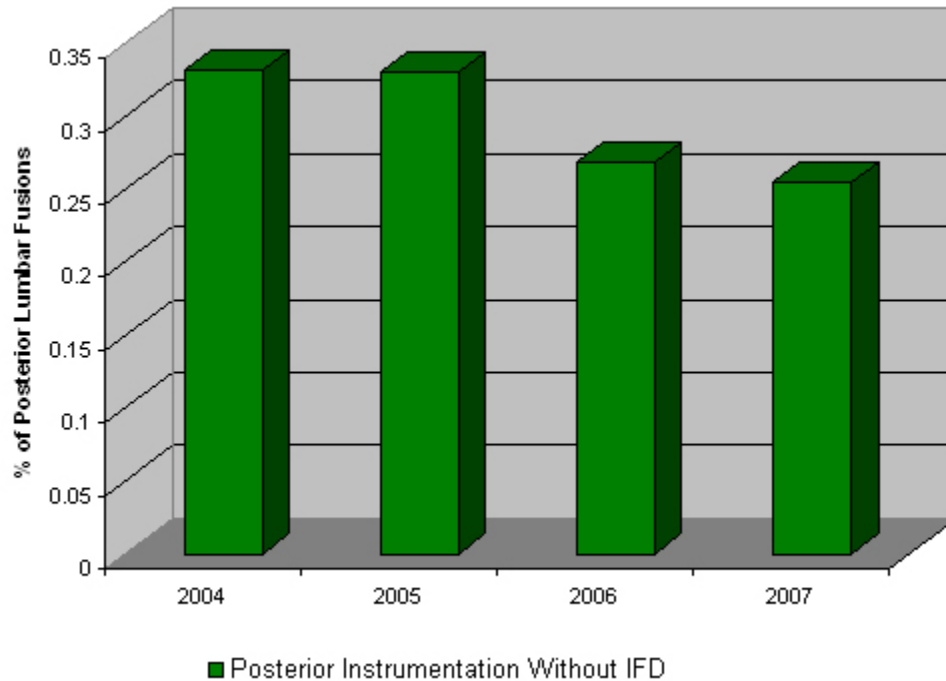


Source: PearlDiver Patient Records Database 2004-June 2007

Chart 2 below illustrates usage of posterior instrumentation without an accompanying interbody spacer. According to PearlDiver data, less than 25% of posterior lumbar fusions as defined by ICD-9 code 81.08 had posterior instrumentation implanted without an interbody fusion device. The increased use of spacers and instrumentation could bode well for medical device companies. Spacers

can cost between \$2,000 and \$5,000, depending, in part, upon height and material.

Chart 2: Use of Posterior Instrumentation Without an Interbody Fusion Device



Source: PearlDiver Patient Records Database 2004-June 2007

Revenue Drivers

Based on an analysis of PearlDiver data, several macro trends can be observed, each of which contributes to the increasing revenues seen in these sectors.

1. While there is no doubt fierce competition in the industry, which could cause pricing pressures on implants, the increased usage of implants in spine fusion may offset pricing pressure on a volume basis.
2. Posterior instrumentation and interbody fusion devices are increasingly being used together.
3. The use of posterior instrumentation alone in fusion has declined, according to PearlDiver data.
4. Fusion volumes are a clear driver of revenue; more specifically, interbody fusion volumes.
5. Spacers used in proprietary surgeries such as NuVasive's XLIF® (Extreme Lateral Interbody Fusion) and Medtronic's DLIF (Direct Lumbar Interbody Fusion) should become revenue drivers as these approaches gain surgeon acceptance and familiarity.
6. A myriad of surgical approaches to interbody fusion allow for a flood of approach-specific products into the market. Current interbody fusion approaches include anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), and the MIS approaches mentioned in point 5. Currently, research is also being conducted as to the efficacy of innovative MIS approaches to TLIFs. These approaches are being undertaken with various retractor

systems.

AAOS 2008: Instrumentation Costs and Paper Related to Interbody Fusion Outcomes

During a symposium at AAOS 2008 in San Francisco, entitled “The Process of Developing Novel Technology for the Spine,” Dr. David Wong explained that both the cost and usage of instrumentation has increased in spine fusion. As an example, a comparison was made between the instrumentation costs for an L5-S1 posterior lumbar fusion performed on a male smoker in 1997 and in 2003. In 1997, the instrumentation for this procedure could have been a Sofamor Danek TSRH® rod and screw system, which cost \$3,207. In contrast, in 2003, an L5-S1 anterior/posterior lumbar fusion on a 51-year-old male smoker could include significantly more instrumentation-related costs. Table 1 below highlights the possible components and costs for the 2003 procedure as shown in the presentation.

Table 1: L5-S1 Posterior /Anterior Fusion Estimated Instrumentation Costs

Instrumentation	Estimated Costs
Sofamor Danek TSRH® Rod/Screw System	\$4,682
RTI Precision Bone Dowel	\$2,800
Synthes DBX® Bone Paste	\$630
Sofamor Danek Bone Void Filler	\$458
Sofamor Danek BMP (large)	\$4,900
Total	\$13,470

Source: AAOS 2008, “The Process of Developing Novel Technology for the Spine,” by Dr. David Wong

Also seen at AAOS 2008 were papers showing continued interest in MIS techniques with respect to interbody fusion, a trend which we believe will be a major revenue driver. Below are summaries of two papers presented dealing with TLIF and XLIF.

Paper Number 086: Clinical Outcome of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion

This paper was written by Dr. Benedict Peng, Dr. Wai Muun Yue, and Dr. Seang Beng Tan. According to the abstract, “The purpose of this study is to compare the clinical results of minimally invasive versus open transforaminal lumbar interbody fusion.” In conclusion, the doctors stated: “Minimally invasive transforaminal lumbar interbody fusion is a safe and efficacious technique. It is associated with less blood loss, less analgesic use and shorter hospitalization when compared to open procedure. It appears that the benefits of minimally invasive surgery are in the early postoperative period with no significant difference in the clinical outcome at 6 months and 2 years postoperation compared to open surgery.”

Other studies will continue to examine the benefits of MIS. However, studies such as this begin to confirm the efficacy of these approaches. Successful outcomes related to surgical approaches that employ interbody implants should be viewed positively with respect to interbody spacer revenues.

Paper Number 528: Extreme Lateral Interbody Fusion (XLIF): Evaluation of Safety and Short-Term Results

This paper was written by Dr. Victor Hsu, Dr. Behrooz Akbarnia, Dr. Bruce van Dam, Dr. Ramin Bagheri, and Tina Chen. According to the abstract, “The purpose of this study is to evaluate the safety and early clinical results for this technique.” In conclusion, the doctors stated: “The complications associated with anterior approach to interbody fusions can be avoided using the XLIF technique. XLIF is performed through a minimally invasive retroperitoneal approach to the spine that allows excellent disc space visualization to place large anterior grafts. Our review shows excellent clinical results are safely obtained using this novel procedure.”

This paper is a positive for NuVasive’s XLIF. And, it helps support one of our theses on revenue drivers in the spine market: Implants used in proprietary surgeries could continue to drive revenues.

These two papers viewed MIS in a positive light. As always, there will be further scrutiny and study of the approaches, as physicians continue to learn about these exciting innovations.

Single-Sided Posterior Instrumentation

With respect to interbody fusion, there may be a possible reversal of trends in instrumentation. Over time, the use of instrumentation has increased in fusion, hence driving revenues. A reversal in the use of instrumentation would obviously affect revenues. Research is currently being conducted with respect to single-sided instrumentation in PLIFs. If outcomes and fusion rates are equivalent to current practice, this approach could be viewed favorably by both surgeons and hospitals given the potential cost savings.

The Rising Tide

The tide of interbody fusion has been a major driver of revenue growth in the spine market. This has been accomplished, in part, through increased usage of spacers and instrumentation. Innovation with respect to materials, surgical approaches, a better understanding of the biomechanics of the spine, and issues surrounding devices made of bone have all contributed to growth in this market.