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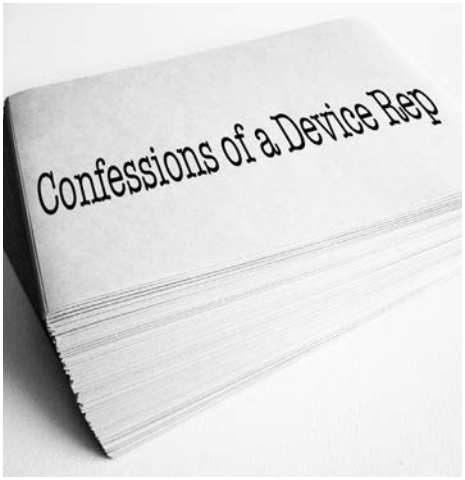
# Orthopedics This Week

## week in review









## breaking news



**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** Ortho stocks are off after Biomet's financial report supported the view that orthopedics is a low growth industry with tough regulatory and pricing headwinds. Globus' IPO filing showed that certain companies are outperforming industry growth and profitability averages. In the coming weeks SYK, ZMH, NUVA and SNN will likely confirm these underlying trends.

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|---|---|---|---|---|---|
| 1 | 1 | Zimmer | 24.95% | 1.02% | ZMH stays on top, barely. The narrative is simple. Is ortho in low gear for the foreseeable future? ZMH's 2% sales growth confirms this hypothesis. |
| 2 | 4 | Stryker | 23.73 | (0.50) | Both ZMH and SYK are sitting on piles of cash. Can these companies deploy it in ways to raise growth expectations? SYK up on expected 5% top-line growth. |
| 3 | 3 | NuVasive | 7.26 | 0.58 | NUVA and Globus showing investors that, in spine, double-digit growth is still possible—15% expected for Q1. |
| 4 | 9 | ArthroCare | (0.95) | 3.75 | Second lowest P/E to growth rate in ortho. Most buyers looking past the next couple quarters a rebound in sales growth 2H. |
| 5 | 5 | Conmed | 9.65 | (2.52) | Expanding margins expected to push EPS growth to 18% on a 5% sales growth quarter. |
| 6 | 8 | Johnson & Johnson | 26.33 | (2.37) | On the home stretch to close Synthes. Reminder—makes DePuy #1 in virtually every major ortho market. |
| 7 | 2 | Integra LifeSciences | 14.81 | (8.81) | Generally good news from the analysts, but sellers piled on IART last week. Expectations of down earnings this quarter no doubt contributed. |
| 8 | 6 | Orthofix | 14.72 | (8.26) | Can't buy a break. OFIX has earned better valuations than this. THE lowest priced orthopedics equity. Market's looking for 18% earnings growth. |
| 9 | 7 | Smith & Nephew | 22.80 | (2.60) | Below industry average sales growth but 2.20% dividend rate and a low turnover and beta. Dull, but that'll work for now. |
| 10 | 10 | Medtronic | 28.63 | (2.87) | Needs a catalyst. New products. Something to point to a future with growth and innovation. Is MDT a deer in the headlights? |

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | Kensey Nash | KNSY | $28.14 | $244 | 15.66% |
| 2 | MAKO Surgical | MAKO | $42.51 | $1,803 | 11.14% |
| 3 | TranS1 | TSON | $3.74 | $102 | 9.65% |
| 4 | Alphatec Holdings | ATEC | $2.22 | $199 | 7.77% |
| 5 | Symmetry Medical | SMA | $6.89 | $245 | 5.19% |
| 6 | Tornier N.V. | TRNX | $24.61 | $967 | 3.84% |
| 7 | Synthes | SYST.VX | $170.69 | $20,274 | 1.52% |
| 8 | Zimmer Holdings | ZMH | $63.37 | $11,288 | 1.02% |
| 9 | NuVasive | NUVA | $15.61 | $671 | 0.58% |
| 10 | Wright Medical | WMGI | $18.24 | $717 | 0.36% |

## WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | Bacterin Intl Holdings | BONE | $2.37 | $100 | -26.85% |
| 2 | TiGenix | TIG.BR | $0.81 | $74 | -12.23% |
| 3 | Exactech | EXAC | $15.12 | $199 | -9.68% |
| 4 | Integra LifeSciences | IART | $31.76 | $854 | -8.81% |
| 5 | Orthofix | OFIX | $36.74 | $687 | -8.26% |
| 6 | CryoLife | CRY | $5.00 | $139 | -8.09% |
| 7 | ArthroCare | ARTC | $24.91 | $689 | -3.75% |
| 8 | Medtronic | MDT | $37.51 | $39,033 | -2.87% |
| 9 | Smith & Nephew | SNN | $48.02 | $8,604 | -2.60% |
| 10 | Conmed | CNMD | $28.65 | $802 | -2.52% |

## LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Medtronic | MDT | $37.51 | $39,033 | 11.69 |
| 2 | Johnson & Johnson | JNJ | $63.54 | $174,422 | 12.71 |
| 3 | Zimmer Holdings | ZMH | $63.37 | $11,288 | 13.17 |
| 4 | Orthofix | OFIX | $36.74 | $687 | 13.61 |
| 5 | ArthroCare | ARTC | $24.91 | $689 | 14.32 |

## HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Wright Medical | WMGI | $18.24 | $717 | 55.26 |
| 2 | NuVasive | NUVA | $15.61 | $671 | 31.22 |
| 3 | RTI Biologics Inc | RTIX | $3.65 | $203 | 24.33 |
| 4 | Symmetry Medical | SMA | $6.89 | $245 | 22.97 |
| 5 | Synthes | SYST.VX | $170.69 | $20,274 | 20.97 |

## LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $36.74 | $687 | 0.82 |
| 2 | Kensey Nash | KNSY | $28.14 | $244 | 1.23 |
| 3 | Integra LifeSciences | IART | $31.76 | $854 | 1.30 |
| 4 | ArthroCare | ARTC | $24.91 | $689 | 1.34 |
| 5 | Stryker | SYK | $53.96 | $20,573 | 1.35 |

## HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Wright Medical | WMGI | $18.24 | $717 | 5.79 |
| 2 | NuVasive | NUVA | $15.61 | $671 | 3.54 |
| 3 | CryoLife | CRY | $5.00 | $139 | 2.16 |
| 4 | Smith & Nephew | SNN | $48.02 | $8,604 | 2.13 |
| 5 | Johnson & Johnson | JNJ | $63.54 | $174,422 | 2.08 |

## LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | Symmetry Medical | SMA | $6.89 | $245 | 0.68 |
| 2 | Exactech | EXAC | $15.12 | $199 | 0.97 |
| 3 | Alphatec Holdings | ATEC | $2.22 | $199 | 1.01 |
| 4 | Integra LifeSciences | IART | $31.76 | $854 | 1.09 |
| 5 | Conmed | CNMD | $28.65 | $802 | 1.11 |

## HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $0.81 | $74 | 64.50 |
| 2 | MAKO Surgical | MAKO | $42.51 | $1,803 | 21.34 |
| 3 | TranS1 | TSON | $3.74 | $102 | 5.32 |
| 4 | Synthes | SYST.VX | $170.69 | $20,274 | 5.10 |
| 5 | Tornier N.V. | TRNX | $24.61 | $967 | 3.70 |

*PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.*

# The 28 Top Spine Surgeons in America

By *OTW* Staff

*Wikimeida Commons and Jaime de la Fuente*

Who are the best surgeons, clinicians, investigators and administrators in spine? We've seen the lists—including in the magazine on the airlines that are often our second homes. But how reliable are these lists? Is this like the Who's Who racket where, for a mere couple of hundred dollars, you can be listed?

We took a different approach. Over the years, we have compiled a fairly comprehensive list of contacts in orthopedics. Who better to pick the top spine physicians than their own colleagues? So we decided to ask leading spine surgeons to select the best of their peers.

It didn't matter to us if we came up with five names or fifty. All we asked was, who among your peers do you think is at the top of your profession? Time and again the same names rose to the top. And we compiled a list of those people who were mentioned most consistently.

*Here is that list. It isn't the be-all and end-all list—but a list of who are arguably the finest spine physicians, teachers, investigators or administrators in the country. This information was obtained via a telephone survey of thought leaders in the field. The information in quotes is what we heard about these surgeons.*

Tell us what you think.

In alphabetical order, then, here are the top 28 spine physicians in America.

**Todd Albert, M.D.**

Dr. Albert is president of the Rothman Institute in Philadelphia and chair of the Department of Orthopaedic Surgery at Thomas Jefferson University. "An incredibly talented surgeon and administrator."

**Howard An, M.D.**

Dr. An is the Morton International Endowed Chair Professor of Orthopaedic Surgery, as well as the director of the Division of Spine Surgery at Midwest Orthopaedics at Rush in Chicago. "A really wonderful surgeon who is very compassionate."

**Scott D. Boden, M.D.**

Dr. Boden is professor of orthopedic surgery and director of the Emory

Orthopaedics and Spine Center. "An accomplished researcher and superior clinician."

**Christopher Bono, M.D.**

Dr. Bono is chief of spine at Brigham and Women's Hospital and assistant professor at Harvard Medical School. "A great thinker and clinical researcher; an honest man."

**Darryl Brodke, M.D.**

Dr. Brodke is professor of Spinal Disorders and director of the Spine Center at the University of Utah School of Medicine. "A great biomechanical researcher and administrator."

**Jens Chapman, M.D.**

Dr. Chapman is chair of the Department of Orthopaedic Surgery at University of Washington in Seattle. He is also director of the Spine Service. "A consummate traumatologist and spine surgeon."

**Mark Dekutoski, M.D.**

Dr. Dekutoski is associate professor of orthopedics at Mayo Clinic in Minnesota. "A great clinician and leader who is very aware of the literature."

**Frank Eismont, M.D.**

Dr. Eismont is chairman and chief of the Department of Orthopaedic Surgery at Jackson Memorial Hospital in Miami. "Known for his terrific trauma and cervical work."

**Sanford Emery, M.D., M.B.A.**

Dr. Emery is professor and chair at the Department of Orthopaedic Surgery at the West Virginia University. "An amazing surgeon, leader, and clinical researcher."

**Steven Garfin, M.D.**

Dr. Garfin is chair of the Department of Orthopaedic Surgery at UC San Diego; he is also chief of the UC San Diego Spine Program. "Thoughtful, incredibly diligent, and a passionate teacher."

**Robert A. Hart, M.D.**

Dr. Hart is associate professor at the Oregon Health and Science University; he is also director of that institution's orthopedic residency program. "Does solid basic science and clinical research and is a great individual."

**Harry Herkowitz, M.D.**

Dr. Herkowitz is chair of the Department of Orthopaedic Surgery at Beaumont Health System in Michigan. Additionally, he is a director of the American Board of Orthopaedic Surgery. "He is a true pioneer."

**John Heller, M.D.**

Dr. Heller is professor of orthopedic surgery at Emory University. "He is very compassionate and is a technically gifted surgeon."

**Alan Hilibrand, M.D.**
Dr. Hilibrand is professor of Orthopaedic Surgery and Neurosurgery at the Rothman Institute in Philadelphia. He is also Director of Medical Education for the Department of Orthopaedic Surgery at the Rothman Institute and Jefferson Medical College "An amazing person who is a talented researcher and leader."

**Serena Hu, M.D.**
Dr. Hu is professor of clinical orthopaedics at the University of California, San Francisco Medical Center. "A top spine surgeon who is tough and smart."

**James D. Kang, M.D.**
Dr. Kang is vice chairman of the Department of Orthopaedic Surgery at the University of Pittsburgh Medical Center. He is also director of the Ferguson Laboratory for Spine Research. "He is a terrific surgeon and basic science researcher."

**Joon Yung Lee, M.D.**
Dr. Lee is assistant professor of Orthopaedic Surgery at the University of Pittsburgh Medical Center. "Known for his quality basic science research; a great clinician."

**Lawrence Lenke, M.D.**
Dr. Lenke is co-chief of Adult and Pediatric Spinal, Scoliosis and Reconstructive Surgery at Washington University School of Medicine and Director of Spinal Surgery at Shriners Hospital for Children in St. Louis. "A real leader in scoliosis surgery who has developed the Lenke classification system which surgeons everywhere use daily."

**Robert McGuire, M.D.**
Dr. McGuire is the chair of orthopedic surgery at the University of Mississippi Medical Center. He is also director of the orthopedic residency at that institution. "A wonderful clinician and leader."

**Daniel B. Murrey, M.D.**
Dr. Murrey is the CEO of OrthoCarolina. "He does an amazing job running what amounts to the largest orthopedic practice in the country."

**Pierce Nunley, M.D.**
Dr. Nunley is the director of the Spine Institute of Louisiana and an assistant professor of orthopedic surgery at the Louisiana State University Health Sciences Center. "He has developed important spine technologies, and is a truly accomplished private practice surgeon."

**Frank Phillips, M.D.**
Dr. Phillips is professor of orthopedic surgery and director of Minimally Invasive Spine Surgery at Midwest Orthopaedics at Rush in Chicago. "A superb innovator and clinician."

**Dan Riew, M.D.**
Dr. Riew is Chief of the Surgical Spine Center and Director of the Cervical Spine Institute at the Washington University School of Medicine in St. Louis. "If someone says, 'cervical spine surgery,' you think of Dan."

**Rick Sasso, M.D.**
Dr. Sasso is a founding member, and the president of Indiana Spine Group. "Phenomenal technical surgeon and a minimally invasive world leader."

**Daniel Sucato, M.D., M.S.**
Dr. Sucato is chief of staff at Texas Scottish Rite Hospital for Children. He is also director of the Sarah M. and Charles E. Seay/Martha and Pat Beard Center for Excellence in Spine Research. "A pediatric surgeon who does great scoliosis work and who runs important deformity study groups."

**Alexander Vaccaro, M.D., Ph.D.**
Dr. Vaccaro is a spine surgeon with the Rothman Institute in Philadelphia. He is also vice chairman of the Department of Orthopaedics at Thomas Jefferson University. "The most prolific clinical researcher in spine."

**Jeffrey Wang, M.D.**
Dr. Wang is the chief of the orthopedic spine surgery service at the David School of Medicine at the University of California, Los Angeles. Additionally, he is professor in the departments of orthopaedic surgery and neurosurgery. "A fantastic researcher and surgeon."

**Thomas Zdeblick, M.D.**
Dr. Zdeblick is professor and chair at the University of Wisconsin Department of Orthopedics and Rehabilitation. "An innovative genius, a researcher of significant renown who has unimpeachable ethics." ♦


# On (and Off) the Record

By Elizabeth Hofheinz

Throw Away Instruments...Not Enough Clinical Evidence for Reverse Shoulder?…Gunnar Andersson Wins Alfred R. Shands Award... Doctor-Owned Hospitals Fighting for Place in the Sun…No Surgery on Obese Patients?…and more.

**Throw Away Your Instruments** An in-the-know orthopedist tells *OTW,* "Companies have picked up on the issue of OR efficiency as it is well known that room turnover can take a long time—in part because the staff has to open five or six instrument trays for one surgery. Several companies have just begun creating disposable instruments and trial implants. For example, there might be a case specific cutting jig created such that you know before the surgery what size you need. Along with disposable instruments, it cuts down on inventory and reduces the number of trays you have to open. Not to mention that you don't have to sterilize. Many surgeons are excited about the prospect of having completely disposable case trays. At some hospitals, it can take an hour to turn over an OR…with this it could be reduced to 15 minutes."

**Not Enough Clinical Evidence for Reverse Shoulder?** "More and more insurance companies are asking us to clearly define the benefits of what we do," says an orthopedic surgeon to *OTW.* "For example, a large East Coast insurance company has recently decided that there is not enough clinical evidence that reverse total shoulder arthroscopy is a valuable procedure… and that they are not going to reimburse for it because they thought it was at best investigational. The issue is that the data we have emanates from case series that do not use cost effectiveness

or quality outcomes measures, and therefore do not allow us to determine the real cost/benefit of this procedure. Insurers have a point…these procedures are more expensive than a traditional shoulder replacement, and they are asking, 'Are they that much better?' and 'These patients are usually sicker… are we improving their quality of life?'"

**Gunnar Andersson Wins Alfred R. Shands Award** The ORS Board has spoken…Gunnar B. J. Andersson, M.D., Ph.D. is the 2012 recipient of the Alfred R. Shands, Jr., M.D. Award, an annual honor bestowed on a North American who has made significant contributions to orthopedics. Dr. Andersson, who is credited with designing the seat in Volvo automobiles, is Professor and Chair in Spinal Deformities at Rush University Medical Center. He is also a former president of the Orthopaedic Research Society. The Alfred R. Shands, Jr., M.D. Award is sponsored by the Orthopaedic Research Society (ORS).

**Thomas Einhorn Wins Distinguished Investigator Award** Thomas Einhorn, M.D. has been named the 2012 recipient of the ORS/OREF Distinguished Investigator Award, an honor bestowed on those who have had a long-standing, productive career in orthopedic research, and who have demonstrated outstanding mentorship of research trainees, service to the professional community and exemplified academic collegiality. Dr. Einhorn, a former president of the Orthopaedic Research Society, has also been chair of the study section on orthopedic and musculoskeletal health at the NIH.

**No Surgery on Obese Patients Coming?** A veteran orthopedic surgeon tells *OTW,* "I am seeing that doctors are becoming more supportive of price controls and more focused on evidence based medicine. Our hospital started an infection reduction program and reduced our rate nearly tenfold in two years. However, part of getting these rates down required limiting access to care. We won't do an elective joint replacement on someone whose body mass index is over 40…or on someone with a HbA1c level over 7.2. With the anticipation of bundled episodes of care, the infection issue looms larger than ever.

*"An infection costs anywhere from $50,000 to $100,000 to clean up. A typical hospital has a profit of around $2,500 on a total joint operation. Let's say the hospital does 50 total joints a month…then with only ONE infection, there goes the entire month's profit*. But we must do something to reduce the cost of healthcare; and, the transparency that's more and more a part of

our lives means that doctors are more motivated to reduce complications. I know of one situation where a doctor was spending more than three times as much to drape a patient than other doctors in his practice. Again, with the increasing transparency, this kind of thing will diminish greatly."



**Doctor-Owned Hospitals Are "No Brainer"** Brian Parsley, M.D. is a partner in a physician-owned specialty hospital. He tells *OTW*, "Many doctors have either cancelled or put their plans to pursue hospital ownership on hold as a result of President Obama's healthcare initiative. The case to watch is now playing out in the federal courts in Houston where several doctor-owned hospitals are challenging the President's law, saying that it is unconstitutional. Another debate involves if the Patient Protection and Affordable Care Act (PIPACA) is voted to be unconstitutional, whether they will throw out the whole law or just the segment on individual mandates. That would create an opportunity for doctor-owned hospitals. Doctor-owned hospitals are a no-brainer as far as quality care. Patients have a much better experience at the hospital, their satisfaction rates are incredibly high… there's no reason they shouldn't have the opportunity to have that level of care. The only reason these restrictions were placed in PIPACA was because the American Hospital Association has quite a strong lobby. It will be interesting…as we move toward Accountable Care Organizations and bundled payments, doctor-owned hospitals will be highly qualified to put together packages that are cost sensitive."

**Jon E. Block, Ph.D. Named Associate Editor at BMC Research Notes** The Jon Block Group has announced that Jon E. Block, Ph.D. has been appointed to Associate Editor at BMC Research. Dr. Block will be focused on musculoskeletal disorders, joining a renowned editorial team that reviews and adjudicates journal submissions across a broad spectrum of research areas. Dr. Block has served on the review boards of numerous publications, including the *Journal of the American Medical Association,* the *Journal of Bone and Mineral Research,* and *SPINE*.

**Dr. Claus Christiansen M.D., MMSci Wins ESCEO-IOF Medal** Dr. Claus Christiansen M.D., MMSci, co-founder of the European Foundation of Osteoporosis—later to become the International Osteoporosis Foundation, is the winner of the 2nd Herbert A. Fleisch ESCEO-IOF Medal. The award is valued at 20,000 EUR, and is named after the late Professor Herbert A. Fleisch, whose pioneering work contributed to the development of the field of scientific knowledge about metabolic bone diseases and their treatment. Dr. Christiansen has published extensively in the field of osteoporosis with over 900 articles and book chapters, particularly in the area of calcium metabolism in postmenopausal women. He was Head of the Department of Clinical Pathology and Clinical Chemistry, Glostrup Hospital, University of Copenhagen for 14 years, and was for several years the youngest department chairman in Denmark. He has been chairman of several international symposia on osteoporosis, and has been an invited speaker on calcium metabolism at almost all international meetings in the field. Dr. Christiansen is currently the Chairman and President of Nordic Bioscience and CCBR-Synarc. ♦

# Anti-Kickback Guilty Plea in Boston

By Walter Eisner

A phony consulting agreement, laundered pay-offs, backdated time sheets and a cast of characters named DZ, RM, JM, Dr. P and Dr. S, star in the latest federal prosecution of medical device reps and, allegedly, docs gone bad.

## Guerrieri Pleads Guilty

Thomas P. Guerrieri, a former medical device company vice-president pled guilty on April 9 to violating the federal Anti-Kickback statute in Boston.

According to the U.S. Attorney in Boston, Guerrieri facilitated signing up a surgeon in New York to a phony "consulting" agreement with the company identified in the court documents only as "Company A", to induce the surgeon, identified as "Dr. S", to prescribe the company's bone growth stimulators.

Guerrieri also pled guilty to "executing" a scheme to pay Michael Cobb, a Rhode Island physician's assistant to a neurosurgeon named "Dr. P" for each bone growth stimulator he ordered for his boss. Cobb, says the government, was paid $50-$100 for each stimulator.

Guerrieri is widely known to have been a vice-president for Orthofix, Inc. and left the company under undisclosed terms in 2010. In court documents released April 9, the government said Guerrieri lied to company lawyers about details of the consulting work.

## Orthofix Resolution

Orthofix was not part of any of these pleadings. The company had already announced on February 6, 2012, that it was finalizing definitive agreements with the U.S. Attorney's Office, the Department of Justice, and the Office of Inspector General (OIG) of the Department of Health and Human Services, to resolve criminal and civil matters related to the investigation of its bone growth stimulation business. The agreements include the resolution of a qui tam lawsuit pending in the U.S. District Court for the District of Massachusetts.

Under the terms of the agreements, the company agreed to pay the government


*Morguefile, Photo Creation by RRY Publications LLC*

$43 million. In addition, the company expects to plead to a violation related to an obstruction of a June 2008 federal audit. The company also expects to enter into a five-year Corporate Integrity Agreement (CIA) with the OIG as part of the resolution of these matters.

When contacted by *OTW* and asked why the names of the surgeons and companies were not identified in the documents charging Guerrieri, a source in the prosecutor's office told us that at this time they could not comment because the investigation is ongoing.

Orthofix management declined to comment other than pointing to their February 6 announcement of the resolution with the federal government.

## Bone Growth Stimulators

As vice-president of sales, Guerrieri was responsible for sales of the company's Spine-Stim and Cervical-Stim bone growth stimulators through a sales force of approximately 75 territory managers who reported to approximately six regional sales directors. The regional directors reported to two area vice-president, who in turn reported to Guerrieri.

The stimulators are worn externally and emit pulsed electromagnetic fields to stimulate regeneration of bone in connection with spinal fusions. Some surgeons prescribe stimulators after surgery.

## Anti-Kickback Act

In order to obtain payment from Medicare, the company is required to obtain an order from the treating physician; records describing the condition; and a Certificate of Medical Necessity (CMN). The government said Medicare beneficiaries accounted for between 20% and 25% of sales for the company. The Medicare-approved amount for reimbursement for stimulators ranged from $2,800 to more than $4,000 per device.

The Anti-Kickback Act prohibits the payment to physicians or their staff to induce them to order items or services to be paid for by Medicare.

## Dr. S "Consulting Agreement"

Guerrieri's guilty plea to facilitating a "consulting" arrangement with New York's Dr. S, was with one of the company's highest prescribing surgeons. The government says the surgeon was paid "tens of thousands" of dollars and did little or no work in return. Guerrieri and others at the company never contemplated that Dr. S would provide legitimate consulting service to the company. Rather, says the government, they offered the "consulting" agreement to Dr. S to induce him to prescribe their stimulators.

The "consulting" agreement, according to the court document, required Dr. S to submit time sheets documenting his work. He failed to complete and submit any times sheets to the company, but was nevertheless paid monthly. During the life of the agreement, Dr. S exclusively prescribed the company's stimulators.

## Backdated Time Sheets

By August 2007, according to the government, Dr. S was aware that consulting arrangements between surgeons and medical device companies were under increased scrutiny. The government said he met with Guerrieri and the company's territory manager, "JM", and informed them that he was con-

cerned about his "consulting" agreement because, among other things, he had not been submitting time sheets. He allegedly instructed JM and Guerrieri to create and backdate time sheets for the previous year, making it appear as though he had filled out time sheets contemporaneously. Guerrieri and JM complied and Dr. S signed the backdated time sheets.

The time sheets included numerous tasks that Dr. S had not completed, "Indeed, the vast majority of the tasks included in the backdated time sheets were phony," say the documents.

## Lying to Company Lawyers

Dr. S also requested that the two sales reps obtain a letter from the company's general counsel stating that the surgeon was compliant with his "consulting" agreement. Guerrieri then brought the request to the company's in-house attorney and his superiors. He told them that time was of the essence because Dr. S was a very large customer.

Prosecutors say the company's lawyers were unaware that Dr. S had backdated the time sheets and that he had not performed any real services for the company.

The following month, September 2007, the company's general counsel sent a letter to Dr. S indicating that "the entries on the Consultant Report forms appear to accurately detail the consulting services that you have provided," that the "services are of use to us, and that "all payments for consulting services must be documented before payments can be made."

Guerrieri, according to his guilty plea, knew that these statements were untrue.



## Guerrieri: "Give Us Our Due"

In spite of asking Guerrieri and JM to create the phony time sheets and obtain a letter from the company's general counsel "under false pretenses," the government says Dr. S still decided to cancel his "consulting" agreement and stopped using the company's stimulators.

After the cancellation Guerrieri sent Dr. S an email stating that he [Guerrieri] "jumped through hoops to get you the information that you requested" and "**please give us our due.**"

## Rhode Island: DZ, RM, Cobb and Dr. P

Guerrieri didn't keep his inducements activities to just New York. He was also busy in Rhode Island.

Between 2001 and 2010, the government says Michael Cobb was a physician's assistant for "Dr. P," a neurosurgeon in Rhode Island. He was also the company's largest customer in New England.

## Cobb Payments

For many years, according to the government, "DZ," the company's territory manager in Massachusetts and Rhode Island, paid Cobb between $50 and $100 for each stimulator prescribed by


*Wikimedia Commons*

Dr. P and ordered by Cobb. The payments were disguised as "fitting" fees: payments for showing a patient how to wear the stimulator. In fact, say prosecutors, Cobb rarely performed such fittings for patients and DZ paid Cobb to induce more orders from Cobb and the surgeon. Cobb was in a position to determine which company's stimulators would be used for Dr. P's patients. In return for the payments, Cobb ensured that the company's device was always used.

Professional acquaintances of Dr. P in Rhode Island and familiar with the case told us that it's a small state and believe the wool was pulled over Dr. P's eyes by those involved. They say physicians normally tell their assistants to order the device and would likely have no knowledge of which company's device was ordered.

## Laundering Required

In September 2008, Orthofix established a new policy that expressly prohibited any payments, including "fitting" fees, to any employee of a surgeon who prescribed the company's products. Prosecutors say Guerrieri understood that the policy was established based on ongoing concerns that payments to surgeons' employees could violate the Medicare Anti-Kickback Act.

Concerned that the company would lose business, Guerrieri contacted three regional sales directors and asked if the company would lose any business when the policy went into effect. He found that if they could no longer pay Cobb, the company might lose the business.

So Guerrieri, according to prosecutors, and others executed a scheme that would allow Cobb to continue to receive payments. The payments to Cobb would be assumed by Company B, a vendor that relied almost entirely on Guerrieri's company for all its business. Cobb would continue to be paid, but it would be more difficult to trace the paper trail for the payments back to the company.

Guerrieri contacted RM, the company's regional sales director while RM was playing a round of golf with Cobb. Guerrieri instructed RM to contact Company B and inform it that it had to begin paying "fitting" fees to Cobb. RM did as he was instructed.

Company B agreed to pay Cobb for several months before informing Guerrieri that it was no longer comfortable assuming these payment and stopped doing so.

## Plea Hearing Set

Guerrieri's plea hearing is set for April 19, 2012 at 3:15 p.m. before Judge George A. O'Toole, Jr. In addition to forfeiting any property derived from the offense, Guerrieri faces up to five years in prison and three years of supervised release as well as a $250,000 fine and forfeiture.

And Dr. S in New York? Apparently the prosecutors aren't done. Stay tuned. ♦

# David Stulberg vs. Robert Bourne Over Stubby Stems

By Elizabeth Hofheinz, M.P.H., M.Ed.


*Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation*

"Short stems work," says David Stulberg, "and they are associated with very good bone remodeling." Robert Bourne counters, "But we don't even have studies where they have varied the stem length to see if the outcomes are similar. This issue is more complicated than Dr. Stulberg has presented."

This week's Orthopaedic Crossfire® debate is "Stubby Stems: When Less is More." For the proposition was S. David Stulberg, M.D. from Northwestern University Hospital in Chicago. Against the proposition was Robert B. Bourne, M.D., F.R.C.S.(C) of the University of Western Ontario; moderating was Cecil H. Rorabeck, M.D., F.R.C.S.(C) of the University of Western Ontario.

**Dr. Stulberg:** "We should begin by recognizing that cementless femoral stems have a variety of shapes and sizes and design rationale and they have worked terrifically well in all patients. But there are issues. One is the desire to optimally load the proximal femur; another is to deal with proximal deformity and proximal-distal mismatch. Extreme cases can be handled with a short stem, but the more common problem we face is young, active, large males with large metaphyses and narrow diaphyses. These can get us into trouble…but can easily be solved with short stems—if they worked."

"The real issue is…exposure. Anterior approaches need something other than long stems to facilitate their use. So the hypothesis is that substantial reduction in stem length would not alter the stable fixation and reliable bony ingrowth of an implant designed to fit and fill the proximal femur. My initial experience was in relatively younger patients with good bone. I've had 2-4-5 year follow up. I used a custom implant to define the problem. In other words, I used one that I knew would fit proximally. We had a lot of experience with bone remodeling. Our DEXA scans showed that bone remodeling proximally was good, and that fixation was impeccable."

"These results have been presented in *Orthopedics* in the last couple of months…no news…they work well and haven't failed. In terms of fixation they function like normal hips. The next step was to take an off-the-shelf device that was very similar in concept, ask the manufacturers to get rid of the length of the stem and see what happened. I used them in all comers, and the results are the same as they were with customs. My conclusion was that short stems work, that the stems have identical clinical outcomes, and are associated with very good bone remodeling."

"From Europe are coming a variety of stems…you could classify these a lot of ways. You could call them, 'shortened standard'—the Biomet microplastic is an example of that. They just cut off the stems…those will work if the fixation that was the basis for their use as a long stem works as a short stem. But the high neck stems are the ones that we're going to have to think about. These can come in two varieties: involving more than 50% of the high neck or less. That doesn't necessarily mean that the cut is high…what it really means is that the lateral cortex is kept intact. That is a little different than what we're used to."

"In addition, you can have fixation of different types: multiple point contact or circumferential contact. This can be done through a high neck approach where you preserve the lateral cortex."

"These stems must have reproducible technique and a short learning curve, secure initial fixation, durable fixation, optimum offset, and good bone remodeling. In the future we'll see extensive proximal contact, neck sparing, extend to or engage the metaphysis, probably modular necks, all head sizes, instruments for all approaches…and they should be revisable."

**Dr. Bourne:** "I have the greatest respect for Dr. Stulberg, but think the importance of femoral stem length in THR [total hip replacement] is perhaps not as simple as he has made it out to be. There are no studies I know of that have varied the stem length to see if the outcomes are similar. And there are a lot of variables to consider…there are many 'stubby stems.' These are important: stem length and design, femoral neck preservation, patient factors, bone quality, and activity level. To be fair, we'll go over these issues: is the stem necessary for ingrowth, bone stock variation (varies greatly), are they MIS friendly? Do they cause less stress shielding? Do they cause less thigh pain?"

"Regarding whether a stem is necessary for proximal ingrowth, that's tough. We need some good studies like radiostereometric analysis (RSA). When you go to a short stem you sometimes have problems with alignment. In one study by Nivbrandt he looked at one particular short stem—which didn't look that dissimilar from what David was describing—and concluded that he had good fixation. When I look at subsidence and varus/valgus migration, I agree… it looks pretty good. But when I look at outer plane rotation I get concerned. At two years there's a progression and perhaps retroversion of the stems."

"MIS friendly? Perhaps. But I think the bloom is coming off MIS surgery in general. As for whether there is less stress shielding, as soon as you put a stem down the medullary canal, you load it very differently and you get a reversal of the stress patterns. We published on this years ago."

"Less thigh pain? Again, we need good studies. Dr. Steve MacDonald presented our data on two types of conventional total hips, and we need to do the same for short stems. Dr. Pipino reported a 14% prevalence and that's a bit concerning and is higher than we'd have with conventional stems. But it may be only for that stem."

"Equivalent outcomes? We need a comparison group—level one versus level four clinical data. Even if you did cohort studies…we need not depend on case studies. When you look at over ten year outcomes the data is skimpy. In Professor Pipino's study of 56 total hip

replacements, 12 were lost to follow up and 44 were available at 13-17 years. His results were reasonable, but the short stem led him to put some stems in valgus, some in varus; thigh pain was 14% (he claims it resolved…we don't know). Only 82% had satisfactory Harris Hip Scores."

"Dr. Morrey's study: perhaps a little better study, published in the *Journal of Bone and Joint Surgery*. Much better follow up, but only 6.2 year mean follow up. He had significant revisions: 3.7%...not terrible, but it hasn't revolutionized care at the Mayo Clinic group. So even though short stems are worth looking at I think we should proceed with caution. Published series of short femoral stems have revealed increased complications. There's a downside in perhaps inferior fixation, more revisions…and we're not even dealing with the neck preserving implants. Thank you."

**Moderator Rorabeck:** "Thanks, Bob. That was excellent. David, could you define what you mean by short stem?"

**Dr. Stulberg**: "One in which the stem reaches the metaphyseal/diaphyseal junction, which in practical terms means that it's somewhere between 95 and 105mm long."

**Moderator Rorabeck:** "Bob?"

**Dr. Bourne:** "I don't see much advantage going to just a shorter stem. I would be looking at more of the stems like the mid-head resection or something like that where you preserve the metaphysis and diaphysis. But if you had to do a revision joint replacement later, they're primaries."

**Moderator Rorabeck:** "David, the genesis of this has come from your love of the anterior approach, and trying to find a stem that you can get in nicely that way. And this seems to solve that problem, I would guess."

**Dr. Stulberg:** "If you go anteriorally you need a stem that accommodates that, and there are other ways to go, but certainly the stem in an anterior approach can be aggravating. If we can shorten it and not lose reliable fixation then I think it's useful."

**Moderator Rorabeck:** "It seems like a good thing on an anterior approach. What would you say to a surgeon who only did posterior approaches?"

**Dr. Bourne:** "It's hard to generalize… to say that just because you see that one particular stem that Dr. Nivbrandt studied and what appears to be rotational instability. Whether you could apply that to Dr. Stulberg's stem or other stems…but those studies need to be done because we've come a long way in total hips, with 97/98/99% survivorship at 10-15 years of our conventional stems. So before we venture off into something else we have to be cautious."

**Dr. Stulberg:** "I want to emphasize that if you're going to get into high neck designs you can't see below the head resection level, and you're setting yourself up for rotational instability. If that was the problem with the Pipino stem, it may be an issue with these point contact high neck devices. So my point was that if you can get circumferential contact that is the safest way to go if you're going to a short stem. But I absolutely agree with you, Bob."

**Moderator Rorabeck:** "David, it seems that to get maximum rotational stability it's probably advantageous to preserve a bit more neck than usual—but that may open up more problems."

**Dr. Stulberg:** "That was my point in showing you how I use these high necks. If I were recommending a short stem and high neck device I would use one that actually violated that lateral cortex. The concept of a high neck resection is fine, but the real issue is getting circumferential contact proximally."

**Moderator Rorabeck**: "Bob, the other thing is that it's hard to go anywhere in the world where you're not seeing new types of short stems. Where do you think it's going to go?"

**Dr. Bourne:** "If we design a stem in North America or Europe and we try to put it in people in Asia they're way too long. There's little data—cemented or cementless—on what the length of the stem needs to be. I think we've accepted this—maybe too long—and I think studies such as David's stimulate us to look at this issue."

**Moderator Rorabeck:** "Interesting. Thank you both." ♦

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company

# Michael Will, Entrepreneur and Executive, Has Died

*Michael Will*

Michael Will, 56 years old, President of Centinel Spine, former CEO and president of Pegasus Biologics and senior vice president of Synthes, died unexpectedly of natural causes on April 10, 2012m at his home in Malvern, Pennsylvania. Michael is survived by his wife and best friend, Joy, their four children Justin-32, Lindsay-31, Jamie-25, Tyler-14 and the many thousands of his friends and co-workers, who came to know, respect and love Michael over his 33 years in the orthopedic industry.

"We have lost a very important person in our family/life that will leave a hole to never be filled." said Centinel Spine Chairman, John Viscogliosi. "Michael was part of our family and someone I considered a brother. He and I worked together shoulder to shoulder to build Centinel. He loved life and everything he did. The only explanation for Michael's passing is that God wanted him on April the 10th 2012."

Michael was born May 15, 1955 in Lebanon, Pennsylvania—the first child of what would eventually become a family of six: parents plus two boys and two girls. Michael attended and graduated from the University of Pennsylvania's Wharton School of Business where he majored in entrepreneurial studies.

While at Penn, he played football on the Sprint football team. "I think he was a running back," remembers Joy Will. Joy met her future husband while helping her girlfriend celebrate a birthday. "I was taking my girlfriend out for her birthday and we met Michael and his roommate." Joy would eventually marry Michael and her girlfriend would marry Michael's roommate. This year Joy and Michael celebrated their 28th year together.

Michael began his career at U.S. Surgical where he rose through the ranks over twenty one years to become senior vice-president and general manager of Surgical Dynamics. Michael was with U.S. Surgical when it was sold to Tyco Healthcare and served as General Manager of Surgical Dynamics while it was part of Tyco. When Tyco sold Surgical Dynamics to Stryker, Michael left to accept the position of Chief Operating Officer for Spine Solutions, Inc. At Spine Solutions, Michael played a critical role in introducing motion preservation technology to spine surgeons. When that firm was sold to Synthes, Michael went along and stayed with Synthes until 2006.

Michael was one of these extraordinary people who approach what they do with passion and a genuine affection for the people he worked with. We are not exaggerating when we say that Michael Will had many thousands of friends in this industry.

"Too early, too fast, too sad. What a very bad news. I will never forget his smile, his open mind and all I learned from him," remembers legendary physician and inventor Thierry Marnay. "He was patient and positive from Spine Solutions to Synthes. Let's pray for his family and let's keep in memory a happy moment with him I am sure that everyone has a good moment that will let him keep on living in our heart."

"Michael leaves a trail of wonderful, thoughtful relationships." remembers Anthony Viscogliosi. "He was a true gentleman in every sense of the word. I will miss his wonderful sense of humor, his zest for life and a mind set to always do right by people. This combination of character made him a wonderful, great friend. Michael will be unbelievably missed. He was always a happy guy. He leaves us with so many memories. He continues to affect all of us with his spirit."

To Michael, business was personal and his business colleagues were like members of an extended family. It wasn't just about business; it was about realizing the best of yourself and your family.

In the days since his passing, Michael and Joy's house has been filled with people from all over the world—including about 25 14-year-olds from the Lacrosse team that Michael's son plays on. Michael was particularly passionate about sports safety and was always trying to learn about ways that concussions could be avoided and helmets made safer.

For that reason, the family has asked that in lieu of flowers contributions be made to the matthewgfellerfoundation.org which is a foundation whose mission is to minimize athletic head injuries.

"He was an extraordinarily honorable person that always strived to put others' interests ahead of his own." remembers Marc Viscogliosi. "I'm proud to have called Michael a friend and I'm a better person because of his presence in my life."

Personal condolences may be sent to the Will family at the following address:

Mrs. Joy Will and Family
37 Meadow Creek Lane
Malvern, PA 19355

A memorial service for Michael will be held on Monday, April 16, at approximately 10 am, at St. David's Episcopal Church, 763 South Valley Forge Rd., Wayne, PA 19087. A reception will follow at the Waynesboro Country Club, 11000 Country Club Road, Waynesboro, PA, 17268.

*—RY (April 13, 2012)*

## New Hampshire Outlawing PODs?

The New Hampshire House of Representatives recently passed legislation to prohibit health care practitioner self-referrals for medical devices.

Larry Biegelsen, senior analyst at Wells Fargo wrote on April 10, that he understands the bill was intended to outlaw physician-owned distributors (PODs) and is expected to pass the state's Senate chamber as well.

HOUSE BILL 1725-FN states:

> *II. Notwithstanding any provision of law to the contrary, a health care practitioner, including an immediate family member, shall not:*
>
> *(a) Profit indirectly or directly from the sale of a medical device by any supplier in which the health care practitioner has a direct or indirect ownership interest.*
>
> *(b) Make a referral of a person to a supplier for a medical device if the health care practitioner has a direct or indirect ownership interest in the supplier.*
>
> *(c) Enter into a contract or business arrangement with another entity where the purpose or effect of the contract or business arrangement is to accomplish prohibited self-referrals indirectly, such as through the use of a third party, or through the use of a cross-referral agreement. Such prohibited contracts or business arrangements shall include any arrangement that requires or has the purpose or effect of causing the purchase of such medical devices from a specific supplier as a condi-*

State of New Hampshire

*tion of, or incident to the provision of medical care by the health care practitioner.*

*III. No claim for payment shall be presented to any individual, third party payer, or other entity, for any medical device provided incident to the provision of a medical device furnished in violation of this subdivision.*

**PODs – 10% Market Share**

"In our view, this law could provide positive momentum for clarity around PODs at the local and federal level. As we wrote in our NuVasive, Inc. initiation report on April 9, PODs continue to take share from the larger spine companies." Biegelsen added that, according to NuVasive, PODs have captured about 10% of the U.S. spine hardware market or roughly $500 million in sales.

In June 2011, five U.S. senators requested that the Office of Inspector General (OIG) within the U.S. Department of Health and Human Services (HHS) investigate the legality of PODs. Biegelsen says his D.C. consultants say the OIG is just at the beginning stage of doing its report but we could see something this fall.

There is continued interest among the five Senators involved with this topic to ask more questions and maybe have an informal roundtable or similar "non-hearing" event to give the issue some attention, added Biegelsen.

In Biegelsen's view, any curtailment of PODs would be positive for spine companies that do not sell to PODs.

*—WE (April 11, 2012)*

## It's Final: Orchid Acquires Sandvik

The ink is dry…Orchid MPS Holdings, LLC, owned by Altor Fund III, has announced the completion of the acquisition of Sandvik Medical Solutions (SMS). The new combined company will be called Orchid Orthopedic Solutions and has approximately 1500 employees.

Asked what led to this decision, Mike Miller, CEO of Orchid, told *OTW*, "Orchid (Altor Partners Fund, LLC) has been in discussions with Sandvik for the last year and a half concluding with the acquisition of Sandvik SMS. Sandvik SMS fits better with Orchid than it did with Sandvik because Orchid is completely dedicated to the Orthopedic and Medical supply chain solution business. Sandvik SMS had capabilities that fit very well with Orchid's existing capabilities and complemented Orchid ability to fully serve its customers and the Orthopedic, Medical, and Dental markets."

Miller also commented to *OTW*, "Orchid will begin immediately to change all four Sandvik SMS site names to Orchid Orthopedic Solutions. Orchid will fully integrate the Sandvik SMS work force in the U.S. and the U.K. Orchid will develop a full service facility to service the European market at its new Sheffield, England facility. Orchid will begin the setup of manufacturing at its facility in Pune, India and will strengthen its current sales operations in Shanghai, China. Orchid is very excited to work with the former Sandvik SMS employees to build the world's leading medical supply chain solution for all of the Orthopedic and Medical customers we serve."

*—EH (April 10, 2012)*


*Image creation by RRY Publications, LLC.*

# Biomet Sales Encouraging for Industry

Biomet, Inc. reported a 5% increase in sales for the company's third fiscal quarter on April 11. Like the groundhog, Punxsutawney Phil of Pennsylvania, the company's sales are widely watched because Biomet is the first company to report orthopedic industry quarterly sales for the start of the year.

The company reported Knees and Hips up 4% and 6%, respectively. Spine and Bone Healing fell by 5%, the fifth consecutive quarter of declines, according to Wells Fargo Analyst Larry Biegelsen. Sports, Extremities and Trauma rose 16%. "Against relatively easy comps, Biomet posted better quarterly growth in nearly all of its product categories," wrote Jefferies & Company, Inc. Analyst Raj Denhoy in an investor note on April 11.


*Wikimedia.org/Groundhog Day*

| Biomet 3Q 2012 | Sales ($ in millions) | % Change |
|---|---|---|
| **Total Reported Sales** | **708.9** | **5%** |
| Large Joints | 422.7 | 5% |
| Knees | | 4% |
| Hips | | 6% |
| Sports, Extremities, Trauma | 92.7 | 16.0% |
| Spine & Bone Healing | 76.5 | **down 5%** |
| Dental | **65.6** | **down 2%** |
| Other | **51.4** | **8.0%** |

*Source: Biomet, Inc.*

### Early Orthopedic Spring?

Biegelsen said Biomet's results are, "an encouraging sign" for the orthopedic sector. However he cautioned against reading too much into these results because of the easier comps and the company's "modest" knee and hip market share.

Joanne Wuensch, BMO Capital Market analyst agreed saying the results are good news for orthopedic companies, and, "in line with our thesis that utilization could pick up at the beginning of the year as the economy chugs along and healthcare savings plans reset."

Jeff Binder, Biomet's president and CEO commented, "We reported strong and improving sales results across many of our product categories this quarter, with particularly good momentum in our Large Joint Reconstructive and S.E.T. product categories. I was particularly happy with the consistency of our performance across all geographies. In addition, we are very excited about our future opportunities in the Trauma market given our pending acquisition of DePuy's worldwide trauma business."

### Losses Widen

While sales rose, *The Wall Street Journal* headline was, "Biomet Loss Widens," on charges related to the company's acquisition by a private-equity consortium including affiliates from The Blackstone Group, Goldman Sachs & Co., Kohlberg Kravis Roberts & Co. and TPG Capital in 2007. *The Journal* said Biomet has seen its losses widen in recent quarters, "Weighed down by charges related to its $11.4 billion buyout in 2007."

Special items during the quarter related to the buyout totaled $108 million.

The company reported a net loss for the quarter of $16.5 million versus $11.6 million in the previous year's third quarter. Interest expenses declined from $124 million to $117.2 million due to lower interest rates. The company's net debt stood at $5.424 billion. That debt was lowered by $749.1 million from May 31, 2008 to February 29, 2012.

During the quarter Biomet made a binding offer to acquire the global trauma business of Johnson & Johnson's DePuy Orthopaedics Inc. for about $280 million. The company also recently agreed to pay $23 million in penalties to settle U.S. allegations that the company bribed physicians in Brazil, China and other countries.

*—WE (April 12, 2012)*

legal

# Anulex's New Indication and Warning Letter Resolution

Anulex Technologies, Inc. has received FDA clearance for additional indications for use of its fiXate Tissue Band product and the resolution of a warning letter about the company's Xclose Tissue Repair System.

The fiXate Tissue Band device had previous clearance for securing spinal cord stimulation (SCS) lead anchors to fascia or interspinous/supraspinous ligaments in patients with chronic, intractable pain of the trunk and/or limbs. The new indication allows for securing intrathecal pain pump catheters in the same tissue.

The company says the device provides "more consistent SCS lead and intrathecal catheter anchor securement by offering a novel delivery system that facilitates efficient fixation to surrounding tissue in less than 30 seconds. By utilizing an in-line design, fiXate facilitates a smaller incision to allow less invasive surgery."

Michael Gofeld, M.D., from the Center for Pain Relief at the University of Washington Medical Center said the device, "firmly secures the catheter anchor in the desired place. Additionally, implantation time and incision size is minimized in patients of all sizes." Jeff Peters, Anulex's CEO, goes on to say, "with the expansion of indications for fiXate Tissue Band, Anulex continues to demonstrate its commitment to developing novel and clinically relevant solutions for soft tissue fixation and repair."

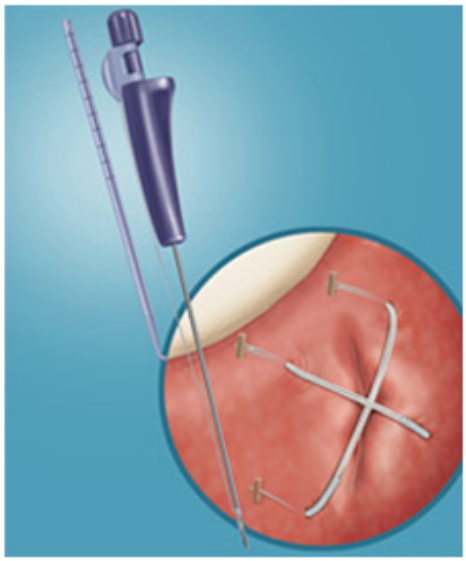
In addition to the new indication announcement, the company was also undoubtedly happy to resolve a previous warning letter from the FDA over indications around its Xclose Tissue Repair System.

The FDA informed the company that actions undertaken to address issues cited in a warning letter from February 2011 have been deemed adequate. The company had received the warning regarding a post-market study and promotional activities over the repair system. The repair system was cleared in 2006 and, according to the company, continues to be available to facilitate surgeons in providing a unique method of approximating soft tissue for procedures such as general and orthopedic surgery.

Peters said the post-market study as well as considerable usage outside the study has not resulted in the reported occurrence of any patient safety issues or adverse events beyond those anticipated for procedures involving suturing in general and other orthopedic surgeries.

Peters joined Anulex in April 2011 with over 20 years of experience in medical technology in both operating and investing roles. He previously worked for Foundation Medical Partners as an entrepreneur-in-residence and as a healthcare portfolio manager for Black River Asset Management LLC. He was also a medical technology equity research analyst for RBC Dain Rauscher Wessels.

*—WE (April 13, 2012)*



*Anulex Technologies, Inc./Xclose and fiXate*

# VertiFlex Ups IP Portfolio by Five

The U.S. Patent and Trademark Office (PTO) has awarded five patents to VertiFlex, Inc. The patents cover the design and implantation method for the company's interspinous spacer technology.

In an April 10 press release, the company stated the five patent numbers are 8,012,207, 8,123,807, 8,123,782, 8,128,662, and 8,152,837. These patents add to the company's previously issued patent 7,763,074 for a total of six. Several additional patents are also currently in review at the patent office.

Earl Fender, VertiFlex's president and CEO, said the patents demonstrate the uniqueness of not only the company's Superion Interspinous Space, but also of the company's minimally invasive approach for spinal access.

"These patents, along with completion of enrollment in the Superion IDE trial, and several recent publications demonstrating the effectiveness of Superion, all provide significant supporting evidence that our Superion ISS is a unique and effective alternative to traditional treatments for spinal stenosis," said Fender.

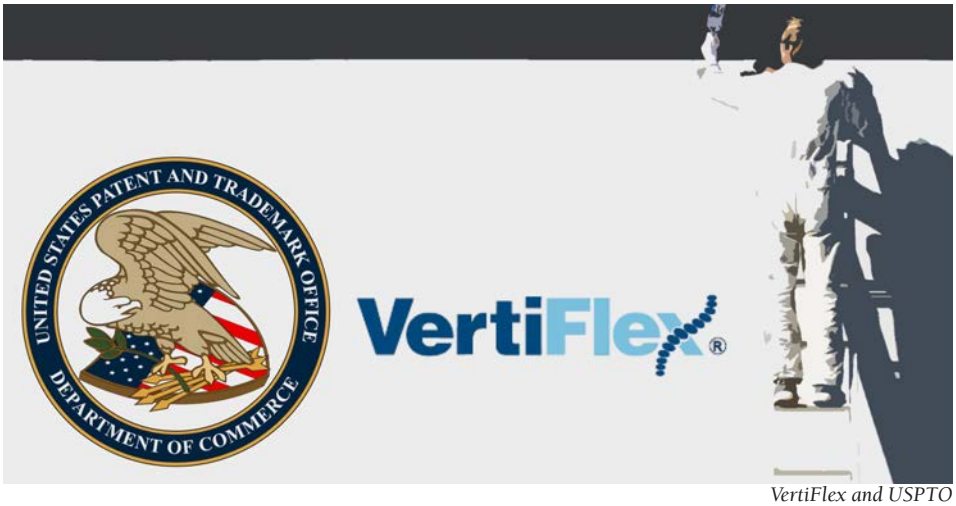
The Superion ISS, according to the company, was designed as an alternative to traditional spinal surgery. The Superion's minimally invasive surgical technique is performed through a single, half-inch skin incision. Once in place, the device is intended to act as a support column to open the passageways that contain the spinal cord and nerve roots. This may reduce the compression on the nerves, resulting in potential pain relief in the leg, groin and buttocks, and the return to a more active lifestyle.

The company says the Superion ISS is the most advanced and least invasive interspinous spacer available and is implanted via a proprietary interspinous access platform. Enrollment was completed in the Superion pivotal IDE trial with 470 patients in December, 2011.

VertiFlex, founded in 2005, is a privately held company in San Clemente, California.

*—WE (April 11, 2012)*





*VertiFlex and USPTO*

biologics

## Steer-Wrestler Opts for Stem-Cell Treatment

Calgary's two-time world champion steer wrestler, Lee Graves, has joined the ranks of NFL players in seeking stem-cell treatment for a broken ankle. Graves had surgery in January to remove the hardware that had been used to repair his right ankle after he broke it winning at the Stampede in 2010

*Wikimedia Commons and Arthur Moraltidis*

Graves recently had his ankle injected with stem cell bearing plasma at a clinic in Denver. "My ankle already feels better," he said, announcing plans to fly to the Cayman Islands where doctors will draw some of his bone marrow, harvest the stem cells and then inject them back into his ankle. Graves is quoted in an April 5 article by Dway Ne Erickson, for the *Calgary Herald*.

Graves explained, "They can only put 500,000 stem cells in you at Denver, but they can inject 20 million on the Cayman Islands. That sounds like a lot of volume, but 20 million stem cells are so concentrated, it amounts to half a cc in a syringe."

Graves anticipates that more treatments will be called for. He said that if a second injection of more mature stem cells from the remaining bone marrow is required, it could be done at the Caymans in June, if the ankle is still giving him problems, or in the off-season if it is not. "A lot of National Football League players, and Olympic athletes as well, get the one-day procedure done so they can play the rest of the season and come back in the off-season to get the more mature stem cells," Graves pointed out.

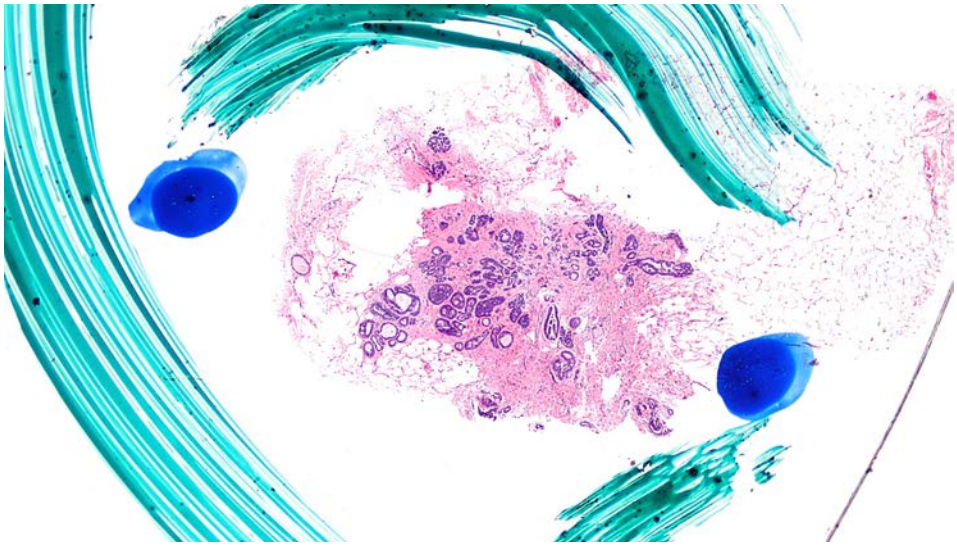
The Calgary Stampede has invited Graves back to his hometown rodeo and has included him on the list of cowboys who will make up the roster for the Centennial rodeo July 6-15.

*—BY (April 12, 2012)*

## Alabama Doc Treats Athletes With Stem Cells

An Alabama physician, Jason Williams, M.D., at Precision Stem-Cell of Gulf Shores, Alabama, has been treating a procession of football players and other athletes with image-guided stem cell therapy, according to an April 3 report in *PR Newswire*. Among his patients has been Oakland Raiders linebacker Rolando McClain.

Bob Hubbard, former University of Alabama assistant basketball coach, saw



*Wikimedia Commons and Nephron*

Williams for the arthritis in his knees. After just one image-guided stem cell therapy treatment, Hubbard reported that he was pain-free for the first time in years. Hubbard had both knees treated in one procedure, and, he says, "My knees have not hurt since the day of the procedure. I have been working out and lifting weights without pain." Williams says that Hubbard's MRI, taken two weeks following the procedure, showed significant cartilage growth.

"Stem cell therapy has had some controversy, but its time has come," said Williams. Stem cell therapy does not have direct approval from the FDA, but the agency allows it if the stem cells are harvested from the patient and re-administered during the same procedure without being significantly altered.

"Harvesting stem cells from the patient's own fat eliminates the need to culture the cells, as is done in some facilities outside the United States," explained Williams. He collects the patient's fat using minimally invasive liposuction. Inside the sterile collection container, he processes the fat to separate and harvest the stem cells, which do not leave the container until he injects them back into the patient. Williams says that he injects them the same day under computed tomography and magnetic resonance imaging guidance.

Williams believes stem cells must be injected into the exact location of an injury in order to function properly and that his method's precision allows him to deliver significantly better outcomes for his patients than they could expect elsewhere.

*—BY (April 9, 2012)*

large joints

## Bupivicaine Tops Opioids for TKA Pain

Pain matters to patients undergoing a total knee arthroplasty. So what are the most effective means for pain management? Researchers at the Rothman Institute at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania, found that intra-articular catheters filled with bupivicaine worked better than did traditional opioids for these patients.

The investigators studied 150 patients who underwent unilateral total knee arthroplasty. They randomized the patients to receive either an intra-articular catheter that continuously delivered 0.5% bupivicaine or else a placebo solution of 0.9% saline for two postoperative days. The patients filled out Visual Analog Scale questionnaires at 5 PM on the day of their surgery, at 8 AM and 5 PM every postoperative day until their discharge. They filled out a final questionnaire at their four-week follow-up.

As reported in April 5 the press release, patients who received bupivicaine had the least pain and lowest narcotics consumption. The researchers found no significant difference between the groups in terms of postoperative complications. "The study opens up a potential new option for better pain management post-surgery for our knee replacement patients," said Nittin Goyal, M.D., one of the study authors.

The level 1 study was presented at the American Academy of Orthopaedic Surgeons 2012 Annual Meeting, where it won the Knee Society Award for best work on a surgical technique.

*—BY (April 12, 2012)*


*The Morquefile and Darren Hester*

trauma

## Osteoporosis Drugs Damaging Eyes?

In some eye-opening new research, a team from the University of British Columbia has found that common osteoporosis drugs may increase the risk of serious inflammatory eye disease in first-time users. The work, published in the *Canadian Medical Association Journal*, shows how important it is for patients taking these medications to be aware of symptoms for these eye conditions so that they can seek treatment.

Given the sparse literature on this topic, researchers from the Child and Family Research Institute and the University of British Columbia, Vancouver, BC decided to examine and quantify the risk associated with uveitis or scleritis and oral bisphosphonates. They included 934,147 people in British Columbia who had visited an ophthalmologist between 2000 and 2007. Of the total, 10,827 were first-time users of bisphosphonates and 923,320 were nonusers.

The researchers found that the incidence rate for uveitis in first-time users was 29/10,000 person-years and 63/10,000 person-years for scleritis compared with 20/10,000 person-years for uveitis and 63/10,000 for scleritis in nonusers.

"We found that first-time users of bisphosphonates are at an increased risk of scleritis and uveitis," writes Dr. Mahyar Etminan in the April 3, 2012 news release. Dr. Etminan is with Therapeutic Evaluative Unit, the Child and Family Research Institute and the Department of Medicine, University of British Columbia.

"The risk of inflammatory ocular adverse events, including scleritis and uveitis, is not highlighted in most package inserts included with oral bisphosphonates," the authors conclude. "Our study highlights the need for clinicians to inform their patients about the signs and symptoms of scleritis and uveitis, so that prompt treatment may be sought and further complications averted."

Asked what signs and symptoms orthopedic surgeons should know about, Dr. Etminan told *OTW*, "The main signs are intense pain, redness around the iris, blurred or decreased vision. I would say that especially for new users of the drugs, if they experience the above signs and symptoms they should see an ophthalmologist ASAP."

*—EH (April 13, 2012)*

*Wikimedia Commons and Sugar Pond, Brooklyn*

spine

## Expanding Orthopedics: New Patent for VCF Device

An Israeli company—Expanding Orthopedics—has announced that the United States Patent and Trademark Office has granted a patent for its novel expandable device for the treatment of vertebral compression fractures (VCF), based on the company's expanding platform technology.

Dr. Mark Levy, an orthopedic surgeon and founder of Expanding Orthopedics, explained in the April 3, 2012 news release that the "versatility of the system will enable the surgeons an increased flexibility with different treatment options." According to the company, the device is expected to offer numerous advantages over current devices and techniques with its multi-dimensional expansion, by enabling a

*Wikimedia Commons and James Heilman, M.D.*

unilateral, minimal invasive approach as well as anatomical fit for better load support and height maintenance.

Mr. Ofer Bokobza, CEO, commented, "We are very pleased by this new addition to our extensive IP portfolio. We are committed to drive innovation in this space and our strong patent portfolio of 11 granted U.S. patents so far and many others in the queue, underscores our vision and leadership in the space of expanding devices technology. We are developing our product pipeline and with this new device technology planning to launch multiple products in the near future following our success with the launch of the XPED Expanding Pedicle Screw System into the European market last year."

Dr. Levy told *OTW*, "The challenge of designing a new device involved delivering the desired height of the device for correction of the VCF during a minimal invasive surgery, while keeping the concept simple and at low cost, but effective."

*—EH (April 11, 2012)*

## $4 Treatment Lowers Infection Rates

Robert Molinari, M.D., associate professor of orthopedics at the University of Rochester Medical Center (URMC), believes he has found a safe, cost effective way to lower post-operative infection rates. He scatters a gram of powdered antibiotic (vancomycin) directly into the spinal surgery wound, a procedure he initiated while deployed as a U.S. Army surgeon working in less-than-sterile environments.

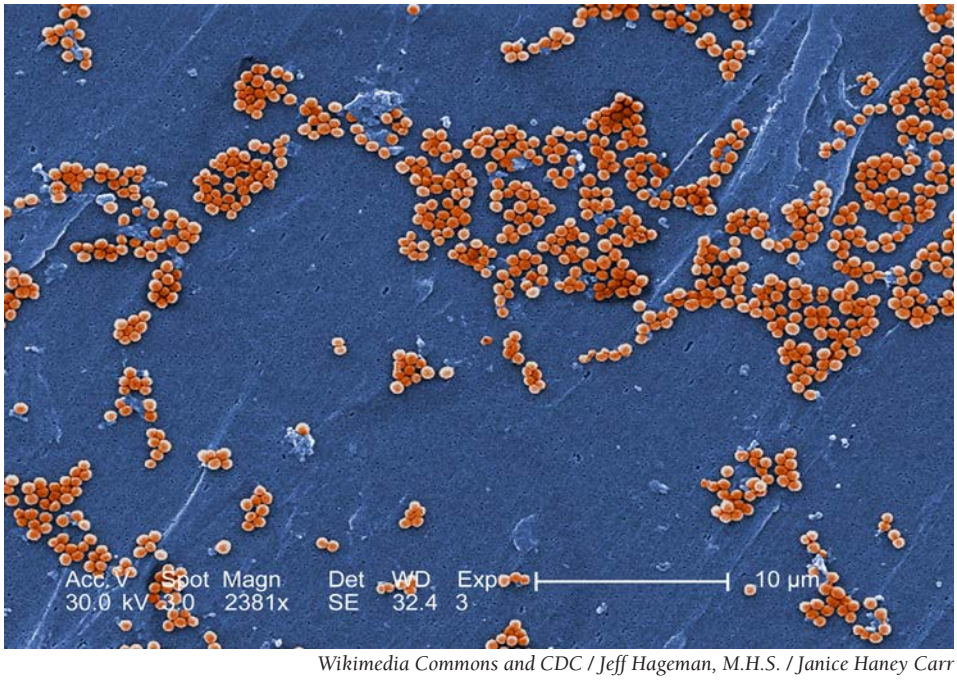
"My theory was that sprinkling powdered antibiotics directly into the wound might provide the highest concentration of medicine where it was needed most," Molinari said in an April 2 press release. "And what I noticed was that my infections rates from that time period were low."

When Molinari's deployment ended in 2003, he began using the same technique at URMC in his most complex cases, with patients most prone to infection due to severe spinal trauma or cancer. He used a dusting of vancomycin ***in addition*** to intravenous antibiotics prior to surgery. When colleagues reviewed the data from Molinari's 1,512 consecutive cases from 2005 through 2010 they found a general infection rate of only 0.99%, equal to 15 patients or one in 100. That compared to a national, general infection average of approximately 2.1% among 108,419 patients in the national database of the Scoliosis Research Society.

Infection after spinal surgery is a dreaded complication that can occur in up to 20% of all cases and is associated with significant long-term illness or death. "Our infection rate is not zero percent—which would be ideal—but no matter how you look at it our rates are below the national averages," Molinari said.

He also noted that a gram of vancomycin costs only about $4.27. He chose this particular antibiotic, he said, because of its relatively low hospital cost, the ease of use in powdered form, and its broad and effective coverage against organisms that infect the spine. "We think we're on to something and our study has been well received by the orthopaedics' community," Molinari said. "The next step would be a large, case-controlled trial—and already several institutions across the country have expressed interest."

*—BY (April 11, 2012)*

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