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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: Probably the most important development of 2013 is MicroPort Scientific emerging as a prospective player in orthopedics. This China based firm became the largest domestic manufacturer of sophisticated medical devices in China—overcoming a long time bias for U.S. brands. They did it with quality and innovation. And now they're planning to enter the U.S. Market.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	6	Wright Medical Group	6.84%	8.17%	Transformative deal announced with MicroPort. If successful, makes WMGI THE major biologics firm in ortho.
2	1	Medtronic	28.65	(0.58)	One year ago, MDT was nearly the cheapest stock in the Power Rankings. Today it is closing in on a 52-week high.
3	2	Stryker	23.68	(3.79)	At the mid-year mark, SYK shareholders have seen the value of their shares rise 19.7%. Not bad for a single-digit revenue growth company.
4	7	Globus Medical	29.00	12.93	Earnings season is on the way. GMED's report is always interesting and usually beats expectations. Up 3 places.
5	5	Orthofix	19.68	2.71	New CEO Brad Mason is making important changes. Realigns units, splits spine. Won't see effects for a while, though.
6	8	NuVasive	7.53	13.09	Famed Wall Street analyst Bill Plovanic raises price target nearly 20%. We'll follow suit and move NUVA up 2 spots.
7	3	Zimmer	29.49	(5.15)	Today's key word is strategy. If not also China. When will ZMH join the party? WMGI, SYK and MDT are already there.
8	10	Johnson & Johnson	25.58	0.25	As a "Dog of the Dow", JNJ has acted like a Greyhound. Up 22% this year. Plus there is that 3.10% dividend.
9	9	Alphatec	(4.29)	4.06	ATEC keeps bumping against the $2.00 per share ceiling. New buyers need to clear out the sellers.
10	4	Integra LifeSciences	12.44	(1.48)	For a while it looked like IART was rebounding—but then investors decided to sell into the bounce.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$2.40	$108	29.03%
2	NuVasive	NUVA	$24.79	$1,096	13.09%
3	Globus Medical	GMED	$16.86	$1,552	12.93%
4	Exactech	EXAC	$19.75	$265	8.70%
5	Wright Medical	WMGI	$26.21	$1,224	8.17%
6	Tornier N.V.	TRNX	$17.50	$812	5.36%
7	Alphatec Holdings	ATEC	$2.05	$198	4.06%
8	Orthofix	OFIX	$26.90	$523	2.71%
9	ArthroCare	ARTC	$34.53	$974	2.04%
10	Johnson & Johnson	JNJ	$85.86	$241,171	0.25%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$0.45	$19	-29.69%
2	Symmetry Medical	SMA	$8.42	$314	-12.20%
3	TiGenix	TIG.BR	$0.83	$83	-9.38%
4	RTI Biologics Inc	RTIX	$3.76	$212	-6.23%
5	Conmed	CNMD	$31.24	$877	-6.10%
6	Zimmer Holdings	ZMH	$74.94	$12,617	-5.15%
7	Smith & Nephew	SNN	$56.09	$10,111	-3.87%
8	Stryker	SYK	$64.68	$24,392	-3.79%
9	MAKO Surgical	MAKO	$12.05	$566	-2.59%
10	Integra LifeSciences	IART	$36.63	$1,028	-1.48%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$26.90	$523	10.47
2	Zimmer Holdings	ZMH	$74.94	$12,617	12.06
3	Medtronic	MDT	$51.47	$51,852	13.84
4	Smith & Nephew	SNN	$56.09	$10,111	13.87
5	Globus Medical	GMED	$16.86	$1,552	14.77

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$26.21	$1,224	113.96
2	NuVasive	NUVA	$24.79	$1,096	65.24
3	Symmetry Medical	SMA	$8.42	$314	29.03
4	ArthroCare	ARTC	$34.53	$974	22.42
5	RTI Biologics Inc	RTIX	$3.76	$212	22.12

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$16.86	$1,552	0.98
2	Conmed	CNMD	$31.24	$877	1.29
3	Zimmer Holdings	ZMH	$74.94	$12,617	1.29
4	Exactech	EXAC	$19.75	$265	1.41
5	RTI Biologics Inc	RTIX	$3.76	$212	1.47

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$26.21	$1,224	10.68
2	NuVasive	NUVA	$24.79	$1,096	5.58
3	CryoLife	CRY	$6.26	$172	4.35
4	Johnson & Johnson	JNJ	$85.86	$241,171	2.80
5	Symmetry Medical	SMA	$8.42	$314	2.42

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.45	$19	0.57
2	Symmetry Medical	SMA	$8.42	$314	0.76
3	Alphatec Holdings	ATEC	$2.05	$198	1.01
4	Orthofix	OFIX	$26.90	$523	1.13
5	Conmed	CNMD	$31.24	$877	1.14

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$7.06	$677	25.04
2	TiGenix	TIG.BR	$0.83	$83	20.44
3	Baxano Surgical Inc	BAXS	$2.40	$108	7.44
4	MAKO Surgical	MAKO	$12.05	$566	5.51
5	Globus Medical	GMED	$16.86	$1,552	4.02

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 North America

BY OTW STAFF

Who do spine surgeons want to see when they or a loved one need treatment? Find out here. We asked leading spine surgeons to select the best of their peers.

Here is that list. It isn't the be-all and end-all list—but ***a*** *list of 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.*

Image created by RRY Publications, LLC / Photography by Andrew Huth

Todd J. Albert, M.D. is the Richard H. Rothman Professor and Chairman of the Department of Orthopaedic Surgery at Thomas Jefferson University in Philadelphia. He is also president of the Rothman Institute and serves as Co-Director of Reconstructive Spine Surgery and the Spine Fellowship Program at Thomas Jefferson University Hospitals. He is past president of The Cervical Spine Research Society (CSRS). "He is a go-to spine surgeon for any kind of procedure. He is also an outstanding leader and talented researcher."

Howard S. An, M.D. is an orthopedic surgeon with Midwest Orthopaedics at Rush in Chicago. Dr. An is the Morton International Endowed Chair, Director of Spine Surgery and Director of the Spine Fellowship Program at Rush University Medical Center. He is a past president of the International Society for the Study of the Lumbar Spine. "He has made great advances in cell biology and has been a real leader in trying to understand the basic science behind a lot of the common spine problems."

Sigurd H. Berven, M.D. is associate professor in Residence in the Department of Orthopaedic Surgery at the University of California, San Francisco. "He is a true health outcomes guru who is always thinking of cost effectiveness. He is an 'outside-the-box' thinker, and is an exceptionally nice guy."

Mark H. Bilsky, M.D. is a neurosurgeon with Memorial Sloan-Kettering in New York City. He is also Director of Memorial Sloan-Kettering multi-disciplinary spine tumor team. "He is an exceptional tumor surgeon who has developed novel techniques for complex surgeries. He really thinks about the entire patient and is very knowledgeable about both operative and nonoperative care."

Christopher M. Bono, M.D. is Chief of Spine at Brigham and Women's Hospital and assistant professor in the Department of Orthopedic Surgery at Harvard Medical School. "He is a leader in the politics of spine surgery, and is helping to define the future of spine by working with the government and other relevant parties."

Keith H. Bridwell, M.D. is the J. Albert Key Distinguished Professor of Orthopaedic Surgery at Washington University School of Medicine, and he is Chief of Pediatric and Adult Spinal Surgery in the Orthopaedic Department at Washington University in St. Louis. He is a former president of the Scoliosis Research Society. "He is a great surgeon, teacher, and researcher who has done groundbreaking work on the surgical management of spinal deformities."

Bradford L. Currier, M.D. is Professor of Orthopedics at Mayo Clinic in Minnesota. He is President of the Lumbar Spine Research Society (LSRS) and past president of The Cervical Spine Research Society. "He has made many strong contributions to the literature and has trained numerous prominent spine

surgeons. He is exceptional at taking someone through difficult cases, working at their level, and having them improve throughout the year. He is extremely ethical and very well respected."

Jason Eck, D.O. is an orthopedic spine surgeon with the Center for Sports Medicine and Orthopedics in Chattanooga, Tennessee. "He has written a series of seminal textbooks on spine surgery, and is consistently contributing to the field via his research."

Michael G. Fehlings, M.D., F.A.C.S., F.R.C.S.C., Ph.D. is a professor of neurosurgery at the University of Toronto, and is the Gerald and Tootsie Halbert in Neural Repair & Regeneration at the Toronto Western Hospital in Ontario. Dr. Fehlings is a past president of the CSRS. "He is a top-notch researcher, as well as an excellent clinician. He has done a great deal of pioneering work in spinal cord injury."

Charles G. Fisher, M.D. is a surgeon at the Combined Neurosurgical and Orthopedic Spine Program at Vancouver General Hospital, University of British Columbia. "He is a great role model who has a great deal of common sense, as well as a sense of how to balance industry relationships and science. He is a thought leader in epidemiology and spine."

Jeffrey S. Fischgrund, M.D. is Professor of Orthopaedic Surgery at Oakland University, William Beaumont School of Medicine in Rochester, Michigan. He is also Fellowship Director of Spinal Surgery at William Beaumont Hospital in Royal Oak, Michigan. Dr. Fischgrund is currently editor-in-chief of the *Journal of the American Academy of Orthopaedic Surgeons*. He is president-elect of the LSRS. "He is a well known authority in spine, especially when it comes to degenerative lumbar conditions."

Steven Garfin, M.D. is Chair of the Department of Orthopaedic Surgery at the University of California, San Diego; he is also Chief of the UC San Diego Spine Program. "He is a brilliant mentor, a fearless surgeon, and is indefatigable… nobody outworks Garfin. He is probably best known for his work in spine trauma and revision spine surgery."

Ziya L. Gokaslan, M.D. is professor of Neurosurgery, Orthopedic Surgery and Oncology at Johns Hopkins; he is the Donlin M. Long Professor of Neurosurgery. He is also director of that institution's spine center. "He is known for his tumor work and for complex reconstructions. He knows the importance of working with a team to reconstruct major segments of the spine, and has developed new ideas for these segmental problems. He has a meticulous surgical technique."

James S. Harrop, M.D., F.A.C.S. is professor of Neurosurgery and Division Director for Adult Reconstructive Spine at Thomas Jefferson University in Philadelphia. "He is one of the most thoughtful cervical spine and trauma surgeons in the United States. He is a technical expert, is editor of Congress of Neurological Surgeons quarterly, and his opinion is extremely well respected."

John G. Heller, M.D. is the Baur Professor of Orthopedic Surgery and spine fellowship director at Emory University. He is the past-president of the Cervical Spine Research Society. "He is one of the first surgeons in the country to perform laminoplasty; he championed this operation and it has steadily gained in popularity. He is an excellent spine surgeon and a mentor to many young surgeons."

Harry N. Herkowitz, M.D. (deceased June 2013) was Chairman of Department of Orthopaedic Surgery at William Beaumont Hospital and professor at Oakland University, William Beaumont School of Medicine. He was a director of the American Board of Orthopaedic Surgery. "Dr. Herkowitz was clearly one of our 'greats.' He was a visionary leader, and was named president of many of our spine organizations. His devotion to the field was enormous, and his high standards for orthopedic education and training were a hallmark of his career."

Serena Hu, M.D. is the David S. Bradford Endowed Professor and Vice Chair of Orthopedic Surgery at the University of California, San Francisco (UCSF). She is also co-director of the UCSF Spine Center. "She is a top female spine surgeon, and is very talented with handling deformity surgery. She is also known for being a great teacher and communicator."

Lawrence J. Lenke, M.D. is the Jerome J. Gilden Distinguished Professor of Orthopaedic Surgery and professor of Neurological Surgery at Washington University School of Medicine in Saint

Louis, Missouri. He is also Chief of Spinal Surgery, Director of the Complex Spinal Deformity Institute and Fellowship at that institution. Dr. Lenke is a past president of the Scoliosis Research Society. "He is renowned for his work with patients who have severe spinal deformities. He pays extra attention to the issue of maintaining safety with respect to neurologic issues. He is detailed oriented, an honest reporter of his data, and is exceptionally hardworking."

Frank M. Phillips, M.D. is professor of Orthopaedic Surgery and co-director of the Spine Fellowship at Rush University Medical Center. He is also Rush University Medical Center Head of the Section of Minimally Invasive Spine Surgery. Dr. Phillips is past president of the Society of Minimally Invasive Spine Surgery. "What a great MIS surgeon. He has done superb clinical and biomechanical research, and is a wonderful teacher and innovator."

John M. Rhee, M.D. is associate professor of Orthopaedics at Emory. "He has done a lot of work in cervical spine disorders and is a wonderful surgeon. He is a terrific lecturer who puts a lot of effort into explaining things (and he doesn't just recycle old talks)."

Laurence D. Rhines, M.D. is professor in the Department of Neurosurgery and director of the Spine Program at The University of Texas MD Anderson Cancer Center in Houston. He is also adjunct professor in the Department of Neurosurgery at Baylor College of Medicine. "He has great judgment, and knows how to make complicated concepts straightforward. He is one of the few people in the U.S. that does En bloc spondylectomy from a posterior approach."

K. Daniel Riew, M.D. is the Mildred B. Simon Professor of Orthopedic Surgery, is a professor of neurological surgery, the Chief of the Surgical Spine Center and Director of the Cervical Spine Institute. "He is an outstanding surgeon, teacher, and researcher. He is a leader in the cervical spine world, has done great research in this area, and has great vision."

Rick C. Sasso, M.D. is a founding member, and the president of Indiana Spine Group. He is also clinical associate professor and Chief of Spine Surgery at the Indiana University School of Medicine, Department of Orthopaedic Surgery. "He is a seminal researcher in cervical spine injuries. His innovations in arthroplasty have moved our field forward. In addition, he is a talented teacher."

James D. Schwender, M.D. is an orthopedic surgeon with the Twin Cities Spine Center in Minneapolis,

Minnesota. He is a past president of the Society for Minimally Invasive Spine Surgery. "He is quite an innovator in the realm of minimally invasive techniques. Technically, he is excellent and has great clinical judgment; he is also a gifted teacher."

Christopher I. Shaffrey, M.D. is the Harrison Distinguished Professor of Neurological and Orthopaedic Surgery at the University of Virginia. He is also director of the Spine Division at that institution. "He is double boarded as an orthopedic surgeon and a neurosurgeon. This gives him rare insight into the structural mechanics of bone and bone biology *and* into neuroanatomy and neurostructures. He is the go-to-guy on the East Coast, and is real innovator."

Daniel J. Sucato, M.D., M.S. is Chief of Staff at Texas Scottish Rite Hospital for Children and associate professor in the Department of Orthopaedic Surgery at The University of Texas Southwestern Medical Center at Dallas. He is also director of the Sarah M. and Charles E. Seay/Martha and Pat Beard Center for Excellence in Spine Research. "He is a great pediatric deformity surgeon who has developed new procedures for scoliosis treatment."

Alexander R. Vaccaro, M.D., Ph.D. is a spine surgeon with the Rothman Institute in Philadelphia. He is also vice chairman of the Department of Orthopaedics at Thomas Jefferson University. He also serves as co-director of Reconstruction Spine Services at the Rothman Institute and as co-director of the Spine Fellowship at Thomas Jefferson University. Dr. Vaccaro is president of The Association for Collaborative Spine Research. "You won't find a better spine surgeon around. He is meticulous and thoughtful, and consistently expands the field with his research."

Thomas A. Zdeblick, M.D. is professor and chair at the University of Wisconsin Department of Orthopedics and Rehabilitation, and director of the University of Wisconsin Spine Center. He is past president of the LSRS and the CSRS. "He is best known for anterior lumbar interbody fusion and anterior spinal column reconstruction. He is particularly innovative with regard to spinal fixation products (his background in mechanical engineering comes into play here). He is creative, thoughtful, meticulous, and has a high degree of emotional intelligence." ♦

Time for a Change

BY ROBIN YOUNG

CARRAGEE MUST RESIGN

RRY Publications LLC

There are the duties and responsibilities which all physicians have to uphold the canons of their profession. There are then the obligations of those on whom we rely for impartial interpretation and analysis of clinical and scientific evidence.

It has become increasingly clear that *The Spine Journal* Editor-in-Chief, Dr. Eugene Carragee, has abandoned even the pretense of impartiality.

Dr. Eugene Carragee needs to step aside. If he doesn't, the publisher (Elsevier) and the board of trustees for the North American Spine Society (NASS) need to meet and review Dr. Carragee's research and public comments regarding BMP-2, Infuse, Medtronic and all of the clinical researchers who've been attacked by him in both press release form and in the pages of *The Spine Journal*.

As for *The Spine Journal*, the peer review publication of the North American Spine Society which has been the standard for excellence in clinical and scientific spine research since 2001, it must act immediately. Dr. Carragee's failure to maintain impartiality and good judgment have clearly damaged this outstanding journal.

This is not about BMP-2 or Infuse or Medtronic. This is about scientific impartiality, avoidance of hyperbole in pursuit of clinical accuracy and navigating the often conflicting opinions of passionate clinicians. In short, it is about mature scientific leadership. Our peer review journal editors must be paragons of clinical and scientific judgment.

It is impossible not to cringe when reading the following hyperbolic public statements from the Editor-in-Chief of *The Spine Journal*:

- "The YODA (Yale University Open Data Access Project) report published today in the *Annals of Internal Medicine* is the latest shock in a series of re-examinations of Medtronic's ill-fated biologics product."
- "Ten years after BMP-2's introduction, we cannot identify a single well-proven area of benefit, but we know it can kill you in the cervical spine and probably can promote cancer, which can then kill you."

- "The hyperbolic fever of BMP-2 promotion before its current fall from grace turned spinal conferences into Elmer Gantry-styled revival meetings."
- "Many of us feel like 10-year-olds after the Black Sox series: "Say it ain't so, Joe."
- "BMP-2's fifteen minutes of fame had ticked by. The cost: maybe 15 billion dollars, maybe cancer, maybe worse."
- "In the end, less than one percent of the 250 participants voted for the old dream…people seemed kind of bored. Older guys thought of the Black Sox, groaned as they got up. Young guys glanced at the time (how confident the reps had seemed). But their attentions had moved away from the carnival hoopla of yesteryear. In the end, people yawned and some chuckled to themselves and… finally…left the room."

Though Carragee is the Editor-in-Chief of *The Spine Journal*, he is also the lead attacker against BMP-2, Medtronic and in that role is an advocate for a particular point of view.

When Carragee appoints himself lead author of BMP-2 studies which subsequently appear in *The Spine Journal* during his tenure as Editor-in-Chief and when, in those same articles, he excludes data which contradicts his pet thesis, uses faulty analysis to arrive at conclusions consistent with his anti-BMP-2 campaign, and accuses researchers of financial bias where none, in fact, exists then everyone should be alarmed.

Dr. Carragee's colleagues will ultimately determine whether his campaign against BMP-2, Medtronic and those researchers who participated in BMP studies has merit. But the pages of *The Spine Journal* and the press office of the North American Spine Society are no place for the kind of hyperbolic advocacy he engages in.

The Yale review of all of Medtronic's patient level BMP-2 data stands in stark contrast to Dr. Carragee's handling of the BMP-2 research and researchers in both the pages of *The Spine Journal* and in press releases issued by NASS.

According to Carragee, for example: "the risk of adverse events [from using BMP-2] is 10 to 50 times higher than reported in trial publications".

10x to 50x higher. The YODA study authors (the York analysis, Simmonds et al.) checked that claim. Here is their conclusion: "Our review differs from the existing review (*the authors then cited the Carragee comments of 10x-50x*)" and that after reviewing all of the data, the difference between the adverse events reported in the trial publications and actual adverse events was minimal.

Quoting from page 883 of the York analysis, the results of their analysis for adverse events was inconclusive and "The only clear evidence of a difference was for pain at or shortly after surgery, which was more common in the rhBMP-2 recipients (odds ratio, 1.78)."

Not exactly 10x-50x. Not even 2x.

That's a mis-measurement of a scale that, for the Editor-in-Chief of *The Spine Journal*, approaches scientific malpractice.

An Editor-in-Chief of a premier peer review journal who lacks balance, judgment and ultimately authority has nothing.

Elsevier and NASS have an obvious decision to make but a difficult process to go through. Carragee won't likely let these two venerable organizations off the hook. He should do the right thing but is probably too caught up in his own advocacy to see the situation he has created.

He has spoken eloquently in the past about eliminating bias from clinical research. Therefore some people will argue that Dr. Carragee should be allowed to finish out his multi-year contract as *The Spine Journal*'s editor.

Given Dr. Carragee's now open partisanship and documented lapses with regard to his own BMP-2 research, we don't agree.

If Elsevier or NASS will, as we recommend, review Dr. Carragee's statements and invite those former BMP-2 researchers whom he has accused of being bought and paid for by Medtronic to present their side of the story, we are confident that the arguments on behalf of Carragee as Editor-in-Chief of *The Spine Journal* will collapse in their entirety.

After reviewing all of Dr. Carragee's press releases as well as published research in the same journal for which he is editor, we believe there is only one conclusion: Dr. Eugene Carragee must resign his position as Editor-in-Chief of *The Spine Journal*.

Robin R. Young, Publisher
Orthopedics This Week
Wayne, PA
June 25, 2013
♦

Chinese Firm Bids for a Share of U.S. Orthopedics

BY ROBIN YOUNG

MicroPort Scientific Corporation

In 2005, a Beijing-based company formerly known as "Legend" acquired IBM's venerable line of PC computers. At the time, Legend was a 21-year-old manufacturer of PC components like the famous Han-card which allowed PCs to efficiently process Chinese characters. Legend was public on the Hong Kong exchange, having raised $30 million in an IPO in 1994 and then an additional $212 million in 2000.

In 2005, Legend stunned the computer world by successfully acquiring IBM's PC line of computers. The U.S. Congress criticized the deal—as it had in years earlier criticized (and blocked) CNOOC's attempt to purchase Unocal or Chinese appliance maker Haier Group's bid to buy Maytag.

Legend, which had changed its name to Lenovo, was ultimately successful where other Chinese firms had failed and paid $1.2 billion to buy IBM's computer business including the trade name ThinkPad.

Why did Lenovo succeed? Part of the reason is that the PC was becoming an increasingly commoditized product and therefore didn't represent the loss of critical intellectual capital. Also Lenovo agreed to maintain IBM's North Carolina assembly plant which diffused the argument that jobs would be leaving the U.S. for China.

In retrospect, the Lenovo purchase of IBM's PC business has been an unqualified success for consumers, IBM, the employees in North Carolina who assembled ThinkPads and the company formerly known as Legend.

Lenovo is now third largest computer maker in the world by volume and, as a brand name, is synonymous with superior quality and innovation. Who remembers the IBM PC brand? Who cares?

Who Is MicroPort Scientific and Why Are They Buying Wright's Recon Business?

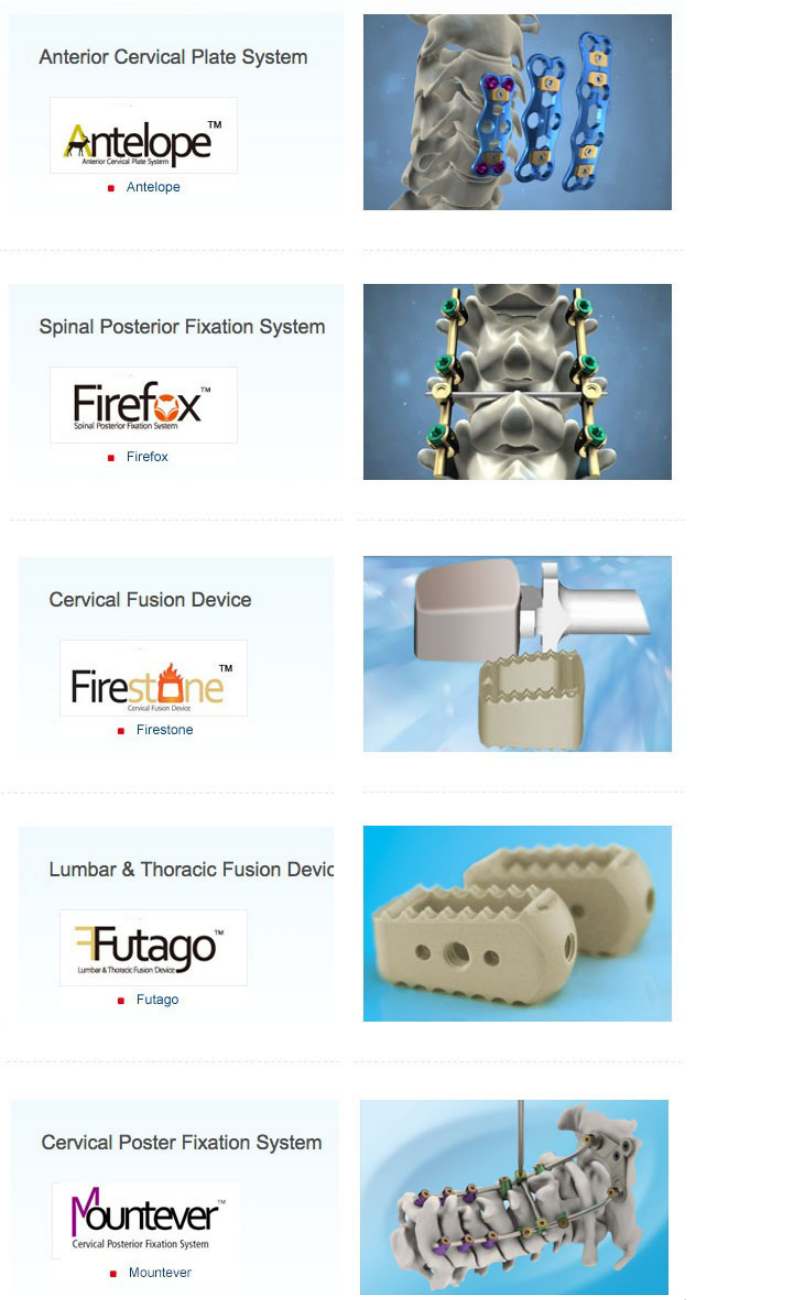
Last week (June 19), Wright Medical Group, Inc. announced that a Chinese firm named MicroPort Scientific Corporation had bid $290 million to purchase its hip and knee implant business. In 2012 Wright's sales of hip and knee implants were $269 million. The brands are DYNASTY and CONSERVE hip implants, PROFEMUR modular stems, SUPERPATH minimally invasive hip surgical instrumentation and ADVANCE and EVOLUTION medial-pivot knee implants.

Considering that global hip and knee recon market is about $14 billion, MicroPort's bid gets them just 2% share of the global market. But MicroPort has zero share of the Chinese hip or knee recon market so these brands should attract, at a minimum, an equivalent share of the $1.3 billion Chinese recon market for another $30+ million bringing the total business size, prospectively, to $300 million.

From all appearances, MicroPort is tracking the Legend/Lenovo play book.

Like Lenovo before it, MicroPort has literally no brand equity outside of China. Furthermore, it's buying a well known, though declining and increasingly commoditized product platform but with very good manufacturing facilities deep in the U.S.

Could MicroPort confound conventional wisdom and become as well known and respected in its target mar-



MicroPort Scientific Corporation

ket (orthopedics) as Lenovo did in computers?

We think that could absolutely happen—because, like Legend/Lenovo, MicroPort is employing quality and innovation (not cheap manufacturing) as tactics to reach market leadership and has, courtesy of the Hong Kong Stock Exchange and Chinese medical community (now among the largest in the world) the wherewithal and scale to make it happen.

The MicroPort Story

In 1995 a vice president of R&D named Zhaohua Chang for Atlanta-based Cryomedical Sciences Inc. (which sold to Endocare Inc. in 2002) attended a business development conference in Shanghai. Dr. Chang, who'd been raised in China and earned a master's degree in cryogenics in China (his Ph.D. degree in biological science is from the State University of New York), realized that China was changing rapidly and that the market for a Chinese-based medical device company was forming.

In 1998 this scientist, author of more than 40 peer-reviewed articles and holder, at the time, of five patents, founded MicroPort Scientific. His first products were minimally invasive surgery (MIS) devices for cardiac catheterization and stent implantation. At the time, only 3,000 patients in China had had coronary stents implanted (vs. 700,000 in the U.S.).

In 1999, with strong Chinese government support, the new MicroPort company launched a balloon dilation catheter. The company would not turn a profit until 2002—but Chinese hospitals began to learn that MicroPort was capable of supplying high quality and reliable implants and instruments. Before then, Chinese hospitals were nearly 100% dependent on imported cardiac instruments and implants.

In 2003, MicroPort received a license to sell its coronary products in Japan—which was a major milestone for the company since it meant that its products were of sufficient quality to compete in the very demanding international markets.

Also in 2003, MicroPort introduced the first Chinese produced drug-eluting stent (DES). Chinese physicians were openly skeptical that a domestically produced implant could match JNJ's or Medtronic, Inc.'s or Boston Scientific Corporation's quality. Very few physicians were willing to use such a technically complex and advanced domestic

product. So MicroPort made clinical studies a particular focus. The resulting clinical data demonstrated the quality of MicroPort's DES. MicroPort was one of the first Chinese medical device companies to overcome the country's deep rooted prejudice against domestically produced complex implants.

In 2010, in order to fund its expansion into markets outside of cardiovascular (electrophysiology (EP), diabetes and orthopedics) the company sold $198 million of its stock on the Hong Kong Stock Exchange.

The MicroPort Culture

MicroPort doesn't innovate very many "revolutionary" or "disruptive" products. At MicroPort safety comes first, efficacy second and convenience third.

Having said that, about 20% of MicroPort's employees are in research & development as befits a company whose founder is also a research scientist.

MicroPort tries to represent not only what is best about Chinese culture, but also what is unique. As one manager at MicroPort was quoted as saying in an interview about his company (Source: Online Business School Case by Professor Zhang Wei and Xu Leiping of China Europe International Business School): "Chinese employees are hardworking and have a strong sense of responsibility, but they are also highly sensitive to their work scope and focus on their own job only. The Americans, on the contrary, are ambitious to exceed their own functions and take the other's job once they've finished theirs. Chinese employees are able to endure hardships and are willing to pay additional time and efforts for better results. The Americans, in contrast, put more value on their personal life and seldom work overtime. American engineers are generally more inspirational and creative than the Chinese, but not as careful and detail oriented as the latter."

Sound familiar?

MicroPort's Orthopedics

Currently MicroPort's orthopedic offerings are for spine and trauma indications. Here they are (see image on page 12):

Orthopedic sales last year amounted to about 3.6% of MicroPort's overall 931 million RMB (about $151 million) or about $5.4 million. MicroPort's profits, however, amount to about 38% of sales, which is about $50 million annually. This is a very profitable company.

With a book value of about $377 million, this $290 million purchase is a significant step forward for MicroPort and represents a major commitment to the orthopedic markets.

What Wright Medical's Recon Business Means for MicroPort.

Assuming this purchase bid is successful, MicroPort will be acquiring about $300 million in additional sales (assuming very modest incremental penetration into the Chinese orthopedic markets). It triples MicroPort's sales. And it gives Microport an important beachhead in the North American and European orthopedic markets.

It also provides MicroPort with a high quality production capability in Memphis—the home, incidentally, of Federal Express. Perfect for overnight deliveries to any hospital in North America.

Could MicroPort's prospective Memphis hub become the basis for new cardiovascular, endovascular, neurovascular, diabetes, electrophysiology and, of course, orthopedic devices for North American customers?

According to MicroPort's press release and comments from Wright Medical's analyst call, if all goes well with regulators, due diligence and other issues, the purchase should close before the end of 2013.

Through the course of 2014 MicroPort will be learning about how to do business in the United States using the solid foundation of Wright's recon implants and instruments. MicroPort will also learn about managing a top flight manufacturing plant in Memphis.

In 2013, investors pushed MicroPort's stock price up 93%. They clearly like this company and its emphasis on quality and reliability. In the world medical device markets, MicroPort intends to be, like Legend/Lenovo before it, a market leader. ♦

Domestic Violence in Orthopedics…Surprises in new Clinical Practice Guidelines…Genetics Rising in Clinical Importance

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

One in Six Women With Fracture Are Victims of Domestic Violence Mo Bhandari's colleagues know him as a consummate researcher. What they may not know, however, is that he is tackling an aspect of orthopedics that few have dared to approach—domestic violence. Mohit Bhandari, M.D., professor and research chair in Orthopaedic Surgery at McMaster University in Canada, says that he had a 'Eureka' moment ten years ago during his subspecialty training. "I was working in Minneapolis and we started seeing quite a number of seriously injured women who got that way at the hands of their domestic partners. I began working with a domestic abuse project and a lightbulb came on…'Wait. Women are not being asked about this. This is not on our radar as orthopedic surgeons.' I did a couple of early studies, which culminated in our recently published paper in the *Lancet*…it is the largest multinational study of its kind to date. Alarmingly, we found that one out of every six women who arrive at an orthopedic fracture clinic report domestic violence. Our work is an attempt to get the orthopedic community and major orthopedic associations to take a position and make concrete recommendations on this topic."

Wikimedia Commons and Concha García Hernández

Clearly, Dr. Bhandari chose a hot button issue that many orthopedic surgeons would rather leave to someone else. "Yes, in this male-dominated profession there was initially resistance, largely due to a lack of understanding about how prevalent these injuries are. 'This is a social services issue,' many of my colleagues said. Surgeons are data driven, and so we had to do clinical studies in order to demonstrate the urgency."

"Even after the data 'spoke,' I would hear, 'But I see 100 patients in a short period of time. I don't have the resources to manage this…and what happens if the patient says that she is being abused?' It became clear that orthopedic surgeons must have a pathway for handling these situations. We began connecting domestic violence groups with surgeons, and creating intimate partner violence tools. One poster available to surgeons shows a woman with a broken bone and says, 'Not every broken bone is due to a fall.'"

Dr. Bhandari says, "If a woman comes in with a suspicious injury and is accompanied by a partner, you will need to speak to her privately. Our surveys indicate that if the doctor raises the issue of women feeling safe in their home, a woman might have taken that opportunity to reveal the abuse. And interestingly, two-thirds of women said that an orthopedic surgeon is the doctor who should bring up this topic. An E.R. doctor is not the ideal person because the patient spends so little time with that person."

Knowing his colleagues need specifics on handling these situations, Dr. Bhandari notes, "Once a woman reveals the abuse, then you must reassure them that they need not go back to the unsafe environment and you all will be making a safety plan. Secondly, it is important to reinforce that the abuse is not her fault. Then, you should ensure that she has appropriate referral to services with

expertise in domestic violence. Even if the woman doesn't reveal the abuse until her fourth visit with you, if you are caring and open at every interaction then that person is more likely to think, 'If I am going to tell anyone it will be today, it will be this doctor, and I will be protected.'"

And how is his work being received? "In 2009 the Canadian Orthopaedic Association developed a position statement on intimate partner violence. The American Association of Orthopaedic Surgeons has had an official position on this for years. I think that as a result of this paper it has reenergized the concern about this issue. This should alarm all of us. Escalating physical injuries is the strongest predictor of intimate partner homicide; and when you get to the stage of a broken bone there's not much further to go. This is a call to duty for our profession."

Some Surprises in AAOS's new Clinical Practice Guidelines The verdict? Hyaluronic acid is still no magic bullet. The American Academy of Orthopaedic Surgeons (AAOS) has just released its revised clinical practice guideline (CPG) on the treatment of osteoarthritis (OA) of the knee. There were two primary changes. One relates to acetaminophen: The recommended dosage was reduced from 4,000 mg to 3,000 mg a day. This is not a change made by AAOS specifically for OA patients, but an overall change made by the FDA since 2009 for individuals who use acetaminophen. The other change is that intra-articular hyaluronic acid is no longer recommended as a method of treatment for patients with symptomatic osteoarthritis of the knee. (The 2009 guidelines review was inconclusive regarding this treatment method.) David S. Jevsevar, M.D., M.B.A., is chair of the AAOS Evidence Based Practice Committee, the entity that oversees the development of clinical practice guidelines. He told *OTW*, "The AAOS CPG was initiated and redone because of concerns about the data analysis (developed by the Agency for Healthcare Research and Quality) used by the original workgroup. All studies that met the study selection criteria were reviewed and utilized if acceptable. The AAOS CPG process uses a 'best available evidence synthesis,' limiting bias and heterogeneity of studies. The workgroup also based analysis of study results with the

determination of clinical significance. In these studies where the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) scores were reported, MCII (minimally clinically important improvement) was used to determine and define patient benefit. This is different from many other meta-analyses that use statistical significance as the endpoint."

"This CPG just summarizes the relative lack of effect for patients. Since the pain and disability associated with knee OA can change daily, and despite the observation that most patients wish to avoid surgery, HA was not proved to be effective for relief of pain and improvement in function. Patients should discuss this treatment with their physicians before undergoing these injections. It is ultimately the patient's choice to use HA."

Unlocking the Code to Genetic Therapies in Orthopedics Javad Parvizi, M.D., director of research for The Rothman Institute in Philadelphia, is going off the beaten musculoskeletal path to find solutions for orthopedic conditions. Epigenetics, says Dr. Parvizi, will lead us toward unforeseen treatment possibilities. "In the old days our understanding of genetics was rather primitive. Over time we have come to realize that it is not just inheriting the gene that determines its expression, but that the environment plays a critical role as to whether the gene is or is not expressed. The recognition of the fact that environmental factors like food can alter gene expression has given rise to the exciting science of epigenetics. So for conditions that have a genetic basis, an alteration in the genetic material (i.e., DNA) can lead to the condition."

"The science of epigentics explains why not every gene mutation may lead to expression of the disease/condition. Thus, this may provide an incredible opportunity in medicine to modulate/affect expression of a gene by altering the environment around the chromosome. If one was able to alter expression of a gene in this manner, there would not be a need for genetic engineering that aimed to alter the genetic expression by working on stem cells. Epigenetics has provided insight into the fact that we can alter the genetic expression of an adult cell by altering the environment around it. A very exciting time in genetic science indeed."

Nicholas A. DiNubile, M.D. Receives Joe Torg Award The chief of the Section of Orthopedic Surgery at Delaware County Memorial Hospital, Dr. Nicholas A. DiNubile was recently chosen by his peers to receive the "Joe Torg" award at the 14th Annual Philadelphia Sports Medicine Congress. The Torg award is named for sports medicine pioneer Joseph S. Torg, M.D., an orthopedic surgeon at Temple University Hospital. The award honors an orthopedic surgeon in the greater Philadelphia area who has devoted his or her career to the care of athletes, who has participated in the educational process, and who has made significant contributions to the body of knowledge of orthopedics. The award holds special significance because Dr. Torg was Dr. DiNubile's mentor during his residency at the Hospital of the University of Pennsylvania.

Dr. DiNubile has served as special advisor to the President's Council on Physical Fitness and Sports (including eight years during the first Bush Administration with Arnold Schwarzenegger as chairman). He also enjoys a strong presence in Philadelphia, where he has served as orthopedic consultant to the Philadelphia 76ers and the Pennsylvania Ballet and has, over the years, cared for members of every Philadelphia professional sports team as well as Olympic athletes.

Knee Replacement and the OTHER Knee How does the preop functioning of the contralateral knee influence post-knee replacement function? Researchers from Boston University and other institutions have taken a step forward in answering that question. Jessica Maxwell, P.T., D.P.T., O.C.S., is Clinical Assistant Professor, College of Health and Rehabilitation Sciences: Sargent College at Boston University. She and her colleagues, interested in the fact that recent research found a proportion of patients who did not receive a favorable outcome after knee replacement, analyzed data on 271 patients in the Multicenter Osteoarthritis Study who had undergone knee arthroplasty. Dr. Maxwell told *OTW*, "We found that 27% of 264 patients had poor post-arthroplasty function, and 30% of 250 patients had a slow walking speed. Among subjects with one knee replacement, the higher the pain was in the other knee prior to the surgery, the more likely one would be to have self-reported functional limitations. This was not the case for slow walking speed. Patients in whom both knees had been replaced at the time of outcome collection were less likely to have poor self-reported function than those in whom only one knee had been replaced.

"We were surprised that although the subjects who had both knees replaced reported more 'acceptable' function than those with only one knee replaced, that the proportions with slow walking speed were still similar, and were higher. This supports the common notion that self-reported measures and performance based measures do not always demonstrate the same results." ♦

COMPANY

Another Whistleblower at Medtronic?

Is another whistleblower behind the latest request by the United States Attorney for information from Medtronic, Inc.?

In a June 24, 2013 SEC 10-K filing, the company disclosed that the U.S. Attorney in Minnesota requested information relating to the company's compliance with the Trade Agreement Act (TAA). The filing also said the company was fully cooperating with the inquiry.

Tom Beimers, a former U.S. Department of Justice prosecutor and now an attorney with Faegre Baker Daniels LLP, told us that whistleblower attorneys are showing an increased interest in this fairly obscure law that implements the World Trade Organization (WTO) agreement on government procurement. He added that we can't know whether Medtronic is dealing with a whistleblower, but a recent settlement with the government, says Beimers, "may pique the interest of other manufacturers."

Recent Settlement

The settlement referred to by Beimers involved a $5.66 million payment by a subsidiary of Illinois-based CDW Corporation, a reseller of information technology, equipment, services, office supplies and related products. The settlement resolved allegations that, during the period 1999 to 2011, the subsidiary improperly charged government purchasers for shipping, sold products to the United States that were manufactured in China and other countries that are prohibited by the Trade Agreement Act, and underreported sales in order to avoid paying GSA (U.S. General Services Administration) its "Industrial Funding Fee," a fee based on total contract sales that is designed to cover GSA's costs of contract administration.

Company Whistleblower

The allegations arose from a lawsuit filed in a federal court in East Saint Louis, Illinois, under the qui tam or whistleblower provisions of the False Claims Act. The relator in this case, former company sales representative Joe Liotine, will receive $1,585,892.56 of the total recovery as a statutory award.

Trade Agreement Act

Mass Device's Brad Perriello reported on June 25 that the TAA governs acquisitions of more than $193,000 by the U.S. government. Its "rule of origin" provision mandates that those products must be either made in the U.S. or from a "designated country" that's part of a trade agreement with the U.S. But several countries that produce medical devices, including China, India, Malaysia, Taiwan and Thailand, are not designated countries under the act.

That means, wrote Perriello, that any U.S. government purchases from those nations are legal only if no U.S.-made or designated country-made alternatives are available.

—WE (June 25, 2013)

dunyatimes.com/Secret Witness

Globus Claims First With Spine Spacer

Globus Medical, Inc. says it has launched the first expandable spacer on the market to offer the benefits of a traditional anterior implant, without a two-part disruptive surgical procedure.

The LATIS implant is a minimally invasive (MIS) lumber interbody fusion spacer.

The implant, for patients with degenerative disc disease (DDD), is inserted through an MIS TLIF (transforaminal lumbar interbody fusion) approach and expands laterally. The company said the spacer provides a footprint and graft volume equivalent to an ALIF (anterior lumbar interbody fusion spacer) or LLIF (lateral lumbar interbody fusion) spacer.

In addition, the company says the spacer does not require anterior access or nerve monitoring, and allows for direct decompression of nerve roots via the MIS TLIF approach. "The 10mm-wide titanium implant can be inserted posteriorly and can expand in-situ up to 26mm square, offering the largest single bone graft chamber for any posterior implant on the market. Designed to reduce subsidence and migration, the spacer has a locking set screw that secures deployment at any position within the expansion range," stated the June 20, 2013, company press release.

The spacer has a locking set screw that secures deployment at any position within the expansion range and is designed to reduce subsidence and migration.

"Combined with posterior stabilization using our Revolve MIS pedicle screw system, the entire procedure is designed and intended to maximize preservation of the stabilizing muscles of the lower back," said the company's Senior Vice President of Global Product Development Andrew Iott.

According to the company, the spacer is "intended for use in patients with DDD at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s)." Spacers are to be filled with autogenous bone graft material and used with supplemental fixation.

—WE (June 25, 2013)

Globus Medical, Inc. /LATIS Spacer

Orthofix "Re-Boots"

Brad Mason, Orthofix International N.V.'s new president and CEO, is re-booting the way the company is organized.

workshifting.com

The company's operational business will now include:

- BioStim (stimulation products),
- Spine Fixation (spine implant products),
- Biologics (biologics products for all applications),
- International Extremity Fixation, and
- U.S. Extremity Fixation (orthopedic fixation systems).

In a June 20, 2013 announcement, Mason said the organization changes are part of an overall strategic initiative to provide more operational focus on the businesses while driving enhanced shareholder value. "By managing all bone growth stimulation products under the BioStim business, spinal implant products under the Spine Fixation business, and biologics products under the Biologics business, we believe we can maximize the growth potential of these businesses. In addition, the creation of the International Extremity Fixation and the U.S. Extremity Fixation businesses will allow us to better focus on our key customers and key product opportunities."

Mason promised a reboot after his recent appointment to head the company. On May 8, the company reported a 14% decrease in first quarter revenue over the previous year's quarter. In his first call with analysts, Mason called the first quarter "disappointing." He added that the good news was that the primary issues that led to the results were, "identifiable, within our control, and fixable. We are developing a strategy with specific initiatives that will both improve our internal competencies and drive growth."

McCollum Out, Niemann Promoted

In connection with the realignment, the Global Spine business will is separated into two businesses: BioStim and Spine Fixation. Brad Niemann, the former senior vice president, Commercial Operations was immediately promoted to president of the BioStim business. Niemann has more than 15 years of experience in the medical device industry, with a particularly strong focus and track record in expanding the utilization of bone growth stimulation technology. Mason will assume all senior management duties for the Spine Fixation business on an interim basis. Brian McCollum, currently president of Global Spine, will be leaving the company on July 15, 2013.

Other Appointments

In addition to the reboot announcement, Mark Atkinson was immediately named the company's Chief People Officer. In this newly created position, Atkinson will oversee all human resources management, as well as be responsible for executive and employee development and "creating a corporate culture conducive to growth and success."

Mason also announced the appointment of Michael Finegan as Chief Strategy Officer and Jeff Schumm as Chief Administrative Officer. In these newly formed roles, Finegan will oversee all strategic activities, while Schumm will supervise all regulatory affairs, legal matters, and government affairs.

"On behalf of Orthofix, I would like to welcome both Mark and Brad to the senior management team, congratulate Mike and Jeff on their expanded roles, and thank Brian for his many contributions and years of service to our company and wish him success in his future endeavors. We are creating a strong leadership team of talented employees at Orthofix and these promotions and appointments, together with our organization changes will advance our objectives for the benefit of our many stakeholders."

The company released the following biographies of the new team:

Brad Niemann

Niemann joined Orthofix in March 2012 and has led the company's reimbursement and commercial operations. With more than 15 years of experience in the medical device industry, he has a particularly strong focus and track record in expanding the utilization of bone growth stimulation technology. From 2004-2012, Niemann worked in a variety of management and leadership roles at DJO Global, Inc. including senior vice president, recovery sciences leading their commercial efforts for the business segment.

Mark Atkinson

Atkinson brings to Orthofix a wealth of organizational development and talent management experience. Most recently, he served as the director, talent management & organizational development for Lennox International. Prior to that, he was a director, talent management, organization design and human resource transformation practices for PricewaterhouseCoopers as well as the national director, human resources for Jenkens & Gilchrist, P.C.

Michael Finegan

Finegan joined Orthofix as vice president of corporate development in 2006. In 2009, he assumed additional responsibilities as the president of biologics. Finegan came to Orthofix from the Boston Scientific Corporation, where he held several management positions of increasing responsibility, including vice president of corporate sales. Finegan began his career in banking with First Union (Wachovia). He graduated from Wake Forest University with a B.A. in Economics.

Jeff Schumm

Schumm joined Orthofix as assistant general counsel in January 2007, and was promoted to senior vice president, general counsel and corporate secretary in October 2010. From 2004 to 2006, Schumm served as vice president and general counsel for Regeneration Technologies, Inc. Earlier in his career, he served as an assistant attorney general for the state of Florida, as an associate at Holland & Knight LLP and as a staff attorney at the Supreme Court of Florida. Schumm received his Bachelors of Science in Electrical Engineering and Masters in Business Administration from Lehigh University, and he is a magna cum laude graduate of the Florida State University College of Law.

—WE (June 24, 2013)

New Spine System From Aesculap

Aesculap Implant Systems, LLC has a new interbody system for ACDF (anterior cervical discectomy and fusion) procedures.

The company says the CeSpaceXP, "fuses two proven materials, an innovative PlasmaporeXP osteoconductive porous Titanium coating and a PEEK-Optima radiolucent core, that delivers enhanced implant stability, artifact-free imaging, and an optimal scaffold for cervical fusion procedures."

According to the June 18, 2013 announcement, the system's design advantages are the result of 30 years of innovation in spinal technology and over 20 years of success in applying Plasmapore coatings to titanium orthopedic and spine implants. "Drawing on the success of Plasmapore, Aesculap developed PlasmaporeXP, an osteoconductive porous Titanium coating that can be applied to PEEK spinal implants. PlasmaporeXP is an innovative surface enhancing technology with proven biocompatibility."

Bob Spiro, Ph.D., vice president of Aesculap Biologics and expert in immunology and tissue regeneration said the coating found on the implant, "provides the ideal surface composition and architecture for direct bone contact, resulting in higher mechanical strength and improved implant stability."

The system is an interbody fusion device designed for use with autogenous bone graft and intended for spinal fusion procedures at one level in the cervical spine from C3 – C7.

The company says the implant has a distinctive interbody design for ACDF procedures and enhances stability and increases migration resistance through the roughened surface area provided by the coating. The system has a comprehensive selection of instrumentation and 30 size options to ensure the best possible fit to patient anatomy and intraoperative flexibility. The CeSpaceXP has excellent imaging properties, incorporating the benefits of the PlasmaporeXP coating, which clearly delineates implant contours during imaging, with x-ray marker pins for intraoperative positioning and verification.1

To view an animation of the system, click here: http://www.youtube.com/watch?v=3THsBlrT45Y&feature=youtu.be

—WE (June 19, 2013)

Aesculap Implant Systems/CeSpaceXP

LEGAL

FDA Grants Five Ortho Approvals in April

The FDA granted five PMA (premarket application) supplemental approvals in April, including two post-approval study protocols.

Post-Approval Study Protocols

NuVasive, Inc. received a study approval for its PCM Cervical Disc and Paradigm Spine, LLC, received the study approval for its Coflex Interlaminar Stabilization Device.

FDA

Hips and Knee Systems

DePuy Orthopaedics received two supplemental approvals for hip and knee systems.

In knees, DePuy received supplemental approval for an additional inspection step after the In Process Clean (IPC). The inspection will ensure that there will be no remaining polishing agents left on the Attune CR and Attune PS femoral components after the IPC step

is performed. The Attune CR and Attune PS femoral components were previously approved as compatible components to the Class III rotating platform Attune tibial components.

In hips, DePuy received supplemental approval for its Ceramax Ceramic total hip system. The device is indicated for noncemented use in skeletally mature individuals undergoing primary total hip replacement surgery for rehabilitation of hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, and post-traumatic arthritis.

Biomet, Inc. received supplemental approval to amend the in-process inspection criteria used at the Warsaw, Indiana site, to include additional dimensional checks after the polishing step for the Oxford Tibial Tray, to align with the Warsaw facility's standard practices.

Agency Performance Summary

The agency currently has 50 PMAs under review, with 35 of those on hold. It also has 613 supplementals under review, with 176 of those on hold.

Since the beginning of the year, the agency has approved 51 applications, including supplementals, with an average time of 179 days from receipt of the application to a decision point.

To view the FDA's entire April list of approvals, click here: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm358627.htm

—WE (June 28, 2013)

Contested Scientific "Speech" Protected Against Defamation Suits

Contested scientific hypotheses are a matter of opinion and are entitled to free speech protection.

That's the June 26, 2013 ruling of the 2nd U.S. Circuit Court of Appeals in ONY Inc. v. Cornerstone Therapeutics Inc. et al. Writing for a unanimous three-judge panel, Circuit Judge Gerard Lynch wrote: "As a matter of law, statements of scientific conclusions about unsettled matters of scientific debate cannot give rise to liability for damages sounding in defamation."

Wikimedia Commons and RRY Publications LLC

While statements about contested scientific hypotheses are in principle "matters of verifiable fact," for purposes of the First Amendment they are closer to matters of opinion, added Judge Lynch.

ONY sued Cornerstone Therapeutics, Italy's Chiesi Farmaceutici SpA, several doctors and the American Academy of Pediatrics (AAP) over a 2001 article publishing the findings of the effectiveness of ONY's Infasurf, a drug meant to help infants with respiratory failure. Chiesi paid for the study which compared their own drug with others, including ONY's Infasurf.

The findings were used by doctors in the AAP's *Journal of Perinatology* and eventually in promotional materials by Chiesi and Cornerstone.

ONY claims the article contained incorrect statements of fact and included selective data. ONY sought damages of $10 million, accusing the defendants of false advertising in violation of the federal Lanham Act, and a New York state law against deceptive business activity.

According to a June 26 Reuters report, Judge Lynch said, "academic freedom is a special concern of the First Amendment," and warned against extending the Lanham Act to intrude on the amendment's values.

—WE (June 27, 2013)

LARGE JOINTS

Heavy? Less Likely to Have RA Remission

A new study has found that overweight and obese patients are less likely to achieve successful remission in early rheumatoid arthritis (ERA) compared to those of normal weight. Obese and overweight ERA subjects required 2.4 times more anti-TNF therapy throughout the study than normal weight participants without achieving similar remission outcomes.

A total of 346 ERA patients with symptom duration <12 months were categorized into one of three BMI (body mass index) classes—normal weight, overweight and obese—and treated according to a treat-to-target strategy aimed at remission. The strategy included strict follow-up visits, treatment with methotrexate up to 25mg/week+steroids, and combination with a TNF blocker if at least a good response according to EULAR (European League Against Rheumatism) criteria was not obtained.

Those who were overweight and obese patients reached a lower rate of remission at 6- and 12-month follow-up visits. A higher percentage of obese and overweight ERA patients were under anti-TNF treatment after 12 months of follow-up compared to normal weight.

"Obesity and rheumatoid arthritis are both on the rise, with devastating effects on individuals and society as a whole. These data reinforce the link between obesity and inflammation, and establish that BMI is one of the few modifiable variables influencing the major outcomes in RA," said Elisa Gremese, Division of Rheumatology, Institute of Rheumatology and Affine Sciences, Catholic University of the Sacred Heart, Rome, in the June 14, 2013 news release. "There is an urgent need to address the issues of overweight and obesity to improve patients' chance of successful remission."

—EH (June 28, 2013)

Wikimedia Commons and Alexander Gerl

Early Arthritis Patients Drink Less

Put a cork in it! Researchers from Leiden University in the Netherlands have found that patients who have early arthritis consume less alcohol than controls, regardless of the type of arthritis. The research, published online in the journal ***Rheumatology***, involved 992 patients and 5,868 controls.

Wikimedia Commons, Mike DelGaudio, and Niels Epting

To date, the only environmental risk factor demonstrated to be associated with rheumatoid arthritis (RA) is smoking. Annekoos L. Huidekoper, Diane van der Woude, and colleagues set out to investigate whether there is an association between alcohol consumption and arthritis in general, and with RA in particular.

Participants were asked either by a research nurse, or through self-administered questionnaires, about their alcohol consumption. Those interviewed by a nurse were asked for an exact number of alcoholic drinks consumed per week, while those who filled in the questionnaire were asked (a) whether they consumed alcohol, and (b) if they did, how many units per week did they consume.

While 83% of the controls reported drinking alcohol, 53 to 68% of arthritis patients reported consuming alcohol.

The lowest figure came from respondents with ACPA-positive RA*, while the highest figure came from patients with psoriatic arthritis. In patients with RA, the inverse association between alcohol and the disease was greater in men than it was in women, although remarkably this difference was not seen in the patients with other types of arthritis. However, the study did not find any significant dose-response relationship, nor did they detect an association between alcohol and the rate of joint destruction when examined over seven years.

Diane van der Woude, one of the lead authors of the study, commented in the June 19, 2013 news release, "Our findings can be interpreted in several ways. One hypothesis might be that alcohol may suppress both the innate and adaptive immune system leading to a decrease of joint inflammation, as has been suggested by some previous studies."

"Another possible explanation for our findings is that people with arthritis drink less alcohol due to their illness. This explanation seems probable since we observed a relationship between alcohol and the level of inflammation."

Dr. van der Woude also said, "…Perhaps men are more susceptible to the influence of alcohol on the pathophysiology of RA, or the decrease in alcohol consumption caused by the decrease in general well-being is more evident among individuals who consume more alcohol to begin with (often men) and who develop the most severe disease."

To the authors' knowledge this is the first research to include not just patients with RA, but also patients with other types of arthritis, and the finding that alcohol is also inversely associated with these other types of the disease sheds new light on the association between alcohol consumption and RA. It also questions whether the effect of alcohol on the underlying pathophysiology is specific to RA.

* Anti-citrullinated protein antibodies (ACPA) are autoantibodies that can be detected in the blood of rheumatoid arthritis patients.

—EH (June 24, 2013)

Aspirin Equal to Dalteparin for VTE

A venous thromboembolism is a threat to patients undergoing a total hip arthroplasty (THA). Which is the better preventative—extended use of aspirin or low-molecular-weight heparin? To find out, a bevy of doctors undertook a study of the somewhat controversial role of aspirin in thromboprophylaxis after total hip arthroplasty. They wanted to compare extended treatment with aspirin and dalteparin for prevention of symptomatic venous thromboembolism (VTE) after a THA.

The researchers conducted their randomized controlled trial in 12 orthopedic referral centers in Canada and enrolled 778 patients who had had unilateral THAs between 2007 and 2010. After an initial 10 days of dalteparin prophylaxis the researchers randomly assigned patients to 28 days of either dalteparin or aspirin.

So what happened? Five of 398 patients assigned to dalteparin and one of 380 randomly assigned to aspirin had VTEs. Doctors found that aspirin was non-inferior but not superior to dalteparin.

Clinically significant bleeding occurred in five patients receiving dalteparin and two receiving aspirin. The doctors concluded that extended prophylaxis for 28 days with aspirin was non-inferior to and as safe as dalteparin for the prevention of VTE after THA in patients who initially received dalteparin for 10 days. Given its low cost and greater convenience, they considered aspirin to be a reasonable alternative for extended thromboprophylaxis after THA.

Because of a difficulty with patient recruitment, doctors had to prematurely halt the study which was reported in the Annals of Internal Medicine.

—BY (June 18, 2013)

Wikimedia Commons and Sauligno

Pre-Surgery Evaluation Cuts Complications

Patients who took a standardized medical evaluation process before their joint replacement surgery experienced 32% fewer postoperative complications than did patients who were not evaluated, according to a *Business Wire* report.

A study of nearly 700 total knee and total hip replacement patients, conducted by John Muir Health, found that the pre-operation project improves the process for patients by identifying potential risk factors and reducing those risks.

The evaluation was administered by a nurse practitioner in a new, dedicated pre-operation clinic. Results were compared to a control group of patients who underwent the same types of surgery in the year immediately prior to the new clinic opening.

"The process produces a standardized medical history and current physical condition and, if appropriate, the process can generate pre- and post-operative order set changes, such as medications and dosages, to minimize the chance of post-surgical complications," said Doug Lange, M.D., orthopedic surgeon at John Muir Health.

"Nationally, more than one million patients annually suffer from serious post-surgical complications," said Lange. "These complications range from simple urinary tract infections to heart attacks, serious infections and death. The toll in patient suffering is staggering as is the unnecessary cost to the health care system."

Among patients in the control group, the complication rate was 12.40%. Patients going through the new pre-operation clinic process had a 32% reduction in perioperative complications—from 12.40% to 8.45%.

"The new process reduces complications and improves surgical outcomes," said Dawn Knight, senior vice president of quality at John Muir Health. "Our work is supported by national trends in the emerging science of perioperative medicine, where there has been a tremendous surge in new information on how to better evaluate and enhance quality of care for patients."

—BY (June 17, 2013)

Orthopedics This Week and A Huth

Exactech Debuts New Hip Replacement System

Exactech has implanted the first of a new hip replacement system that, according to company officials, is designed to preserve a key portion of patients' bone in a total hip arthroplasty procedure.

Courtesy of Exactech

The company press release states that the LPI Prime hip system is a more conservative treatment option, designed to maintain the maximum amount of proximal femoral bone while providing excellent initial stability, enabling biological fixation. The geometry of the stem is designed to facilitate insertion through smaller incisions.

"The materials and methods used in hip replacement have improved dramatically over the last two decades," said orthopedic surgeon and Exactech CEO Bill Petty, M.D. "The LPI Prime system is one of those engineering advances; it is designed to meet the growing demand for conservative treatments that make it possible for patients to stay active longer, since many patients are being treated at younger ages."

Orthopedic surgeons John Aldridge, M.D, at Mary Immaculate Hospital, Newport News, Virginia, and Scott Dunitz, M.D., at Tulsa Bone and Joint Associates, Tulsa, Oklahoma, performed the first surgeries using the new hip system.

Dunitz said, "The new implant saved more healthy bone compared to other implant designs I have used. The design allowed me to use a more minimally invasive approach, and I was impressed that it provided the stability of a traditional hip implant."

"I am very pleased with the new hip implant geometry," Aldridge said. "The stem's size and design minimized disruption to soft tissue, and my patients are able to return to active mobility quickly—an important goal of hip replacement." The initial launch of the new system is underway in the United States, with full market release planned in 2014.

—BY (June 19, 2013)

EXTREMITIES

No Unraveling in the OR: Novel Knot Technique

A research team from Mayo Clinic has designed and tested a novel knotting technique that could decrease stress in the OR. The innovation, a two-strand-overhand locking (TSOL) knot, was designed and mechanically evaluated with use of different suture materials and knot configurations and in actual tendon repairs.

The researchers compared the knot holding strength of the TSOL knot with that of a 4-throw square knot with use of three different suture materials that are in common clinical use. With use of braided polyblend suture, the TSOL knot was also compared with five other surgical knot configurations. Finally, the strength of tendon repairs performed with use of the TSOL knot and a 4-throw square knot was studied.

Chunfeng Zhao, M.D. and his team told *OTW*, "Our team has been active in flexor tendon repair research for over 15 years, and we have explored many techniques to improve strength and healing. Knot unraveling using modern tendon repair techniques has been reported to be a relatively common occurrence; we have seen this in our own laboratory experiments. This is a critical complication that may occur in the repair of any tissue subjected to high-tension loading. Recognizing that both the tensile strength of the suture material and suture holding strength of tissue are typically higher than loads required to unravel commonly used knots, we saw a great opportunity to improve repair strength by overcoming this weak link in the chain."

Dr. Zhao continued, "The impact of very strong suture materials is greatly limited by the strength of the knot used. When using a high-tensile-strength suture, 4-throw square knots unraveled at tensile loads as little as one-quarter of the intact suture tensile strength. The proposed two-strand overhand locking (TSOL) knot performed better, with failure loads nearly one-half of the intact suture tensile strength. A simple change to the repair technique provides opportunities to take greater advantage of a suture's strength."

Asked about the most important findings, Dr. Zhao noted, "Not only did we observe that the TSOL knot was significantly stronger (both statistically and practically speaking) than the other common surgical knots tested, it does not result in a significantly increased knot size. This is particularly important in flexor tendon repair, as the knot is buried between the two repaired tendon ends, and the presence of a large foreign body can negatively impact healing. The type of suture used does influence the mechanical advantage of this new knot over the 4-throw square knot. However, for all suture materials tested, the advantage of the TSOL knot was substantial. This knot is quick and simple to make with or without an assistant."

—EH (June 20, 2013)

Mayo Clinic

Customizing PRP "Ingenious"

A June 5, 2013 scientific article by Satoshi Terada, M.D., et al. recently appeared in the *Journal of Bone and Joint Surgery* (*JBJS*). The study, "Use of an Antifibrotic Agent Improves the Effect of Platelet-Rich Plasma [PRP] on Muscle Healing After Injury," was sufficiently interesting to provoke an invited commentary. Christopher H. Evans, Ph.D., D.Sc. of Beth Israel Deaconess Medical Center, Boston, Massachusetts, was a referee on the paper and was asked by those at *JBJS* to give his thoughts.

Dr. Evans, concerned about PRP being the latest ortho-panacea, says it is "administered promiscuously for whatever ails the musculoskeletal system." Interestingly, he notes that ingredients that are an advantage in one setting may be a disadvantage in another. For example, vascular endothelial growth factor (VEGF), a prominent angiogenic component of PRP, might be helpful for bone healing, which has an absolute need for angiogenesis, but a hindrance for repairing cartilage, which is avascular.

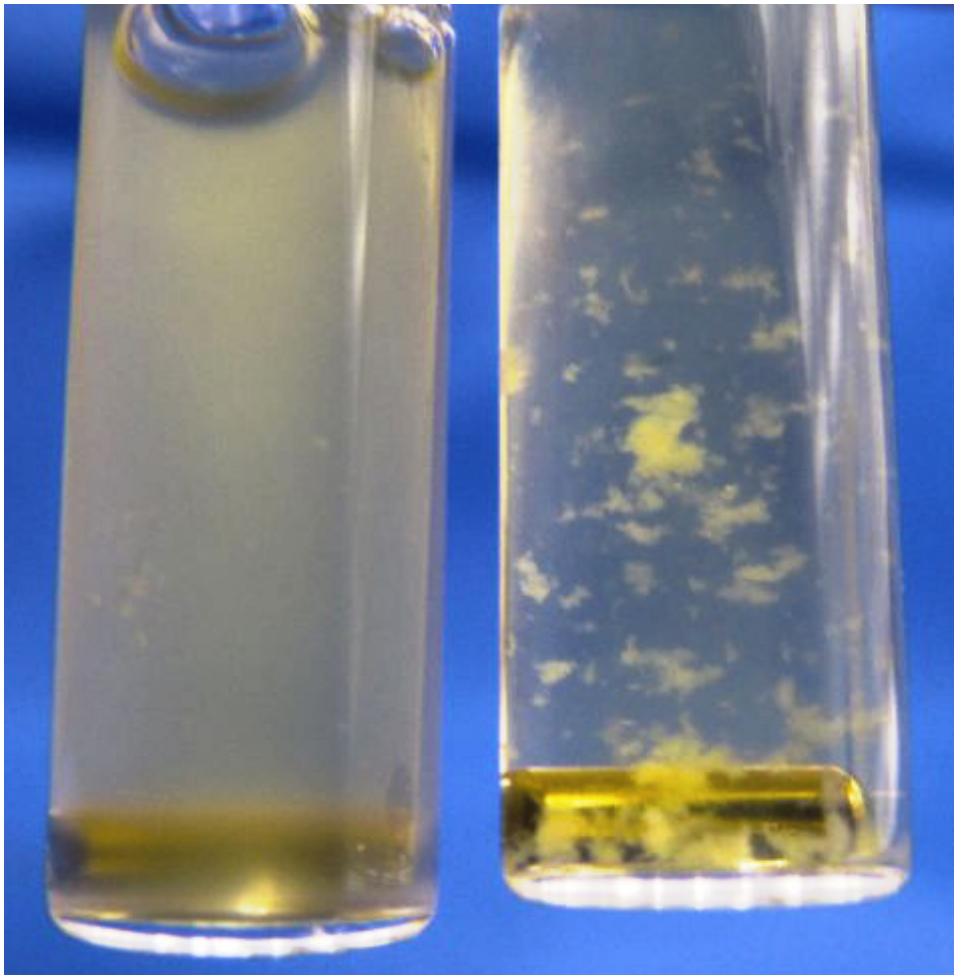
Dr. Evans indicates that Dr. Terada and colleagues do address the point that PRP cannot be all things to all tissues. Their solution is to customize PRP for specific indications; they used a murine model of skeletal muscle injury and repair. PRP has the potential to improve healing by enhancing angiogenesis and myoblast proliferation, but the presence of TGF-b impairs healing by promoting fibrosis and inhibiting satellite cell differentiation.

To improve the performance of PRP in their model, the investigators simultaneously treated the injured mice with losartan, an orally active inhibitor of the Smad signaling pathway used by TGF-b. This accelerated the rate of muscle vascularization while inhibiting fibrosis, leading to improved functional recovery. Losartan is already approved by the FDA for the treatment of hypertension and congestive heart failure. This, says Dr. Evans, should facilitate the clinical translation of their findings, assuming that short-term use of losartan does not have adverse cardiovascular sequelae in subjects who do not otherwise need it. The authors, as well as Dr. Evans, point out that further work is needed to establish the optimal dose, timing, and frequency of application.

Dr. Evans told *OTW*, "I thought that the approach of customizing the PRP to the biological need is quite ingenious. Most practitioners just slap it on willy-nilly, regardless of the indication."

Asked where he thinks we will be with PRP in five years, Dr. Evans told *OTW*, "I am concerned that in five years, PRP might turn out to be another non-event: a fashionable, new, relatively untested panacea that did not stand up to scrutiny. However, if we could learn more about this product, standardize it, ask the right questions and do the necessary research, perhaps it could form the basis of something useful. The paper I reviewed by Terada et al. suggests one way forward in this context."

—EH (June 19, 2013)



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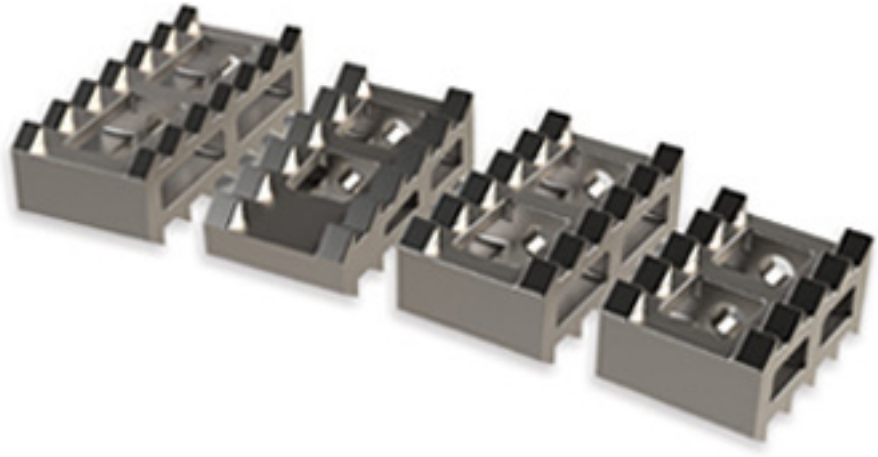
SPINE

PMT Cervical Cage Gets FDA Clearance

Providence Medical Technology, Inc., based in San Francisco, California, has received 510(k) clearance from the FDA for its PMT Cervical Cage. The cage is a minimally invasive implant and delivery system for cervical fusion procedures.

According to Jeff Smith, chief executive officer of Providence Medical Technology, the PMT Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease of the cervical spine with accompanying radicular symptoms at one disc level.



Courtesy of Providence Medical Technology, Inc.

The firm defines discogenic disc disease as degeneration of the disc confirmed by patient history and radiographic studies. Smith says that patients should have received at least six weeks of nonoperative treatment prior to treatment with the device. Devices are intended to be used with autogenous bone graft and supplemental fixation, such as an anterior plating system.

This FDA clearance completes the company's current U.S. product portfolio, which also includes DTRAX Spinal System, DTRAX Graft, and PMT Bone Screws. DTRAX Spinal System and DTRAX Graft are on the market, and PMT Cervical Cage and PMT Bone Screws will launch the third quarter of 2013.

Smith said, "Our U.S. launch of PMT Cervical Cage will build upon our successful international experience, where we have sold over 500 DTRAX Facet System units since its launch in Q4 of 2011. The clinical outcomes achieved by our customers and their patients have surpassed our expectations and we are excited to bring this clinical value to U.S. surgeons and patients."

—BY (June 19, 2013)

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