

Orthopedics This Week

WEEK IN REVIEW

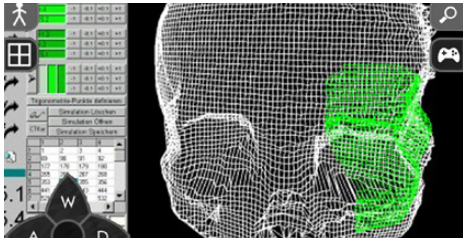
4 Top 28 North American Sports Knee Surgeons: 2014 >> Elite athletes with knee pain need expert help...and fast. To whom do they turn? We asked! Leaders in the sports knee realm let us know their thoughts on the top North American orthopedic surgeons in their subspecialty.

8 The Forgotten Acquisition >> Stryker is buying MAKO for \$1.65 billion. Zimmer is paying \$13.3 billion for Biomet. But there is another, quiet, perhaps forgotten billion dollar acquisition that is also working its way to closing. Interestingly enough, this other billion dollar deal could trigger yet ANOTHER billion dollar orthopedic industry transaction.

13 "Spinal Cap" Caper in California >> A small hospital in California performing half a billion dollars in spine surgeries over six years became the target of an FBI investigation called, "Spinal Cap." This story has it all. Tens of millions in illegal kickbacks, public corruption, device sales schemes and one businessman who pled guilty to it all. Read it here.



17 Award Winning 3D System Improves Surgical Precision // PT Doesn't Improve Pain, Function in OA// HSS Designated FIFA Medical Centre of Excellence >> Johns Hopkins researchers have created high-speed computing methods for 3D imaging and registration. New JAMA study: physical therapy doesn't help those with hip OA. HSS is celebrating its designation as one of only three FIFA Centres of Excellence in the U.S.



BREAKING NEWS

19 Stryker CEO Refutes S&N Purchase, Sort Of

Medtronic Spine Sales Decline – Waiting for Infuse and Kyphoplasty

\$33 Million for SI-BONE

Kinamed's Polymer SuperCable Cleared in Japan

Over 50% TKR Patients Obese – New JBJS Study

75% of Doctors Accuse Colleagues of Unnecessary Procedures

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Stryker is sizing up Smith & Nephew. So buyers flocked to hip and knee recon companies—the number of which you can count on a single hand. Large joint recon is changing fast. Scale will likely define who will be most competitive in an environment of bundlers, ACOs and activist payers. Innovation is taking a back seat at the moment to scale. Though, when it returns, it will be exciting.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.31%	7.80%	Zimmer's purchase of Biomet, much like DePuy's purchase of Synthes, is changing the recon chess game.
2	3	Smith & Nephew	20.25	12.61	SNN has been a perennial buy-out candidate. London traders trot this story out every once in a while. This time it might be accurate.
3	7	Stryker	15.71	8.67	Stryker's CEO disclosed that his firm is indeed looking at SNN. Given Zimmer's purchase of Biomet, how could they not?
4	9	Exactech	10.15	4.82	Large joint recon is the new preferred orthopedic asset. Could EXAC be on someone's buy list too? It's a long shot, for sure.
5	4	Medtronic	28.84	3.76	Medtronic has got to be the squeaky-cleanest company in medicine after a decade of whistleblowers, deferred prosecutions and settlements.
6	5	Orthofix	6.75	4.93	CEO Mason is hitting the road to tell his story. Jefferies, JMP Securities to start. Will almost certainly attract positive interest.
7	2	ConMed	10.19	(3.09)	Sellers swamped buyers these past couple of weeks. Have most of the activist shareholders moved on?
8	8	Integra LifeSciences	11.77	(1.38)	Although sales are expected to grow 11% this quarter, investors have a hard time defining IART's niche. Got to make neuro sexy.
9	NR	Symmetry Medical	6.55	6.78	Big news. SMA divested its troubled Clamonta unit in the UK. Buyers were cheered and it looks like earnings prospects also improved.
10	6	Johnson & Johnson	26.58	0.17	Getting expensive. Trading at 18x trailing earnings, 4x sales (!) and 2.6x PEG. If you own JNJ at 2010 prices, you're feeling really good. But now? Eh.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Tornier N.V.	TRNX	\$21.51	\$1,045	26.75%
2	Smith & Nephew	SNN	\$87.77	\$15,672	12.61%
3	Wright Medical	WMGI	\$30.40	\$1,517	11.15%
4	Alphatec Holdings	ATEC	\$1.50	\$147	11.11%
5	Stryker	SYK	\$84.49	\$32,030	8.67%
6	Zimmer Holdings	ZMH	\$104.35	\$17,512	7.80%
7	Symmetry Medical	SMA	\$8.82	\$331	6.78%
8	Orthofix	OFIX	\$31.69	\$584	4.93%
9	Exactech	EXAC	\$23.29	\$318	4.82%
10	Medtronic	MDT	\$61.03	\$61,080	3.76%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	\$2.70	\$42	-35.71%
2	Baxano Surgical Inc	BAXS	\$0.66	\$32	-22.35%
3	Bacterin Intl Holdings	BONE	\$0.64	\$35	-7.69%
4	MiMedx Group	MDXG	\$5.47	\$579	-5.36%
5	ConMed	CNMD	\$44.90	\$1,222	-3.09%
6	CryoLife	CRY	\$8.83	\$248	-2.75%
7	Integra LifeSciences	IART	\$44.95	\$1,464	-1.38%
8	NuVasive	NUVA	\$33.34	\$1,554	-1.10%
9	Globus Medical	GMED	\$24.18	\$2,259	-0.98%
10	TiGenix	TIG.BR	\$0.68	\$110	-0.73%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	\$61.03	\$61,080	16.19
2	Zimmer Holdings	ZMH	\$104.35	\$17,512	17.87
3	Johnson & Johnson	JNJ	\$101.46	\$287,040	17.99
4	Exactech	EXAC	\$23.29	\$318	19.16
5	Stryker	SYK	\$84.49	\$32,030	20.42

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	\$31.69	\$584	264.37
2	NuVasive	NUVA	\$33.34	\$1,554	107.56
3	Symmetry Medical	SMA	\$8.82	\$331	79.45
4	ArthroCare	ARTC	\$48.50	\$1,680	33.46
5	Smith & Nephew	SNN	\$87.77	\$15,672	27.84

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	\$23.29	\$318	1.06
2	Globus Medical	GMED	\$24.18	\$2,259	1.54
3	ConMed	CNMD	\$44.90	\$1,222	1.96
4	Zimmer Holdings	ZMH	\$104.35	\$17,512	2.17
5	Stryker	SYK	\$84.49	\$32,030	2.25

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$31.69	\$584	14.37
2	NuVasive	NUVA	\$33.34	\$1,554	9.71
3	CryoLife	CRY	\$8.83	\$248	6.66
4	Symmetry Medical	SMA	\$8.82	\$331	6.62
5	ArthroCare	ARTC	\$48.50	\$1,680	2.79

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$1.50	\$147	0.72
2	Symmetry Medical	SMA	\$8.82	\$331	0.82
3	Bacterin Intl Holdings	BONE	\$0.64	\$35	1.06
4	RTI Biologics Inc	RTIX	\$4.35	\$246	1.13
5	Exactech	EXAC	\$23.29	\$318	1.32

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.68	\$110	19.21
2	MiMedx Group	MDXG	\$5.47	\$579	8.62
3	Wright Medical	WMGI	\$30.40	\$1,517	5.90
4	Globus Medical	GMED	\$24.18	\$2,259	5.20
5	ArthroCare	ARTC	\$48.50	\$1,680	4.40

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

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Top 28 North American Sports Knee Surgeons: 2014

BY OTW STAFF

Elite athletes with knee pain need expert help...and fast. To whom do they turn? We asked! Leaders in the sports knee realm let us know their thoughts on the top North American orthopedic surgeons in their subspecialty.

Here is that list. We don't have "the market" on lists...this isn't the be-all and end-all list—but it is a list of who are arguably the finest sports knee 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.

In alphabetical order, here are the top 28 sports knee surgeons in North America:

Ned Amendola, M.D., F.R.C.S.(C), DABOS is professor of orthopedic surgery and rehabilitation at the University of Iowa (UI) Sports Medicine Center. Dr. Amendola is the Kim and John Callaghan Endowed Chair in Sports Medicine and the Director of Sports Medicine at UI. He is past president of the Canadian Academy of Sport Medicine. "As an expert in both the knee and the ankle, Ned has a sophisticated understanding of lower extremity anatomy and kinematics. Coupled with his comprehensive understanding of tissue transplantation, Ned is widely viewed as a thought leader in the area of knee surgery."

James R. Andrews, M.D. is an orthopedic surgeon and co-founder of the Andrews Sports Medicine and Orthopaedic Center. He is clinical professor of orthopedic surgery at the University Alabama Birmingham Medical School,



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the University of Virginia School of Medicine, the University of Kentucky Medical Center, University of South Carolina Medical School and adjunct professor in the Department of Orthopaedic Surgery at the University of South Alabama. "Dr. Andrews is one of the pioneers for advanced surgical treatment and rehabilitation for sports injuries. While he is nearing the end of his illustrious career, he is acknowledged as one of world's sports medicine authorities and has probably the most experience in dealing with athletic knee injuries."

Elizabeth Arendt, M.D. is a professor of orthopedic surgery at the University of Minnesota and vice chair of the Department of Orthopaedic Surgery at the same institution. "She does very specialized work with patellofemoral

dislocations; much of her research is focused on patellofemoral instability. She does great work with pediatric patients who have the special situation of open growth plates. She is an international leader in the realm of patellofemoral surgery."

Bernard R. Bach, Jr., M.D. is the Claude M. Lambert M.D. Professor at Midwest Orthopaedics at Rush. Dr. Bach is also the Helen S. Thompson Endowed Chair of Orthopaedics and Head of Sports Medicine at Rush University Medical Center. He is a past president of American Orthopaedic Society for Sports Medicine (AOSSM). "He is an outstanding knee surgeon who takes great care of his patients; not all physicians are good doctors *and* surgeons, but he is. Dr. Bach is meticulous in his work, and he has a long history

of ACL surgery. He has evolved this surgery from open to minimally open and then to fully arthroscopic.”

William D. Bugbee, M.D. is an attending orthopedic surgeon at the Scripps Clinic and director of the Adult Reconstruction Fellowship and of the Cartilage Transplant Program. He is an adjunct professor of orthopedic surgery at the University of California, San Diego. “He is a pioneer in the field of joint preservation. He has published extensively on these topics and is considered one of the nation’s foremost experts on cartilage damage and osteochondral allograft transplantation.”

Brian J. Cole, M.D., M.B.A. is an orthopedic surgeon at Midwest Orthopaedics at Rush, as well as professor in the Departments of Orthopaedics and Anatomy and Cell Biology. Dr. Cole is section head of the Cartilage Restoration Center at Rush University Medical

Center. “He is widely respected for his cartilage work. When he looks at injuries he examines not just the one injury, but looks at the complexity of the entire knee. He is well known for meniscal transplants, and is an extremely innovative and research oriented surgeon.”

Dennis C. Crawford, Ph.D., M.D. is an associate professor at the Oregon Health Sciences University (OHSU) and Director of Sports Medicine & Cartilage Reconstruction at OHSU. “He is active in sports and knee and led the Phase 1 and Phase 2 studies of NeoCart. He sets himself apart because he is interested not only in clinical science, but basic science as well. He is adaptive and inventive as a researcher.”

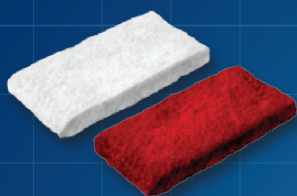
Jack Farr, II, M.D. is an orthopedic surgeon at OrthoIndy and a professor of Orthopedic Surgery (Volunteer) at Indiana University Medical School. He is also medical director of the OrthoIn-

dy Cartilage Restoration Center of Indiana. “He has the experience to manage a patient with knee arthritis from A to Z. He is innovative, thoughtful, and is a technically excellent surgeon. He is always thinking of new ways to improve our current treatments.”

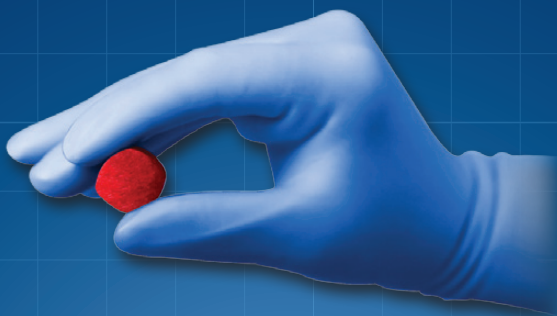
Freddie H. Fu, M.D. is the David Silver Professor of Orthopaedic Surgery and chair Department of Orthopaedic Surgery at the University of Pittsburgh School of Medicine and the University of Pittsburgh Medical Center (UPMC). He is a past president of AOSSM. “He is a true pioneer in sports medicine and leading us into the next generation in the field. He has tremendous energy that is infectious; he is persistent and has built a superb research team at Pittsburgh. Over the last decade he has devoted his research endeavors towards the anatomy and biomechanics of the ACL. He is a very thoughtful innovator who takes a critical look at his results.”

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Alan M. J. Getgood, M.D., F.R.C.S. is an assistant professor at the University of Western Ontario in Canada. He is also a sports orthopedic surgeon at the Fowler Kennedy Sport Medicine Clinic. “He is rapidly becoming known for his work on articular cartilage, and is quite active in the International Cartilage Repair Society. He is developing a comprehensive book on meniscal transplantation, and is an energetic researcher and clinician. He has holistic approach, i.e., he looks at the entire limb. He understands the importance of meniscal alignment and stability.”

Scott D. Gillogly, M.D. is an orthopedic surgeon and founder of the Atlanta Sports Medicine & Orthopaedic Center, LLC. He is also the medical director of the Cartilage Repair Centers of America. “He is a pioneer in articular cartilage lesions of the knee. His research and clinical applications for this critical knee disorder have been acclaimed here in the U.S. as well as internationally.”

Andreas H. Gomoll, M.D. is an assistant professor of orthopedic surgery and clinical leader in orthopedic surgery at the Brigham and Women’s Hospital. “He has built a thriving practice in cartilage restoration and knee surgery. He participates in various knee trials and his approach to realignment surgery is one of great breadth. He is adept at meniscal transplantation, not just with Carticel but also autograft, microfracture, etc. He does his utmost to try and fit the best cartilage procedure for a given individual lesion.”

Jo A. Hannafin, M.D., Ph.D. is an attending orthopedic surgeon and director of orthopedic research at Hospital for Special Surgery (HSS) and a professor in the Department of Orthopedic Surgery at Weill Cornell Medical College. Dr. Hannafin is the current president of the AOSSM. “Her extensive

experience with elite athletes has lent her great perspective in the treatment of knee issues. She is forward thinking in her approach to surgery, is a consummate researcher, and has exceptional leadership skills.”

Christopher D. Harner, M.D. is the Blue Cross of Western Pennsylvania Professor of Orthopaedic Surgery at the University of Pittsburgh School of Medicine (UPMC). He is also the medical director at the UPMC Center for Sports Medicine and the Sports Medicine Fellowship Program director. He is a past president of AOSSM. “He is a terrific surgeon because he is scientific and is a real student of the literature. He is innovative and is honest about what works with his own cases. He does not hesitate to say, ‘This didn’t work with my patients.’ He is also a great educator.”

Darren L. Johnson, M.D. is a professor and chair of the Department of Orthopaedic Surgery at the University of Kentucky. He is also the chair of Sports Medicine. “He does a significant amount of complex revision surgery and follows his patients very closely. He is very scientific, and is extremely honest about his research results. He also serves as head orthopedic surgeon for the Kentucky Wildcats.”

Robert F. LaPrade, M.D., Ph.D. is an orthopedic surgeon at the Steadman Clinic and is the director of biomechanics research at the Steadman Philippon Research Institute. “He is outstanding at merging basic science, translational research, and clinical application when it comes to complex ligament issues. He is an intelligent and thoughtful surgeon.”

C. Benjamin Ma, M.D. is chief of the Sports Medicine and Shoulder Service at the University of California, San Francisco (UCSF). He is also an associ-

ate professor in residence. “He is a leading researcher in cartilage damage of the ACL. He stands out as far as his surgical technique and education. His research, funded by NIH [National Institutes of Health], is a collaboration between orthopedics and radiology at UCSF. I believe the funding level is more than \$6 million over five years.”

Bert R. Mandelbaum, M.D., D.H.L is an orthopedic surgeon with the Santa Monica Orthopaedic and Sports Medicine Group. “He is a pioneer in the field because he is constantly committed to advancing and disseminating knowledge through leadership in many sports medicine organizations. He defines what a sports medicine doctor truly is.”

Matthew J. Matava, M.D. is a professor of orthopedic surgery and a professor of physical therapy at the Washington University School of Medicine in St. Louis. “As the team physician for the St. Louis Rams he has led the way as a clinical scientist on the sports knee. His dedication to teaching and education in this subject has been a revelation in sports medicine.”

Eric McCarty, M.D. is an associate professor of orthopedics at the University of Colorado. He is also the chief of Sports Medicine at that institution. “He is the team physician for the University of Colorado Buffalos. He is an outstanding surgeon and has conducted award-winning research. He is active in leadership roles in the AOSSM.”

Mark D. Miller, M.D. is the S. Ward Casscells Professor of Orthopaedic Surgery at the University of Virginia. Dr. Miller is also a retired Air Force Colonel. “He is a leader in education and has written many papers and book chapters on the knees. He has held numerous leadership roles in several national societies. He runs the Miller review course

for the resident board exam for 20 years, which is extremely well attended.”

Frank R. Noyes, M.D. is chairman and medical director of the Cincinnati SportsMedicine and Orthopaedic Center. He is also president of the Cincinnati SportsMedicine Research and Education Foundation. “He was one of the early researchers in knee sports medicine who gave credibility to orthopedic sports medicine with his biomechanical studies. He has written ‘the book’ on knee surgery and is a go to person for the most complex knee conditions. He is a meticulous researcher and has investigated the double and triple varus knees and improved our understanding of posterolateral corner injuries. He is the crème de la crème.”

LTC Brett D. Owens, M.D. is chief of orthopedic surgery, John A. Feagin, Jr. Sports Medicine Fellowship at the Keller Army Hospital, United States Military Academy. “He is an associate editor for *The American Journal of Sports Medicine* and a prolific writer. He is an excellent surgeon and highly sought after speaker.”

Matthew T. Provencher, M.D., C.D.R., M.C., U.S.N.R. is the chief of the Sports Medicine Service at Massachusetts General Hospital (MGH) and a visiting professor at Harvard Medical School. “He is a self critical leader who will only grow in stature. He was in the Navy and treated active duty Naval officers who rely on their knees for their lives...these are people who stress their bodies even more than most elite athletes. He was recruited to MGH last year and I know for a fact that there were at least five academic programs trying to recruit him.”

Scott A. Rodeo, M.D. is a professor of orthopedic surgery at Weill Cornell Medical College and co-chief of the Sports Medicine and Shoulder Service

at Hospital for Special Surgery. “He does important research on the knee and the effect of growth factors. He is a go to person for critical analysis of that topic in the U.S. He is a great educator and leader, and has dedicated an enormous amount of time and energy to the Olympic teams. He is calm and professional, and is an honest physician.”

C. Thomas Vangsness, Jr., M.D. is a professor in the Department of Orthopaedic Surgery at the Keck School of Medicine of the University of Southern California. He is the chief of sports medicine at the same institution. “He is a great and innovative thinker, with all the attributes of a true clinician scientist. He consistently asks difficult questions and constantly pushing the envelope of knowledge.”

Russell F. Warren, M.D. is an attending orthopedic surgeon at Hospital for Special Surgery and professor of orthopaedic surgery at Weill Cornell Medical College. He is a past president of AOSSM. “He has been one of the major thought leaders in orthopedic sports medicine for his entire career. He has trained 200 fellows, many of whom have gone on to become fellowship directors themselves. He is a surgeon’s surgeon; he is one of those individuals to whom other surgeons direct difficult problems to because he is so thoughtful and has such an enormous breadth of wisdom.”

Robin V. West, M.D. is an associate professor of orthopedic surgery in the Division of Sports Medicine at the UPMC Center for Sports Medicine. “She is assistant head doctor for the Pittsburgh Steelers and is an outstanding surgeon. She interacts with professional athletes in a way that engenders a real respect from the players. Her work on stability in patellofemoral dislocation is excellent.” ♦

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* Walsh WR, Oliver RA, Gage G, et al. Application of resorbable poly (lactide-co-glycolide) with entangled hyaluronic acid as an autograft extender for posterolateral intertransverse lumbar fusion in rabbits. *Tissue Eng Part A*. 2011;17:213-220.

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The Forgotten Acquisition

BY ROBIN YOUNG

Stryker Corporation bought MAKO Surgical Corp. for \$1.65 billion. Zimmer Holdings, Inc. is paying \$13.3 billion for Biomet, Inc..

Both transactions have far reaching effects on the future of orthopedic care.

But there is another, quiet, perhaps forgotten billion dollar acquisition that is also working its way to closing. Interestingly enough, this other billion dollar deal could trigger yet ANOTHER billion dollar orthopedic industry transaction.

Furthermore, as we've dug into the SEC filings for this deal, we think it is arguably a more telling indicator of changing orthopedic treatment paradigms, shifting distribution channels and alternative care providers than either Stryker's or Zimmer's deals.

In case you've forgotten, Smith & Nephew, plc (SNN) hopes to close the \$1.7 billion (\$48.25/share) purchase of ArthroCare Corporation (ARTC) in mid-2014, subject to regulatory approval from the United Kingdom.

When they do close, this deal will bring together two major sports medicine and arthroscopic treatment companies, as well as tee up the other major MIS (minimally invasive surgery) firm—ConMed Corporation—and give strategic heft to two major orthopedic trends—the accelerating growth of outpatient care and MIS.

The Sleeper Deal

With ArthroCare, Smith & Nephew moves to the front ranks in both sports



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medicine (which is a half a billion business for SNN *pre-ArthroCare*) and arthroscopy (a \$440 million business *pre-ArthroCare*) and will essentially control RF Coblation technology.

Combined, the two firms create a powerful gravitational pull on these rapidly evolving outpatient markets.

Sports medicine/arthroscopic products are among the fastest growing categories in orthopedics and support, quite powerfully we think, the broader trends to outpatient and increasingly diversified points of care.

William Plovanic of Cannacord Genuity has modeled the impact of ArthroCare on Smith & Nephew as follows: (*See table on page 9*)

According to Plovanic, with ArthroCare blended in, sports medicine sales will jump 12% this year and 20% next year. Arthroscopic sales will increase 23% this year and 25% next year. But not factored into Plovanic's analysis is the

effect of size and new technology, which we think could put upward pressure to his forecasts.

Smith & Nephew has distributed some of ArthroCare's older products for years although they did not have access to ARTC's latest generation Coblation product, Ambient (Ambient is capable of providing "real-time temperature of the operative environment").

Tortuous History

Getting to "yes" on this agreement was tortuous.

But, given ArthroCare's troubled history, it was perhaps inevitable.

A year ago (May 2013) just before merger discussions started, ArthroCare's former chief executive officer and former chief financial officer were indicted for allegedly leading a \$400 million fraud scheme—said the U.S. Department of Justice (DOJ).

SNN Revenue Model (\$ in millions)	2011	2012	2013	2014 Estimate	2015 Estimate
Sports Medicine	\$491	\$474	\$496	\$557	\$668
Arthroscopic Enabling Technologies	425	458	441	541	678
Knees	869	874	865	884	920
Hips	705	666	653	657	674
Trauma	457	474	486	512	533
Total Advanced Surgical Devices	3,251	3,108	3,015	3,293	3,658
Advanced Wound Care	1,019	1,029	1,336	1,394	1,457
Total Revenues	\$4,270	\$4,137	\$4,351	\$4,687	\$5,115

Source: William Plovanic, Cannacord Genuity

In May, the former head of ArthroCare's spine division David Applegate pleaded guilty to his role in the scheme. In July, ArthroCare's former senior vice president of strategic business units John Raffle also pled guilty.

While all of this was playing out (which occurred 2008 through 2009) ArthroCare's stock plummeted to prices that were unimaginably low—less than \$4/share. Lawsuits popped out like cherry blossoms in spring.

The company's CEO and other executives quit, leaving the board to clean up the mess. David Fitzgerald, who'd served on ArthroCare's board since 2003 and was 75 years old at the time, stepped up and began his service as the company's president and CEO. Prior to ArthroCare, he'd been 25 years at Pfizer, Inc., serving as president and chief executive officer of its Howmedica Orthopedics division during his last fifteen years.

Background of the Deal

Most analysts expected that ArthroCare would ultimately be sold. But the baggage of lawsuits and Department of Justice investigations were big hurdles.

In early 2013, as the DOJ investigations to beginning to look solvable,

ArthroCare formed a committee of its board of directors to review its strategic alternatives. Gregory A. Belinfanti, Terrence E. Geremski and Peter L. Wilson, with James G. Foster as an alternate were its members. Piper Jaffray was the outside advisor.

At the committee's direction, Piper contacted three medical device manufacturing companies (Smith & Nephew was left off the list) to see if they'd consider buying ArthroCare.

Two months later, however, it was "no sale" at two of the prospects and the third only wanted ArthroCare's crown jewel—the ENT business. No one wanted sports medicine.

Then, somewhat unexpectedly in late October 2013, Mike Frazzette, Smith & Nephew's president of Advanced Surgical Devices, asked for a meeting. About two weeks later, Frazzette and Cyrille Petit, Smith & Nephew's chief corporate development officer, met with David Fitzgerald and Todd Newton, ArthroCare's executive vice president, chief financial officer and chief operating officer, in Austin, Texas.

Smith & Nephew laid their cards on the table. They were interested in buying the whole enchilada (or words to that

effect). Sports medicine, ENT...everything.

Three days later Piper Jaffray, at the Transaction Committee's direction, re-contacted the two companies who'd passed on ArthroCare a few weeks earlier, plus three new firms to ask if they'd consider or reconsider buying ArthroCare.

With a real buyer at the table, three other firms decided to take a longer look at ArthroCare and signed confidentiality agreements. By the end of November 2013, there were four potential buyers for ArthroCare.

At this stage ArthroCare decided to disclose what would eventually become its block buster announcement. With Piper attending, ArthroCare described the material terms of a pending deferred prosecution agreement with the U.S. Department of Justice. That agreement would be made public a couple of months later and have a dramatic impact on the merger negotiations.

But the prospect of settling with the DOJ wasn't enough. Three of the potential acquirers decided to pass on the deal leaving only Smith & Nephew.

By December, the deal was Smith & Nephew's to win or lose.

Setting a Price

On December 10, 2013, SNN's Petit called Fitzgerald and presented a preliminary non-binding acquisition offer to buy ArthroCare for \$43.00 per share in cash, contingent on completion of due diligence.

Petit reiterated during the call that Smith & Nephew would be unwilling to participate in any auction process and would require a 60-day exclusivity period as a condition to continued discussions or negotiations. The \$43.00 per share bid was approximately 11.54% above ArthroCare's \$38.55 per share closing price on December 10, 2013.

On December 13, 2013, ArthroCare's Transaction Committee asked Fitzgerald to tell Petit that \$43.00 per share

was financially inadequate and to try to get the price up to at least \$50.00 per share.

In addition, the committee instructed Piper Jaffray to shop the deal some more. So Piper contacted two more medical device manufacturers each of whom had prior experience in making large acquisitions. The committee also considered taking the deal to private equity firms and other financial investors.

Within a week, Piper passed along the word to the committee that the other two medical device companies had both passed.

The number of companies who'd looked at ArthroCare and passed was now up to seven.

On December 18, 2013, Smith & Nephew raised the offer price to \$45.50 per share in cash, which was about 14.04% above the then current market price on December 18, 2013. But nowhere near \$50.

For the next two days, ArthroCare's board talked the new offer through with Piper and its other advisors. So, again, ArthroCare's board asked management to try to negotiate a higher price and, if possible, also a reduced termination fee and to eliminate or reduce the time of any exclusivity period.

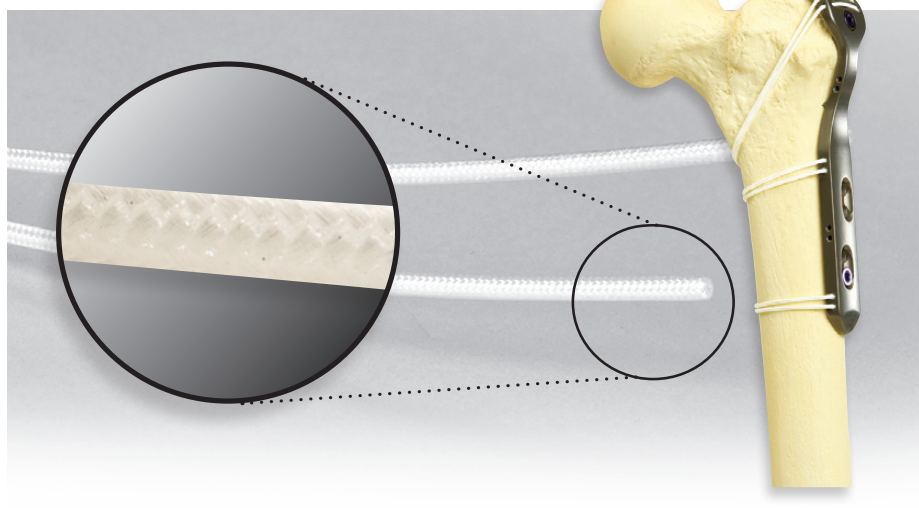
Counter Offer and Counter, Counter Offer

The next day, December 19, Piper contacted Smith & Nephew's bankers (JP Morgan and Centerview) and told them to expect a counter offer of \$47.00 per

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share and a termination fee equal to 2.5%. Then, five days before Christmas, Fitzgerald personally delivered the counter offer to Petit.

Petit's counter, counter offer was \$46.00 per share and a termination fee equal to 3.5% and an exclusive negotiating period ending February 5, 2014. He also told Fitzgerald that that was Smith & Nephew's best and final offer—\$46.00 per share was 16.75% more than ArthroCare's \$39.40 per share closing price December 20, 2013.

There were no other bidders—other than the public. And they would weigh in shortly.

On December 26, 2013, the two companies entered into a written exclusivity

agreement and the due diligence process began.

The Public Buyers Take Charge

On January 7, 2014, ArthroCare announced a deferred prosecution agreement with the Department of Justice. The closing price on the day following the announcement jumped to MORE than Smith & Nephew's offer. It was now \$46.57, an increase of approximately 14.48% from the \$40.68 per share closing price the prior day.

On January 13, 2014, Piper called JP Morgan and Centerview and asked them to raise the offer price—again. Smith & Nephew said they would. Some day.

Nothing came on January 14. The exclusivity period was expiring so ArthroCare's board extended it to January 24 to give SNN time to raise their offer.

Nothing came on the January 15. So Fitzgerald spoke with Petit by telephone and Petit said to expect a new price proposal which would be higher than the then-market price.

On January 21, when ArthroCare announced the dismissal of other DOJ charges, the stock price rose again, this time to \$47.72.

No new price came that day. Nor the next. And on January 23 Petit called Fitzgerald with the bad news. He would not be able to update the price at that time.



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On January 24, the exclusivity period was set to expire again.

That very morning, Petit called Fitzgerald and said that they would revise their bid after Smith & Nephew's January 29 board meeting and that the new offer would be higher than the then-current price per share of common stock, which was \$47.05 per share.

As promised, Petit called Fitzgerald on January 29 and raised the offer to \$48.00 per share in cash. Petit also told Fitzgerald that the offer would expire the following day at 12:00 p.m. unless agreed to by the company. Smith &

Nephew's offer of \$48.00 per share was 4.78% higher than the \$45.81 per share closing price.

The Final Gambit

The final gambit was interesting. ArthroCare's transaction committee discussed Petit's final offer and decided to direct Fitzgerald to ask for \$50 per share—**not because it believed that \$50.00 per share was the fair value of the company, or the minimum bid that it would accept**, but rather as a means to elicit from Smith & Nephew the highest price that it was willing to pay to acquire the company.

It worked.

On February 1, 2014 Petit and Olivier Bohuon, Smith & Nephew's chief executive officer called to propose \$48.25 in cash per share.

The merger agreement was executed the evening of February 2, 2014.

On February 3, 2014, before the opening of trading on the London public stock markets, Smith & Nephew issued a press release announcing that they were buying ArthroCare. ♦



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“Spinal Cap” Caper in California

BY WALTER EISNER

When Michael Drobot, Sr. owned and operated the Pacific Hospital in Long Beach, California, the hospital billed out more than half a billion dollars for spine surgeries over a six year period, primarily to the California Workers’ compensation system.



Michael Drobot/nbclosangeles.com

Business was good at the 147-bed hospital. A 2012 *Wall Street Journal* investigation found that Pacific Hospital led all California hospitals in conducting spinal fusions between 2001 and 2010. According to local press reports, Drobot lived in a two-story, three-car garage residence nestled amongst multi-million dollar homes about a minute away from the posh Bahia Corinthian Yacht Club.

Maybe business was too good. The FBI and the State Compensation Insurance Fund, which oversees workers’ comp claims for the state, took notice and started an undercover investigation called “Spinal Cap.”

According to a secret 125-page affidavit leaked by the *Al Jazeera* America news service, the agency launched the investigation in part because of a 2007 tip from the California Fair Political Practices Commission about a \$1 million payment from a company affiliated with Drobot to the Calderon Group, a firm owned by Tom Calderon, the brother of State Senator, Ron Calderon.



Wikimedia Commons and FBI

History Making Fraud

Before it was over, the investigators discovered one of the largest workers’ comp fraud cases in California’s history involving more than 150 insurance companies, replete with tens of millions in illegal payoffs to docs for referrals, double and overbilling for devices and alleged bribes to a powerful state senator.

The State Compensation Insurance Fund wanted to recoup some of the \$160 million it paid over the past dozen years under civil statutes used to prosecute organized crime syndicates.

On February 21, 2014, Drobot pled guilty to the criminal fraud charges and offered to testify against Senator Calde-

ron, whom Drobot claims he bribed to keep his enterprise going. Calderon surrendered to authorities, but maintains his innocence. Drobot’s sentencing, which could result in 10 years in prison, will be delayed until the conclusion of the Calderon case.

Kick-Backs and Bogus Contracts

From 1997 to 2013, according to the FBI, Drobot billed workers’ compensation insurers hundreds of millions of dollars for spinal surgeries performed



Long Beach Pacific Hospital/Photo by Brittany Murray courtesy of Press Telegram

on patients who had been referred by dozens of doctors, chiropractors, and others who were paid illegal kickbacks.

For referrals for spinal surgeries, Drobot typically paid a kickback of \$15,000 per lumbar fusion surgery and \$10,000 per cervical fusion surgery. Some of the patients lived as far as hundreds of miles away from Pacific Hospital and closer to other qualified medical facilities. The patients were not informed that the medical professionals had been offered kickbacks to induce them to refer the surgeries to Pacific Hospital.

There are no allegations that any of the surgeries were unnecessary or resulted in harm to the patients.

Drobot and his co-conspirators, according to the FBI, concealed the kickback payments by entering into bogus con-

tracts with the doctors, chiropractors, and others who received kickbacks. In reality, the contracts merely provided a cover story for the kickback payments.

More Prosecutions to Come

All told, the government says the kickbacks amounted to \$20 to \$50 million. No charges have been filed yet against any healthcare providers who accepted the kickbacks, but Eric Weirich, deputy commissioner of the enforcement branch of the California Department of Insurance, said in a joint press conference with the U.S. Attorney's Office, "I assure you, this is the first in many cases to come."

In a separate civil whistleblower lawsuit, doctors were referred to by initials in documents released by a local NBC affiliate.

Spinal "Pass-Through" Legislation

The kickbacks were financed largely by money generated from inflated prices for medical devices implanted into state workers' comp patients during spinal surgeries. Drobot exploited a now-repealed California law known as the spinal "pass-through" legislation, which permitted hospitals to pass on to workers' comp insurers the full cost of medical devices implanted in spinal surgery patients.

Drobot set up shell companies to inflate the costs of those devices and then billed the insurers at the inflated rates. According to the FBI affidavit, Drobot and others inflated the prices by up to 10 times the actual cost.

Beginning in 2001, California workers' comp law allowed hospitals to col-

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lect a second time for spinal devices implanted in the backs of injured workers. That's in addition to a lump sum payment that included the cost of the device. The law permitted hospitals to pass on spinal medical device costs, plus up to an additional \$250, to workers' comp insurers.

If the surgeon did not use the devices specified by Drobot, the kickbacks were smaller, the documents said. Drobot's hospital bought the medical supplies for the surgeries from International Implants LLC, a company he controlled.

California Insurance Commissioner Dave Jones said, "The co-conspirators lined their pockets by ripping off insurance companies to the tune of hundreds of millions of dollars. This is one of the largest workers' compensation fraud cases in the history of the Department of Insurance—our successful investigation of this complex criminal scheme underscores our commitment to bring law breakers to justice regardless of who they are."

Bribery

To keep the "pass-through" loophole open, Drobot needed help from lawmakers in Sacramento. State Senator Calderon, a Democrat from Montebello, California, was a powerful committee chair. According to the secret affidavit, Drobot allegedly paid Calderon \$28,000 in bribes to meet with other lawmakers and stop legislation to close the loophole.

The government specifically alleges that Drobot bribed Calderon by hiring Calderon's college-age son to work as a file clerk at his company and paying him approximately \$30,000 over

the course of three summers. Calderon's son showed up for only about 15 days of work each summer, according to the indictment, which also accused Calderon of accepting plane trips, golf outings, and expensive dinners from Drobot.

Drobot reportedly contributed \$167,000 in campaign contributions to Ron and Tom Calderon. Drobot also reportedly contributed more than \$1.3 million in total campaign contributions since 2000, nearly all to Democrats.

Calderon took an indefinite leave of absence from the Senate due to the federal investigation.

The repercussions of the investigation, guilty plea and Calderon's indictment shook the leadership of the California Assembly and caused the Speaker to require all members to attend a one day ethics training seminar this spring.

Drobot Enemies

Drobot made enemies.

An article in the *Press Telegram*, a local paper quoted a neighbor calling Drobot a "real jerk" who "thought he was above it all," and was always showing off his cars.



Ron Calderon/senate.ca.gov

After the story appeared some readers offered comments to the story. One reader wrote:

"I worked at Pacific Hospital when Drobot took over. It was pretty obvious, from the get-go, that this guy was a scammer. The authorities and overseers of the workmen's compensation fund looked the other way. Who would foolishly pay out 500 million dollars with[out] asking a single question or realizing what was going on. My guess, other people were being supplied kickbacks at the workmen's compensation authority. What a thief Drobot was. Everyone who worked at the hospital knew what was going on. Even the orderlies."

Whistleblowers Go Public

In February 2014, two whistleblowers went public on the local NBC television affiliate, *NBC4*, talking about what they said was insurance fraud involving counterfeit medical hardware.

"The red flags started immediately," said Mark Sersansie of Orange County, who was hired as a sales representative for a man he said worked for Drobot. According to Sersansie, Drobot and his co-conspirators bullied their employees to keep quiet about their scheme.

"These guys are absolute thugs," Sersansie told *NBC4*. "They tried different ways to intimidate me and my family. We had instances where they actually came to my home, three of them and threatened me."

Justin Berger, Sersansie's attorney, showed *NBC4* an invoice—an exhibit in the suit—which totals \$24,000. "These are bribes to get these surgeons to do

surgeries at this hospital with this particular hardware,” said Berger. “Much of this hardware, if not all of it, we believe is counterfeit.”

Bill Reynolds, an insurance fraud investigator and the other whistleblower, said this scheme bilked the state’s workers’ compensation system out of millions and put thousands at risk. “Initially, we were looking at 500 to a thousand (surgeries),” said Reynolds. “But we have obtained records now that could (show) 10[000]-15,000 surgeries nationally.”

“We thought Drobot would be the last person to plead guilty,” Sersansie told *NBC4*. “We thought he would go down with a fight because he had the financing and resources to do it, because he was the big bully. When we found out he pled guilty for reasons that he pled guilty. It was a bit of vindication.”

Drobot Sings

Drobot’s attorneys, Janet I. Levine and Jeffrey Rutherford, said he accepts responsibility for his actions and “is providing information to assist the

government in its expanding investigations.”

The FBI said the investigation is continuing. Drobot is talking and there are records. We have likely not heard the last of “Spinal Cap.”

Pacific Hospital was sold to Santa Fe Springs-based College Health Enterprises in early October. The facility is now named College Medical Center Long Beach and is operated by a Molina Healthcare affiliate. ♦



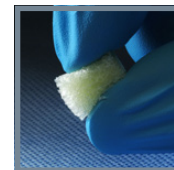
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Award Winning 3D System Improves Surgical Precision // PT Doesn't Improve Pain, Function in OA// HSS Designated FIFA Medical Centre of Excellence

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

Award Winning 3D Imaging System Improves Surgical Precision When surgeons and engineers get together, great things can happen. New work from the Johns Hopkins University School of Medicine is pointing the way for major progress in spine surgery. Jeffrey Siewerdsen, Ph.D. is a professor of biomedical engineering at Johns Hopkins. He tells *OTW*, “Our group is developing imaging for the OR that will improve surgical precision and patient safety. Using simple systems like a mobile C-arm, we can form high-quality 3D images, achieve surgical guidance without conventional tracking systems, and provide decision support for accurate, streamlined target localization. In each case, we are striving for solutions that fit with natural surgical workflow and are suitable for broad utilization—simple on the surface, with sophisticated high-speed computing methods for 3D imaging and registration under the hood.”

An example of their work is the LevelCheck algorithm, which won the 2013 Spine Technology Award and is undergoing clinical studies at Johns Hopkins. Dr. Siewerdsen told *OTW*, “This technology aims to eliminate wrong-level surgery by automatically labeling vertebrae in intraoperative radiographs. As a means of decision support, LevelCheck provides an independent check on vertebral localization that should improve workflow and reduce human error compared to conventional manual level counting. The system automatically registers a patient’s preoperative CT to any radiograph acquired in the OR and superimposes the radiograph with clearly visible labels on the target verte-

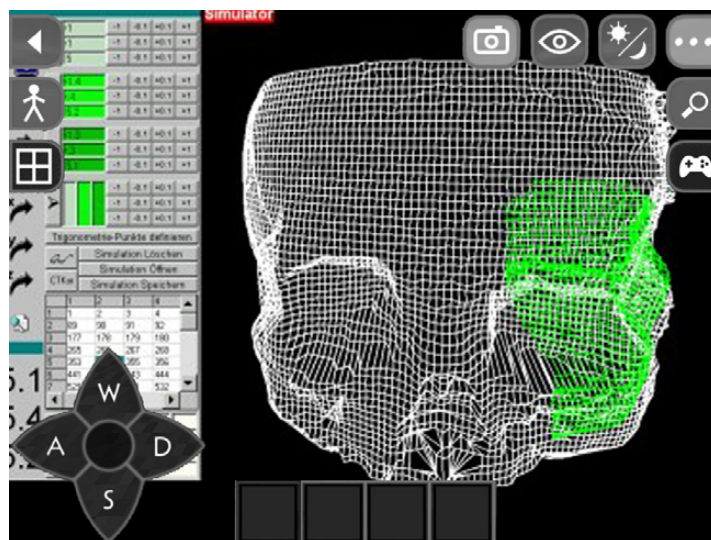
brae. The registration involves tens of thousands of calculations performed in just a few seconds thanks to high-speed graphics processing units (GPUs) that are common to modern video games.”

The LevelCheck system was evaluated in preclinical studies by Dr. Jay Khanna from the Department of Orthopaedic Surgery at Johns Hopkins University, showing it to be robust against changes in patient setup between the preoperative CT and the OR table and also robust against the presence of surgical tools in the radiograph. The system is now undergoing clinical studies at Johns Hopkins under the direction of Dr. Ziya Gokaslan from the Department of Neurosurgery. “We are finding LevelCheck to give an accurate independent check in localizing the target vertebrae,” Dr. Gokaslan told *OTW*. “Our studies so far show it to be fast and reliable, providing useful decision support within our natural workflow in way that could reduce time and stress.”

The Johns Hopkins team of surgeons and engineers is now taking such technology further. Studies underway include a means for surgical navigation without conventional trackers and markers attached to the patient. “The C-arm is the tracker, and the

patient is the marker,” says Dr. Siewerdsen. “Using a high-speed registration method similar to LevelCheck, we can provide 3D navigation for the surgeon with precision better than conventional trackers, without markers attached to tools or the patient, and reducing radiation dose compared to conventional fluoroscopy.”

The team is demonstrating the potential for systems like a mobile C-arm to bring high-end functionality to mainstream procedures. “We want to build simple, streamlined systems that answer major challenges in mainstream surgery, rather than increasingly sophisticated systems with limited impact,” says Dr. Siewerdsen. “The ability to form high-quality 3D images on a mobile C-arm offers the ability to measure the quality of surgical product and detect problems that might otherwise be detected hours later in post-operative CT. And the ability to accurately register preoperative images and planning data into intra-



Wikimedia commons, Korochun and Rüdiger Marmulla/Photo creation by RRY Publications

operative radiographs gives a means of quality assurance that should help surgeons operate more effectively and safely without disrupting workflow.”

Many of these advances leverage high-speed computing methods from the video game industry. “With such a large base of consumer technology getting faster and cheaper year after year,” says Dr. Siewerdsen, “we can expect these kinds of imaging solutions to benefit strongly, making them faster, more reliable, and suitable to a broad spectrum of surgery.”

PT Doesn't Improve Pain, Function in Hip OA

A study from The University of Melbourne has found that among adults with painful hip osteoarthritis (OA), physical therapy does not produce greater improvements in pain or function compared with a placebo treatment. The study was led by Professor Kim Bennell.

In an article published in the *Journal of the American Medical Association*, Professor Bennell and her colleagues randomly assigned patients with hip osteoarthritis to attend 10 sessions of either active PT (which included education and advice, manual therapy, home exercise and walking with an aid, if needed) or placebo treatments (which included inactive ultrasound and gel). Post treatment, the PT group continued unsupervised home exercise while the placebo group self-applied gel three times a week. The team found that patient outcomes were roughly the same the 13 and 36 week intervals.

Dr. Bennell told *OTW*, “We had expected that ‘real’ physical therapy would have greater benefits for pain and function than placebo physical therapy—in actual fact, while both treatments did improve pain and function, there was no difference in these benefits between the two groups. I think this highlights the very powerful ‘placebo’ effects of

seeing a caring therapist who listens, shows empathy and lays hands on the affected part together with the patient’s beliefs and positive expectations around the treatment.”

She added, “We have a number of other trials for people with hip osteoarthritis and others for people with knee osteoarthritis. We are testing a range of different interventions including knee unloading shoes, pain coping skills training and use of a walking stick as well as other studies looking at what factors trigger increases in pain to help us design better treatments.”

HSS Designated FIFA Medical Centre of Excellence

The Fédération Internationale de Football Association (FIFA) has designated Hospital for Special Surgery (HSS) in New York City, as a FIFA Medical Centre of Excellence (FMCoE). HSS is one of only three hospitals in the United States to receive this distinction.

“As the former medical director of Schulthess Clinic in Zurich (the first FIFA Medical Center of Excellence) I am very familiar with HSS’s sports medicine, rehabilitation and performance care for professional and elite athletes because both institutions are members of the International Society of Orthopedic Centres,” said Professor Jiri Dvorak, FIFA’s chief medical officer, in the May 19, 2014 news release.

“This recognition is an extraordinary privilege and complements HSS’s longstanding connection to world-class athletes through a broad range of sports, including soccer, as the official hospital of the New York Red Bulls,” said Louis A. Shapiro, president and CEO, Hospital for Special Surgery. “While our sports medicine service is dedicated to the care of professional athletes, clinicians throughout HSS are committed to getting them back safely to their highest level of play.”

Riley J. Williams, III, M.D. is an orthopedic surgeon and member of the Sports Medicine and Shoulder Service at HSS. He has served as the medical director for the New York Red Bulls since 2006. Dr. Williams told *OTW*, “Taking care of elite athletes takes a great deal of focus. One doctor doesn’t do it all. At Hospital for Special Surgery, we have a multi-disciplinary team consisting of the head team physician, additional sports medicine specialists, physical therapists, athletic trainers, nutritionists, and strength and conditioning coaches. It’s a rewarding endeavor, and we enjoy what we do.”

Julie Zielinski, M.D. Receives “One With Courage Award”

Per a May 24 article in *The Chattanooga (.com)*, “Julie Zielinski, M.D., pediatric orthopedic surgeon at Children’s Hospital at Erlanger, Chattanooga, Tennessee, has received the “One with Courage Award” for Healing from the Children’s Advocacy Center of Hamilton County. Dr. Zielinski received the award during the inaugural One with Courage Awards Luncheon on Thursday, April 3, at the Downtown Marriott. The One with Courage Awards Luncheon celebrates champions of children in the area who enrich the lives of kids through Help, Hope or Healing and honors those who support the children served by the CACHC through giving, service, or voluntarism. The Healing award goes to champions who have the courage to make hurting children whole by providing healing to their mind, body or spirit.”

Dr. Zielinski received a medical degree from Wayne State University Medical School in Detroit, Michigan. She completed an orthopedic surgery residency program from McLaren Regional Medical Center in Flint, Michigan and fellowship training in pediatric orthopedic surgery at Arnold Palmer Hospital for Children in Orlando, Florida. ♦

COMPANY

Stryker CEO Refutes S&N Purchase, Sort Of

Stryker Corporation is evaluating a purchase of Smith & Nephew plc (S&N). However, in response to a United Kingdom regulator request to declare the company's intentions, Kevin Lobo, Stryker's CEO, said there would be no bid for the company...today.

Lobo even went on *Fox Business News* on May 28, 2014 to confirm that the company had no intention of acquiring (S&N)...for at least six months.

Traders Gone Wild

Lobo was responding to traders gone wild on the London Stock Exchange after a story in the *Financial Times* reported that Stryker was evaluating a takeover of S&N. That caused the UK Takeover Panel to contact Stryker.

"We confirmed we do not intend to make an offer for S&N. We were in preliminary evaluations about considering a transaction," said Lobo. "For the next six months we are not in a position to make an offer." Under the UK Take-

over Code, Stryker is not permitted to announce an offer or possible offer for S&N or make any statement that raises the possibility that such an offer might be made for six months, unless a third party steps in to announce their intention to acquire S&N.

Ortho Musical Chairs

Lobo cited the Zimmer/Biomet deal as evidence of consolidation in an industry that has been growing slowly over the last four to five years. He pointed out that we will now be down to only four large hip and knee makers after the Zimmer/Biomet deal is completed.

Asked about the \$4 billion burning a hole in his pocket, Lobo told *Fox* that mergers and acquisitions remain the company's top priority, noting that he's engineered five acquisitions since he took over from Stephen MacMillan 18 months ago. He highlighted the deal in China with Trauson Holding Limited for low cost orthopedics and MAKO Surgical on the high-tech end.

What If...

Wells Fargo analyst Larry Biegelsen stated in an investor note that he thinks that an acquisition of S&N by Stryker would, "make strategic sense, given the recently announced Zimmer/

Biomet transaction and the speculation of further consolidation in the orthopedic industry. The combined Stryker and S&N would have over 30% market share of the hip and knee markets, second only to the combined Zimmer/Biomet." Given that Stryker was only at an early stage of evaluating a takeover of S&N, Biegelsen said he would not be surprised to see Stryker eventually bid on S&N.

Big Three

Glenn Novarro of RBC Capital Markets also did not rule out an eventual deal. He said acquiring S&N would give Stryker more recon scale, particularly in international markets and leave Johnson & Johnson's DePuy Synthes a distant third. A new Big Three would share 98% of the market with Zimmer/Biomet at 40%, Stryker/S&N at 34% and DePuy Synthes with 24%.

Additionally, says Novarro, a deal would increase Stryker's international recon presence as only approximately 39% of the company's recon sales are from international markets (vs. approximately 54% for S&N). A deal would also help Stryker with institutional purchasers and lead to more stable longer-term recon implant pricing as only three competitors share the market.

Stryker would also get a bigger presence in trauma, sport medicine and advanced wound management, which is a \$6 billion global market and growing at about 4% per year.

Stryker may be prohibited from talking about a deal for the next six months, but the company is not prohibited from continuing to talk to S&N about becoming number three in orthopedics. Stay tuned.

—WE (May 28, 2014)



Logos courtesy of Stryker Corporation and Smith & Nephew

Medtronic Spine Sales Decline – Waiting for Infuse and Kyphoplasty

Medtronic Inc.'s overall spine sales declined by 2% to \$786 million during the company's previous quarter.

During a call with Wall Street analysts on May 20, 2014, company leaders said with core spine sales growing, they are counting on the stabilization of kyphoplasty and Infuse to get them back to overall growth.

Core Spine Business Growing

Excluding sales of balloon kyphoplasty (BKP), company management reported that its core spine business grew by 1% to \$662 million in a spine market that remained relatively flat on a year-over-year basis. Infuse sales of \$124 million declined 11% due to difficult comparisons following the resolution of a supply disruption in the prior year. An Infuse liability settlement also impacted net earnings.

Core spine sales were driven by the company's surgical Synergy program, which includes imaging, navigation and powered surgical instruments. Management said hospitals are leveraging surgical Synergy by adopting flexible integrated procedural solutions for spine surgery. "They see clear value from improved surgical precision and more efficient procedures. This is resulting in solid growth in capital equipment sales in our surgical technologies business, as well as increased spinal implants growth," said company CFO Gary Ellis.

"In fact," continue Ellis, "in accounts that have adopted our surgical Synergy program, core spine revenue growth



Medtronic Spine Headquarters/Memphis Business Journal

is meaningfully higher. Outside of the U.S., our Kanghui acquisition continues to deliver solid revenue growth in the value segment of orthopedics, both in China and in other emerging markets.

Waiting for Infuse and Kyphoplasty

When will things get better for Medtronic spine sales?

Company Chairman and CEO Omar Ishrak said stabilizing Infuse is a "big, big driver" and then punted to Chris O'Connell, the head of the company's restorative therapies business (which includes spine).

"We've obviously been suffering through some declines in Infuse and BKP over the past couple years...we've been working very hard to try to stabilize, and actually as we look forward, we think there is a very nice story developing," said O'Connell.

"Obviously after the Yale publication on Infuse last summer, we saw some softening and confusion following that. But now that the market has digested that information, we've actually seen three quarters in a row of sequential stability, which we believe points to a pattern of

stability heading into next fiscal year. And so, it's our goal to see the overall Infuse program be somewhat flattish over the next year."

O'Connell said he was seeing encouraging trends in BKP, principally in the U.S. As the company continues to diversify its spine product line and looks to build a bigger platform of interventional spine off the core Kyphon business, he

Medtronic Spine 4Q14	Sales (\$ in millions)	% Change*
Total Sales	\$786.0	down 2%
Core Spinal	\$662.0	flat
Biologics	\$124.0	down 11%

Source: Medtronic, Inc.
* constant currency

expects to remain "flattish" into next year. He repeated that the Infuse and BKP businesses have been relatively stable sequentially for three or four quarters. "So if we get BMP and BKP to be flat, then you're going to see the overall spine franchise lift.

Stable and Improving Markets

The markets are stable and gradually improving in core spine, according to O'Connell. "And so our expectation is that the overall spine franchise continues its transition to positive growth for the overall business. when we look across the last few quarters and see an overall spine market that's up in the 1% to 2% range, with the U.S. being flattish and international up in the low-to mid-single digits.... That represents a somewhat of an improvement pattern over the last four to six quarters. We are seeing market conditions very stable."

Ellis said both the global and U.S. core spine markets appear relatively flat on a year-over-year basis, a slight decelera-

tion from the growth the market saw last quarter. He told analysts that this was principally driven by the U.S., where he believes some elective surgeries were pulled forward ahead of the changes from the Affordable Care Act at the beginning of the calendar year.

Medtronic made big bets on kyphoplasty and Infuse before Ishrak's arrival. His predecessor took great criticism for those acquisitions and now his lieutenants are on the hot seat. The bets have been laid down. Let the wheel ride.

—WE (May 28, 2014)

\$33 Million for SI-BONE

SI-BONE, Inc. recently received a major infusion of funding with which to grow and expand...\$33 million in capital will go a long way. Those disbursing the funds included Orbimed and Novo A/S, as well as current investors Skyline Ventures and Montreux Equity Partners.

Proceeds from the investment will be used to fund expansion of the U.S. sales organization and add additional resources in R&D, medical affairs, regulatory, compliance and reimbursement.

Regarding use of funds for growth of the U.S. sales organization, Jeffrey Dunn, president and CEO of SI-BONE told OTW, "We plan to double the size of our direct U.S. sales force this calendar year to address growing surgeon demand and interest in SI joint [sacroiliac joint] diagnosis and treatment with iFuse. Due to that level of sales force growth, we will also increase our supporting infrastructure primarily within our medical affairs, marketing

and reimbursement organizations to better handle the demand for new surgeon training, case coverage and field support."

The company is also pursuing regulatory approvals for iFuse in Asia, the Middle East, Canada and South America and initiating commercialization in Australia, New Zealand and Hong Kong.

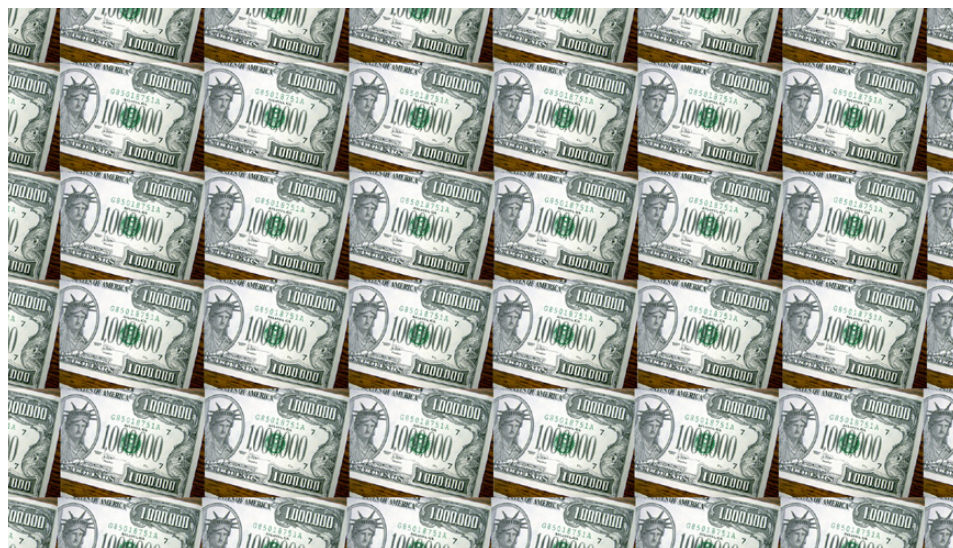
On this topic, Dunn told OTW, "We have already begun the process of obtaining regulatory approval in over a dozen countries outside of the U.S and Europe. The decision on what countries to target was based on a combination of demand from specific countries for minimally invasive SI joint fusion plus the size of each market as well as accessibility of health care delivery in each market. We will commercialize in new countries based on where regulatory approvals are first obtained. The iFuse Implant System was recently approved in Australia, New Zealand, Israel, and Hong Kong with more approvals to follow this year and next."

Dunn added, "Over the past year or so, there have been a dozen papers published on the safety and effectiveness of

the iFuse Implant System. The positive results of these studies have resulted in the assignment of a Category I CPT code for minimally invasive SI joint fusion. In addition, results from these studies have generated an accelerated interest among surgeons and other health care professionals to identify and treat patients suffering from chronic SI joint mediated pain due to degenerative sacroiliitis and sacroiliac joint disruptions. More and more, medical device growth and adoption is contingent on great clinical evidence."

"By early next year we expect to publish the first prospective randomized controlled study in this area. Additional publications are expected sooner, such as the first analysis of five-year data on iFuse. This high quality evidence will influence payers in the United States and the rest of the world to establish coverage. Given the strength and consistency of our data, reimbursement coverage is increasing both in the U.S. and abroad. For all of these reasons, we felt it was the right time to take on additional investment capital to meet the growing patient and surgeon demand."

—EH (May 23, 2014)



Morguefile and jdurham

Kinamed's Polymer SuperCable Cleared in Japan

Kinamed Inc.'s SuperCable Iso-Elastic Polymer Cerclage System has been cleared in Japan by the Ministry of Health, Labour and Welfare.

According to a May 12, 2014 company press release, the cable system is the only iso-elastic, polymer cerclage system in the market anywhere in the world. It is used in a wide range of orthopedic reconstructive and trauma applications. It has been in clinical use in the U.S. for ten years.

Addresses "Fretting Wear"

The key word here is "polymer" because fretting from ancillary fixation devices,

such as braided metal cerclage cables, can generate a substantial volume of metallic debris that contributes to local and systemic particulate burden.

Traditional metal cerclage cables are made up of many tiny braided metal wire filaments that, by the very nature of their construction, result in a large number of metal-on-metal wear interfaces. Wear between nonbearing surfaces can occur at modular connections, at interfaces between the prosthesis and cement or bone, and with ancillary devices employed to reattach the trochanter or to stabilize periprosthetic fractures or bone grafts. There have been reports of loose and broken stainless steel hardware in patients due to this "fretting wear."

A 2004 study by Urban, et al. in the *Journal of Arthroplasty*, metallic particles

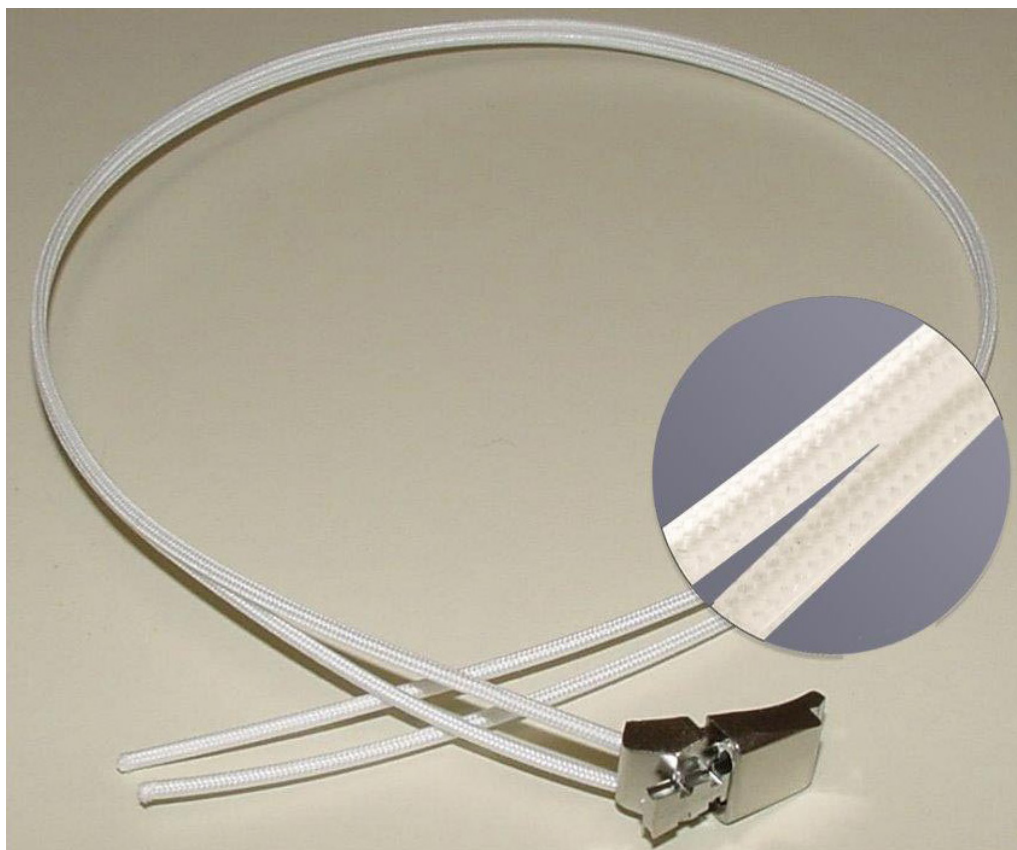
generated between nonbearing surfaces were present in the liver and/or spleen of 73% of patients with a prior failure and revision of their hip arthroplasty.

According to the company, the polymer cable system offers an alternative cerclage cable that eliminates cerclage fixation as a source of metal debris burden. Constructed from high-strength polyethylene fibers and nylon, and fixed with a titanium clasp, immunogenic metals such as chromium and cobalt are avoided. The pliable polymer fibers offer extraordinary fatigue strength and resistance to abrasion. The "Iso-Elastic" nature of the SuperCable is designed to allow it to move with the bone during cyclic loading in order to help prevent "digging in" and to remain tight during the bone healing phase.

Commercialization

The company will begin commercializing the system through its longtime Japanese distribution partner, Yufu Itonaga Co., Ltd. of Tokyo. Yufu also represents two other Kinamed product lines in Japan: the CarboJet CO2 Lavage System used for cleaning and drying the bone bed in cemented arthroplasty procedures and the NeuroPro Cranial Fixation System used by neurosurgeons for cranial closure. The company's portfolio also includes associated cable-plates and trochanteric grips for the cerclage cables; the KineMatch Patello-Femoral Replacement, a CT based custom arthroplasty technology; the NaviPro Surgical Navigation System, and the NeuroPro Cranial Plating System.

—WE (May 22, 2014)



SuperCable Iso-elastic, Polymer Cerclage System /Kinamed Inc.

Dvorak and Binder Encourage Zimmer/Biomet Employees

Dave Dvorak and Jeff Binder (the CEOs) tell their sales reps in a May 20, 2014 letter that it is their intention to retain all sales rep positions when their companies, Zimmer Holdings, Inc. and Biomet, Inc. merge in 2015. We reviewed the letter from a regulatory filing.

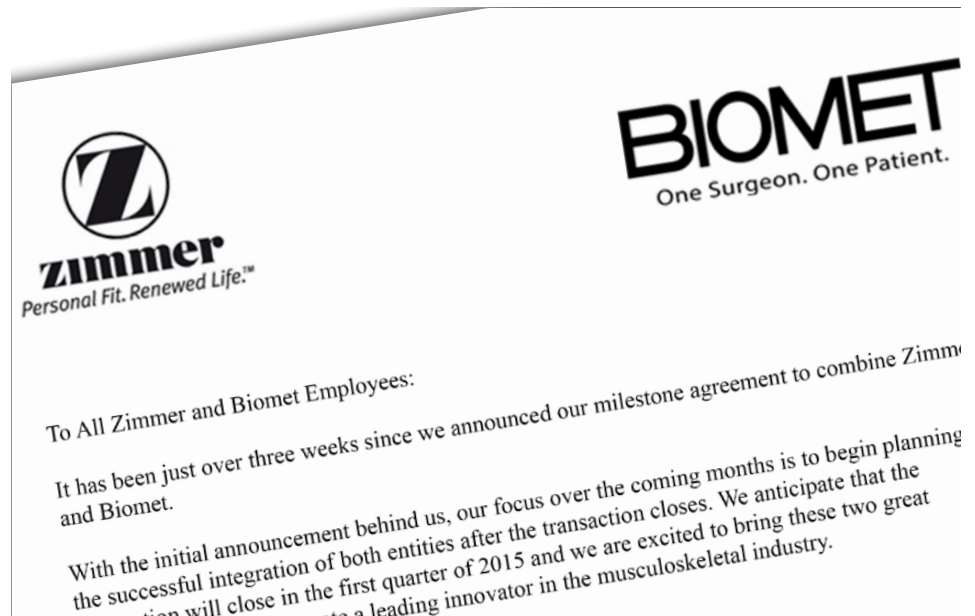
Judging by the overwhelming response by OTW readers to Drue De Angelis' letter to his former colleagues, it's clear that many employees are concerned over keeping their jobs, understanding how the very different cultures of the companies will coexist and what happens to their competition for customers while integration takes place. The CEOs address those issues.

Protect Ongoing Business

The CEOs write that an important objective during integration "is to protect our ongoing businesses' momentum by continuing to focus on our respective Customers and their patients. While using this integration planning process to create a shared vision of our culture, strategy and operating model, we should keep in mind that we are independent companies until the transaction closes and we must compete as vigorously as we did before the announcement of the merger."

Because the companies have highly recognizable names, they write there is often significant media attention and employees are to direct media inquiries to the proper company spokesperson.

"We have heard from many of you since the merger announcement... [So] we



Zimmer Holdings, Inc. SEC Form 425

have attached an updated list of FAQs (Frequently Asked Questions). If you have additional questions, feel free to direct them to ComingTogether@zimmer.com. We will provide periodic updates to the FAQ document over the coming weeks and months and we are committed to keeping you informed as important decisions are made."

Here are the first issues addressed by the CEOs:

Sales Integration

"It is important to remember that this transaction is in large part about growth, and it is our intention that all sales representative positions from both companies will be retained post-closing. In fact, we believe this combination will lead to greater opportunities for the advancement and growth of sales representatives of the combined company."

Spine

"Enhancing the market competitiveness of some of the smaller businesses of each company was one of the reasons

behind this combination. The addition of the Biomet Spine business will provide Zimmer an increased opportunity to reinvest in product development, offer additional medical education and training, and enhance our global distribution channel. In addition, we will be better positioned to recruit and retain sales talent with an expanded product portfolio.

Customer Feedback

"The feedback and tone has overall been positive. Many Customers have expressed their excitement regarding how the combined company will have a greater opportunity to innovate, not just at the product and technology level, but through services and comprehensive solutions offered by virtue of the increased resources and talent of the combined company."

Merging Cultures

"There are many aspects of our cultures that make for a very good fit... We will be identifying the best organizational and cultural practices from both orga-

nizations in order to form a new entity that leverages the strengths of both companies...shap[ing] the optimal culture...is critically important for our successful integration. The objective is to build an even stronger organization that offers more for employees, sales representatives and our Customers after the integration is completed. Employee involvement in this process will be vital to our success.”

Status of Zimmer’s Quality Excellence Initiatives

“Until the transaction is successfully completed...we remain an independent company, and it will be business as usual at Zimmer. Successful execution is a top priority and this will not change as a result of the integration planning work. Remaining focused and concentrating on doing your best is how you can have a positive impact on the success of Zimmer.”

Integration Steering Committee

There will be an Integration Steering Committee (ISC), an Integration Management Office and a variety of functional, business unit, regional and other dedicated integration teams. “Importantly, all integration oversight and planning teams will be composed of representatives from both Zimmer and Biomet.”

The ISC will oversee the execution of an integration planning strategy; and will identify a multi-phase planning process to facilitate a “smooth and seamless integration after the close of the transaction.”

There will be eight members of the committee made up of four leaders from each company. In addition to the CEOs (Dvorak and Binder), CFOs (Jim

Crines and Dan Florin) and Human Resource Senior VPs (Bill Fisher and Peggy Taylor), Zimmer is sending Chad Phipps, their general counsel and secretary, while Biomet is sending in Dan Williamson, their head of reconstructive joints.

To read the letter in its entirety, click here: <http://investor.zimmer.com/secfiling.cfm?filingID=1193125-14-206672>

—WE (May 21, 2014)

Ceterix Orthopaedics Raises \$18 Million for Meniscus Repair

Ceterix Orthopaedics, Inc. has raised \$18 million in a new round of funding to expand the market for its minimally invasive surgical tools.

The technology enables surgeons to place stitches in very tight joint compartments, while protecting sensitive surrounding structures such as nerves, arteries and cartilage. This technology has applications in numerous proce-

dures in knees, hips, and shoulders. The company, formerly known as SuturePro Technologies, Inc. released its first product last year, aimed initially at helping doctors fix tears of the knee’s meniscus, rather than removing the cartilage and potentially damaging nerves and other structures. According to the company, more than 100 physicians in the U.S. use the tools.

The procedure was developed by Justin Saliman, M.D. an orthopedic surgeon at Cedars-Sinai in Los Angeles.

“Due to the difficulty of access and the limitations of current arthroscopic instruments, the vast majority of meniscal tears are not repaired but are either partially or totally resected,” said John McCutcheon, Ceterix’s president and CEO, in a 2013 press release. “This means that almost a million patients each year are undergoing procedures that will significantly increase their risk of osteoarthritis later in life.”

Previous investors Novo A/S, Versant Ventures and 5AM Ventures participated in the round, which also included debt financing from Silicon Valley



Suture Passer/NovoStitch Ceterix Orthopaedics, Inc.

Bank and Oxford Finance. Armentum Partners acted as financial advisor to Ceterix in the transaction.

In addition, Ceterix announced the issuance of two key U.S. patents, related to methods of meniscal and soft tissue repair with its proprietary technology.

The Menlo Park, California, company, founded in 2010, was backed by investors Novo Ventures, Versant Ventures and 5AM Ventures with \$19.5 million in a Series B venture financing in January 2013.

Kevin Stone, M.D., a San Francisco knee

surgeon and advocate of biologic solutions for knee repair, told OTW, "While we love tools that help us place sutures in hard to reach places, buyers beware. As orthopedic surgeons we are good at continually coming up with novel ways to do it and the patent protection on our small iterations is very vulnerable. Translated: you will see multiple variations each year. So exit quickly." Dr. Stone is the founder of Aperion Biologics, Inc.

To view a video of the procedure, click here: <http://www.ceterix.com/suture-passing/>

—WE (May 22, 2014)

LEGAL

FDA to Review Additional Oxiplex Data

FzioMed, Inc.'s hearing with the FDA's Dispute Resolution Panel for its Oxiplex PMA (premarket approval) application has been postponed. The hearing was scheduled for June 10, 2014.



Oxiplex/FzioMed, Inc.

The company announced on May 28, 2014 that the Office of Device Evaluation (ODE) is going to take more time to review additional clinical information.

OUS Data

The additional information, which the company expects to submit in June, will consist of analyses of additional data obtained in a clinical investigation of Oxiplex outside the U.S. (OUS) ODE has committed to an expeditious review of this information within 90 days of receipt. If the additional clinical information is determined to be sufficient to support approval, together with previously submitted data, the company would proceed with submission of a PMA amendment. The company intends to renew the dispute resolution process in the fourth quarter if the postponement fails to result in a resolution.

Commenting on this development, FzioMed President and CEO John

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Krelle stated, “We appreciate the continuing cooperation of ODE staff, the Center Ombudsman’s Office, the Center Director’s Office, and the Commissioner’s team throughout this process. We look forward to working collaboratively with FDA to analyze and evaluate the additional data.”

This is a positive development for the company, as they have been attempting to convince the FDA to accept clinical information from outside the U.S. for a long time.

Application Road

FzioMed has been seeking FDA approval of Oxiplex for more than a decade. The FDA’s Center for Devices and Radiological Health (CDRH) has reviewed data on approximately 500 patients from four peer-reviewed published clinical studies spanning three continents. The company says the totality of data from the various studies submitted to FDA on Oxiplex, combined with extensive clinical success achieved around the world, demonstrate that Oxiplex can offer increased clinical benefit compared to discectomy surgery alone, while presenting no significant safety risk.

FzioMed filed their PMA application in August 2007. The agency’s orthopedic panel met in July 2008 and voted to recommend against approval. The FDA then issued “not approval” letters in September 2008 and once again in January 2010. In October 2011, the company requested supervisory review by the Office of the Center Director of the not approvable decision. A letter issued on October 9, 2012, by William Maisel, M.D., on behalf of the Office of the Center Director, upheld the not approvable decision.

The company then chose to exercise the option to consider the October 9,

2012 decision letter to be a denial of approval of the PMA and requested an administrative review by filing a petition for reconsideration on November 5, 2012. On November 4, 2013, the company announced that FDA Commissioner Margaret Hamburg, M.D. approved their petition for an independent review of their PMA and a rare special Medical Devices Dispute Resolution Panel meeting.

Oxiplex

Oxiplex is an absorbable, clear, viscoelastic hydrogel that is applied during lumbar spine surgery. Oxiplex has been approved for sale in the European Union since 2002 and is now approved in 70 countries. It has been used in more than 350,000 surgeries worldwide. The company has been working for 12 years to gain FDA approval to market this device in the U.S.

—WE (May 30, 2014)

75% of Doctors Accuse Colleagues of Unnecessary Procedures

Seventy-five percent of doctors think their contemporaries order at least one unnecessary test or procedure a week, according to a survey by Choosing Wisely reported by writer Zack Budryk of *Fierce HealthCare*.

The reasons physicians gave for ordering extraneous tests were malpractice concerns (52%), to be extra cautious (36%), to get more information so as to reassure themselves on their diagnosis (30%) and patient insistence on the procedure (28%). About 5% said they had been motivated by the fee-for-service system.

Budryk wrote that 47% of the respondents reported that one patient a week requests an unnecessary test or procedure. When that happens, 48% of the doctors reported that they advise the patient against it but eventually defer to the patient’s wishes.

“I think we’re afraid of not being liked,” Donald Ford, M.D., a vice president at Hillcrest Hospital in Mayfield Heights, Ohio, told *Kaiser Health News*. “We want to be the hero to the patient.”

None of the doctors responding to the survey thought that Medicare was in the best position to address the problem and more than half (58%) put the responsibility for correcting the problem on the doctors themselves. More than three in four (78%) of those who responded said it would help to have more time to talk with patients and 61% said that changing the system of payment so physicians were not incentivized to order more tests would be effective.

—BY (May 28, 2014)



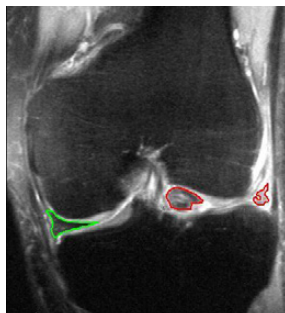
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BIOLOGICS

Tiny Trial Increases Knee Cartilage 41%

From *Huffpost Healthy Living* comes a story by Amanda Chan about a trial for an experimental knee osteoarthritis treatment in India. Running the trial was Vjay Vad, M.D., a sports medicine specialist at the Hospital for Special Surgery in New York. His treatment, called “percutaneous cartilage bone interphase optimization” (PeCaBoo) involved collecting a patient’s own stem cells and injecting them in the knee where the bone meets the cartilage.

The trial, which included 10 patients and was completed through Vad’s own biotech company, Vad Scientific LLC., showed that the treatment increased cartilage matrix in the knee an aver-



Wikimedia Commons and MBq

age of 41%, as measured by MRI. Vad reported the results at a meeting of the European Society for Sports Traumatology, Knee Surgery and Arthroscopy.

Vad explained to *HuffPost’s* writer, “We’re stimulating your own bone marrow so that it spits out embryonic-like stem cells, we’re gathering those stem cells, and we’re putting them where the bone meets the cartilage.” Vad claimed this accomplished two benefits, it increased blood supply to the knee and simulated stem cell activity. He said that stem cells

act like whatever cells they’re near so putting them near cartilage makes them “want to become like cartilage,” he said. Vad noted that it remains unknown whether the stem cells turn into cartilage or a cartilage-like substance.

Vad said he hopes this new PeCaBoo method could provide another option beyond joint replacement. He told Chan, “It’s much cheaper than a knee replacement. There’s no hospitalization, [and] there’s really no issue with blood clots and pulmonary embolism of a total knee replacement,” he said. “There’s no metal, and there’s a much smaller risk of joint infection. And last but not least, the downtime is small—you can go back to work the next day.”

Vad is planning to expand the PeCaBoo trial in India, and is working on gaining approval for a trial in the United States.

—BY (May 29, 2014)

LARGE JOINTS

Over 50% TKR Patients Obese – New JBJS Study

Obesity is associated with longer hospital stays and higher costs in total knee replacement (TKR) patients, according to a new study published in the *Journal of Bone and Joint Surgery*. The increases hold true regardless of whether the patient has an obesity-related disease or condition.

The study investigators found that more than half of TKR patients have a body mass index (BMI) that is within the obesity range—a range that is linked to a higher risk for related comorbidities such as diabetes, hypertension and

osteoarthritis. *Medical Press*, which reported the study, indicated that research is inconclusive as to whether the higher medical costs in the cases of obese TKR patients are due directly

to their higher BMI or to their related comorbidities.

In the study, researchers reviewed the BMI, comorbidities, complications,



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outcomes and cost of care of 8,129 patients who had undergone 6,475 primary TKRs and 1,654 revision TKRs at a major medical center between January 1, 2000 and September 30, 2008. The median patient age was 68. Fifty-seven percent of the patients who underwent primary TKR and 53% who underwent revision TKR were female. The mean patient BMI for the study subjects was 31.6 kg/m²—slightly higher than the range of 30kg/m², which is the level defined for obesity.

The investigators found that the most common patient comorbidities were hypertension and diabetes. The length of stay and medical costs were lowest for patients with BMI values in the normal to overweight range. Every 5-unit increase in BMI beyond 30 kg/m² was associated with higher hospitalization costs and every 5-unit increase in BMI beyond 30 kg/m² was associated with a mean hospital stay that was 0.11 days longer for patients undergoing primary TKR and 0.06 days longer for patients undergoing revision TKR.

“The higher costs associated with obesity are largely due to managing comorbid medical conditions linked to obesity, such as diabetes,” said lead study author Hilal Maradit-Kremers, M.D., an associate professor of epidemiology at Mayo Clinic in Rochester, Minnesota. “Even in the absence of comorbidities, patients with obesity had longer stays and higher hospital costs,” he said.

“The bottom line is that obesity is increasingly common among patients undergoing joint replacement, which creates a myriad of technical and medical challenges, and likely contributes to the financial burden of the surgery,” said senior author David G. Lewallen, M.D., an orthopedic surgeon at Mayo Clinic.

—BY (May 28, 2014)

EXTREMITIES

Tommy John Surgeries on the Increase

The tiny ulnar collateral ligament—barely more than two inches long—is a major worry for major league baseball. According to Ronald Blum, an AP sports writer, more than a dozen major league pitchers have already undergone Tommy John surgery—the replacement of their elbow ligament with a tendon from some other part of their body.

Blum reports that all-stars Patrick Corbin, Josh Johnson and Matt Moore have had the surgery, and National League Rookie of the Year Jose Fernandez is scheduled to have his operation soon. A 2013 survey, referred to by Blum, showed that 25% of big league pitchers and 15% of minor leaguer pitchers have undergone the Tommy John procedure. Glenn Fleisig of the American Sports Medicine Institute, who conducted the survey with Stan Conte of the Dodgers, told Blum, “This does not include the guys who didn’t make it back. These are the success stories.”

So how many balls can a pitcher throw before he puts his pitching arm in jeopardy? A study published in 2011 examined 481 pitchers ages 9-14, and then checked with them 10 years later. The study found that those who threw more than 100 innings in a year were 3.5 times more likely than pitchers throwing fewer balls to need elbow or shoulder surgery. Or they had to stop playing baseball.

Blum noted that the USA Baseball Medical/Safety Advisory Committee recommends limits of 50 pitches per game and 2,000 pitches per year for 9- and 10-year-olds, and 75 pitches per game and 3,000 per year from pitchers age 11-14. The limit rises to 90 at ages 15-16 and 105 for ages 17-18, with no more than two games a week.

Major League baseball officials agree there is a problem and they are looking for ways to protect the pitchers’ valuable elbows before surgery becomes necessary. Officials say they plan to launch a research project “to help figure this out.” They agree that the problem has “gotten everyone’s attention.”

—BY (May 29, 2014)



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PEOPLE

NuVasive: Lambert Retiring, Blackford Rising to CFO

NuVasive, Inc. has announced that Michael Lambert intends to retire from his role as chief financial officer later this year and that Quentin Blackford, its current executive vice president of Finance, Accounting and Investor Relations, will succeed Mr. Lambert.

Lambert has been NuVasive's CFO since November 2009. His retirement as chief financial officer, which will be effective on July 31, 2014, is for personal and family reasons. Lambert plans to stay actively employed with NuVasive through March 31, 2015 to assist with the transition to Blackford. His continued engagement will also focus on driving ongoing initiatives relating to expanding operating margin and process efficiencies.

Blackford will assume the role of chief financial officer on August 1, 2014. He will have responsibility for finance, accounting, tax, treasury and investor relations. Blackford has nearly 15 years



Quentin Blackford, courtesy NuVasive, Inc.

of financial experience within medical device organizations, and that experience will be invaluable as NuVasive drives toward \$1 billion and beyond in revenues with a strong focus on continually expanding profitability.

Blackford has served as NuVasive's executive vice president of finance, accounting and investor relations since February 2014, following his tenure as senior vice president of finance & investor relations since July 2012. Prior to that, he served as vice president,

finance from January 2011. Blackford joined NuVasive in 2009 as corporate controller. His experience in the medical device industry includes his time at Zimmer Holdings, Inc. where he held various roles and responsibilities, including the director of finance & controller for Zimmer's Dental Division where he was responsible for all finance, accounting and IT activities for the worldwide division. Prior to his role at Zimmer's Dental Division, Blackford directed the corporate-wide financial planning and analysis function for Zimmer Holdings, Inc. Blackford is a certified public accountant and obtained Bachelor of Science degrees in both accounting and business administration from Grace College.

Blackford told OTW, "I am extremely excited to be stepping into the role of CFO here at NuVasive. The future has never been brighter as we are uniquely positioned to continue our share taking top-line growth while delivering meaningful improvements in the profitability profile of our business. I look forward to continuing with our plan to drive meaningful earnings growth well into the future as we approach \$1B in revenue."

—EH (May 30, 2014)

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