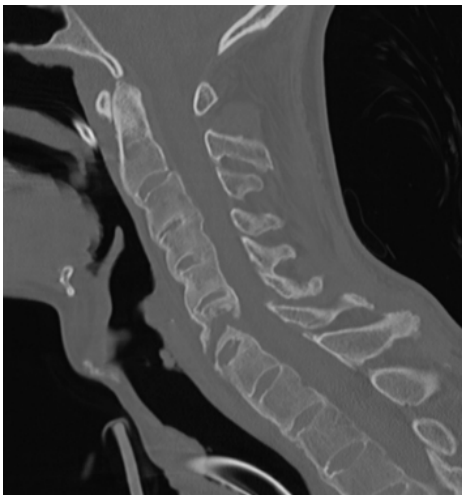
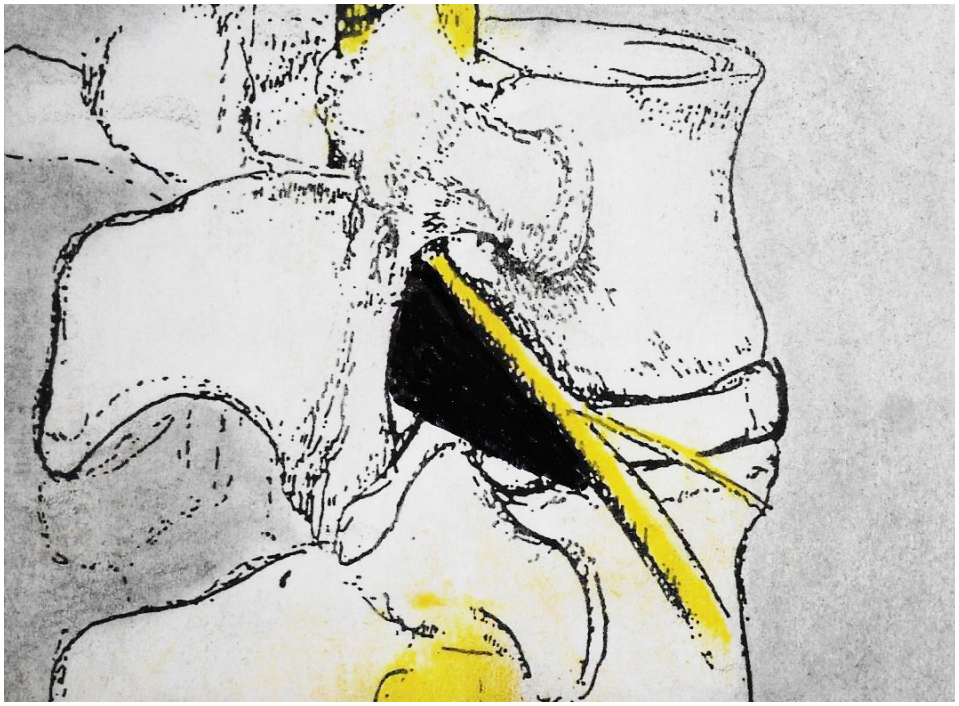
VOLUME 11, ISSUE 28 | SEPTEMBER 1, 2015

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: China's economy has two basic problems—too much government, too little financial transparency. Markets assume that the liability side of China's economy is bad. With commodity prices falling as rapidly as they are (see oil) the generalized anxiety is a Chinese-triggered global deflation. But the BIG fear is central banks can't stop it. We're not out of the woods yet.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	22.78%	(2.25%)	It will be interesting to hear management's comments re the China business this quarter. In all other respects, SYK is rolling along.
2	4	Xtant	(16.41)	7.43	CEO Goldberger has pulled off a neat hat trick. X-Spine merger. Recapitalized the company. Name change. Bingo: growth stock.
3	6	Orthofix	2.35	13.23	Institutional investors were waiting to fall back in love with OFIX. Stock is up 13% in a truly miserable market. If that's not love, what is?
4	3	Johnson & Johnson	28.44	(4.57)	With the lowest P/E ratio in all of orthopedics and the 2nd lowest future P/E, JNJ is certainly someplace to park $$ in uncertain times.
5	2	Smith & Nephew	20.19	2.64	Investors are enamored with SNN's wound care and orthopedic businesses. Solid, staple. Unfortunately only 1% growth.
6	7	Zimmer Biomet	30.35	(2.46)	Really looking forward to the next couple of quarterly earnings calls to see how integration is playing out.
7	5	Medtronic	27.92	(5.55)	MDT spine reports results this week. Most analysts expect 3-4% sales growth including higher Infuse sales.
8	8	RTI Biologics	7.50	(6.50)	Zacks research thinks RTI's earnings will grow 90% and cash flow will leap 100%. But markets remain cautious with RTI.
9	9	Integra LifeSciences	13.74	(5.28)	Strong strategic moves this year (SeaSpine for example). Key is translating into higher profits and growth.
10	10	Globus Medical	30.87	(9.57)	Lost 10% of its value in the last month. For a company generating 30% operating profit margins, that is irrational.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$1.15	$184	31.20%
2	Orthofix	OFIX	$38.08	$718	13.23%
3	Bacterin Intl Holdings	BONE	$3.76	$44	7.43%
4	Smith & Nephew	SNN	$36.16	$16,173	2.64%
5	NuVasive	NUVA	$53.75	$2,630	-1.54%
6	Stryker	SYK	$99.69	$37,539	-2.25%
7	Zimmer Biomet	ZBH	$104.37	$21,225	-2.46%
8	K2M Group Holdings	KTWO	$21.65	$895	-3.82%
9	Johnson & Johnson	JNJ	$95.17	$263,536	-4.57%
10	Integra LifeSciences	IART	$60.79	$2,217	-5.28%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$0.54	$54	-60.29%
2	MiMedx Group	MDXG	$9.60	$1,046	-22.64%
3	Aurora Spine	ASG	$0.25	$5	-13.62%
4	Tornier N.V.	TRNX	$22.29	$1,098	-11.09%
5	LDR Holding Corp.	LDRH	$38.67	$1,121	-11.04%
6	Wright Medical	WMGI	$23.28	$1,197	-10.77%
7	Globus Medical	GMED	$24.75	$2,353	-9.57%
8	MicroPort Scientific	853	$0.37	$531	-7.65%
9	CryoLife	CRY	$9.90	$294	-7.48%
10	Exactech	EXAC	$18.64	$262	-6.85%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$95.17	$263,536	16.16
2	Exactech	EXAC	$18.64	$262	16.64
3	Zimmer Biomet	ZBH	$104.37	$21,225	18.98
4	Globus Medical	GMED	$24.75	$2,353	19.05
5	Medtronic	MDT	$73.56	$104,028	22.06

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$53.75	$2,630	85.84
2	CryoLife	CRY	$9.90	$294	82.78
3	MiMedx Group	MDXG	$9.60	$1,046	64.00
4	RTI Biologics Inc	RTIX	$6.33	$365	36.63
5	Smith & Nephew	SNN	$36.16	$16,173	32.28

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$24.75	$2,353	1.56
2	Zimmer Biomet	ZBH	$104.37	$21,225	1.69
3	Exactech	EXAC	$18.64	$262	1.87
4	Smith & Nephew	SNN	$36.16	$16,173	2.10
5	ConMed	CNMD	$53.77	$1,489	2.14

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$53.75	$2,630	5.73
2	MiMedx Group	MDXG	$9.60	$1,046	4.27
3	Johnson & Johnson	JNJ	$95.17	$263,536	3.34
4	Medtronic	MDT	$73.56	$104,028	3.34
5	CryoLife	CRY	$9.90	$294	2.76

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$0.54	$54	0.26
2	Exactech	EXAC	$18.64	$262	1.05
3	Bacterin Intl Holdings	BONE	$3.76	$44	1.25
4	RTI Biologics Inc	RTIX	$6.33	$365	1.39
5	MicroPort Scientific	853	$0.37	$531	1.50

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.15	$184	29.24
2	MiMedx Group	MDXG	$9.60	$1,046	8.84
3	LDR Holding Corp.	LDRH	$38.67	$1,121	7.51
4	Medtronic	MDT	$73.56	$104,028	5.13
5	Globus Medical	GMED	$24.75	$2,353	4.96

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

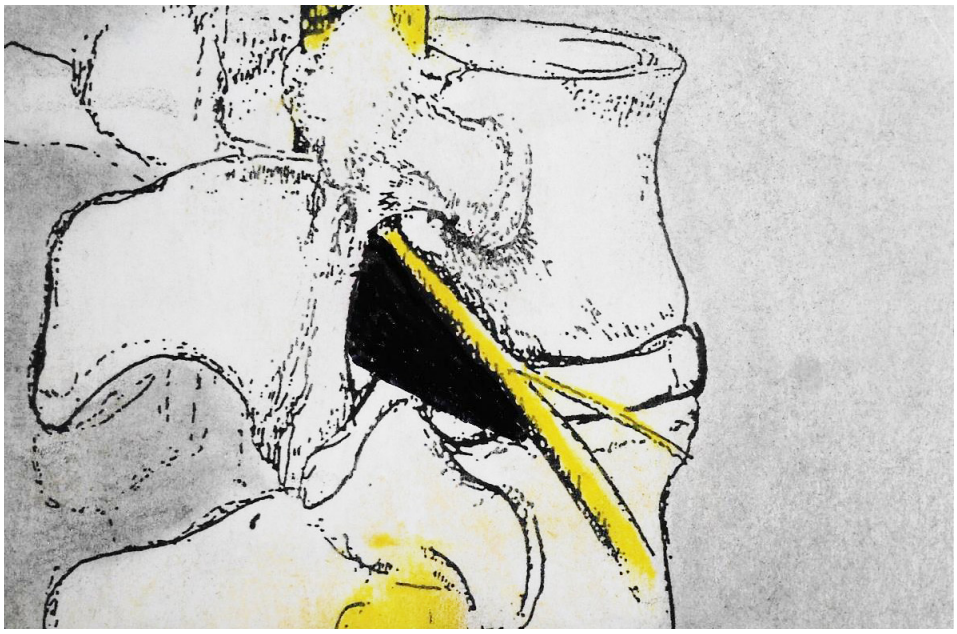
Big Changes Coming to Spine Surgery?

BY ROBIN YOUNG

On October 31, 2014 Medicare added nine new spine codes to its final 2015 Ambulatory Surgery Center (ASC) payment rules. Those codes are:

22551	Neck spine fusion & removal below c2
22554	Neck spine fusion
22612	Lumbar spine fusion
63020	Neck spine disk surgery
63030	Low back disk surgery
63042	Laminotomy single lumbar
63045	Removal of spinal lamina
63047	Removal of spinal lamina
63056	Decompress spinal cord

Source: Centers for Medicare and Medicaid Services



Wikimedia Commons and JDS319

Given the rise of outpatient spine surgery, these new codes could make outpatient spine surgery as common or perhaps more common than inpatient spine surgery. Holding the majority share of the $9 billion in annual spinal implant and instrumentation market would make the outpatient spine surgery market a very big deal indeed.

But, beyond the procedure and sales volumes, these codes have the potential to push innovation in new and interesting directions in order the meet the unique needs of the ASC market.

Outpatient vs. Inpatient Spine Surgery

Outpatient spine procedure volumes have exploded in the last ten years. In 2005, according to Jeff Leland, CEO of Blue Chip Partners, a manager of ambulatory surgery centers, only about 5% of all spine surgeries were performed in an outpatient basis. This year, he estimates, approximately 280,000 spine procedures will be performed in an outpatient setting. Between 2005 and 2015, he figures, the percentage of spine surgeries performed in an outpatient setting has risen from 5% to 44% of all spine surgeries.

Furthermore, even when a patient undergoes an inpatient surgical spine procedure, the number of days they are staying in the hospital are declining. So, even "inpatient" is becoming more and more "outpatient".

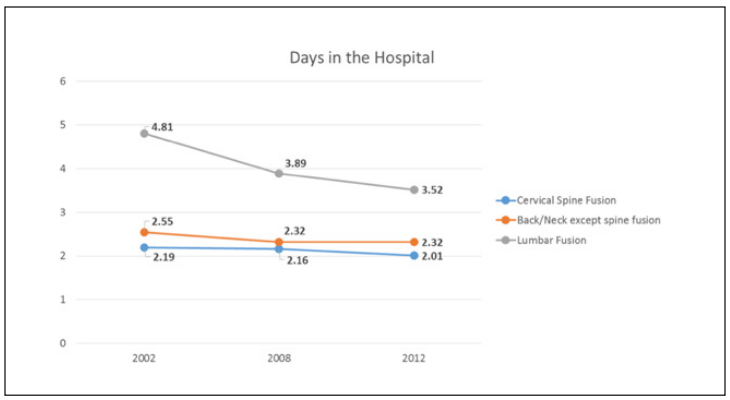
The following chart from Accelero illustrates this trend. *(See chart on page 5.)*

And what better way to accelerate this trend then to approve nine new ASC reimbursement codes? With outpatient spine case volumes approaching inpatient numbers, it won't be long before the majority of spine surgery is performed in the outpatient setting.

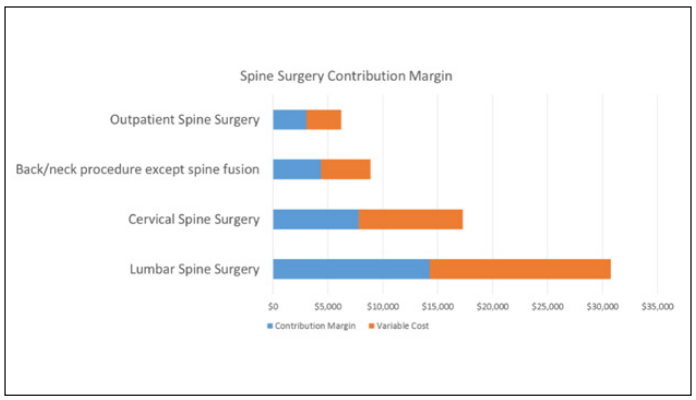
The economic incentives are clearly aligning to support significant expansion of outpatient spine surgery. According to a recent study of spine surgery procedures by Accelero Health Partners (a practice management consulting group), surgical spine cases accounted for 37% of the total musculoskeletal case contribution margin in 2012 and of that, the outpatient portion amounted to a little under half that at 15%.

Accelero compiled this data from a database of more than 45,000 inpatient and outpatient surgical spine cases.

Traditional outpatient spine procedures like hernia repair or decompression deliver among the lowest contribution



Source: Accelero Health Partners



Source: Accelero Health Partners

margin of any spine surgery. According to Accelero, the higher contribution procedures are lumbar fusion cases. As the table below illustrates, lumbar fusion contributes an average of $14,249 per case while traditional outpatient spine surgery contributes about one third as much or $3,048 per case. *(See chart above right.)*

But the BIG story is the difference between inpatient variable cost and outpatient variable cost. Inpatient variable costs are FIVE TIMES greater than outpatient for spine surgery.

Payers understand that outpatient surgery will inherently cost less than inpatient. But ASC-based spine surgery is largely new territory. According to Leland:

> "Because outpatient spine is a relatively new phenomenon, payers are uncertain about what it means to their business or how to approach it. Equipment and supply providers have been similarly hesitant. As a result, many payers have dragged their feet on signing on any contracts for fear that they would sign bad ones. Some even preferred to ask their customers (employers) to pay higher rates than admit their confusion."

"Specifically, spine-focused ASCs should work directly with payers to define algorithms for specific treatments and forge a comprehensive payment system for outpatient spine. Collaborating in this way may cost established spine ASCs some of the massive revenue they're currently generating, but by demonstrating a savings for the payers, they'll be more likely to capture a steady, long-term profitable revenue stream."

Spine Surgery in a Box?

Some of the most innovative new instruments and spinal implants are being designed for this rapidly growing market.

Case in point is Safe Orthopaedics. This French company is innovating a line of single use, sterile and fully traceable instrumentation systems for spine surgery. And Safe is not limiting themselves to decompression or hernia repair. The company is offering the entire range of spinal implants with associated, but disposable, instrumentation in kit form. They are ready to use out of the box.

Safe's goal is to streamline the expensive, complex and inefficient process by which traditional implant systems are delivered. One cost. No re-use. No sterilization.

The promise of single use implant and instrumentation kits is that they will:

Safe Orthopaedics

Save time:
- Less operating room prep time
- Always new and ready to use instruments for each surgery
- Fewer instruments (16 instruments)
- Pre-loaded implants
- No stolen/lost implants or instruments

Lower OR procedure costs:
- No cleaning, decontamination and sterilization of instruments
- No sterile paper, detergent, containers needs
- No energy and water costs

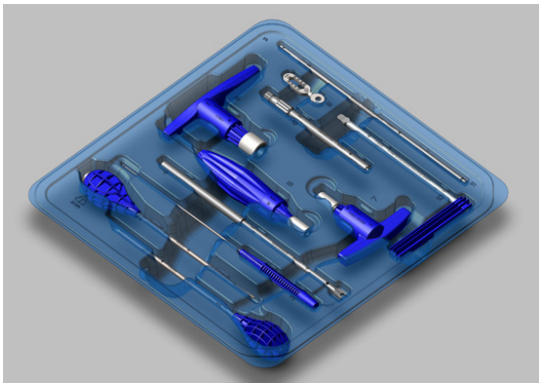
Optimize logistics:
- Easier storage
- Simplified and limited inventory
- No delivery delay

The company was founded near Paris in 2010 by Dominique Petit, a 22-year entrepreneur and engineer veteran of innovative spine technologies, Pierre Dumouchel, industrialization expert, and Thomas Droulout, technology and materials expert. The company opened its U.S. subsidiary in 2011 in Memphis, Tennessee.

Surgical instrumentation and implants in a kit is nothing new—it's just new for spine. ECA Medical Instruments, for example, has been designing and manufacturing sterile-packed single use procedural kits for surgeons since 1979 and has sold more than 30 million single use instruments to date.

Customers for ECA implant device leads, fasteners, screws or connectors are ambulatory surgery centers and outpatient clinics at hospitals and the indications for ECA kits include Cardiac Rhythm Management, Cardiovascular, Neuromodulation, Orthopaedic, Spine, Trauma, Extremity, Sports Medicine and Cranio-Maxillofacial markets.

Horsham, Pennsylvania based Flower Orthopedics also has a spine surgery kit in development. Flower Orthopaedics, which has innovated a number of very



ECA Medical Instruments

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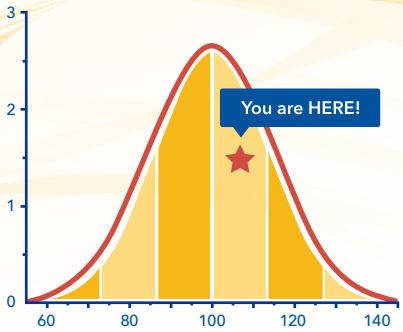

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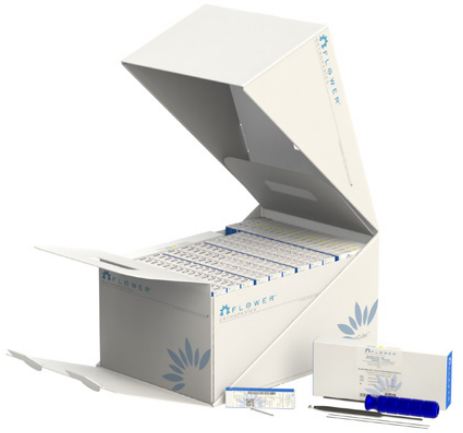
clever orthopedic surgical kits, sells the "FlowerCube". The Flower Cube is a standardized yet comprehensivesystem of implants, instruments and appliances. Each FlowerCube is tailored to the indication. So there are Flower Cubes for ankle bone fixation, or shoulder, or elbow or wrist—you get the idea. Instruments are single-use and disposable. No preoperative, on-site sterilization required.



Flower Orthopedics

All the implants in the FlowerCube are visible in the sterile pack, marked and color coded. Each sterile pack has its requisite QR Code and Bar Code.

Keep it Simple; Put it in a Kit and Price Accordingly

A recent study in the *Journal of the American College of Surgeons* (*J Am Coll Surg.* 2014 Oct;219(4):646-55. doi: 10.1016/j.jamcollsurg.2014.06.019. Epub 2014 Jul 11) titled *Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays* authored by Stockert EW and Langerman A, found that the average percentage of instruments used from individual trays were 21.9% for neurosurgery cases, 18.2% for bariatric surgery and 15.5% for plastic surgery. That means that the vast majority of implants and instruments in a typical surgery tray are not used and then repeatedly sterilized.

According to these researchers, the cost of this re-sterilization and repackaging can be as much as $0.51 per instrument or more.

Another study, which was published in the *Journal of Otolaryngology Head and Neck Surgery* (*Reducing otolaryngology surgical inefficiency via assessment of tray redundancy.* Christopher J Chin, Leigh J Sowerby, Ava John-Baptiste and Brian W Rotenberg), found that a simple analysis of utilization rates led to a dramatic reduction in the size and complexity of the surgical tray.

Said the authors:

> "We conducted a review of instruments on surgical trays for 5 commonly performed procedures between July 5th, 2013 and September 20th, 2013 at St Joseph's Hospital. The Instrument Utilization Rate was calculated; we then designed new 'optimized' trays based on which instruments were used at least 20% of the time. We obtained tray building times from Central Processing Department, then calculated an overall mean time per instrument (to pack the freshly washed instruments). We then determined the time that could be saved by using our new optimized trays.:
>
> In total, 226 instrument trays were observed and the average Instrument Utilization Rate was 27.8% (+/– 13.1). Our optimized trays, on average, reduced tray size by 57%. The average time to pack one instrument was 17.7 seconds."

Outpatient Spine Surgery

All the pieces for a very different approach to spinal implant and instrumentation have been in place for a while. But CMS's (Centers for Medicare and Medicare Services) nine new ASC spine surgery codes plus single use, fully disposable spine surgery kits (which rationalize the instrument tray and eliminate pre-op sterilization) may well be the catalyst to make outpatient care the predominate form of spine surgery. ♦

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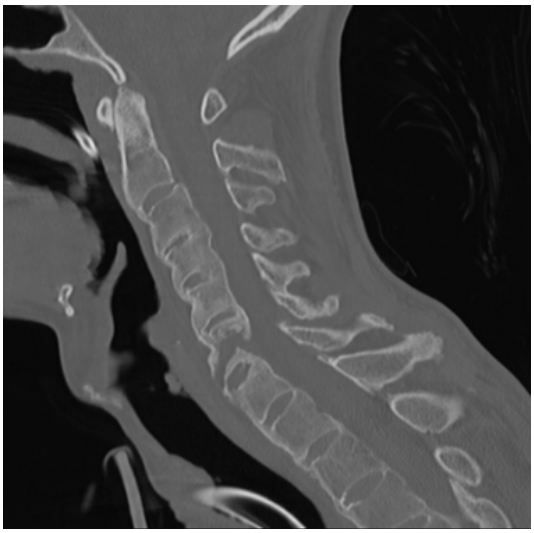
New Study: 60% More Stroke Risk for Ankylosing Spondylitis // Diabetics: 10x Less Bone Formation With Loading // TKR Effective for Blount Disease

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

Ankylosing Spondylitis Patients: Increased Cardiovascular, Cerebrovascular Mortality A surprising new study from Canada has found that people with ankylosing spondylitis (AS) have a higher risk of dying from a heart attack or stroke than do those in the general population. Specifically, the researchers found that AS patients have a 35% higher risk of dying from heart attack and a 60% higher risk of dying from stroke than those without the disease.

Nisha Nigil Haroon, M.D., DM, DNB, is with Toronto Western Hospital. Her co-author (and husband), Nigil Haroon, M.D., Ph.D., DM is an assistant professor of rheumatology and medicine at the University of Toronto, and a clinician scientist and staff rheumatologist at Toronto Western Hospital. Their research, a population-based study, included over 21,000 AS patients and 86,000 individuals without AS.



Ankylosing spondylitis/Wikimedia Commons and Radiopedia

Dr. Nigil Haroon commented to *OTW*, "An increase in incidence of heart disease including atherosclerosis is known in rheumatoid arthritis and is the subject of active study in ankylosing spondylitis. A significant increase in death from heart attacks and especially stroke in AS patients has not been well described before. This is a disease affecting young patients and they suffer from direct effects of inflammation for a long period of time. This is the likely cause of this observation. Anti-inflammatory agents have been considered to increase the risk of vascular mortality in osteoarthritis. However in this study, AS patients who took anti-inflammatory agents had a significantly lower risk of dying from heart attacks and strokes."

"AS patients have significant inflammation that can affect their cardiovascular risk profile. In addition due to effects on mobility, the patient's ability to exercise may be affected increasing cardiovascular risk. Hence patients with AS should be screened for conventional cardiovascular risk factors and treated as required. Smoking is known to increase the risk of progression in AS. Stopping smoking can thus help reduce the rate of progression as well as protect against vascular morbidity and mortality."

Diabetics: 10x Less Bone Formation With Loading Liyun Wang, Ph.D., is an associate professor of mechanical engineering at the University of Delaware. She is working with colleagues to put diabetic mice "through their paces" in order to examine the effect of diabetes on bone health. Their work, "Bone's Responses to Mechanical Loading Are Impaired in Type 1 Diabetes," has just been published in the journal *Bone*.

Dr. Wang told *OTW*, "We wanted to know whether physical exercise would be as effective in promoting bone formation in diabetics as in normal subjects. There are plenty of studies that have shown the adverse effects of diabetes on the functioning of bone cells. So we thought that we would probably see a reduced response to mechanical loading signals in diabetics compared to normal controls. We tested this idea by cyclically compressing one forearm of an anesthetized mouse (with the other arm being non-loaded). This allowed us to quantify the loading response within each individual mouse and compare the degrees of loading responses between the severely diabetic and normal mice as well as between mildly diabetic and normal mice."

"I anticipated some adverse effects from diabetes, but I was much surprised with the GREAT effect shown in the severely diabetic group. This group had a 2.3 times higher glucose level and showed 10 times less bone formation than the normal group. It appeared that hyperglycemia at this level totally shut down bone's response to loading. At the same time, I was pleased to find that mildly diabetic mice with only a 40% elevation of glucose level responded to the loading as vigorously as the normal controls. This means that bone can tolerate a cer-

tain level of hyperglycemia without sacrificing its ability to respond to loading."

"Orthopedic surgeons already know that healing is challenging for their diabetic patients. Our data using diabetic mice further suggest that the efficacy of post-op physical rehabilitation programs for diabetics could be impaired if the blood glucose level is not well controlled. Further studies are needed to confirm this in humans. Our research—as well as research from other institutions—supports the importance of proper glycemic control in the care of diabetic patients."

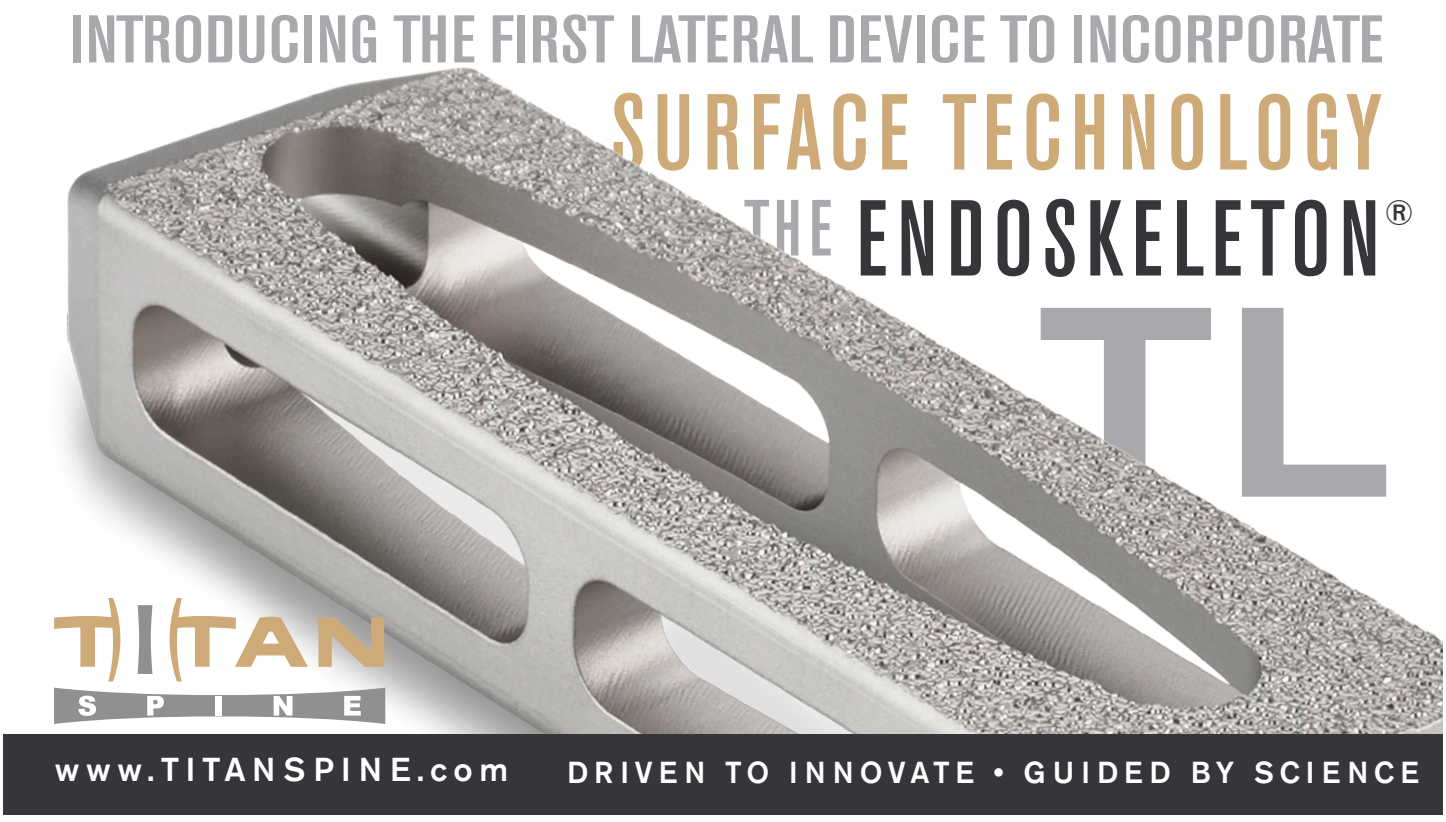
TKR Effective for Blount Disease

Researchers from Loyola University Medical Center have undertaken a first-of-its kind study. They showed that total knee replacement (TKR) can be an effective way to treat degeneration caused by Blount disease, a tibial bone deformity that occurs in young children and adolescents. The study, published in the *Journal of Arthroplasty,* found that TKR in middle age Blount disease patients resulted in stable knees, excellent range of motion and zero need for pain medications.

Harold Rees, M.D., one of the study authors, told *OTW*, "I had several patients who seemed to have a common deformity of their knees that required more effort to obtain a balanced knee replacement. When I looked into their medical history, they had always been very bowlegged or had an actual diagnosis of Blount Disease that was treated when they were children. I wanted to write about this common deformity so that other surgeons could be prepared to tackle these cases, which often require nonstandard implants to obtain a stable knee."

"I was surprised that these patients had such good outcomes. One of the patients in the study had multiple surgeries to correct problems, but the others actually did very well after their surgeries and improved their function. Patients with Blount Disease tend to be obese, which is associated with increased complications after surgery, but in spite of that these patients did well overall. It is important to remember that this is a very small study, so it is possible that with a larger group of patients we may have seen more problems."

"Surgeons approaching knee replacement for these patients should be prepared to release all the medial tissues, and be prepared to use a constrained device or a hinged knee if they cannot balance the soft tissues even after aggressive releases. The patient who had multiple revisions eventually ended up with hinged knees and has done well after those were implanted." ♦



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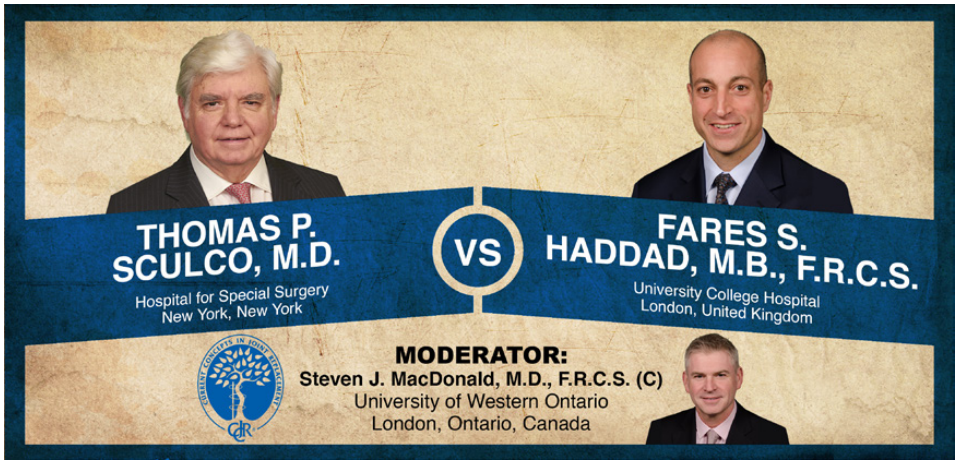
Haddad vs Sculco — Is TKA the Answer for Medial Compartment Arthritis?

BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the 16th Annual Current Concepts in Joint Replacement® (CCJR) – Spring meeting, which took place in Las Vegas this past May. This week's topic is "Medial Compartment Arthritis: TKA the Only Tried and True Solution." For the proposition is Thomas P. Sculco, M.D., from the Hospital for Special Surgery. Fares S. Haddad, M.B., F.R.C.S., University College Hospital, London, United Kingdom, is in opposition. Moderating is Steven J. MacDonald, M.D., F.R.C.S.(C) from the University of Western Ontario.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Sculco: The title is probably a little extreme here. The only true and tried solution. I think certainly there is a place for unicompartmental knee replacement, but I'll present an argument in the opposite direction. There are many, many advantages of total knee replacement [TKR]. You all know these. Technique is very reproducible. Long-term results have been outstanding and revision techniques and implants have certainly gotten much better. For some patients total knee replacement is, in fact, the only option. So if you have a patient with severe malalignments and deformity after a fracture, medial compartment arthritis, there is no way you can do a unicompartmental knee in that situation. It lends itself to augmentation and use of stems.

In fact, if you look at medial compartment osteoarthritic knees, about 85-95% of arthritic knees in general are really indicated only for total knee arthroplasty, in my experience. We looked at 250 osteoarthritic knees and followed the criteria that were outlined by Scott and Kozin. We found that about 8% of the knees were really good candidates for unicompartmental knee. That means, in the United States, the average orthopedic surgeon does 25 total knees per year, he's really seeing only 3, maybe 4 patients at most that are really ideal candidates for unicompartmental. That can be a problem in that, as David Hungerford has said, the real disadvantage of unicompartmental arthroplasty is the technical difficulty of the procedure.

The technique pitfalls are in the area of soft tissue balancing; how much you do, how much you not do. Instrumentation can be a problem as well. Visualization as you put the device in could also be a problem. Technique in the hands of neophytes, or those who are not doing these on a large volume, and the un-replaced lateral compartment, are problems in terms of failure as well.

There are some real disadvantages to total knee replacement. They do have some functional limitations, probably will not flex as much as a unicompartmental. The revision can be more complex, and the recovery is longer in the short-term.

But the rehabilitation is not always slower with total knee replacement patients and if you have a fit, younger patient with good motion, in fact, he/she will recover very quickly. Probably not dissimilar to a unicompartmental.

Now what about results. If you go to the literature, you'll find results all over the place. They show excellent long-term results with unicompartmental as well as tri-compartmental. But overall today the chance of a total knee replacement lasting greater than 20 years is better than both osteotomy and unicompartmental. I think most surgeons who even do unicompartmentals would agree with that.

Rodriguez-Merchan (*Arch Bone Jt Surg*, 2014) performed a meta-analysis that looked at medial OA, unicompartmen-

tal versus total knee replacement, and what the paper showed is higher revision, as you would probably expect, at 5, 10, and 15 years in the unicompartmental group. But complications were greater in the total knee group, who are often sick or older and have co-morbidities. Parratte, et al. (*JBJS-BR*, 2009) wrote a paper where the medial compartmental group under age 50, 35 knees followed out to almost 10 years, had 6 revisions with an 80% survivorship at 12 years.

And revisions of unicompartmentals are not as straightforward as often they may look. Bone loss can be significant on the tibial side and require augmentation and stems.

In summary, I think there are limited indications for unicompartmental knee replacements, but in the hands of Professor Haddad the results will be good and surgeons who do high volumes of them, the results will be good. Technique for the average orthopedic surgeon is more difficult. Revision rate is higher as we've demonstrated, and most people agree, and revision can be more complex.

Mr. Haddad: You just had a very nice exposition for total knee from Tom, but the realities in my practice is that over 30% of my patients have unicompartmental disease. There is no doubt that my best joint replacements are unis. They've got better kinematics, better proprioception, better range of motion, and higher activity levels with fewer complications.

And it's even recognized at HSS [Hospital for Special Surgery]. I remember first visiting there and you hear a pin drop when uni was mentioned. Nowadays if you use Doctor Google, you'll find unis are going in very regularly at HSS and patients recover pretty quickly and do well.

Now we know that medial OA [osteoarthritis] is ideal for unicompartmental knee replacement. It's been well studied. The indications are clear. The patient needs to have medial osteoarthritis, full thickness cartilage loss, an intact ACL, and correctible deformity with preservation of lateral cartilage.

The problem is the old contraindications. You've heard about the Kozinn and Scott criteria already. The reality is they no longer apply. There is now good data to suggest that they don't really change outcome. An Oxford series compared the idealized Kozinn and Scott criteria with cases where that didn't apply. In over two-thirds of the cases, those criteria were not met. Yet, when we look at the outcomes in terms of scores, there's no difference in score, no difference in failure rate. If we look at survivorship, good survivorship at 96% at 12 years. No difference between whether you follow those criteria or not.

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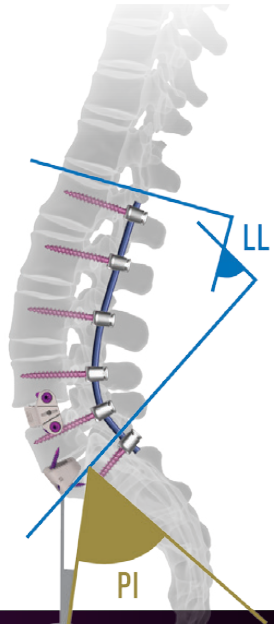

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Therein lies the rub, because if you follow those criteria as you heard, you'll do unis in less than 10% of your cases. But if don't, and let's still stick within the rules I gave you, that percentage goes up dramatically. Up to 50% for the enthusiasts and you extend the indications beyond where they were traditionally.

A study from Sweden showed that if you do that, you have a 20-year survivorship of over 92%. Very impressive, rivaling a lot of total knee studies. And there are multiple studies out there that show you similar data where you can have high survivorship with good looking unis.

Why do this? Well, the reality is, it's better. Patients retain the cruciate so they have better function. They have better range of motion, better gait and better pain relief. They recover more quickly with fewer complications.

Let's look at function. That's what it's really all about. For our patients we've looked at function a number of ways. I'll just focus for a moment on gait analysis and when we put them on a force plate treadmill. The reality is if you make them do something demanding, like walking downhill, UKAs [unicompartmental knees] can do that, but less than two-thirds of TKAs can. If you get them to maximum speed that's much better for the UKAs than it is for the TKAs. They're much closer to normal on most gait perimeters.

So in a matched group of patients, we've seen a dramatic difference in functional outcome, that doesn't seem to be age or sex dependent. The really interesting thing is if you look at complications, across the board, fewer complications, fewer DVTs, fewer infections in the UNIs than the totals. And that's something we need to take seriously for our patients.

Look at mortality. Significantly decreased for UNIs in the first year, and that continues out to eight years. That can have a huge impact. Now the elephant in the room, of course, is revision. You've already heard that. There is a high revision rate for UNIs. Sometimes that's because they're put in badly. The reality, however, is that seems to relate to low volume use. You've got to be doing quite a few of these if you're going to do them well and succeed. If we look at just those who do 20-50% UNIs, we see no difference in reoperation rates.

So what we should do is treat medial OA as unicompartmental disease because sometimes less if more.

Moderator MacDonald: Thank you gentlemen for a well-balanced debate. So Tom, do you do any UNIs yourself?

Dr. Sculco: I do not.

Moderator MacDonald: Have you in your practice over your career? Have you at some point in the past in your career?

Dr. Sculco: Yeah, I did UNIs when they originally became available in the early '80s. The technique was not as good. The implants were not as good. We had a lot of problems with them and we abandoned it. We have 5-6 guys now who are doing UNIs regularly. And if I get a patient who comes in to me who's a good candidate and absolutely insists on a UNI, I'll refer to one of the people who do it.

Moderator MacDonald: Fares, who's an ideal UNI patient?

Mr. Haddad: I think we get messed up in this. Most people are ideal UNI candidates, as you know Steve.

It's not age or sex, it's not about obesity. I think we got hung up on Kozinn and Scott way too long. If you've got bone-on-bone medially, and you have a preserved ACL and your deformity is correctible, you're probably a good candidate.

Moderator MacDonald: Tom, who do you think should not get a UNI?

Dr. Sculco: I think if somebody has tricompartmental or significant bicompartmental disease, those patients in the end will not do well with a UNI. I only found 8-9% of people who are ideal candidates for it. Now you can expand that to maybe 15%. There may be more. There's some people who would expand it more, but I think roughly 10-15% of patients are ideal candidates.

Moderator MacDonald: Fares, anything to add to that. If someone walks in the door and you say, "No, you're not a good candidate."

Mr. Haddad: If your lateral compartment has significant disease with cartilage loss, you should absolutely have a total. And I think it's worth stressing…I'm not a mad enthusiast. If you look at the UK data, there is that little group who do a fair proportion of UNIs very well. We've got a few guys who are doing far too many UNIs; when your UNI proportion goes up beyond 50% your failure rate goes up. You can definitely push the envelope too far. I think we've gone from 2%, 5%, 6%--we've cracked up to beyond 20% up to about 30% and I think we'll find a middle point where everyone's comfortable.

Moderator MacDonald: Thank you gentlemen for the wonderful debate. ♦

Please visit www.CCJR.com to register for the 2015 CCJR Winter Meeting, December 9 - 12 in Orlando, Florida.

COMPANY

Stryker Recalls 17,000 Elbow Implants

Stryker Howmedica Osteonics Corp. is voluntarily recalling 16,992 elbow devices because of the potential of damage during shipping caused by a packaging problem.

According to an August 20, 2015 Food and Drug Administration (FDA) notice, the recall includes five devices: the rHead lateral stem and Recon radial implant, both for replacement of the proximal end of the forearm's radius bone; the uHead ulnar implant and Sigmoid Notch radial plate, both for replacement of the distal radioulnar joint; and the Radio-Capitellum to improve elbow function.

The FDA notice includes the part and lot numbers of all affected devices.

"There have been no reported adverse events related to this lot-specific voluntary recall," Jeanine Guilfoyle, senior public relations manager, Stryker Orthopedics, told *Medscape Medical News*. "With the product quarantined as a result of a product hold placed in February 2015, limited field impact was expected."

This is a class 2 recall, which is defined by the FDA as "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."

The products were manufactured in Stryker's Mahwah, New Jersey, plant and were distributed worldwide.

Stryker has notified customers of the recall by e-mail and an urgent medical device removal letter/acknowledgement response form. Customers were notified by Stryker of this action by e-mails on June 24, 2015 and an Urgent Medical Device Removal Letter/Acknowledgement Response Form dated June 25, 2015 was sent to the attention of the Risk Manager.

"All affected customer locations have been notified, the majority of which includes locations with product prior to Stryker's acquisition of Small Bone Innovations, Inc. (SBi) assets in August 2014. This voluntary recall is reflective of our continued commitment to quality in all of our products and services," Guilfoyle said.

For more information, customers may contact Paul Jahnke at 201-831-5826.

Click here to read the full recall notice: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=138723. — *WE*

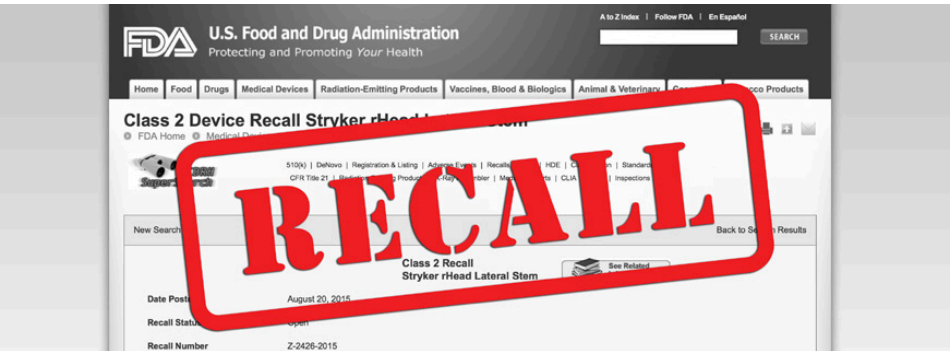
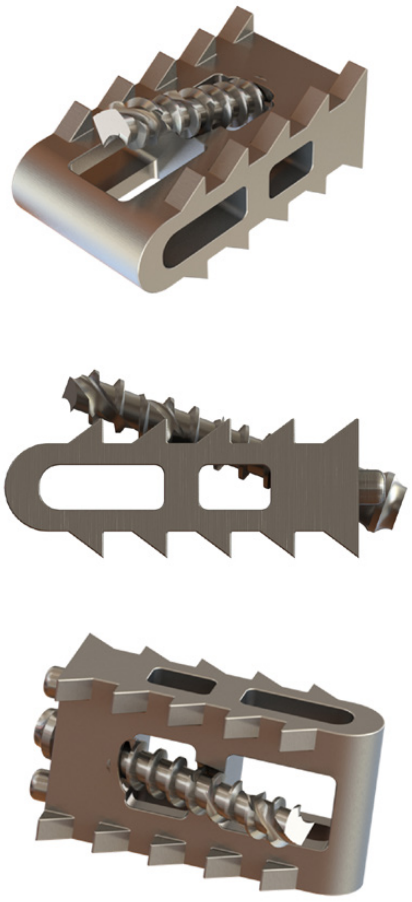


Photo creation by RRY Publications, LLC/Courtesy of Food and Drug Administration

$12 Million and a New VP for Providence Medical Technology!

A $12 million infusion of new funding to Providence Medical Technology, Inc. means that the company can ramp up work on its tissue-sparing



Providence Medical Technology, Inc

cervical spine technology. The funds are to be utilized to further commercialize and expand the company's portfolio of DTRAX cervical fusion products designed to help patients suffering from cervical degenerative disc disease.

"We are expanding our portfolio of cervical fusion products to address the majority of cervical pathologies requiring surgery," said Providence Chief Executive Officer Jeff Smith, in the

August 26, 2015 news release. "Our focus is on differentiated, tissue-sparing devices and instruments that are designed to improve clinical outcomes, minimize complications, increase procedural efficiency, and reduce recovery times. With our new financing, we can accelerate our research and development activities to broaden our innovative product portfolio and further scale our global sales and marketing capabilities."

In other news from Providence, Jason Hoffman has been named as the vice president of Global Sales. According to the news release, "Hoffman is an experienced commercial leader with 20 years of sales and marketing experience in the medical device and life sciences industries. Most recently, Hoffman was vice president of U.S. Sales, Therapeutic Support Systems for ArjoHuntleigh and Kinetic Concepts for four years. Prior to that, he spent 13 years at Johnson & Johnson in senior sales and marketing leadership roles."

"Jason is a seasoned sales leader who has successfully driven impressive top-line growth for major medical device and life sciences companies," added Smith. "He brings outstanding strategic and tactical sales leadership skills to further enable the rapid growth and surgeon adoption of our DTRAX cervical fusion portfolio."

Regarding the new funding, Jeff Smith told *OTW*, "Providence is planning a prospective, multi-center clinical study in the United States evaluating the safety and efficacy of DTRAX cervical fusion products for the treatment of cervical degenerative disc disease. Additionally, the company is planning to conduct a series of biomechanical studies to further study the impact of its implants on the spine."

The new financing comes from existing investors Stanmore Medical Investments, Aphelion Capital and other existing private investors, and the establishment of a new debt facility with Silicon Valley Bank. — *EH*

LEGAL

Medtronic Patent Suit Offers "Marking" Lesson for Surgeons

Mark Barry, M.D. sued Medtronic plc in February 2014 alleging that the company infringed on his patents covering scoliosis treatments.

The lawsuit offers some lessons for surgeons on the proper way to protect their inventions.

Barry claimed that the company's CD Horizon Legacy spinal system infringed on his patent entitled, "System and Method for Aligning Vertebrae in the Ameliorating of Aberrant Spinal Column Deviation Conditions." According to court documents reported by *MassDevice* in July, the patent claims cover a "method for aligning vertebrae with a tool that allows a single surgeon to rotate the spinal column as a whole, using pedicle screws, spinal rods and a 'pedicle screw cluster derotational tool.'"

Failure to Mark

A federal judge ruled in mid-July that he won't dismiss the case, but also said the company won't be subject to pre-case damages on all of the patents. Medtronic has asked for a summary judgement against Barry's suit alleging prior public use of the invention and

Photo creation by RRY Publications, LLC

that Barry failed to mark the patents and is therefore not entitle to pre-suit damages.

The judge for the U.S. District Court for Eastern Texas, Ron Clark, disagreed with Medtronic's public use claim, but partially agreed with the company over the pre-suit damages. But, Judge Clark ruled that the company can't, according to *MassDevice*, "escape Barry's inducement and contributory infringement claims."

"Medtronic has not established its prima facie case by clear and convincing evidence that the entire invention was in public use more than 1 year before the priority date of the parent patent. Dr. Barry has raised a genuine issue of fact as to whether any prior use was experimental," Clark wrote in the July 21 rulings. "Dr. Barry's testimony that the first complete public use of the invention was a private surgery attended by a small group of hospital workers suggests that the 'nature of the activity' and 'public access' was limited. There is a fact issue as to confidentiality, based on affidavits submitted by individuals who had previously worked with Dr. Barry."

On the induced and contributory infringement claims, *MassDevice* reported that the judge found that "Dr. Barry's evidence at least establishes a fact question as to whether Medtronic 'subjectively believe[d] that there [was] a high probability' of infringement and took 'deliberate actions to avoid learning of that fact.'" The judge also ruled that, because Barry failed to mark 2 of the 3 patented articles with "patent" or "pat," he isn't entitled to pre-suit damages on those devices. — *WE*

Advertisement

FDA Extends UDI Deadline to October

The FDA has extended the deadline for getting compliant with the new Unique Device Identification (UDI) system until October 24, 2015.

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According to an August 14, 2015 agency guidance, the deadline was moved back one month due to undisclosed "security vulnerabilities" when the agency's Global Unique Device Identification Database (GUDID) was taken offline on August 7, 2015.

The new deadline also applies to Class III devices whose manufacturers have filed for and obtained compliance extensions that expire between August 7 and September 24, 2015.

The FDA issued regulations in September 2013 establishing the UDI system and gave companies until September 2015 to comply with the labeling and data submissions. But the security "vulnerability" caused the agency to take system offline while a patch is being implemented.

UDI Requirements

According to Stewart Eisenhart of the Emergo Group, complying with UDI requirements involves more than just etching a number onto a medical device or adding a bar code to a label. Several components are involved:

Each UDI must can two numbers: a device identifier and a production identifier. A device identifier must correspond to the specific model or version of a medical device and the company name. A production identifier must provide a medical device's lot or batch information or serial number, expiration date and related production data.

- *Class I devices must be assigned device identifiers only. Class II and III devices must be assigned both device identifiers and product identifiers.*
- *Manufacturers must obtain UDI numbers only from FDA-accredited issuing agencies.*
- *All medical devices registered for sale in the US will have to include UDI information on their labeling and packaging.*
- *Devices intended for more than one use as well as devices requiring reprocessing before each use must also have UDI data marked directly on them.*
- *Manufacturers must provide UDI information in both plain-text (human readable) and AIDC (Automatic Identification and Capture) formats.*

Manufacturers will be required to submit UDI data into a new FDA database, the Global Unique Device Identification Database (GUDID) using proper formatting.

To read the FDA guidance document, click here: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM458634.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery — WE

OIG Solves "Blinding" Dilemma

Let's say you are a device manufacturer that wants to conduct and pay for a prospective, randomized, double-blind, placebo-controlled trial that is also covered by CMS (Centers for Medicare and Medicaid Services) under its Coverage with Evidence Development (CED) program.

The "Blinding Problem"

But you have a "blinding" problem.

One arm of the study of a percutaneous image-guided lumbar decompression ("PILD") procedures for patients with lumbar stenosis, requires a "sham" procedure. CMS will not pay for non-therapeutic treatments and patients would have to pay for it themselves. There goes your double-blind because patients would know which procedure they were receiving.

So the manufacturer subsidizes the co-payments owed by the treatment arm subjects by paying the co-payments directly to the providers. The manufacturer also subsidizes all of the costs of the control subjects who, after the endpoint had been reached, elected to have the PILD procedure.

But now you've got another problem. By offering to pay, the physician and provider might be subject to the Stark Law prohibiting any inducements to use a product.

OIG Opinion

The OIG (Office of Inspector General) solved this problem in a June Advisory Opinion 15-07, (http://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-07.pdf) by approving manufacturer's subsidies for products and services provided to clinical trial subjects.

"Minimal Risk"

According to the *fdalawblog* from Hyman, Phelps & McNamara, the OIG said that this arrangement presented minimal risk of fraud and abuse because the study was designed in consultation with CMS and the program was necessary to enable a properly designed study to be conducted. The OIG said this was "a reasonable means of achieving the Study's goals because it both encourages necessary patient enrollment in the Study and allows for the true impact of the PILD using the System on patient health outcomes to be isolated and assessed."

In other words, according to the blog, the subsidies were necessary both to keep financial considerations from inhibiting enrollment or causing drop-outs, and to maintain the blind.

The OIG also said that compensation paid to investigators was fair market value, thus not designed to induce physicians to use the system, and that overutilization would not be a problem because of the small number of subjects, the requirement that investigators follow the study protocol, and the oversight of an IRB (Institutional Review Board). — *WE*

OIG Opinion/hhs.gov and Pixabay

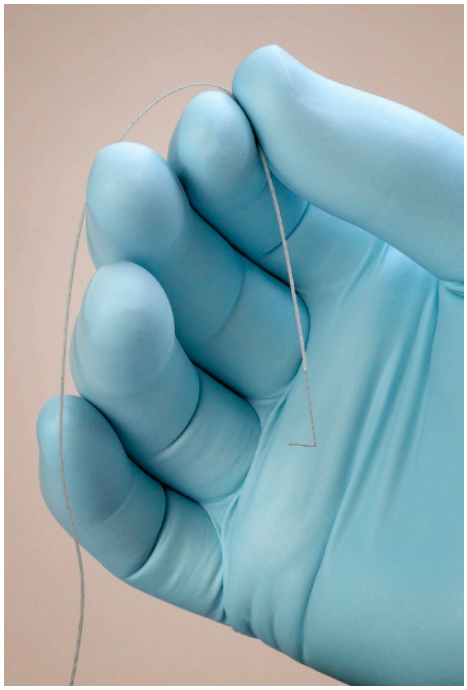
LARGE JOINTS

$1.6M to SPR Therapeutics for Non-Narcotic Pain Management System

Recovering from knee surgery shouldn't send you to THAT kind of rehab...Fortunately, SPR Therapeutics, LLC is advancing the science of non-narcotic postop recovery—now via a $1.6M grant from the National Institute on Aging, an Institute of the National Institutes of Health (NIH). Their creation? The SPRINT peripheral nerve stimulation (PNS) System.

Orthopedic surgeon and joint replacement specialist, Keith Berend, M.D., one of the leaders advancing the movement of knee replacement surgery into the outpatient setting said in the August 25, 2015 news release, "We have seen significant advancements in anesthesia and pain control as we have moved the majority of our joint replacement procedures into the outpatient space. However, even our best, most advanced techniques do not eliminate the need for narcotics. Establishing an effective pain management solution that reduces or eliminates the need for opiates following surgery and discharge, particularly during the early rehabilitation phase, is the ultimate goal. We are optimistic that the SPRINT System may provide a pivotal link that will enable joint replacement procedures to be performed with little to no reliance on opiates during the peri-operative and recovery period."

As indicated in the news release, "The SPRINT peripheral nerve stimulation (PNS) System is designed to provide pain relief by stimulating nerves in the leg using a fine wire, or lead, temporarily implanted using a small needle-based introducer. The FDA has approved an Investigational Device Exemption to study the safety and effectiveness of SPR's novel PNS system for up to 60 days following knee replacement surgery. Data from this clinical trial will be used to support regulatory clearance and commercialization in the United States. Promising early study results using SPR's platform technology were presented at the Cleveland Clinic Pain Management Symposium earlier this year."



SPR Therapeutics, LLC

Mark Stultz, senior vice president of Market Development, told *OTW*, "We are very pleased to have received this grant from the National Institute on Aging which will allow us to further evaluate the effects the SPRINT System may have on post-TKA [total knee arthroplasty] pain, function and opiate use. Grants such as these pass through an extensive vetting process before being awarded adding further credence to the science behind our approach and the level of unmet need that exists in this very large space where approximately 800,000 procedures are performed each year in the United States."

Asked about details on the research, Stultz noted, "We are getting started with the first phase of the research now. During this phase of the research the MicroLead, made from a very fine 0.2mm wire, will be placed via a small 20 gauge introducer needle under ultrasound guidance prior to surgery. This approach will be very familiar to the regional anesthesiologists performing the procedure as it is quite similar to the manner in which they have been trained to place a femoral catheter. We will assess the ability of the SPRINT System to foster accelerated return to function and to provide relief of acute post-operative pain in the hospital and during the post-discharge recovery period. We hope to see reduced opiate use and a concomitant reduction in opiate side-effects, in addition to the enablement of the subjects to more fully engage in their post-discharge rehabilitation and recovery."

"Based on some of the TKA candidate research we've been conducting, those considering TKA are quite averse to using opiates to manage their pain and those working are very concerned about the amount of time they will need to be off work. It is well understood that recovery from TKA is often quite painful and that patients have limited pain management options outside of opiates. A recent study indicated that TKA patients suffered the highest median time to opiate cessation (47 days) among the major surgeries they assessed. Patient access to a non-opiate option such as that offered by the SPRINT System may play a major role in bringing patients to the surgeon with less apprehension and significantly less delay once it has received regulatory clearance." — *EH*

India Poised for Lead in Medical Tourism

The money spent on worldwide medical tourism is expected to reach $5 billion by 2016, according to a writer for *News 24*, with much of that remaining in India. The writer called India the "next crown prince shaping the future of the healthcare industry."

More than 27 million tourists from the United States, Canada and Great Britain visit India each year. Estimates suggest that health related services will grow at 5% per year over the next ten years. Global chains of hospitals like Apollo, Wockhardt, Max, Fortis & Tata are investing in modern hospitals with tourism related services to cater to a new kind of visitors from abroad.

More than 55% of foreign medical tourists chose hospitals in the major cities of Delhi, Mumbai or Chennai where, besides receiving a high-quality of hospital care, they can find quality hotels and other services.

The writer stated that hospital administrators and mangers of healthcare facilities in India are acutely aware of quality perceptions held by medical tourists, especially those coming from the West. As a result, most Indian hospitals meet U.S. standards set by the FDA and the Joint Commission for Accreditation for hospitals in order to dispel any concerns about quality and safety.

When compared with costs in the West, hip and knee replacements are far less expensive in Indian hospitals than they are in the U.S.—even when the costs of accommodation and travel are figured in. The writer estimated that the Indian medical tourism industry would grow at annual rate of 30% which would make it a $2 billion industry in that country alone by the end of 2015. — *BY*

Courtesy of Fortis Hospital India

REIMBURSEMENT

ACOs Failing Transparency Requirements

Accountable Care Organizations (ACOs) in Medicare's Shared Savings Program are supposed to make public not only how much money they saved, but also how they'll spend the savings.

According to a new report published in the *American Journal of Managed Care* (*AJMC*), just over half of the ACOs in the program shared what they would do with their savings. For 2012-2013, those ACOs generated $383 million in savings to Medicare, with the 52 highest performing ACOs generating $315 million of those savings.

According to the report's researchers, John Schulz, Matthew DeCamp, M.D., and Scott A. Berkowitz, M.D., of the 52% of ACOs that detailed spending plans on their websites, 63% said they would give the savings to their member primary care providers, specialists or hospitals. Meanwhile, 33% said they would spend that savings on infrastructure.


Photo creation by RRY Publications, LLC

Health Care Finance News reported that the authors also said ACOs that included a hospital planned to give more to participating entities than ACOs that did not include a hospital.

While only 52% of program participants reported their spending details, 84% offered some "vague" information about their savings distribution, said the researchers.

In the *AJMC* article published online the authors said "There are several possible explanations for this finding. First, all of the ACOs without a website were in the January 2014 start date, and these ACOs might have created websites since the study was conducted mid-year, or the websites existed but were unable to be found with normal search functions. Second, since initial public reporting guidance was issued in 2012, CMS has issued updated guidance in September 2014 that explicitly clarifies that ACOs must adhere to the reporting format of CMS."

The extra transparency is supposed to give patients an opportunity to see if those dollars are being used to directly affect them in the form of new programs or indirectly by supporting physician development or infrastructure, the authors wrote. At the same time, policy makers could use the results to better understand where ACOs see the biggest drivers of their successes.

Ultimately, the authors said research should continue as the program matures to be able to tell which plans for spending shared savings better benefit the ACOs. "There appears to be no single shared savings distribution plan determinate of ACO success. Continued investigation of predictors for generating savings is needed to inform future shared savings models." — *WE*

SPORTS MEDICINE

UPMC to Host First-of-a-Kind Concussion Summit

It will be the most important team huddle yet…as far as the science of concussion goes. On October 15, 2015, nearly 30 concussion clinicians and researchers from around the U.S. will attend a two-day meeting at the University of Pittsburgh Medical Center (UPMC) with a goal of creating standard guidelines on the best practices, protocols and active therapies for treating concussions. The resulting white paper will be published in a medical journal and shared nationwide. Attendees will be discussing Targeted Evaluation and Active Management (TEAM) Approaches to Treating Concussion.

"There's a gaping need for a consistency of care for concussions across the country, if not the world. To try to fill that void, we're thrilled to host a meeting of some of the greatest minds in concussion science and clinical care," said Micky Collins, Ph.D., executive and clinical director of the UPMC Sports Medicine Concussion Program, in the August 18, 2015 news release. Dr. Collins, the chairman of the conference to be held at the U.S. Steel Tower in Pittsburgh (UPMC headquarters), added, "It is a privilege to bring together such a group, discuss the issues truly facing concussion health care today, and attempt to share with caregivers everywhere what we find to be the best evidence, science and practices in getting people better."

"Never before has evidence-based science and clinical experience been brought to bear in advancing concussion treatment like we're attempting here," said Anthony Kontos, Ph.D., research director for the UPMC Concussion Program, associate professor in the University of Pittsburgh Department of Orthopaedic Surgery, and co-director of the meeting. "We believe that this meeting will bring together cutting-edge research knowledge and clinical approaches to this injury that will blaze a trail for concussion treatment moving forward."

Added conference co-director David Okonkwo, M.D., Ph.D., professor of neurological surgery and clinical director of the Brain Trauma Research

Anthony Kontos, Ph.D., University of Pittsburgh Medical Center

UPMC LIFE CHANGING MEDICINE

Center at the Pitt School of Medicine: "It is high time to assemble neurosurgeons, neurologists, neuropsychologists, emergency medicine physicians, physiatrists, athletic trainers, physical therapists and all the multidisciplinary health care professionals who are the primary caregivers to people, and not just athletes, troubled by concussions. Let's effect change and improve outcomes now and for the future."

Dr. Kontos told *OTW,* "The primary focus of the meeting is on advancing current approaches to 'treatment' and there will be many important topics including the role of prescribed rest and exertion, use of targeted approaches to treatment based on clinical pathways, and conceptualizing the injury as a heterogeneous disorder rather than a one-size-fits-all injury. Overall, we hope to advance the discussion and clinical approach to treating concussion across disciplines. With regard to evaluation, although a comprehensive approach—including a thorough clinical exam and assessments of balance, cognitive, vestibular and oculomotor dysfunction—is a critical component to inform subsequent treatment strategies, we will be focusing primarily on active treatment approaches during the meeting."

"Just getting this group of experts together in the same room to candidly discuss active approaches to treating concussion is an accomplishment in and of itself. I think the meeting will be successful if we can come to agreement on some basic tenets related to treating this injury that go beyond prescribed rest. I also think that the meeting will be successful if it helps to inform health-care professionals across the country and across disciplines about best therapy practices, and it serves as catalyst to promote additional funding and research on how best to treat concussion."

"Because of the vital nature of the concussion conversation, it's critical to support leading institutions in the country, like UPMC, that are promoting science in an effort to advance treatment, evidence and clinical experience," said Charlotte Jones Anderson, chair of the NFL Foundation and executive vice president of the Dallas Cowboys, in the news release.

The two-day meeting is fully funded by a grant from the NFL Foundation. — *EH*

SPINE

0% Complication Rate! NYU Pioneers Closure Technique

Thanks to the vision of clinician-researchers at NYU Langone Medical Center, scoliosis patients who undergo surgery can now emerge from the OR with less chance of an infection. The NYU team has developed a new wound closure technique whereby the surgeon can close several layers of muscle and fascia while maintaining blood supply from the donor site to the recipient site. The new closure method has been on the rise at NYU Langone since 2009, and is a collaborative effort between the Departments of Orthopaedic Surgery and Plastic Surgery.

"This game-changing method for closing incisions after surgery can benefit all patients with scoliosis, especially those most at risk for complications depending on the cause of their spine problems," says corresponding study author David S. Feldman, M.D., professor of orthopedic surgery and pediatrics at NYU Langone, in the August 20, 2015 news release. "All of our patients with scoliosis—from the basic to most complex cases—can feel confident knowing their safety is our top priority."

This retrospective study, published online this past July in the *Journal of Pediatric Orthopaedics,* involves a multilayered flap that, according to the news release, "reduces complication rates by eliminating 'dead space,' or pockets around spinal hardware and fusion sites where infection can start. The technique also creates a better barrier to separate surgical hardware and bone grafts from the skin's surface."

Included in the study were 76 patients aged 8 to 25 years, with non-idiopathic scoliosis who had undergone a posterior spinal fusion surgery; 42 patients had their incisions closed using conventional techniques, while 34 underwent the new flap technique. While roughly 19% of patients who experienced the conventional closure methods had a wound complication, those who under-

Thomas Errico, M.D., courtesy of John Karsten Moran

went the new, multilayered muscle flap closure method experienced a 0% complication rate.

"The success of this procedure speaks to our Medical Center's commitment to collaborate with other medical specialties to ensure our patients receive optimal patient care," said senior study author Michael S. Margiotta, M.D., assistant professor of plastic surgery and neurosurgery at NYU Langone.

According to the news release, patients with non-idiopathic scoliosis (curve caused by underlying disease) are 25-76% more likely to experience complications following spinal fusion and 4-23% more likely to have an infection, compared to those with idiopathic scoliosis.

Asked about the collaboration between plastic surgery and orthopedic surgery, Dr. Margiotta and Thomas Errico, M.D., chief of the Division of Spine Surgery at NYU Langone, told *OTW*, "Plastic surgeons and spine surgeons have a long history of cooperation and collaboration at NYU Langone Medical Center, dating back over 40 years. It began with re-operations on radiated spinal cord tumors that required revisions. The handling of previously radiated tissue is a complex wound healing problem. As instrumentation became more complex and wound healing problems ensued, it was a natural for spine surgeons at NYU to turn to our Plastics colleagues."

"Limb salvage was another area of intense cooperation with early efforts at reimplantation of limbs from accidental amputations. Bony stability had to be accomplished to protect the vascular and soft tissue work that was being done. As surgery becomes more complex, cooperation is a natural consequence." — *EH*

Advertisement

PEOPLE

Tobias Buck: New Chair at OrthoWorx

Tobias "Toby" Buck, chairman, president, CEO and founder of Paragon Medical, Inc., is the new chair of the


Tobias Buck

board of directors at OrthoWorx. Buck was one of the founding board members of OrthoWorx, and has served the organization in that capacity since 2009.

"We greatly appreciate the service and contributions made by our outgoing board chair, Jon Serbousek, who will remain on the board," said Sheryl Conley, president and CEO of OrthoWorx, in the August 26, 2015 news release. "Jon's counsel and commitment to our region's vitality have been extremely beneficial to our efforts. And we are very grateful to Toby Buck for taking on this expanded leadership role. Those who know Toby are well aware of his accomplishments in and commitment to our industry. He also has an outstanding record of personal and corporate contributions to our region and our state. He helped bring OrthoWorx to life and we look forward to his leadership of our board.

As indicated in the news release, "Buck is a graduate of Purdue University and The Harvard Executive Development Program as well as the MIT Birthing of Giants Program, a 3-year graduate certificate program. His educational background is in engineering and finance, both at the undergraduate and graduate levels, respectively. He has worked for the past 30 years in three different markets: aerospace, automotive and the medical device and life science area."

"He was named 1998 Entrepreneur of the Year for small manufacturing firms, and received the 2004 Ernst & Young Entrepreneur of the Year award in the life sciences category for the State of Indiana. The Warsaw Kosciusko County Chamber of Commerce named him the 2006 Man of the Year and he and Paragon Medical were selected for the Kosciusko Economic Development Corporation's 2012 Innovation and Entrepreneurial Hall of Fame."

Buck told *OTW,* "OrthoWorx has made tremendous progress since 2009 in education, workforce development and university engagement, so the first task is to make sure we continue to drive initiatives that build on that foundation. Beyond that, we've started some promising work in capitalizing on the talent and technical resources in our area to expand innovation and entrepreneurship and we believe that can be key for our industry and for the State of Indiana."

According to its website, OrthoWorx is a community-based initiative that works closely with the orthopedic industry and other stakeholders in order to ensure that the Warsaw, Indiana region benefits from its position as "The Orthopedic Capital of the World." — *EH*

James H. Mackaness: New CFO at Invuity

James H. Mackaness, a seasoned medical device and operations executive, has been named chief financial officer (CFO) of Invuity, Inc. Mackaness has amassed more than 20 years of experience, and specializes in financial and strategic planning, public reporting and controls, mergers and acquisitions, and operations management within the medical device and technology industries.

"We are very pleased to have Jim joining Invuity at this time as he brings a rare combination of skills that is well suited to our company profile," said Philip Sawyer, president and CEO of Invuity, in the August 10, 2015 news release.

According to the news release, "Most recently, Mackaness served as Chief Financial Officer and Chief Operating Officer for Mountain View, Calif.-based IRIDEX Corp., a publicly traded medical device company. Prior to IRIDEX, Mackaness was the CFO at two privately held companies one of which was sold to Cisco Systems where he went on to assume a business development role. Early in his career, he was an audit manager for Ernst & Young LLP."

Mackaness told *OTW*, "Invuity is filling an important unmet need that has the potential to transform the standard of care in surgery. Going public is a huge

James H. Mackaness

milestone for the company, and a critical step towards becoming the market leader in surgical illumination technology. I am excited to work with Philip, the team, and our partners to continue driving the company's business forward." — *EH*

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