VOLUME 9, ISSUE 34 | OCTOBER 29, 2013

Orthopedics This Week

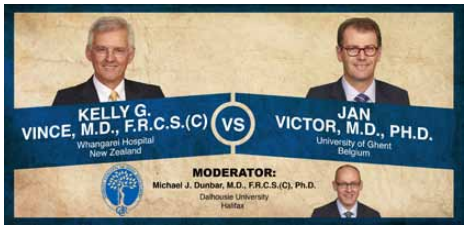
WEEK IN REVIEW

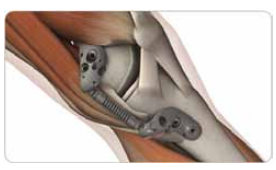
4 OIG POD Order Challenged by Reliance Medical >> The government's stand that PODs are inherently suspect is a violation of the First Amendment. That's the position of two former sales reps, now owners of Reliance Medical. They claim "Big Corporations" got the OIG to go on a "crusade" against physician-owned businesses because of their success in the marketplace. Not all PODs are on board.

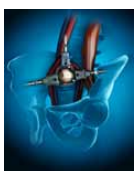
9 Major Surprise From NASS' Best Paper//You Could Be Mis-Diagnosing Cervical Fusion. Here's Why//Spinal Elements Steps UP for Children with Major Donation >> A team from Hong Kong teased out some truly remarkable data regarding diagnosing early stage back pain. It was NASS' best paper. Dan Riew, M.D. and his team make a strong case that most cervical fusions are at risk of mis-diagnosis. Find out why. Thank you Spinal Elements for your magnificent support of children.

12 The Insurance Industry Strikes Again! >> In mid-September Aetna reversed an eight-year policy and now "…considers lumbar prosthetic intervertebral discs…to be experimental and investigational…" REALLY??!! After 8 years? This would be funny if it weren't so tragic for patients.

15 Ligament Tensioners: Kelly Vince Versus Jan Victor >> "Tensioners optimize stability and alignment…and stability *controls* alignment," argues Kelly Vince. "Look, we share the same goals," says Jan Victor. "I think the issue is basically *how* to achieve these goals."







BREAKING NEWS

18 Zimmer Sales Growth Best in 6 Years

Oops! Soft Shoes Won't **Prevent Running Injuries**

Disturbing News: Number of **Orthopedic Students Declining**

NICE Wants **Longer Lasting Hips**

OIG: PODs Don't Save Money

Longer Life, Poorer **Quality of Life for Women**

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: October has been a strong month for orthopedic equities. Overall, the average orthopedic stock rose 6.4% in the last 30 days. Seven companies are up by double digits. Nearly 80% of orthopedic companies increased in value this month. Why? Two basic reasons, we think. Demand for orthopedic implants is rising and Obamacare fuels more demand. Second, the device tax appears to have bi-partisan support for repeal.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	7	Stryker	15.22%	8.46	Stryker's strong recon showing reminds the markets of why orthopedics is such an attractive business. Rising demand. Low elasticity.
2	3	Exactech	10.00	11.73	Up nearly 12% in the last month. This smaller diversified supplier of orthopedic implants is a gem.
3	1	Zimmer	27.31	6.38	Bumping up against 52-week high. RBC says buy on weakness. But Baird downgrades. Too soon. Should wait for device tax news.
4	2	Conmed	9.78	10.36	Disappointing quarter. Moves year-end sales and earnings guidance down. So management decides to increase cash dividend 33%.
5	4	Medtronic	28.84	8.62	MDT is one of the few companies whose operating margins rose this quarter. This is not MDT of old.
6	5	Integra LifeSciences	11.77	12.34	CEO Arduini announced closing two plants and simplifying product lines. Driving efficiencies.
7	6	Smith & Nephew	20.78	4.89	Will SNN join the recon party? Most analysts are expecting an 8% sales jump for Q3. But stock buyers seem skeptical.
8	8	Globus Medical	28.53	1.15	GMED reports Q3 results this week. While the market's attention is on large joint recon, GMED will likely post up double-digit sales growth.
9	9	NuVasive	6.30	5.78	NUVA also reports Q3 this week and consensus on Wall Street is for 6.80% sales growth and a penny EPS gain.
10	10	Johnson & Johnson	26.73	5.75	Execution, execution, execution. Strategically Synthes + DePuy wins big. Only way to screw it up is lack of execution.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$5.85	$564	41.99%
2	TiGenix	TIG.BR	$0.39	$49	18.97%
3	CryoLife	CRY	$8.09	$223	16.57%
4	Integra LifeSciences	IART	$43.42	$1,220	12.34%
5	Exactech	EXAC	$22.19	$299	11.73%
6	Tornier N.V.	TRNX	$21.69	$1,036	10.66%
7	Conmed	CNMD	$36.64	$1,007	10.36%
8	Medtronic	MDT	$57.36	$57,215	8.62%
9	Stryker	SYK	$74.61	$28,234	8.46%
10	Zimmer Holdings	ZMH	$86.91	$14,735	6.38%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	RTI Biologics Inc	RTIX	$3.17	$178	-14.09%
2	Alphatec Holdings	ATEC	$1.94	$188	-5.83%
3	Orthofix	OFIX	$20.94	$407	-4.56%
4	Baxano Surgical Inc	BAXS	$1.25	$56	-3.85%
5	Symmetry Medical	SMA	$8.16	$304	-0.12%
6	Bacterin Intl Holdings	BONE	$0.60	$31	0.45%
7	Globus Medical	GMED	$17.65	$1,639	1.15%
8	MAKO Surgical	MAKO	$29.84	$1,535	1.29%
9	Wright Medical	WMGI	$27.18	$1,279	3.15%
10	Smith & Nephew	SNN	$64.99	$11,650	4.89%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$20.94	$407	8.41
2	Zimmer Holdings	ZMH	$86.91	$14,735	15.55
3	Medtronic	MDT	$57.36	$57,215	15.59
4	Globus Medical	GMED	$17.65	$1,639	15.65
5	Smith & Nephew	SNN	$64.99	$11,650	15.98

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$25.44	$1,134	90.86
2	Symmetry Medical	SMA	$8.16	$304	28.95
3	ArthroCare	ARTC	$37.82	$1,073	25.63
4	RTI Biologics Inc	RTIX	$3.17	$178	23.62
5	CryoLife	CRY	$8.09	$223	23.11

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$17.65	$1,639	1.04
2	Orthofix	OFIX	$20.94	$407	1.20
3	Conmed	CNMD	$36.64	$1,007	1.44
4	Exactech	EXAC	$22.19	$299	1.48
5	RTI Biologics Inc	RTIX	$3.17	$178	1.57

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$25.44	$1,134	9.56
2	CryoLife	CRY	$8.09	$223	5.78
3	Johnson & Johnson	JNJ	$92.09	$259,516	2.73
4	Symmetry Medical	SMA	$8.16	$304	2.41
5	Medtronic	MDT	$57.36	$57,215	2.34

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$8.16	$304	0.74
2	Orthofix	OFIX	$20.94	$407	0.88
3	Bacterin Intl Holdings	BONE	$0.60	$31	0.91
4	Alphatec Holdings	ATEC	$1.94	$188	0.96
5	RTI Biologics Inc	RTIX	$3.17	$178	1.00

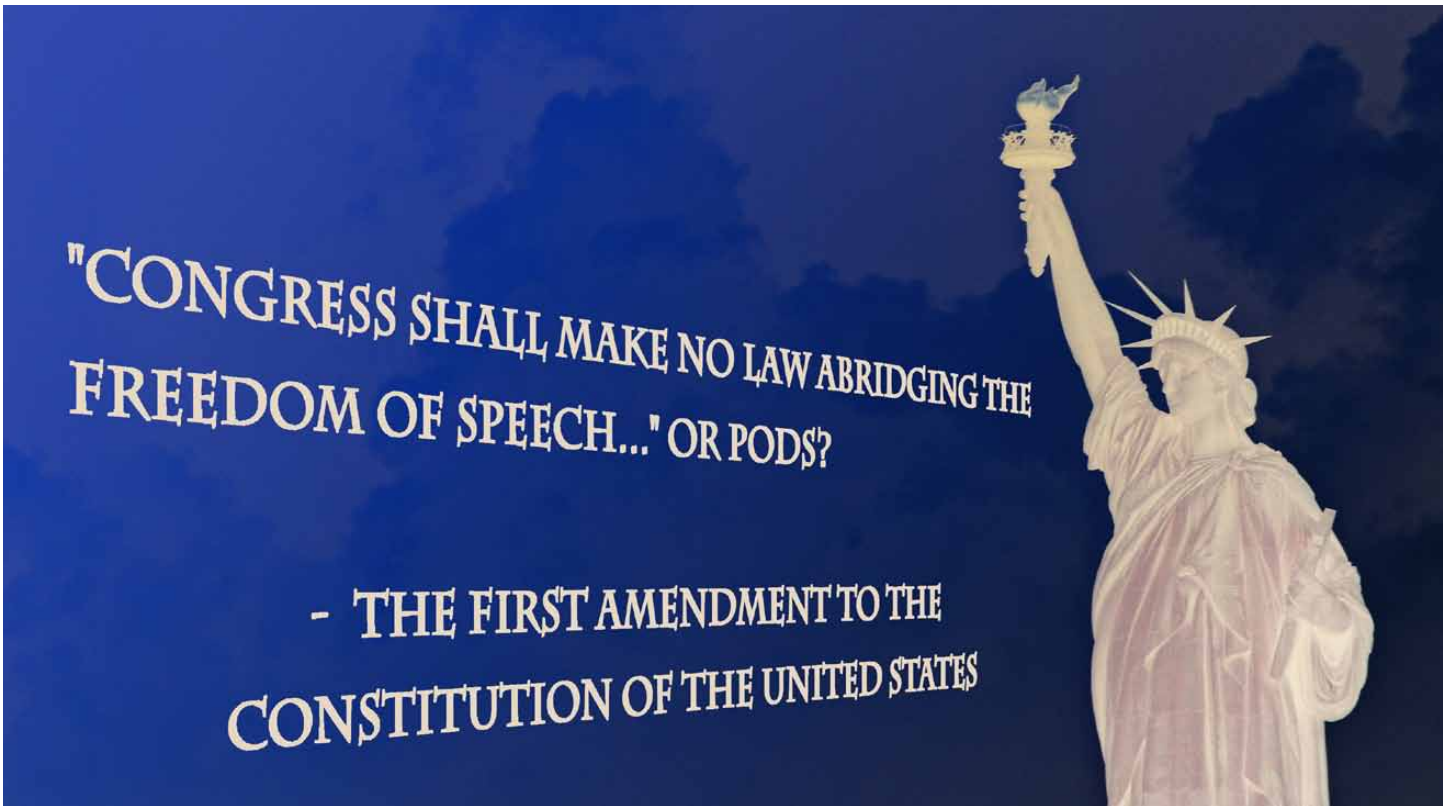
HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$5.85	$564	20.84
2	MAKO Surgical	MAKO	$29.84	$1,535	14.95
3	TiGenix	TIG.BR	$0.39	$49	11.94
4	Globus Medical	GMED	$17.65	$1,639	4.25
5	Baxano Surgical Inc	BAXS	$1.25	$56	3.88

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

OIG POD Order Challenged by Reliance Medical

BY WALTER EISNER



RRY Publications/Wikimedia Commons

Adam Pike and Bret Berry would not seem like the most obvious choices to lead a constitutional challenge to physicians being discouraged from having ownership in their own production and distribution businesses.

But on October 9, 2013, Pike and Berry announced they had gone to federal court in California to argue that a March 2013 special order from the Office of Inspector General (OIG) regarding physician-owned distributorships (PODs) is unconstitutional because it prevents them from speaking to physicians about physician-owned businesses.

In their claim, Pike and Berry argue that the OIG order states that physician-owned businesses are "inherently suspect," and therefore discourages them from speaking to physicians about doing business together. This chilling of speech, they claim, violates the freedom of speech provision of the First Amendment.

Pike, Berry and Reliance

Pike and Berry are both former sales reps. Pike worked at Synthes, Inc., while Berry worked at Medtronic, Inc. Both ended up at Amedica Corporation in Utah. In 2006, the two founded Reliance Medical Systems, LLC, in Bountiful, Utah. From its inception through 2012, Reliance and its related companies included physicians as owners to design and distribute orthopedic devices.

In one such company, Apex Medical Technologies LLC, according to a sensational *Wall Street Journal* article on July 26, 2013, two surgeons bought a 20% interest in the company, with 60% going to Pike and Berry and one of their business associates. According to public records, there are, or were, at least 11 such related companies across six states.

The *Wall Street Journal* article, "*Surgeons Eyed Over Deals With Medical-Device Makers*", described a federal investigation of one of the Apex surgeons, Aria Sabit, M.D., over potential improper use of devices designed and distributed by Apex. Reliance claims the government "inappropriately leaked" details of the OIG investigation.

Pike and Berry had already moved away from a physician ownership model in 2012. But now, they want to return to physician ownership and structure a business model that, like its prior business model, fully complies with federal law, including the anti-kickback statute,

However, the OIG is currently investigating Reliance and physicians with whom Reliance previously communicated, in connection with Reliance's prior formation of physician-owned entities.

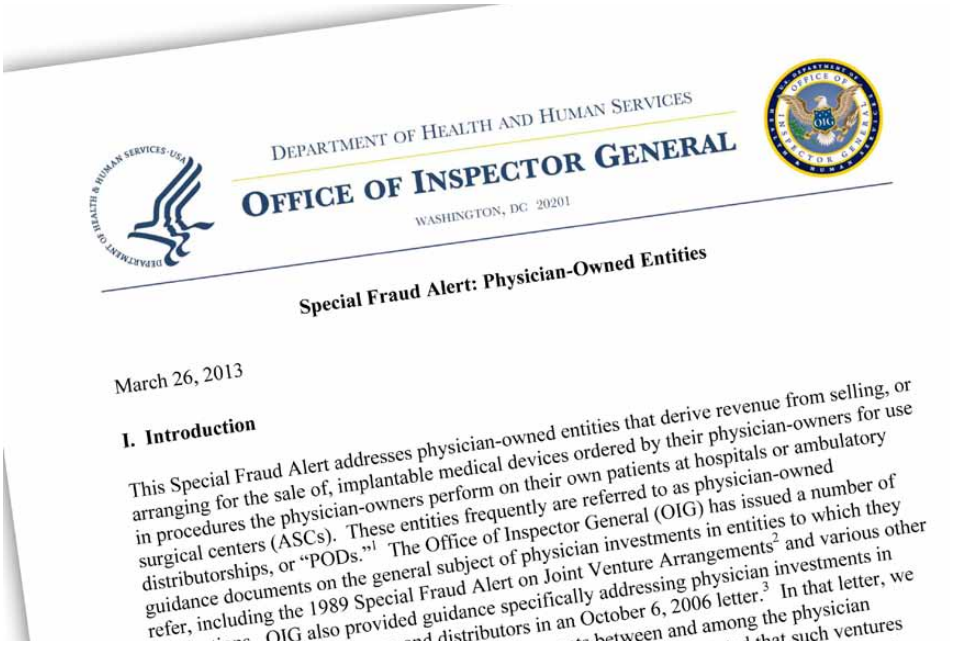
Chilled Speech, Chilled Business

Reliance claims it cannot exercise its First Amendment rights to communicate with physicians about forming new physician-owned entities out of fear that any such entities are instantaneously cloaked with a presumption of guilt, in violation of Reliance's due process rights, since these entities are presumed by the OIG to be "inherently suspect," according to their lawsuit against the government.

The federal pressure has presumably also had an effect on the growth of physician-owned distributorships. After the most recent annual meeting of the North American Spine Society, a number of Wall Street analysts reported that the POD challenge to large spine instrument suppliers has eased.

Hospitals, which either have purchased or are considering purchasing products from PODs, have apparently gotten the message.

In May 2013, Intermountain Health care system, (with 160 healthcare institutions in Utah and Idaho and insures about 19% of Utah's residents) issued a policy statement, saying that, with


DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Special Fraud Alert: Physician-Owned Entities

March 26, 2013

I. Introduction

This Special Fraud Alert addresses physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). These entities frequently are referred to as physician-owned distributorships, or "PODs."[1] The Office of Inspector General (OIG) has issued a number of guidance documents on the general subject of physician investments in entities to which they refer, including the 1989 Special Fraud Alert on Joint Venture Arrangements[2] and various other ... OIG also provided guidance specifically addressing physician investments in ... and distributors in an October 6, 2006 letter.[3] In that letter, we ... between and among the physician ... such ventures

oig.hhs.gov/fraud

some exceptions, it will not enter into any agreement to purchase from a POE (physician-owned entity). Others have followed with outright bans or restrictions, citing "legal entanglements."

"Big Corporations," Big Government Crusade

Reliance alleges that "Big Corporations" are behind the government's crusade.

Kevin Booth, M.D., an owner of a POD in Northern California told *OTW* in an August article that ePODs (ethical PODs) easily cut implant costs by 40% and that these physician-owned businesses are "causing great consternation with the major companies. They stand to lose billions of dollars if third party distributors are widely embraced."

According to Reliance's Complaint for Declaratory Relief, "Big Corporations" were losing business to physician-owned businesses and undertook a "crusade" against such businesses. They claim a major international law firm was hired to advocate for stronger legislative and regulatory action to halt the proliferation of physician-owned businesses. They then, allegedly, financed a lobbying effort with substantial contributions and successfully lobbied for congressional hearings in 2011, resulting in the OIG's special order.

Competition by Regulation

This crusade, claims the lawsuit, has caused a "substantial number of hospitals" to stop doing business with physician-owned businesses.

Because current laws allow physician-owned entities to manufacture and distribute devices, the "Big Corporations" were forced to compete in the marketplace.

"Unable to win in the marketplace, the Big Corporations embarked on a multi-year effort to win at the legislative/agency level through substantial lobbying efforts," claims Reliance.

Still
the first to market.

Still
available today.

Still
a safe and truly biologic solution.

OP-1® Products from Olympus Biotech.

If you're using BMP to heal bone, you still have a choice in products, and the choice is easy. OP-1, the first true osteoinductive* biologic commercialized in the United States, is still available today and still formulated for ease of use and predictable delivery. For healing the most challenging cases, the first way is still the better way.

*Data is available on file.

IMPORTANT SAFETY INFORMATION

HUMANITARIAN DEVICE

OP-1 IMPLANT is authorized by Federal law for use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. The effectiveness of this device for this use has not been demonstrated.

OP-1 PUTTY is authorized by Federal law for the repair of symptomatic, posterolateral (intertransverse) lumbar spine pseudoarthrosis in patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion and who have at least one of the following compromising factors: osteoporosis, diabetes or nicotine use. The effectiveness of OP-1 PUTTY for this use has not been demonstrated.

Brief summary of contraindications and warnings:

- OP-1 IMPLANT/OP-1 PUTTY is contraindicated in patients who (1) are pregnant (2) have or have had a malignancy (3) are skeletally immature (4) are pregnant or want to become pregnant within 2 years of treatment (5) have a known hypersensitivity to the active substance or to collagen (6) have an autoimmune disease or immune suppression (7) have been previously treated with OP-1 IMPLANT or OP-1 PUTTY.
- The use of OP-1 IMPLANT/ OP-1 PUTTY may result in (1) the formation of localized ectopic or heterotopic bone outside of the treatment site (2) development of an immune response against BMP-7 or Type I collagen.
- There are no adequate well controlled studies of OP-1 IMPLANT/OP-1 PUTTY in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

Please see the package insert for the complete indication, contraindications, warnings, precautions, adverse events and other important medical information.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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Ignoring Precedent

The Reliance complaint argues that the OIG special order clashes with previous OIG guidance and court decisions.

The leading court case which considered the limitations that the anti-kickback statute imposes on physician-owned entities is Hanlester Network v. Shalala, 51F.3d 1390 (9th Cir. 1995).

The court addressed whether appellants violated the provisions of the Medicare-Medicaid anti-kickback statute by:

- Offering or paying remuneration to physician limited partners to induce the referral of program-related business to limited partnership laboratories, or
- Soliciting or receiving remuneration "in return for" referrals by virtue of their management agreement
- The court found that "mere encouragement would not violate the statute."

Permissible Conduct

The court further found that the following conduct was permissible under the anti-kickback statute:

1. *Enlisting physician investors who were in a position to refer substantial quantities of tests to the joint venture laboratories;*
2. *Intending to encourage limited partners to refer business to the joint venture laboratories;*
3. *Offering physicians the opportunity to profit indirectly from referrals by referring patients to laboratories they owned when they could not profit directly;*
4. *Telling potential investors that the success of their investments depended upon referrals from investors, with the practical effect of low referral rates being failure of the business;*
5. *Making substantial cash distributions to investors based on each individual's ownership interest, and not on the volume of their referrals; and*
6. *Offering a potentially high rate of return on investment if the investors made a large number of referrals.*

"By approving this conduct, the court held that the foregoing are insufficient to prove that appellants offered or paid remuneration to induce referrals," stated the Reliant Complaint.

Illegal Conduct

According to the Reliance suit, after approving those six kinds of conduct, the court then underscored specific actions which the court held were violations of the anti-kickback statute and constituted an offer of payment to induce referrals of program-related business.

1. *Implying that eligibility to purchase an investment interest in a business depends on an agreement to make referrals;*
2. *Telling prospective investors that the size of the investment interest they would be permitted to purchase depends on the volume of business that the investor referred to the laboratories;*
3. *Stating that investors who did not refer business to the laboratories would be pressured to leave the business; and*
4. *Telling potential investors that the investors' return on their investment would be virtually guaranteed.*

After Hansler, the California Attorney General issued an opinion on February 27, 2006 establishing the lawfulness of

physician-owned entities after being asked to answer two questions by a legislator.

First, may a physician prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest? And, second, if the physician may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest, may the company solicit physicians as investors in the company?

The California Attorney General said:

- *A physician generally may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest, provided that any return on investment is based upon the physician's proportional ownership share and requisite disclosures are made; and*
- *Where a physician may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest, the company generally may solicit physicians as investors in the company.*

Where's the Calvary?

One might think that other physician-owned distributors would be eager to join Reliance in fighting the government.

Surprisingly, they have found few allies so far.

We put the question to John Steinmann, D.O., one of the founders of the American Association of Surgeon Distributors (AASD).

Steinmann told us that until there are well-accepted and enforced standards that clearly identify proper conduct, the healthcare community will continue to be frustrated by the lack of clarity that suppresses beneficial, ethical distribution models and facilitates the presence of models with unacceptable conduct.

Well-Intentioned ePODs

"The AASD has provided well-intentioned physician-owned distributorships the ePOD certification process to systematically address suspect characteristics by requiring transparency, disclosure, cost savings, product quality assurance, utilization tracking and adherence to all state and federal Anti-kickback and Fraud and Abuse Laws. AASD confers upon its members the designation of ePOD in recognition that there is a distinction between the appropriate use of the physician distributorship model by ethical individuals, and the inappropriate use of the model."

Steinmann added that the AASD is supportive of an enforcement regimen that eliminates POD's whose conduct does not demonstrate the highest ethical and legal standards. **"Instead of attacking the government for their use of words, Reliance should instead focus on proving proper conduct, patient protection, and merit."**

Pike and Berry have been short on transparency with their privately held companies. They don't have a web site and have not authored papers documenting cost savings at medical conferences as some other physician-owned businesses have done.

Judge's Declaration Sought

Reliance wants the federal judge to enter a judgment declaring that physician-owned entities that comply with the law are not "inherently suspect under the anti-kickback statute," and hospitals and ambulatory surgery centers are not "at risk" if they enter into arrangements with physician-owned entities.

The First Amendment, concludes the Reliance Complaint, protects Pike's and Berry's right to speak to physicians about doing business together. ♦

Major Surprise From NASS' Best Paper//You Could Be Mis-Diagnosing Cervical Fusion. Here's Why//Spinal Elements Steps UP for Children with Major Donation

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

Wrong Cervical Fusion Diagnosis, Doctor! Here's Why. Using the largest series ever undertaken—262 surgically explored segments—Kwang Sup Song M.D., Dan Riew, M.D. and the Cervical Spine Service at Washington University are defining plain radiographic criteria for anterior cervical fusion. They have found that when using plain X-rays, 2mm of interspinous motion (ISM) was inaccurate for diagnosing anterior cervical fusion status. Dr. Riew tells *OTW*, "There remains controversy surrounding the use of interspinous motion (ISM) on flexion/extension cervical radiographs as a way of determining anterior cervical fusion status; the issue is the exact distance and measurement accuracy. There are many previous studies using different criteria for diagnosing cervical fusion as being solid using plain X-rays. In a paper recently accepted by *JBJS*, we found that the interspinous distance of >1mm at 150% magnification on a plain X-ray, where the adjacent, non-fused segment moved at least 4 mm (to ensure that there was an adequate flexion and extension view) was the best way to tell if there was a pseudoarthrosis. This was based on objective criteria using CT as well as surgical exploration for confirmation. Many people have used criteria such as less than three degrees of angular motion, but this gives inaccuracies. Despite widespread literature, we found that 2mm of ISM was inaccurate for diagnosing fusion status. To our knowledge, this is the first report of dynamic plain radiographic parameters for determining fusion status that equal CT scans and our results were strengthened by the largest number of segments surgically analyzed."

L to R: Jason Blain, president and co-founder Spinal Elements, Jackie Heroman, Make-A-Wish Texas Gulf Coast and Louisiana Chapter, Danielle Chauvin, Regional Event Specialist at St. Jude Children's Research Hospital, Todd Andres, CEO and co-founder Spinal Elements.

NASS's Fellowship Award Goes to…Deb Kumar Roy! Deb Kumar Roy, MBBS, MRCS (Ed) from Birmingham, UK has been honored with the 2013 NASS Clinical Traveling Fellowship Award. Dr. Roy, who is with the Department of Neurosurgery at The Queen Elizabeth Hospital, tells *OTW*, "This fellowship involves visiting a few of the best spinal units in the U.S. and learning what is the practice in the units considered best in the world in terms of patient care, protocols for managing various spinal pathologies, use of modern techniques and the importance of multidisciplinary team approach in the management of various spinal conditions like tumors, trauma and infection. My role will be in the capacity of a clinical observer and as such I will be in operating rooms, outpatient clinics, and departmental meetings. I will be spending a month in the U.S. and will be visiting Johns Hopkins University Hospital in Baltimore with Professor Ziya Gokaslan, Rothman's Spine Institute in Philadelphia with Dr. Todd Albert and in Cleveland clinic with Dr. Edward Benzel. I am really happy and I am looking forward to meeting spending time in the best spinal units in the world."

NASS' Best Paper for 2013 Delivered Surprising Data! A team from Hong Kong recently walked away with a "Best

Paper" award from the annual Meeting of the North American Spine Society (NASS). Their finding? That a mere baseline MRI in patients without back pain can accurately predict first-time lower back pain and its severity. The study was led by Dino Samartzis, Ph.D. (C) from the Department of Orthopaedics and Traumatology at The University of Hong Kong. He tells OTW:

> "A low back pain risk profile was identified based on baseline MRIs and environmental/lifestyle factors. This profile focused on the development of first-time low back pain episodes. In that risk profile, heavy workload increased the risk of first time low back pain; however, being active and engaging in physical activity decreased the risk. Having overall disc degeneration or disc bulging/extrusion doubled the risk of developing low back pain. Having moderate to severe disc degeneration of the lumbar spine significantly increased the risk of developing first time low back episodes. A 'dose response' of lumbar degeneration and pain profile was identified. The more lumbar disc degeneration, the more severe the pain. This is the largest prospective study ever conducted to address if baseline MRI characteristics can predict in asymptomatic individuals who will develop first time low back pain and severity of pain.
>
> This study identifies clinically relevant spinal phenotypes that are related to the development of low back pain and its severity. This study further stresses the importance of the phenotype of disc degeneration and its clinical relevance. Understanding clinically relevant spinal phenotypes may lead to better understanding of 'red flag' findings on MRI. This study will further contribute to various genetic and biomarker studies looking to identify clinically relevant degenerative phenotypes. As such, novel preventative and therapeutic interventions may be developed in the future, which may lead to a healthier and productive society.
>
> Our study is the largest ever conducted to assess our objectives, and one that in particular looked at the phenotype of degenerative changes in a different manner. What this study has also taught us is that the phenotype of how degenerative changes are regarded needs to be properly defined and standardized, and that environmental and lifestyle factors cannot be disregarded in the make-up of the pain profile. Conducting such a huge study can be very costly and time consuming in many parts of the world, in particular the USA. We were fortunate to draw from our ongoing population-based study (Hong Kong Disc Degeneration Cohort), which we

have continued to follow-up subjects on different platforms at different time points since they were initially recruited.

I want to acknowledge my coauthors, Kenneth Cheung and Keith Luk from Hong Kong (Department of Orthopaedics and Traumatology, The University of Hong Kong) and Jaro Karppinen from Finland (Institute of Clinical Sciences, University of Oulu). The study was funded by the Hong Kong Area of Excellence and Theme-Based Research scheme programmes."

Spinal Elements Donates $250,000 to Children The Make-A-Wish Foundation and the St. Jude Children's Research Hospital are benefitting from the generosity of the people at Spinal Elements. Just recently, as the annual NASS meeting wound up, Spinal Elements announced that an estimated $250,000 for children's charities will have been raised from its Hero Allograft sales by the end of 2013. Two $125,000 check presentations were made to local Make-A-Wish and St. Jude representatives, and local Make-A-Wish and St. Jude families were honored and spoke of how the organizations have changed their lives. Dr. Mike Leahy, one of the first surgeons in the U.S. to participate in Spinal Elements "Pledge to Be a Hero" program, was also honored at the event. Dr. Leahy uses Hero allograft exclusively.

Spinal Elements is the first spine company to donate 100% of the net proceeds from the sale of its allograft tissue product called Hero to charities benefiting children with life-threatening medical conditions. Although many companies earn significant profits from the sale of allograft, Spinal Elements has chosen to donate all profits from the sale of its Hero allograft to Make-A-Wish Foundation and St. Jude Children's Research Hospital.

"Spinal Elements sees Allograft as much more than a product or a commodity, "said Jason Blain, president and co-founder of Spinal Elements. "Allograft is the physical embodiment of a human life and deserves that level of respect. We are honored to be stewards of this precious gift."

Todd Andres, CEO and co-founder of Spinal Elements, said, "We feel that the best way to pay respect to the donation of human tissue is to donate our efforts to get it to the patients who need it and to extend that gift to ailing children. We refer to that as honoring the gift and paying it forward." ♦

The Insurance Industry Strikes Again!

BY JACK ZIGLER, M.D.

As of September 13, 2013, Aetna reverses an eight year policy and now "…considers lumbar prosthetic intervertebral discs…to be experimental and investigational…"

REALLY????!!!!!!!!!!

When the Charité lumbar artificial disc was approved by the FDA in 2005, and labeled for use in appropriate patients with single-level degenerative lumbar disc disease, Aetna was the first of the major indemnity insurers to approve its use for on-label indications. How much of this was due to foresight on Aetna's part, or the fact that Johnson & Johnson (manufacturer of the Charité disc) contracted with Aetna for health insurance for its >100,000 global employees is open to conjecture.

In fact, Aetna remained the only major insurer to do so until Cigna began approvals a few years later, and Blue Cross finally approved lumbar arthroplasty in 2013. Amazingly, UnitedHealthcare still considers lumbar disc replacement "experimental and investigational" some eight years following FDA approval, and publication of two- and five-year clinical follow-ups, publications reporting lower reoperation rates than fusion, and lower adjacent level degeneration than above fusion. This is obviously an internal and proprietary definition of the term.

When ProDisc-L was approved by the FDA in 2006, Aetna extended its lumbar coverage to ProDisc, adding L3-4 as a covered level for that device, per FDA labeling. This remained status quo through September 2013. Charité was pulled from the worldwide market in 2012. Long-term five year data was published on the ProDisc IDE (investigational device exemption) patients in late 2012, as well as information showing statistically significantly less adjacent level lumbar degenerative disease in patients who had been randomized to arthroplasty rather than fusion (by a factor of 3), along with a very low reoperation rate following arthroplasty.

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With no warning or explanation (such as new scientific data or claims history not shared with the medical community), Aetna released a new Clinical Policy Bulletin on Intervertebral Disc Prostheses in mid-September 2013, abruptly reversing its eight-year-old coverage policy, now stating that:

> "Aetna considers lumbar prosthetic intervertebral discs (e.g. the Charité Artificial Disc and the ProDisc-L Total Disc Replacement) experimental and investigational for lumbosacral degenerative disc disease and for all other indications"

Really?? And for substantiation, it recycles a superficial and biased literature review of articles that are negative or lukewarm-at-best towards the technology.

1. Specifically, this "documentation" spends a lot of time reviewing the early Charité literature, which is pretty moot since the device is no longer available for implantation anywhere in the world. Didn't

Aetna get the memo that Charité was pulled off the market over a year ago? One would think that a major global health care company so obviously interested in making key decisions regarding approval of devices for its insured population, would at least know that the device they devote several pages to "disrespecting" is now part of history, but no longer germane to the present discussion.

2. The cited literature is a fairly weak collection of early interim single-site analyses. These are not the strong Level I studies that have been published, using multicenter, multi-surgeon prospectively collected data on externally randomized patients, with high long-term follow-up. Instead, most of the literature cited is at least five years old, and is certainly not considered the strongest evidence by the spine surgeon community. Ignoring the published two-year data (included in the reference list but not mentioned in the review), the published five-year data, the published adjacent level degeneration data, the reoperation rate data, the published economic data from 2010 through 2013, etc. does a disservice to everyone.
3. Aetna certainly has the resources to update their analyses, to disregard lengthy discussion of an extinct device, and to properly ascribe weight to very strong Level I studies (or at least to mention them!) rather than to insult the scientific community with its obviously biased and self-serving literature review of weaker articles. Aetna should be embarrassed by this document.
4. What was the rationale for the complete reversal of their position? Health care providers are certainly going to have to inform Aetna's policy holders that they may no longer receive a lumbar disc replacement. Patients will then angrily ask their surgeons to explain why, and Aetna has not supplied that information. Has there been an uptick in negative claims experience (reoperations, increased need for subsequent medical expense) or some real data analysis that Aetna has chosen not to share with the scientific and medical provider commu-

nity? If so, why aren't they letting us know, so we can understand their decision and explain it to our patients?

Where is the oversight to the insurance industry? We had previously questioned Anthem Blue Cross' decision to require spondylolisthesis as a pre-condition for arthroplasty, which changed the FDA labeling, and asked the FDA, in an open letter, to intercede.

We now see a complete 180º reversal of policy by a major insurance carrier with no good explanation. Lumbar arthroplasty is a proven technology with 40,000 to 50,000 patients implanted worldwide, post-market surveillance of U.S. IDE patients out to five years by the FDA, and publication of high quality data analysis. How can boardroom decisions be allowed to alter patient care based on a business model, rather than by careful scientific analysis of comparative effectiveness modeling?

New technologies that have shown effectiveness, cost savings, and better outcomes, like lumbar arthroplasty, should be supported and made available to patients. Patients are doing their homework, researching on the Internet, reading and understanding the literature, and are frustrated by draconian decision-making by their insurance companies. Medical decisions should be made by educated health care providers, and not by insurance company executives, whether they have M.D. degrees or not.

Who besides health care providers (spine surgeons, in this case) is watching out for patient's rights? We need the FDA or Congressional committees to turn their searchlight onto the insurance industry. Physicians cannot do this alone.

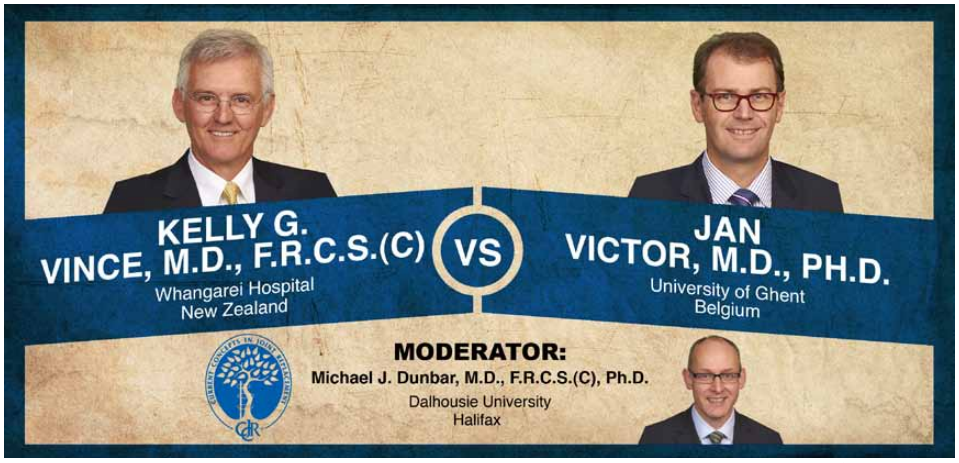
Our role is to point out the problems, but we need help. ♦

Ligament Tensioners: Kelly Vince Versus Jan Victor

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

"Tensioners optimize stability and alignment…and stability *controls* alignment," argues Kelly Vince. "Look, we share the same goals," says Jan Victor. But there are several hidden "icebergs" which can sink the operation.

This week's Orthopaedic Crossfire® debate is "Ligament Tensioners Optimize Stability and Alignment." For the proposition is Kelly G. Vince, M.D., F.R.C.S.(C) of Whangarei Hospital in New Zealand; against the proposition is Jan Victor, M.D., Ph.D. from the University of Ghent in Belgium. Moderating is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Vince: "I think what trumps Level I evidence is physics, logic and common sense. So if we look at lever arms we see that the bigger the lever arm the larger the load that it balances on the other side; conversely, the smaller the lever arm the smaller the load it balances. If we don't correct deformity then the patient is left with bad biomechanics and bad loads in strategic points on the joint."

"There was a 2010 paper in *JBJS* that looked at mechanical axis alignment (15 year survival). The paper doesn't say that alignment is not important; it says that maybe there is a permissible range of alignments within which knees function well. But there are certainly boundaries beyond which we would call a knee 'mal-aligned' and expect bad things to happen."

"Whether you have varus/neutral/valgus alignment, the knee that is stable will function better right off the bat. But even if you don't have the optimal alignment, you at least only have one alignment. That is why stability is important…it controls alignment. By contrast, if you have instability it means that you have many alignments; you usually have the worst one for any given loading pattern."

"We need alignment; the knee must be stable, and that process is one of tensioning. And if you're going to break those rules you have to ask yourself if you are recreating anatomy for your patients or are you recreating pathology. I use the famous on-board computer as my tensioner, but any device that helps with that has got to be good."

Dr. Victor: "I share common goals with Dr. Vince. Both of us want to achieve the desired alignment in a reliable and consistent way. We both want to obtain functional stability throughout ROM [range of motion], with gap equality (flexion-extension) and gap symmetry (medial-lateral). Most of all, we would like to restore the flexion axis of the knee because that is what will return the patient to normal kinematics."

"We share the same goals, so the debate is basically over *how* to achieve these goals. If I were to visit Kelly and make my way around Antarctica, I could take the Eastern route or the Western passage—both will bring me to my goal. But one route might be more dangerous than the other."

"With tensioners they cut the tibia. Then they crank up the femur until the ligaments are tight. They position the block parallel to the tibial cut then make the femoral cuts and put in the prosthesis."

"Where are the icebergs? The first one is that the ligaments do not have a linear load elongation curve. Secondly, it's incorrect to think that the knee is symmetric. The medial side does not equal the lateral side. We know that the central fibers of the medial collateral ligament (MCL) are isometric; in contrast, the lateral side of the knee is non-isometric, is lax in flexion, and is stabilized by muscles."

"Thirdly, tensioners check balance at 0 degrees and 90 degrees of flexion, but

there is no information on mid- or deep flexion. Fourth, there is a dependent relative position in the sagittal plane of the tibia and the femur. If you crank up the femur you basically verticalize the PCL by pushing the femur backwards and pulling the tibia forwards. That is what you do with a tensioner."

"It might not be much of a problem if it weren't that your prosthesis will define the sagittal relationship between the tibia and femur…and that might not be the same as what you did with your tensioner. Fifth, there are uncontrolled variables such as a dislocated patella, or chronic ligament injury or insufficiency. So with these five icebergs I think it's fair to state that there is room for improvement."

"We should go for adapted measured resection. We know the medial side of the knee is the stable isometric side. Therefore, we want to restore the medial joint line level and the medial posterior condylar offset. To do the former, you insert an intramedullary rod, you hit the medial condyle distally, perform the cut, and you restore the original joint line level."

"But what about the varus knee where there is cartilage and bone wear? Without realizing it you have already raised the joint line by 4mm. More importantly, you might do the same in flexion. As you put on this block and you have central pivoting when you apply external rotation you will take out more bone on the medial side."

"If you look at the medial condyle you see that flexion-extension occurs around the single point of pivot. If you insert a prosthesis with the same geometry and the same size then the isometry of the MCL will be maintained. However, if you perform the cuts with a proximalization of your femoral component and an increased cut on the posterior medial side, then you raise the femoral component and place it more anteriorly."

"So the center of rotation has been shifted proximally and anteriorly. In kinematic terms the knee will now flex and extend around this new center of rotation. As you get to 90 degrees there is normal tension; as you reach 120 degrees of flexion you have a tight MCL and that may be painful for the patient."

"It's better to pivot around the posterior side of the medial condyle in order to preserve your posterior medial offset. You do that by putting on a spacer if there is cartilage or bone wear posterior or medially, and then apply the desired amount of rotation that you want to add to that reference line. As for reference lines, we looked at the surgical transepicondylar axis and found this to be very close to the optimal flexion axis. However, we found that the posterior condylar axis had the smallest standard deviation."

"My conclusive algorithm: I perform measured resection, compensating for cartilage or bone loss on the medial side. I try to use the posterior condyles as a reference; I add three degrees of external rotation, and except for severely deformed knees where I perform a CT scan, measure the condylar twist and then correct the measured value. Finally, I confirm if these settings align with gap balance."

Moderator Dunbar: "So Jan, you're advocating that we should avoid the tensioners because it gives us a false sense of security since we're looking at

flexion-extension and the metrics are perhaps old. Is that a fair assessment?"

Dr. Victor: "My point is: use as much information as you can. For me, the geometry is the basis. The ligaments will adapt to that. If I see a big mismatch I will cheat a bit on the geometry and try to go a little bit towards the ligaments."

Moderator Dunbar: "If we could provide a tool that gave you on-board information that was more reliable and reproducible…and more importantly we could give it to our colleagues who are starting their practices so they could start with your knowledge."

Dr. Vince: "I think most of what I know goes on a napkin. These are very sophisticated and important concepts that we need to think about more thoroughly. To translate this into correcting the entire range of deformities that we're going to face on any given morning is a tough job."

Moderator Dunbar: "Excellent point. We have a lot of happy patients despite the fact that we're all kind of doing it this blunt way."

Dr. Victor: "It's very simple. You restore the medial joint line level, and you can do that in extension and in flexion. Then you adapt your rotation in order to have a rotational axis that is close to the optimal flexion axis. That is simple and reproducible."

Moderator Dunbar: "So why do we get so many good patients just doing it conventionally?"

Dr. Victor: "There is a next step, which is to keep that original coronal orientation of the tibia. What we do now is adapt for the fact that we make a perpendicular cut on the tibia. That means externally rotating the femoral component. If you cut parallel to the original orientation of the joint line you would not need that rotational correction. That's a new concept."

Dr. Vince: "If you're going to change the rotational axis by making the rotation of the femoral component a function of something else—instead of where we would like it to be anatomically—then we know empirically that this can play havoc with patellar tracking. And if you're saying that the axis is important because it represents the function of the ligaments, the ligamentous environment is part of the pathology in many cases. Get the mechanics right and then adjust the soft tissues with surgical techniques."

Moderator Dunbar: "In the future will we be looking at biomarkers to say that 'this collagen type is different than this patient and should tension it differently?'"

Dr. Vince: "That's a long way down the track."

Dr. Victor: "The amount of laxity you accept at the end of the operation will be a bit different from patient to patient."

Moderator Dunbar: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.

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COMPANY

Zimmer Sales Growth Best in Six Years

Zimmer Holdings, Inc.'s third quarter reconstructive sales rose 4% on a reported basis to $788.3 million. Excluding currency, sales climbed 6%. Overall, said BMO Capital Markets analyst Joanne Wuensch, the company's total revenue increased at the highest rate since the fourth quarter of 2007.

Excluding currency, knees were up 7%, hips up 2%, extremities up 15%, trauma up 8% and spine was down 3%.

Gaining Knees, Ceding Hips

Wuensch said it looked like the early sales of the company's Persona Personalized Knee System is gaining traction, with volume/mix up 9.1% offset by 1.7% negative price, and "excellent feedback" from new and current physicians. Given the early read from other companies, Wuensch said it looks like the knee market was up ~4%; excluding currency, with Zimmer's share increasing almost 100 basis points year-over-year.

At this stage of the reporting season, Wuensch says the hip market looks to have increased ~5% excluding currency, with Zimmer ceding some share. Overall, Wuensch views the third quarter as a good quarter for Zimmer, taking knee market share, leveraging the income statement, in stable to improving end markets.

Entry Into Spine Lateral Access Market

In its October 24, 2013 quarterly report, the company cited the recent receipt of 510(k) clearance from the FDA to market the Zimmer Patient Specific Instruments (PSI) Shoulder system to complement its Trabecular Metal Reverse Shoulder system for reverse shoulder arthroplasty procedures.

Logo courtesy of Zimmer

Zimmer 3Q13	Sales ($ in millions)	% Change
Total Reported Sales	**$1,070.0**	**4.8%**
Reconstructive	$788.3	4.0%
Knees	$434.5	6.0%
Hips	$308.3	flat
Trauma	$78.5	5.0%
Spine	$48.0	down 4%
Extremities	$45.5	15.0%

Source: Zimmer Holdings, Inc.

Additionally in the quarter, Zimmer Spine announced its entry into an exclusive global distribution agreement to market the Lateral Locking Cage (LLC), a first of its kind, minimally invasive lateral interbody cage for the treatment of degenerative disc disease and instability. Implanted through a unique minimally invasive approach, the LLC represents Zimmer Spine's entry into lateral access lumbar surgeries, a fast growing segment of the global spine market.

4.5% Growth Expected for 2013

The company reaffirmed its 2013 revenue guidance. Full-year revenues for 2013 are expected to increase approximately 4.5% on a constant currency basis from 2012. The company now estimates that foreign currency translation will decrease revenues between 1.5% and 2.0% for the year, resulting in reported revenue growth between 2.5% and 3.0%.

Dave Dvorak, the company's president and CEO, said Zimmer achieved accelerated top-line growth in the third quarter, fueled by innovative new product offerings and the focused execution of the global sales team. "For the balance of 2013, we expect to continue building stockholder value through the ongoing execution of our growth, operational excellence and capital deployment strategies."

—*WE (October 25, 2013)*

Medtronic Claims "First" in Lateral Access Spine Surgery

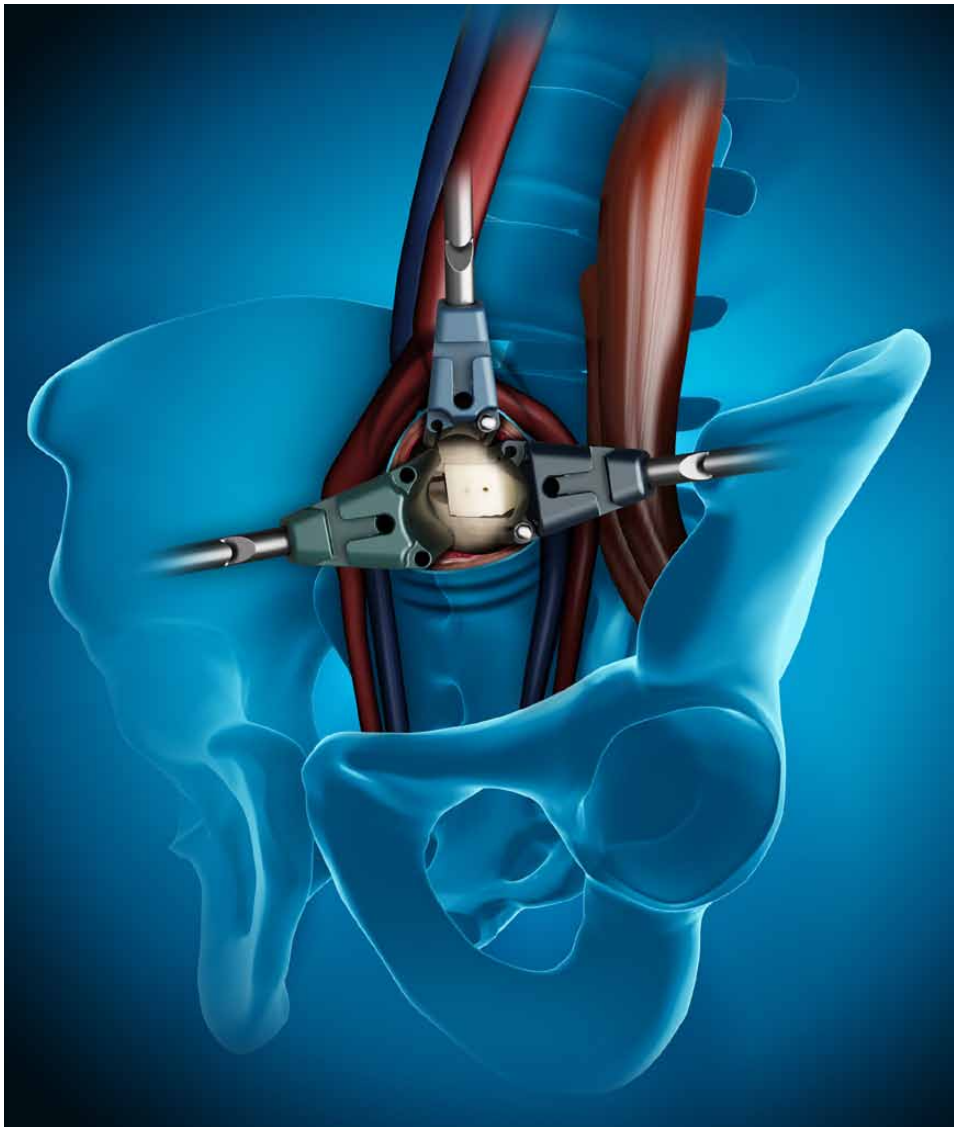
Medtronic, Inc. says it has scored a first by introducing the first procedure that allows lateral access to the most common operative level of the spine. According to an October 21, 2013, announcement, the OLIF51 procedure enables reproducible lateral access to the L5-S1 disc space.

"For the first time, along with the OLIF25 Procedure, the surgeon community has a combination of procedures that offer an extensive approach to all levels of the lower lumbar spine in one patient positioning," said Richard Hynes, M.D., spine surgeon at The B.A.C.K. Center in Melbourne, Florida.

Referred to as Oblique Lateral Interbody Fusion for L5-S1, this procedure, says the company, eliminates the need to reposition the patient during surgery and incorporates Medtronic's comprehensive surgical platform of access, interbody, neuromonitoring, navigation, fixation and biologic options," said stated the announcement.

Doug King, Medtronic Spine's president and Medtronic senior vice president, said, "With the launch of the OLIF51 Procedure, Medtronic has aligned with expressed needs from the global surgeon community for procedures that require less muscle disruption and enable greater intraoperative efficiencies."

The OLIF25, which was introduced at last year's annual meeting of the North American Spine Society, targets the L2-L5 region of the spine, which is a slightly smaller range of the lumbar region than reached by the OLIF51.



Medtronic, Inc. OLIF51

Lateral Access Benefits

According to Adam S. Kanter, M.D., of the University of Pittsburgh, traditional posterior fusion techniques require the dissection and retraction of back muscles, bones, vessels, ligaments, and nerves; whereas traditional anterior approaches through the abdominal musculature risk injury to major vascular structures such as the aorta and iliac vessels, as well as the very delicate genitourinary structures. The lateral transpsoas approach enables the means to reproducibly address spinal pathology from the side of the patient, (utilizing novel dynamic real-time nerve localizing and monitoring techniques, thus minimizing surrounding tissue trauma and maximizing safety and efficacy.

The announcement was made during the annual meeting of the Congress of Neurological Surgeons in San Francisco, California.

—*WE (October 21, 2013)*

LEGAL

OIG: PODs Don't Save Money

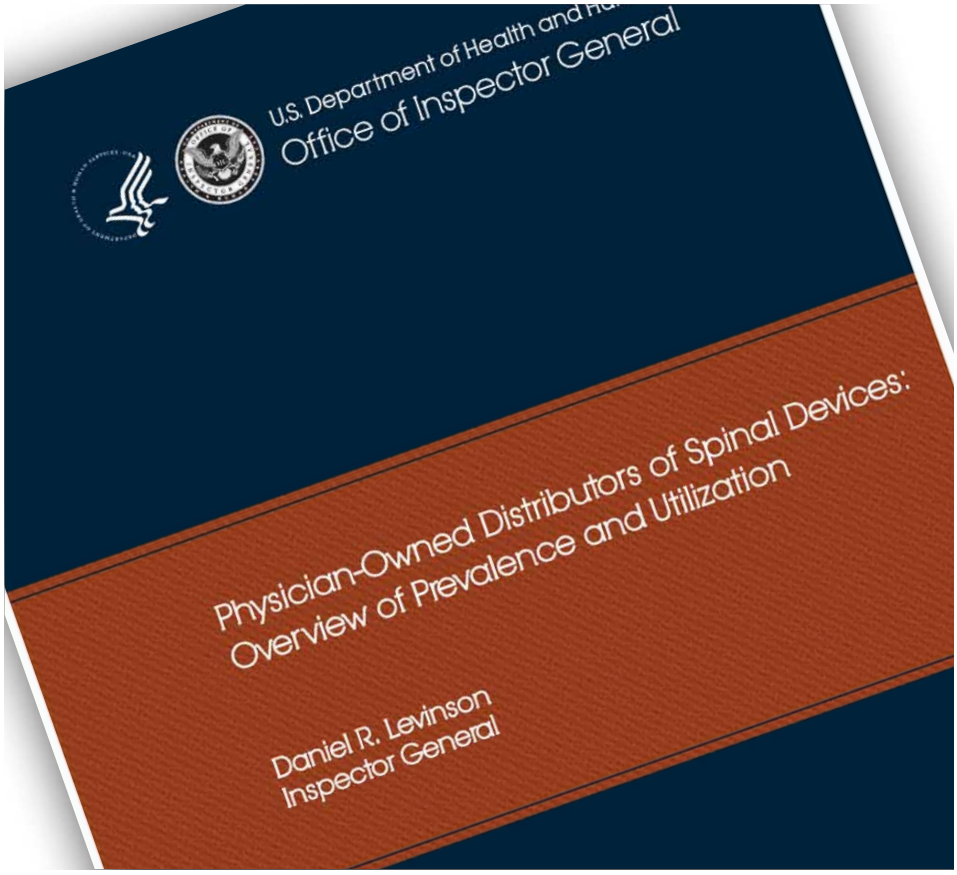
PODs do not supply devices at a lower cost than other suppliers and may increase the cost of spinal surgery to Medicare over time.

That's the conclusion drawn by the long overdue report of the Office of Inspector General (OIG) requested by Congress last year on physician-owned distributorships.

The OIG concluded in the 31-page report released on October 24, 2013, that PODs are a substantial presence in the spinal device market. Said the report:

"Our findings raise questions about PODs' claim that their devices cost less than those of other suppliers. Surgeons performed more spinal surgeries at hospitals that purchased from PODs, and those hospitals experienced increased rates of growth in the number of spinal surgeries performed in comparison to the rate for hospitals that did not purchase from PODs.

"Taken together, these factors may increase the cost of spinal surgery to Medicare over time. Finally, hospitals' policies varied in whether they required physicians to disclose ownership interests in PODs to either the hospitals or their patients. Thus the ability of hospitals and patients to identify potential conflicts of interest among these providers is reduced."



www.oig.hhs.gov

Medicare and Spine Surgery

In fiscal year 2012, Medicare paid hospitals a total of $3.9 billion for 178,789 spinal surgeries. Medicare reimbursed hospitals an average of $21,613 for each of these surgeries. On average, Medicare reimbursed hospitals $10,289 for the least complicated spinal surgeries and $34,676 for the most complicated surgeries, according to the report.

The OIG selected a sample of 1,000 claims billed to Medicare in fiscal year 2011 that included spinal fusion surgery. They then asked each hospital associated with these claims to complete a questionnaire about its knowledge of physician ownership of spinal device suppliers. They also asked each hospital to complete a worksheet with details about the spinal devices used in each surgery in the sample.

In 2011, finds the report, PODs supplied devices used in nearly one in five spinal fusion surgeries billed to Medicare. Spinal surgeries that used POD devices used fewer devices but did not have lower per surgery device costs than surgeries that did not use POD devices. Among the hospitals in the sample, about a third reported buying spinal devices from PODs. When hospitals in the sample began buying from PODs, their rates of spinal surgery grew faster than the rate for hospitals overall.

Impact on Major Spine Manufacturers

Wells Fargo analyst Larry Biegelsen says the major spine players could benefit from a retrenchment in PODs. "We previously estimated that PODs have captured about 10-15% of the $5.7 billion U.S. spinal hardware market; however, the OIG report suggests that PODs may have captured almost 20%.

Although the impact of the OIG report is unclear at this time, Biegelsen esti-

mates that if PODs went away completely, NuVasive, Inc., Globus Medical, Inc. and LDR would benefit the most among the major spine players with potentially 6-10% upside to their annual sales because they do not sell to PODs. "At the very least, the OIG report should curtail the growth of PODs, which would be good for the large spine players, in our view."

Court Challenge

The POD debate has headed to court, as Reliance Medical Systems, LLC, has challenged the constitutional basis for OIG's determination that legally doing business with PODs is "inherently suspect"?

To read the entire OIG report, click here: http://oig.hhs.gov/oei/reports/oei-01-11-00660.pdf

—*WE (October 24, 2013)*

NICE Wants Longer Lasting Hips

The Brits, who first raised warnings about metal-on-metal hips, have issued a new draft guidance with stricter benchmarks for quality.

The National Institute for Health and Care Excellence (NICE) issued the draft guidance on October 18, 2013. The guidance recommends that a new hip should work well in at least 95% of cases over 10 years.

NICE's Professor Carole Longson commented, "Importantly, as we now have more information about how long artificial joints can last, we have recommended the use of prostheses with a proven lower revision rate. This means that a new joint should work well in at least 95% of cases over 10 years, so a revision may be needed in 5% or fewer cases over this period. Our existing guidance advises that prostheses should work well in at least 90% of cases, so repeat surgery may be needed in up to 10% of cases over 10 years."

England's Department of Health asked NICE to produce guidance on using total hip replacement and resurfacing arthroplasty in the National Health Service in England and Wales. The Appraisal Committee considered the evidence submitted and the views of non-manufacturer consultees and commentators, and clinical specialists and patient experts.

The guidance document was prepared for consultation with the consultees. It summarizes the evidence and views that have been considered, and sets out the draft recommendations made by the Committee. NICE invites comments from the consultees and commentators and the public for this appraisal. The document should be read along with the evaluation report.

The Appraisal Committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the provisional recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure avoiding unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

The closing date for comments is November 8, 2013. The second Appraisal Committee is scheduled to meet on November 20, 2013. A final guidance is expected to be issued in February, 2014.

To comment, click here: http://guidance.nice.org.uk/TAG/307/Consultation/DraftGuidance

—*WE (October 23, 2013)*

BBC News/artificial hips

BIOLOGICS

Researchers Make Cartilage From Skin Cells

The impossible keeps on getting easier. Researchers at Kyoto University, Japan, have found a way to use human skin cells to produce new types of cells—including cartilage cells. Instead of using stem cells to create different cells, which, they found, takes longer, they are using a direct reprogramming method where genes are implanted directly into skin cells to produce a different type cell.

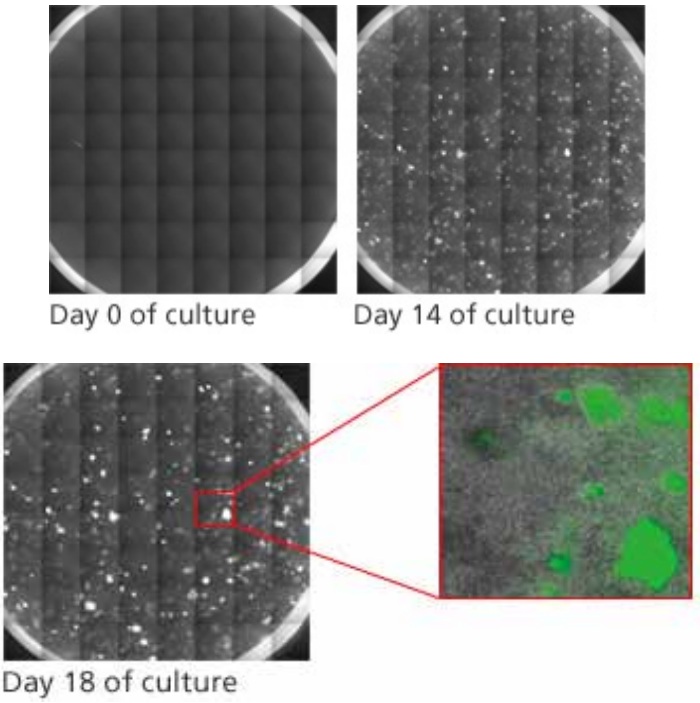
The technique is expected to help treat cartilage damaged by disease or injury by reducing the time needed to produce new cells. The so-called old method involves using artificially created induced pluripotent stem cells. Though they can grow into any type of human body tissue the cells take longer to produce.

The team, including Professor Noriyuki Tsumaki, introduced three genes—c-MYC, KLF4 and SOX9—into the skin cells of a newborn using a virus. Within two weeks, cells bearing the features of cartilage cells had formed.

When these cells were transplanted into mice, they subsequently formed cartilage tissue. The team's report stated that no tumor was observed and it only takes about two months to produce a sufficient amount of cells to transplant. That is about half the time required for the iPS cell technique, the team said.

An advantage of the direct reprogramming method over the iPS cell technique is that it eliminates the possibility of contamination occurring from undivided cells that can develop into tumors, Tsumaki said.

—BY (October 22, 2013)

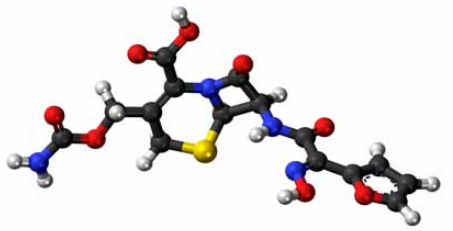


Courtesy of Associated Professor Noriyuki Tsumaki, Department of Bone and Cartilage Biology, Osaka University Graduate School of Medicine

LARGE JOINTS

Cefuroxime Infused Bone Cement Cuts Risks

The online publication *TeleManagement* reports that knee replacement patients are less likely to experience complications following their surgery if surgeons used bone cement along with the antibiotic cefuroxime. Potential complications for diabetics after knee replacement surgery include slow wound healing, problems with fracture healing and lack of sensation in the joint that can lead to un-noticed trauma.



Wikimedia Commons and Jynto

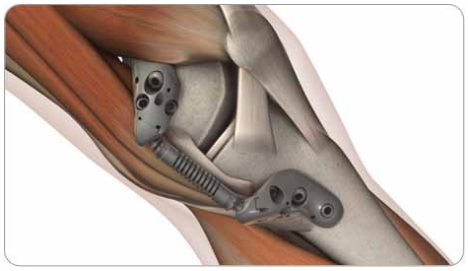
Researchers in Indiana studied the records of over 5,000 patients who had knee replacement surgery. Six percent had diabetes. They found that deep infections in the operation area ran at 0.7% for people without diabetes, and at 1.2% in the diabetic group. Those diabetics treated with bone cement and the antibiotic cefuroxime were less likely to have a deep infection.

About one in five of people in the United States who are over the age of 65 now have diabetes, according to *TeleManagement.* That is also the age range where individuals are most likely to need a knee replacement.

—BY (October 22, 2013)

Moximed Installs 500th Knee Kine-Spring

Five years ago a surgeon implanted the first KineSpring in an aching knee and this month Jack Farr, M.D., Director of the OrthoIndy Cartilage Restoration Center of Indiana and the OrthoIndy Sports Medicine Fellowship Program installed the 500th KineSpring worldwide. The KineSpring System, made by Moximed, Inc. of Hayward, California, is an implantable medical spring that works by unloading the weight on the diseased knee joint, without changes to the anatomy. Farr is the Lead Principal Investigator of the U.S.-based SOAR clinical study of the KineSpring System.



Courtesy of Moximed, Inc.

According the Moximed officials, the KineSpring System is intended to provide an innovative treatment option for patients with mild to moderate knee osteoarthritis (OA) who find conservative therapy such as pain medication and knee braces unsuccessful but who are not ready for joint-altering knee surgery. The KineSpring System is implanted in the subcutaneous tissue alongside the joint to cushion the knee from excessive loading. The KineSpring System is completely joint-sparing, so future treatment options are maintained.

As David Hayes, M.D., of the Brisbane Orthopaedic and Sports Medicine Centre, Australia, who implanted the first KineSpring System in 2008 stated, "The KineSpring System offers a joint-preserving surgical alternative for my younger, more active patients with medial knee OA. Five years after implanting the first ever KineSpring System, I remain enthusiastic about the potential of the KineSpring System as an effective treatment option for this difficult patient group."

"The continued and growing acceptance of the KineSpring System, as evidenced by the achievement of this significant milestone, is very encouraging. It is clear that both surgeons and patients worldwide value the clinical and economic benefits shown by the KineSpring System. Above all, we are most proud to have played a part in the return of a significant number of patients to an active, high-quality lifestyle," said Kevin Sidow, President and CEO of Moximed.

According to the Centers for Disease Control and Prevention, OA affects 27 million adults in the U.S. and 15 million of them have knee OA. They estimate the costs associated with arthritis and joint pain in the U.S. at nearly $300 billion annually.

In knee OA, as the cartilage wears away, the bone ends may begin to rub against each other, causing severe pain. Drugs and cartilage repair procedures may temporarily relieve pain. Moximed officials have found that if the excess stress on the joint is removed, as with the KineSpring System, pain may decrease and the natural joint tissues may demonstrate some recovery. The KineSpring System is CE marked in Europe. It is investigational in the U.S. and only available in the U.S. as part of the FDA approved SOAR clinical study.

—BY (October 21, 2013)

Disturbing News: Number of Orthopedic Students Declining

Driven by an aging population the demand in the U.S. for hip and knee replacements will double in the next ten years, according to researchers. Disturbingly, the number of medical students going into orthopedic and joint reconstruction is going in the other direction. It is declining.

To the rescue have come four of the leading orthopedic societies—the American Association of Hip and Knee Surgeons (AAHKS), The Hip Society, The Knee Society, and The American Orthopaedic Association's (AOA) Council of Orthopaedic Residency Directors (CORD). They have banded together to organize the Orthopaedic Resident Training Initiative (ORTI) to develop, organize and

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fund three courses in hip and knee arthroplasty for medical residents. The International Congress on Joint Reconstruction (ICJR) will manage the organization and logistics coordination for the courses.

According to *PRWeb*, the ORTI will engage up to 250 second and third year residents during the spring of 2014 through three inaugural courses taking place in the greater Los Angeles, Atlanta, and Philadelphia areas. Participants will receive cadaveric training in hip and knee replacement procedures and the course curriculum will be developed and delivered by faculty who are members of The Hip Society, The Knee Society, and AAHKS

"Residency is a critical part of training our future orthopaedic surgeons, but there is more we can do to ensure they begin practicing with the best hands-on experience," said William P. Barrett, M.D., chair for the AAHKS's Committee on Joint Education Ventures.

"One of the core values of our organization focuses on active collaboration with other groups to help forward the practice of orthopaedics and to ultimately improve patient care," said Vincent D. Pellegrini, Jr., M.D., president of The Hip Society. "This is a great example of how we can work together to improve resident training."

"The practice of orthopaedics is constantly changing, as new techniques and technologies become available. The ORTI will be another way to get residents trained and ready for improved patient care," added Steven J. MacDonald, M.D., FRCSC, president of The Knee Society.

—BY (October 21, 2013)

EXTREMITIES

Oops! Soft Shoes Won't Prevent Running Injuries

Putting soft cushioning in running shoes to prevent injuries may be a great marketing tool, but it does not prevent injuries. That is the result of a test with nearly 250 runners running in identical-looking shoes with different levels of cushioning in a blind trial. Factors such as body weight and fitness made a difference in injury rates of the runners, but shoe-softness did not.

Miriam Stix, writing for *Reuters*, quoted Daniel Theisen of the Sports Medicine Research Laboratory of the Department of Public Health in Luxembourg, as saying, "The results do not support the common argument from the running-shoe industry that runners with higher body mass should be recommended shoes with greater shock-absorption characteristics." Theisen, a physical therapist with a Ph.D. in sports science and a runner himself, fully expected to see a difference.

The researchers divided the 247 study participants into two groups. The participants were both men and women, were all between the ages of 30 and 50 years old, had body mass indexes ranging from normal to slightly overweight and all ran a minimum of 10 miles a week. Researchers gave the runners shoes that appeared to be identical except that half of the pairs had a soft midsole—a spongy layer beneath the insole of the shoe's interior. The difference in shock-absorbing qualities between the shoes with and without the extra cushioning was calculated to be about 15%.

The runners were required to train at least once a week. Participants used the shoes for five months, and posted information about how much they ran and the kinds of injuries they experienced. Out of the 69 runners who had injuries, 32 used the hard-soled sneakers, and 37 used the softer-soled shoes. Heavier runners were about 13% more likely to have injuries than those in the normal weight range—and shoe softness did not modify that extra risk for heavy runners who got the softer shoes.

Mark P. Kelly, M.D., an exercise physiologist with the American Council on Exercise and a veteran runner, was not surprised by the findings. Cushioning "takes away from the tactile sensation that tends to protect a runner," Kelly said. "In other words, if something hurts our feet when we are jogging, we will naturally change things up so it doesn't hurt. If anything, a harder midsole offers more protection, because it may induce more stability on the plantar surface of the foot and thus spread the impact out more evenly."

—BY (October 21, 2013)

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TRAUMA

Longer Life, Poorer Quality of Life for Women

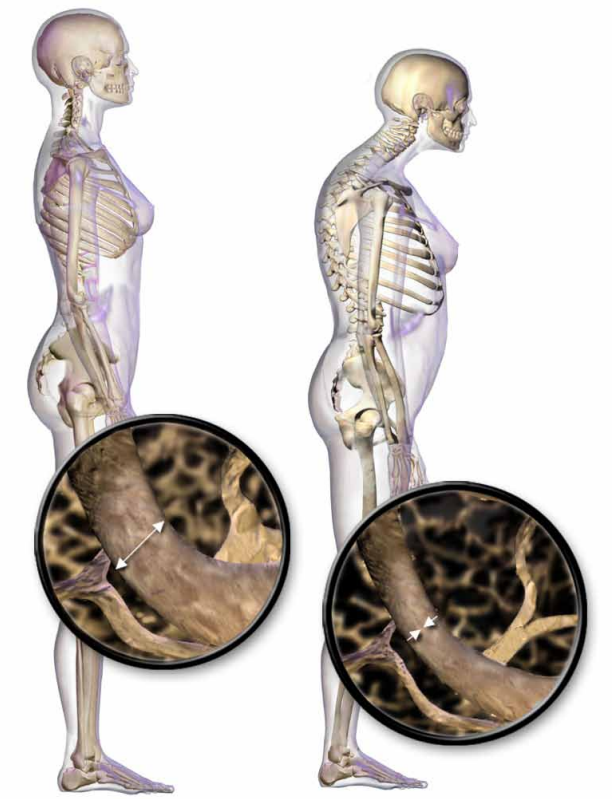
According to a new report just published by the International Osteoporosis Foundation (IOF), women may expect to live longer but their quality of life will be seriously jeopardized if action to protect their bone health is not taken.

IOF President Professor John A. Kanis urged in the October 10, 2013 news release, "The time to act is now, those of us working in the non-communicable disease (NCD) community congratulated governments for their commitment to reduce the NCD burden by 25% by 2025, at the World Health Assembly in 2012. As advocates for bone, muscle and joint health we have identified cost-effective evidence-based solutions that can be implemented immediately, which will not only save lives but reduce health care costs, and ultimately help governments reach this target."

"Although the earlier prevention begins the better, when a woman reaches menopause she must not delay any longer. Menopause is the critical time to take preventive measures against bone loss and muscle weakness that can lead to osteoporosis, falls and fractures," said report co-author Professor Bess Dawson Hughes, Director of the Bone Metabolism Laboratory, Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University in Boston.

The report also emphasizes secondary fracture prevention. "An individual who has experienced a fracture is at double the risk of suffering a second fracture as compared to a person without fractures. In postmenopausal women, a broken wrist or a spinal fracture is often the harbinger of more fractures to come and should be taken as a warning that testing and preventive treatment is needed. Given that 20% of those who suffer a hip fracture die within one year, it is not only unacceptable but unjust not to take action to change this," said Professor Cyrus Cooper, chair of the IOF Committee of Scientific Advisors.

—EH (October 22, 2013)



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SPINE

Amedica Launches Valeo II

The names of devices grow longer and longer. Note Amedica Corporation's new Valeo II Silicon Nitride Anterior Lumbar Interbody Fusion Device. The device is made from the firm's silicon nitride biomaterial which, according to the company, has been shown to help promote bone growth and provide anti-infective properties. The device is indicated for intervertebral body fusion of the spine in skeletally mature patients and is designed for use with autograft to facilitate fusion.

Courtesy of Amedica Corporation

Gary Powell, M.D./ Source: Dr. Powell

Gary Powell, M.D., a civilian neurosurgeon at Elgin Regional Hospital, Elgin Air Force Base, Fort Walton, Florida, praises the surface on the re-engineered device. While the surface of the original device was textured to facilitate new bone growth, the new ones contain

ridges that are placed in such a direction that they facilitate insertion into the interspaces in the lumbar spine but resist pulling out. "It really does work," Powell told *OTW*.

Powell praised Amedica's diligence in gathering surgeon feedback on their revised product. "Before they put it on the market they brought it to a bunch of us and asked for our opinions. We were putting a lot of those devices in and wanted to help make them better," he said. There were about four years between the launching of the first and second modified product.

Powell is also impressed with the silicon nitride material out of which the devices are made. Unlike plastic or metal implants bone grows into it. "I can't wait until I see coming down the pipe line artificial joints and other bodies made from this material. That could solve a lot of problems," he said.

Eric K. Olson, Amedica president and CEO said: "Amedica is committed to delivering products that address the changing needs of spinal surgeons. Our next generation Silicon Nitride AL device provides an optimal environment for bone growth while reducing the risk for infection due to its innate anti-infective properties. These benefits have the potential to improve the efficacy of spinal fusion procedures resulting in enhanced patient care. As Amedica continues to collaborate with surgeons to develop innovative, safe and effective interbody fusion devices, Silicon Nitride is increasingly becoming the gold standard material for spinal fusion devices."

—BY (October 22, 2013)

PEOPLE

Joe Zuzula, Bill Ditty Promoted at Orchid Orthopedic Solutions

Orchid Orthopedic Solutions is proud to announce the promotions of two key individuals. First, Joe Zuzula has been named Vice President of Sales and Marketing. Zuzula has spent 19 years at Orchid, and has demonstrated "an uncanny ability to manage a sales and marketing staff and to drive the sales throughout Orchid." Zuzula is known for keeping the sales staff both motivated and accountable while cultivating strong relationships with customers and media partners. He is a graduate of Michigan State University with a B.S. in Physical Science Secondary Education with a minor in Mathematics.

Second, Bill Ditty is being elevated to the position of Vice President of Quality and Regulatory Compliance for Orchid. Ditty has been serving as Director of Quality and has done "an outstanding job of advancing Orchid's quality team." He has successfully led the company through the new FDA registration requirements. Ditty possesses a broad base of experience at companies such as Monteris Medical and Stryker Instruments. He spent eight years as an officer in the Coast Guard, has an M.B.A. in Finance and a B.S. in Naval Architecture and Marine Engineering from the United States Coast Guard Academy.

Asked about his new role Bill Ditty commented to *OTW*, "In alignment with our mission 'To provide an Opportunity for People to Live a Better Life' I will continue to raise global product quality

Bill Ditty/ Orchid Orthopedic Solutions

Joe Zuzula/Orchid Orthopedic Solutions

levels by leveraging industry best practices. Also, I will seek to bring value to our customers by identifying changes and opportunities for improvement in the ever changing medical device regulatory climate and ensuring we have the correct resources in place to proactively manage them."

Joe Zuzula noted, "I will begin by participating in the regular executive team meetings with the CEO, CFO, CAO and EVPs. I will provide input into our long term strategy for growth and will support board of director initiatives such as our three year management plan. My continued focus will be on expanding in new geographic markets such as Europe, South America and Asia and aligning our global sales organization with our strategic goals for process and growth. I will also reach to expand our acumen in intelligence about our markets."

—EH (October 25, 2013)

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