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Orthopedics This Week

WEEK IN REVIEW

SpineLine's 20 UNDER 40

BREAKING NEWS

For all news that is ortho, read on.

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: As you know, the Power Rankings highlight low valuation companies with above average financial strength and sales growth prospects. If sales growth is low, then I look for a nice cash dividend. If sales growth is low, but there is a change of management, culture or a catalyst driving clinically relevant innovation, then a company can make the Power Rankings. So it is clearly so this week with our top four companies—Bioventus, up 33%, ZimVie up 33%, Integra, up nearly 9% and Zimmer Biomet up 7%. Back on the Rankings is OFIX at #10, which is now restructuring the board of directors. Overall, ortho market sentiment is as positive as I've seen in years. 2023 is ending on a high note.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Bioventus	(5.33)	33.08%	Why has BVS been such a hot stock in the last 90-days? One major reason is the $0.37 per share profit Wall Street is forecasting for 2024. Big contrast to 2023's losses.
2	2	ZimVie	(5.96)	33.10	ZimVie sells its spine business to a private equity firm for $375 million. As a pure dental company, ZIMV should be routinely profitable with a leading market share. And a cash rich balance sheet.
3	3	Integra LifeSciences	17.32	8.77	IART buys JNJ's ENT (ear, nose, throat) company Acclarent for $275 million in cash. Will fold into its Codman Specialty Surgical unit. Synergistic with Neurosurgery.
4	5	Zimmer Biomet	19.31	7.41	Under new CEO Ivan Tornos, more management changes and a new energy up and down the ranks. Will not be apparent in the sales and earnings for a couple years, but the change is for real.
5	9	Medtronic	19.26	11.60	China's Volume Based Procurement (VBP) hit Medtronic and played a role in this years soft spine numbers. Other ortho suppliers are simply leaving China.
6	4	ConMed	7.42	4.93	CNMD should have a really solid end of the year report—sales up nearly 20% and a big earnings jump, from $2.65 per share last year to $3.50 EPS this year.
7	7	Axogen	(9.75)	26.56	CEO Zaderej replaced former CFO with Nir Naor, a 20-year veteran finance exec with tours of duty at Arbor Pharma, Mölnlycke Healthcare and AstraZeneca. Investors like the move.
8	10	Pacira Biosciences	12.86	9.56	PCRX should end 2023 reporting $678 million in sales and a 20+% earnings growth to $3.01 per share. At this valuation ($1.45 billion) PCRX is the best value in ortho.
9	6	Anika Therapeutics	(20.94)	8.93	ANIK has so many innovative, clinically relevant new products launching, sales growth should find a way into the double digits in 2024.
10	NR	Orthofix	(8.51)	13.06	Latest news: Board Chair Catherine Burzik is stepping down and 3 more independent board members are joining. Just me, or has OFIX had more than a fair share of board and c-suite change?

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	ZimVie	ZIMV	$11.22	$298	33.10%
2	Bioventus	BVS	$5.17	$407	33.08%
3	Nevro Corp	NVRO	$21.62	$783	26.58%
4	AxoGen	AXGN	$7.29	$314	26.56%
5	Alphatec Holdings	ATEC	$13.43	$1,831	19.91%
6	Orthofix	OFIX	$12.12	$445	13.06%
7	Medtronic	MDT	$82.61	$109,843	11.60%
8	Pacira Biosciences	PCRX	$31.29	$1,453	9.56%
9	Anika Therapeutics	ANIK	$22.32	$327	8.93%
10	Medacta	MOVE	$139.77	$2,795	8.81%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MicroPort Scientific	0853	$1.06	$1,946	-39.88%
2	Aurora Spine	ASG.V	$0.27	$19	-11.15%
3	SINTX Technologies	SINT	$0.39	$2	-6.38%
4	Xtant Medical HIdgs	XTNT	$1.10	$143	-4.35%
5	Dynatronics Corp	DYNT	$0.51	$2	-1.12%
6	OrthoPediatrics Corp	KIDS	$31.16	$728	1.15%
7	Stryker	SYK	$290.15	$110,226	2.30%
8	Smith & Nephew	SNN	$26.44	$11,546	2.92%
9	Johnson & Johnson	JNJ	$155.16	$373,513	4.27%
10	ConMed	CNMD	$113.18	$3,481	4.93%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Integra LifeSciences	IART	$42.77	$3,344	18.52
2	Johnson & Johnson	JNJ	$155.16	$373,513	18.73
3	Medtronic	MDT	$82.61	$109,843	19.60
4	Globus Medical	GMED	$49.54	$6,965	25.45
5	Zimmer Biomet	ZBH	$118.69	$24,804	26.21

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medacta	MOVE	$139.77	$2,795	53.44
2	Smith & Nephew	SNN	$26.44	$11,546	51.78
3	ConMed	CNMD	$113.18	$3,481	42.01
4	Pacira Biosciences	PCRX	$31.29	$1,453	39.97
5	Stryker	SYK	$290.15	$110,226	32.87

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Smith & Nephew	SNN	$26.44	$11,546	-6.47
2	ConMed	CNMD	$113.18	$3,481	1.47
3	Globus Medical	GMED	$49.54	$6,965	1.57
4	Medacta	MOVE	$139.77	$2,795	1.92
5	Stryker	SYK	$290.15	$110,226	3.10

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Medtronic	MDT	$82.61	$109,843	5.82
2	Integra LifeSciences	IART	$42.77	$3,344	5.14
3	Johnson & Johnson	JNJ	$155.16	$373,513	3.93
4	Zimmer Biomet	ZBH	$118.69	$24,804	3.78
5	Pacira Biosciences	PCRX	$31.29	$1,453	3.48

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$0.51	$2	0.06
2	ZimVie	ZIMV	$11.22	$298	0.33
3	Bioventus	BVS	$5.17	$407	0.80
4	Orthofix	OFIX	$12.12	$445	0.97
5	Aurora Spine	ASG.V	$0.27	$19	1.00

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	SI-BONE, Inc	SIBN	$19.00	$770	7.23
2	Globus Medical	GMED	$49.54	$6,965	6.81
3	Medacta	MOVE	$139.77	$2,795	6.39
4	Stryker	SYK	$290.15	$110,226	5.97
5	OrthoPediatrics Corp	KIDS	$31.16	$728	5.95

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

From Personal Tragedy to Hot Spine Start Up

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

How did you decide to start a medical device business?

Most often, it's a personal experience with the transformational power of healing.

At the just completed North American Spine Society (NASS) 2023 annual meeting, we asked the CEO of a young and emerging technology company that question. How did you decide to start your business?

Her answer turnout out to be both interesting and inspiring.

We want to share it with you.

The young CEO is Alyssa Huffman, 44 years old, M.B.A, founder and CEO of Allumin8.

Here is her remarkable story.

Alyssa Huffman, M.B.A, founder and CEO of Allumin8 / Courtesy of Alyssa Huffman

When Revisions Become Personal

Huffman had been working for years as a rep distributing for many of the biggest total joints, trauma, extremity, spine, sports medicine, and biologics companies. She had been in hundreds of surgeries, sold thousands of products, and worked with many of the top surgeons.

Then, her uncle, Richard Whittington, in 2010 at 63 years old, had a failed lumbar fusion. His screws backed out and his rod broke. Coincidentally, Huffman's 21-year-old cousin was living with incomplete quadriplegia and experienced the same result.

That's when the downside of her business became personal.

Her uncle would eventually have six spine surgeries. "If someone is 45 and in good health, things are fairly straightforward. But if you have a diabetic patient—like my uncle—then the risk of a poor outcome, infection or immune system issues sky rocket."

"I simply grew tired of watching failures occur while seeing the effects they had on the patient and their loved ones," remembers Huffman. "The industry needed a new perspective on design which would more closely reflect research and build on what is available to surgeons within the hospitals but also incorporate gold standard practices and the emerging advanced manufacturing technologies."

In 2009, Huffman began sketching out some design concepts for reducing screw pull out and rod breakage.

She then ran across a paper published in *Biomaterials & Tissue Biomechanics,* written by Professor Amir A. Zadpoor, Ph.D., which compared the architecture of bone in the vertebrae to other areas in the body. "Vertebral bone is much more porous…the lattice structure is thinner and more rounded. Which helps explain why bone in the spine needs more assistance with respect to the demands of hardware."

Tapping into some engineers in her network, Huffman looked more closely at the trabecular pattern of bone in the spine and used that to re-imagine what a pedicle screw might be.

"We engineered hundreds of micro and macro changes to the design of a pedicle screw. Our engineering team took my ideas and created functional art," remembers Huffman.

In effect, she was aligning pieces of a complex puzzle for, she hoped, one of the companies she was repping for. Perhaps, she thought, they would get

excited about her ideas and agree to take them through the regulatory process and ultimately to spine surgeons.

But, as thousands of entrepreneurs have learned before Huffman, "By 2019 I realized it was up to me to bring it to life."

Breaking the Mold

Alyssa Huffman's father was an orthopedic flight surgeon in the Air Force. Like him, she enjoyed research, thinking limitlessly, and focus. Surgery was where she found her calling.

In college, at 19 years old, Huffman was aiming for medical school. But life has a way of laughing at our best laid plans and intentions.

Medical school, at least at that stage in life, was not an option, so she pivoted to journalism—a career that is also, at its core, research based. To pay the bills, Huffman took advertising and medical equipment gigs while also applying—repeatedly it turns out—for sales rep jobs at orthopedic companies.

It took six years. Six long years.

"Finally, I heard from a distributor at Smith & Nephew who had just interviewed my brother. He wound up going to NASA (smart family!) but he recommended they contact me. Through some divine intervention, I gratefully accepted my first role as a total joint rep in 2007. It was a phenomenal, yet character-building experience…Smith & Nephew was great to me, and I made lifelong friends."

Huffman rose through the ranks becoming over the years a comprehensive orthopedic and spine product distributor rep, managing spine, biologics, total joints, trauma, sports medicine, computer navigation, and foot-and-ankle products through various manufacturers.

And, breaking the mold.

"I recall being at a Smith & Nephew meeting where there were hundreds of men—and me—the only woman who wasn't an assistant."

Huffman also learned about the less savory aspects of the medical device business. "I was once criticized by a manager who stated I needed to stop reading research because my job was to sell. It's easy to say I overlooked it, but comments like that creep into the psyche."

"Just because I wasn't a researcher didn't mean I couldn't read data from all over

the world and correlate the emerging trends."

And then there were the short cutters. "I've seen it all. From shady business partners to unethical management, and poor business practices."

There are no short cuts to quality medicine.

The Indelible Power of a Good Mentor

At the persistent urging of her mentor, the late Dr Luke Vaughan, former Orthopedic Oncology Director at the Scripps Institute, Huffman kept working on her personal project—reducing pedicle screw failure. "At that time, I didn't have a lot of support and honestly didn't believe a woman without a research or surgical background in the Midwest could go up against the likes of titans in the field."

The year 2018 took a turn for the worse for Huffman.

Huffman's marriage was unraveling. She had a young son. At about the same time, she jumped into a taxi cab and on the way to her destination, was slammed by a drunk driver speeding along at 77 mph. She was gravely injured with a traumatic brain injury. That started her on a journey of multiple surgeries, trigeminal neuralgia, and lawsuits. She asked her employer for sick leave for emergency brain surgery and was laid off—which, to her, seemed incomprehensible given her string of promotions and performance. Then there was the PTSD.

She was at a crossroads in her life.

"Giving up wasn't an option. Working for a large company wasn't an option anymore. I was tired of being disposable after delivering great successes for companies. If I wasn't willing to bet on myself, why should anyone else?" says Huffman.

"I wanted to teach my son he could thrive through life's failures by growing mentally, physically, and spiritually. So, the first thing I did was invest in myself to bring my pet pedicle screw project to fruition by getting an MBA at Washington University - St Louis. I had always believed these designs could really help patients, surgeons, and hospitals alike. Now I had to prove it."

Going for Gr8

She gave her pedicle screw project a name. A8 Integr8™. She formed a company named Allumin8.

Huffman's next move was to reach out to Dr Khoi Than, M.D., a neurosurgeon at Duke University. "Dr Than published a powerful paper at the North American Spine Symposium (NASS) 2019. If anyone was going to give me honest feedback, it was going to be him."

Dr. Than's reaction to Huffman's new pedicle screw was encouraging. He, in turn, took it to several of his colleagues around the U.S.—Wilson Zach Ray, M.D., M.B.A., and Chief of Neurosurgery at Washington University - St Louis, Alekos Theologis, M.D. at the University of California, San Francisco, and later Mayur Jayarao, M.D. at Cox Health and University of Missouri.

For about a year, Huffman, Than, Ray, & Theologis met regularly to write grants and review design concepts. Of course, this journey led Huffman to the Dean of Spine and Orthopedic engineering—Mike Sherman. Also joining the initial small team was Charlie Barfield.

"We went through eight full redesigns with several engineers over the last four years and through some careful considerations for corrections finally found the one that could take the title of A8 Integr8 with additive manufacturing design guru Matthew Shomper.

"In the last series of tests, we threw everything we could think [of] into the designs while testing 16 different versions. To say the Allumin8 team was on the edge of our seats during the testing would be an understatement. We couldn't have done this without the support of our manufacturers."

Classic Bootstrapping

To pay Alumin8's bills, Huffman consulted with start-ups, small device companies, and private equity groups.

And she learned about how to start, fund and develop a start-up organization.

"The A8 team and I were methodical and very selective as far as investors. We got lucky because capital has been exceedingly challenging to come by in the U.S. Through the team's long-standing industry friendships, we found excellent manufacturers in India who not only invested in us but are also helping commercialize the A8 Integr8 Porous Pedicle Screw in Asia. We couldn't be more grateful for the support of 3D Incredible (the largest patient specific customized implant manufacturer in India) and Solco India for all their extraordinary efforts. This is truly what working globally and supporting a belief in helping the patient looks like."

Bill Walth, Ph.D. and Matt Pelletier, Ph.D., got interested.

"Once Bill showed interest, I knew we had something that could be profoundly impactful, said Huffman."

A Difference With a Distinction

"The A8 Integr8 Porous Pedicle Screw System offers a unique lattice structure commensurate with vertebral bone that internally collects freshly harvested autograft during insertion. Combined with the ability to draw in bone marrow, A8 Integr8 is designed to facilitate cell adhesion to the autograft. In essence, we aim to study if we can create a long-term biological ripple effect that demonstrates an increase in bone mineral density through regenerative processes. It's taking what is done in an interbody cage and translating it to pedicle screws without multiple steps."

And, of course, her A8 Integr8 is 3D printed.

"While we aim to focus within the spine market due to the high revision rates, we recognize this technology can help in many applications and are meeting with manufacturers to license the IP out. The goal is to solve global problems by providing options."

FDA Submission Q1 2024

Huffman and her small Allumin8 team are on track to submit 510(k) data to the FDA in Q1 2024.

"Honestly, I regard this pedicle screw as a masterpiece of macro and micro changes! This is such a clear 'win' for surgeons, patients, hospitals, and insurance companies alike that we have named our campaign, 'Why not?'—as in, 'If you're not changing your surgical technique, pricing, post-op or pre-op care, yet providing options that never before existed in hardware…then why not try A8 Integr8?'"

In addition, Huffman plans to study the effects of injecting off-the-shelf injectables through the pedicle screw to see if, with these new designs, surgeons will be able to reduce the sometimes catastrophic need for removal of hardware due infections, which she personally experienced with her uncle.

If the business of supplying orthopedic and spine surgeons is all about solving tough clinical problems, then Huffman has certainly chosen a promising market—the market for reducing spine surgery revision risk.

And, if we were to bet on any young entrepreneur, Alyssa Huffman would be at the top of the list. ♦

SpineLine's "20 Under 40" 2023 Honorees

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

Courtesy of spine.org

The North American Spine Society (NASS) has announced its selections of the most outstanding 20 musculoskeletal professionals under the age of 40 years old.

Truly, here is the future of spine surgery.

The young leaders were formally recognized in the most recent edition of NASS's publication *SpineLine*.

"We have an exceptional class of honorees and are thrilled by the quality of candidates we receive year after year," said F. Todd Wetzel, M.D., *SpineLine's* Editor in Chief and a former NASS president. "The 20 Under 40 program has continued to grow over the past six years, and we've enjoyed watching our honorees advance into leadership roles within NASS and the spine care field."

In their "20 Under 40" application statements, the honorees described factors that led them to spine care and named mentors who helped along the way. They also shared the highlights of their spine careers thus far, their philosophy of care, and how they contribute to the betterment of their communities.

This year's "20 Under 40" honorees as selected by the *SpineLine* Editorial Board are:

- Abduljabbar Alhammoud, M.D., MSc, Orthopedic Surgeon, Tucson, Arizona
- Massiel Alvarado Morales, M.D., Neurosurgeon, San Jose, Costa Rica
- Bryce Basques, M.D., M.H.S., Orthopedic Surgeon, Providence, Rhode Island
- Daniel Choi, M.D., FAAOS, Orthopedic Surgeon, Ronkonkoma, New York
- Hoon Choi, M.D., Ph.D., FAANS, Neurosurgeon, Weston, Florida

- Christine M. DiPompeo, M.D., Orthopedic Surgeon, Peoria, Illinois
- James Eubanks, M.D., D.C., M.S., Physiatrist, Charleston, South Carolina
- Juanita Garces, M.D., FAANS, Neurosurgeon, San Antonio, Texas
- Stephanie Halloran, D.C., MS, Chiropractor, Boston, Massachusetts
- Brian Karamian, M.D., Orthopedic Surgeon, Salt Lake City, Utah
- Justin M. Lantz, D.P.T., Physical Therapist, Los Angeles, California
- Alexander Lemons, M.D., FAAOS, Orthopedic Surgeon, Pinehurst, North Carolina
- Alex P. Michael, M.D., Neurosurgeon, St. Louis, Missouri
- Jacob Rohrs, M.D., Physiatrist, Scottsdale, Arizona
- Renee Rosati, D.O., Physiatrist, Charleston, South Carolina
- G. Sunny Sharma, M.D., Physiatrist, Dallas, Texas
- Gabriel A. Smith, M.D., Neurosurgeon, Cleveland, Ohio
- Courtney Toombs, M.D., Orthopedic Surgeon, Ronkonkoma, New York
- Aditya Vedantam, M.D., Neurosurgeon, Milwaukee, Wisconsin
- Andrew S. Zhang, M.D., Orthopedic Surgeon, Shreveport, Louisiana

OTW asked Dr. Wetzel about the increasing popularity of *SpineLine's* "20 Under 40" and he said, "I think the program is gaining momentum for two reasons. Firstly, the membership is becoming a bit younger, which we would like to encourage. I think younger physicians also see this as a great opportunity to get engaged in committee administrative and academic work at NASS. Secondly, there is the human-interest angle. More senior practitioners enjoy getting to associate names with faces, and 20 under 40 is the perfect introductory vehicle."

"Selection criteria include clinical, academic, and educational achievement," stated Dr. Wetzel to *OTW*. "Recipients need not necessarily be in an academic post but need to be outstanding and committed leaders and their particular situations." ♦

Point of Care Device Printing Gets BIG Boost

BY KIM DELMONICO

Source: Ricoh USA, Inc. and Materialise

Ricoh USA, Inc. and Materialise have partnered to expand access to Point of Care 3D printing.

The partnership combines Materialise's software solutions with RICOH 3D's equipment and distribution infrastructure for Healthcare.

According to the company RICOH 3D for Healthcare is a "HIPAA-compliant, ISO 13485 certified 3D medical manufacturing center for the development, design and production of 3D-printed anatomic models." The companies are bringing together the software and 3D printing in both Ricoh's centralized production facility and Ricoh's Point of Care facilities.

Bryan Crutchfield is the vice president and general manager of Materialise North America. Crutchfield commented, "Outside of large academic medical centers, physician and patient access to 3D printing applications has been limited."

Crutchfield continued, "This is often due to a lack of resources and technical knowledge to implement and operationalize the technology in the hospital environment. This partnership with Ricoh brings a large managed services infrastructure, which will enable hospital systems to more quickly and affordably implement and scale 3D technology for their physicians and patients. We are excited to partner with Ricoh to bring our end-to-end software platforms to support 3D planning and 3D printing applications at the Point of Care."

Ricoh has engaged in other partnerships to further its goal of expanding access to RICOH 3D for Healthcare. Ricoh has partnered with Merge by Merative, a provider of medical imaging solutions. Ricoh has also partnered with Stratasys to utilize its 3D printing technology and materials.

Gary Turner is managing director of additive manufacturing North America for Ricoh USA. Turner spoke to *OTW* about the goals for the partnership for the upcoming year. "The goal is to collaborate with partners, like Materialise, to develop new approaches to make this game-changing technology accessible to all."

"We will work to merge our strengths to determine better methodologies as we continue to expand our partnership. Through our collaboration, we will be able to tailor our Point of Care solutions to meet unique hospital and health system needs, such as volumes and specialties. Like our solutions, there is no one-size-fits-all for creation of Point of Care Managed 3D Printing Services." ♦

COMPANY

IncludeHealth Partners With Healthcare Marketing Platform

IncludeHealth, Inc., a provider of musculoskeletal technology solutions, is partnering with SocialClimb to improve the patient experience and expand access to its digital self-assessment tool.

SocialClimb offers its clients a healthcare marketing platform to bring together physicians and patients online. The partnership will enable SocialClimb to provide its orthopedic clients access to IncludeHealth's digital front door, a digital self-assessment tool.

OTW spoke with IncludeHealth about the partnership and the digital self-assessment tool. When asked about the number of practices implementing the tool, IncludeHealth told *OTW*, "This tool launches in November so none yet, but we have the first 10 practices signed up."

OTW also asked IncludeHealth about how many practices would have access to this tool through the partnership. IncludeHealth explained to *OTW*, "Any practice can have access to it by reaching out to SocialClimb or IncludeHealth."

IncludeHealth's digital front door is designed to enhance the patient's intake experience. It was created to engage the patient and provide essential information, all before the patient enters the orthopedic practice. Patients are able to use their own devices at home to complete real time movement assessments. All without the need for download, sensors, or passwords.

IncludeHealth's Digital Front Door / IncludeHealth, Inc.

Patients are able to access the digital front door from either a targeted marketing campaign or from the orthopedic practice's website. Once the patient accesses the digital front door, the patient completes an interactive movement assessment via computer vision and then completes a pain survey. The data is then immediately shared with the patient and the orthopedic practice.

SocialClimb CEO Ty Allen commented, "Our mission at SocialClimb has always been to enable our customers to attract the patients they need for growth."

Allen continued, "Bringing IncludeHealth's patented computer vision capabilities into the marketing tools we offer is changing the way orthopedic patients engage with practices creating a differentiated patient experience." — *KD*

LEGAL

Two Patents Issued for Bone Growth Stimulator System

The United States Patent and Trademark Office has issued two new patents for a therapeutic stimulator system, patent numbers 11,717,685 and 11,759,637.

The patents were issued to Theragen, Inc. and are for different elements of Theragen's ActaStim® bone growth stimulator system.

According to the company's press release, patent number 11,717,685 "focuses on tracking the intensity level

ActaStim® bone growth stimulator system / Source: Theragen, Inc.

of patient activity together with device usage, comparing this data against the prescribed therapy regimen to deliver insight into the recovery process for patients and surgeons."

Patent number 11,759,637 "correlates system usage with the patient's physiology to ensure patient confidence in the ongoing treatment and encourage patient compliance with the therapy regimen."

OTW spoke with Theragen CEO and President Chris McAuliffe about what sets ActaStim apart from its competition. McAuliffe explained to *OTW*, "The patient's healing journey to a successful fusion can take 9 or more months. During that time, patients benefit from support and assurance that they are on the right track. But they also need post-operative therapeutic technology that improves fusion success and guides them through continual improvements in mobility and activity in accordance with their surgeon's instructions."

McAuliffe continued, "The ActaStim-S device is the first major advancement in non-invasive spinal fusion bone growth stimulation in nearly 20 years. ActaStim is intentionally designed to improve patient compliance and improve fusion success with clinically proven therapy. It's the only system that facilitates all-day wear and automatic, daily time-stamped capture of wear time and relative activity levels, combined with pain scores, to better support a successful healing journey."

Theragen also received a notice of allowance for patent application publication number 2022/0387783. Per the press release, the patent application has "claims of comparing patient physiological data with patient-reported outcome measures, such as post-operative pain level, and to optimize the therapy regimen using this data." If that patent is issued, it will mean that Theragen will have been issued five patents in just over two years.

OTW also spoke with McAuliffe about the company's goals for the upcoming year. McAuliffe told *OTW*, "In 2024, Theragen will achieve significant growth and market share gain in only a few years in this very competitive market. That means thousands of patients and surgeons seeking improved spine fusion outcomes will benefit from our small, compact, wearable device that delivers Level I proven therapy and helps them monitor their progress."

McAuliffe continued, "In support of this goal, we will continue building a national presence of highly trained sales and customer care professionals who will deliver our VIP Customer Care. Our philosophy of 'customer care first' is in our DNA, it always wins the day, and it is helping us earn the support and business of established prescribers who every day are choosing ActaStim over legacy competitive bone growth stimulators." — *KD*

SPINE

Novel 3D Printed Lateral Interbody Device Launched

Orthofix Global Spine has announced the full U.S. commercial launch of the WaveForm® L Lateral Lumbar Interbody System. The 3D-printed WaveForm L, meant for lateral lumbar interbody fusion (LLIF), features a porous structure focused on strength and stability to provide a robust fusion environment.

"Designed to treat the spine safely and reproducibly through indirect decompression and sagittal alignment restoration, the WaveForm L features a large core aperture for the placement of bone graft material to optimize bony fusion throughout the interbody," said Donald Blaskiewicz, M.D., director of Spinal Deformity at St. Luke's Boise Medical Center in Boise, Idaho, and faculty at UCSD in San Diego, California. "The WaveForm L also has improved imaging characteristics to aid in radiographic visualization during intraoperative and postoperative imaging. These combined features make it one of the best 3D-printed interbodies available."

WaveForm interbodies are uniquely created with a primary focus on structure, surface and stability, says the company. "Constructed from a repeating wave-like structure, WaveForm L is designed to efficiently distribute compressive loads and provide high porosity for optimized stiffness without compromising strength.[1,2] At 80% body porosity, WaveForm L provides enhanced imaging characteristics and increased graft packability, while the optimized 65% endplate porosity of

WaveForm L Interbody System / Courtesy of Orthofix Global Spine

the wave-like structure provides for boney ingrowth and early mechanical stability." [3,4,5]

When asked how the size of the aperture differs from existing systems, Orthofix Global Spine President Kevin Kenny told *OTW*, "WaveForm L features an innovative graft aperture that mates directly with our best-in-class biologics. When coupled with Osteo-Strand® Plus, an osteoinductive environment is created within the WaveForm interbody, where the graft can flow from the inside out, forming a connection endplate to endplate, and ultimately be contained within the WaveForm structure."

Regarding how the imaging characteristics been improved, he added, "Waveform L's 80% body porosity and sheet-based gyroid design requires less material to achieve the desired strength. In turn, less titanium aims for improved imaging and imaging contrast." — *EH*

References

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PEOPLE

Inferior Screw Fixation Study Wins Technique & Technology Award

Is inferior screw fixation a safe and reliable way of reducing acetabular component failure after revision total hip arthroplasty (THA) in cases of severe acetabular bone loss?

Gregory G. Polkowski II, M.D., M.Sc. (left) congratulates Lead Author Christopher M. Melnic, M.D. (right) / Courtesy of AAHKS

"Yes" says a new award-winning study.

Led by Christopher M. Melnic, M.D. with co-authors Amy Z. Blackburn, B.A., Ashish Mittal, M.D., Brian Velasco, M.D., Colin M. Baker, D.O., Nicholas Vandal, B.A., Saad Tarabichi, M.D., P. Maxwell Courtney, M.D., Neil P. Sheth, M.D. and Hany S. Bedair, M.D., this new study of inferior screw fixation won the AAHKS Surgical Techniques and Technologies Award, which recognizes outstanding advancement in surgical innovation within reconstructive surgery.

"My co-authors and I are honored to receive the AAHKS Surgical Techniques and Technologies award for our manuscript on inferior screw fixation in revision total hip arthroplasty. In this multicenter, retrospective study, we found that the addition of inferior screw fixation for Paprosky Type II or III acetabular bone loss was associated with a lower rate of aseptic failure compared to fixation with superior screws alone," said Dr. Melnic.

The researchers looked at 250 patients with Paprosky Type II or III defects who had acetabular revision from 2001-2021 (four institutions).

They collected data on demographic factors, the number of screws, location of screw placement (superior versus inferior), use of augments and/or cup-cage constructs, Paprosky classification and presence of discontinuity. Inferior screw placement was defined as placement in the superior pubic ramus or ischium based on radiographs.

At mean follow-up of 53.4 months, 16 patients (6.4%) required re-revision for acetabular loosening. There were 140 patients (56.0%) with inferior screw fixation, all without neurovascular complication during screw placement. Patients with inferior screws had a lower rate of acetabular re-revision than those with only superior screw fixation (2.1% vs. 11.8%). Multivariate regression revealed that inferior screw fixation decreased the likelihood of re-revision for acetabular loosening when compared to superior screw fixation only.

"The number of revision total hip arthroplasties continues to increase despite total hip arthroplasty being a very successful procedure," said Dr. Melnic to *OTW*. "Revision total

hip arthroplasty is complicated in the setting of acetabular bone loss. Successful treatment is predicated on achieving a stable construct which often necessitates the use of additional fixation. One additional fixation technique is the use of inferior screw fixation into the ischium or superior pubic ramus."

"The use of inferior screw fixation into the ischium or the superior pubic ramus has been evaluated biomechanically where it was found to decrease micromotion of the cup and increase abduction stability.

Going forward, Dr. Melnic told *OTW*, "Additional focuses of research could include determining if screw length played a factor in stability of the construct and if a specific implant had an impact on the stability of the construct." — *EH*

Sethi, Albert, Lenke Join National Spine Foundation Board

The only patient-centered nonprofit dedicated to helping patients overcome spinal conditions—the National Spine Health Foundation—has announced that Rajiv Sethi, M.D. has been named Chairman of the Medical & Scientific Board, while Todd Albert, M.D. and Lawrence Lenke, M.D. have joined the organization's Board of Directors.

Dr. Sethi, Medical Director of the Center of Neurosciences and Spine at Virginia Mason Franciscan Health, succeeds Thomas Schuler, M.D., who remains on the Board of Directors.

"I am delighted to pass the torch to Dr. Rajiv Sethi as the next Chairman of

Left to Right: Rajiv Sethi, M.D., Todd Albert, M.D. and Lawrence Lenke, M.D.
Courtesy of The National Spine Health Foundation

the Medical & Scientific Board," said outgoing Medical and Scientific Board chair and current Board President Dr. Thomas Schuler to *OTW.* "The National Spine Health Foundation will always be dedicated to building a trusted resource for patients where we not only celebrate the positive strides in spinal healthcare but also enhance the patient experience through education, advocacy and research."

Dr. Sethi explained to *OTW*, "My priority for the National Spine Health Foundation is to be the pre-eminent source for patient empowerment in decision-making. This includes bringing together experts from around the country and providing cutting-edge information in a user-friendly format for all patients with spinal conditions. This includes highlighting the best center-of-excellence models of spinal care and value-based platforms that embody the highest quality for patients."

"My first steps in my new role are to connect with all members of the medical and scientific board in order to develop a cohesive and transparent strategy around content and philanthropic contribution to our mission and vision."

Todd Albert, M.D., Surgeon-in-Chief Emeritus at Hospital for Special Surgery, commented to *OTW,* "I became involved with the National Spine Health Foundation because the mission really resonated with me and what I desire for our patients, which is great information and a resource of honesty and truth about spinal disorders."

"The National Spine Health Foundation's profile will be raised naturally by continuing to pursue that mission and incrementally reaching more patients and their providers."

Lawrence Lenke, M.D. is Chief of Spinal Deformity Surgery in the Department of Orthopedic Surgery at NewYork-Presbyterian/Columbia University Irving Medical Center. He told *OTW*, "I am fortunate to be a part of the National Spine Health Foundation, which serves as a platform for disseminating patient-centered factual information. My commitment to educating and advocating for patients with various spine afflictions, especially various spinal deformities, aligns seamlessly with the NSHF's mission."

"I have been amazed at the coordination and communication of the NSHF at its administrative level, especially with the past and current leadership of Dr. Schuler and CEO Rita Roy. This is a 'let's get things done' organization looking at improving knowledge and education for patients with spine disease on many different fronts."

When *OTW* asked what priorities and projects he would like to see undertaken at the nonprofit, he stated, "I believe the National Spine Health Foundation has only reached the tip of the massive iceberg of patients needing treatment for spinal problems. It has thus far focused on surgical patients, but since more than 90% of patients with spine disease will not require surgery, focusing on this extensive non-operative population will be critical to future success."

About the National Spine Health Foundation

The National Spine Health Foundation (NSHF), a 501(c)3 nonprofit organization, is the only patient-centered organization dedicated to making moves that keep Americans moving. The NSHF helps Americans avoid and alleviate neck and back pain by educating consumers on practical ways to lead a spine-safe lifestyle; researching and amplifying life-saving treatments and surgeries; and advocating for changes that would improve the state of spine health in America. The NSHF is home to a prestigious Medical & Scientific Board that includes 50 of the nation's leading experts in spine, as well as the "Get Back to It" podcast, which shares real stories of healing and recovery from individuals who have overcome neck and back pain. Learn more at spine-health.org. — *EH*

REMEMBRANCE

Emmanuel Konstantakos, Leading Ortho Surgeon, Dies Age 49

Emmanuel K. "Manny" Konstantakos, M.D., incoming chairman of

Emmanuel K. "Manny" Konstantakos, M.D.
Courtesy of the Albany Times Union

orthopedic surgery of the American Board of Physician Specialties (ABPS), and board-certified orthopedic surgeon known for his dedication to and caring for patients and colleagues, died suddenly on November 2, 2023, at the age of 49.

Dr. Konstantakos graduated Magna Cum Laude with a B.A. in biology from Case Western Reserve University in Cleveland, Ohio, in 1996 and went on to earn an M.D. degree from the Pre-Professional Scholars Program in Medical Education and Musculoskeletal Research from Case Western Reserve University School of Medicine in 2002.

He completed his residency in orthopedic surgery at the Boonshoft School of Medicine at Wright State University in Dayton, Ohio, followed by completing an orthopedic sports medicine and arthroscopic surgery fellowship at the University of Chicago.

He began his clinical practice of orthopedic surgery at the Holzer Clinic Health System in Gallipolis, Ohio. The death of Dr. Emmaneul leaves a gaping hole in the small, Ohio River community of Gallipolis, population 3,313, and the surrounding rural Ohio and West Virgina communities.

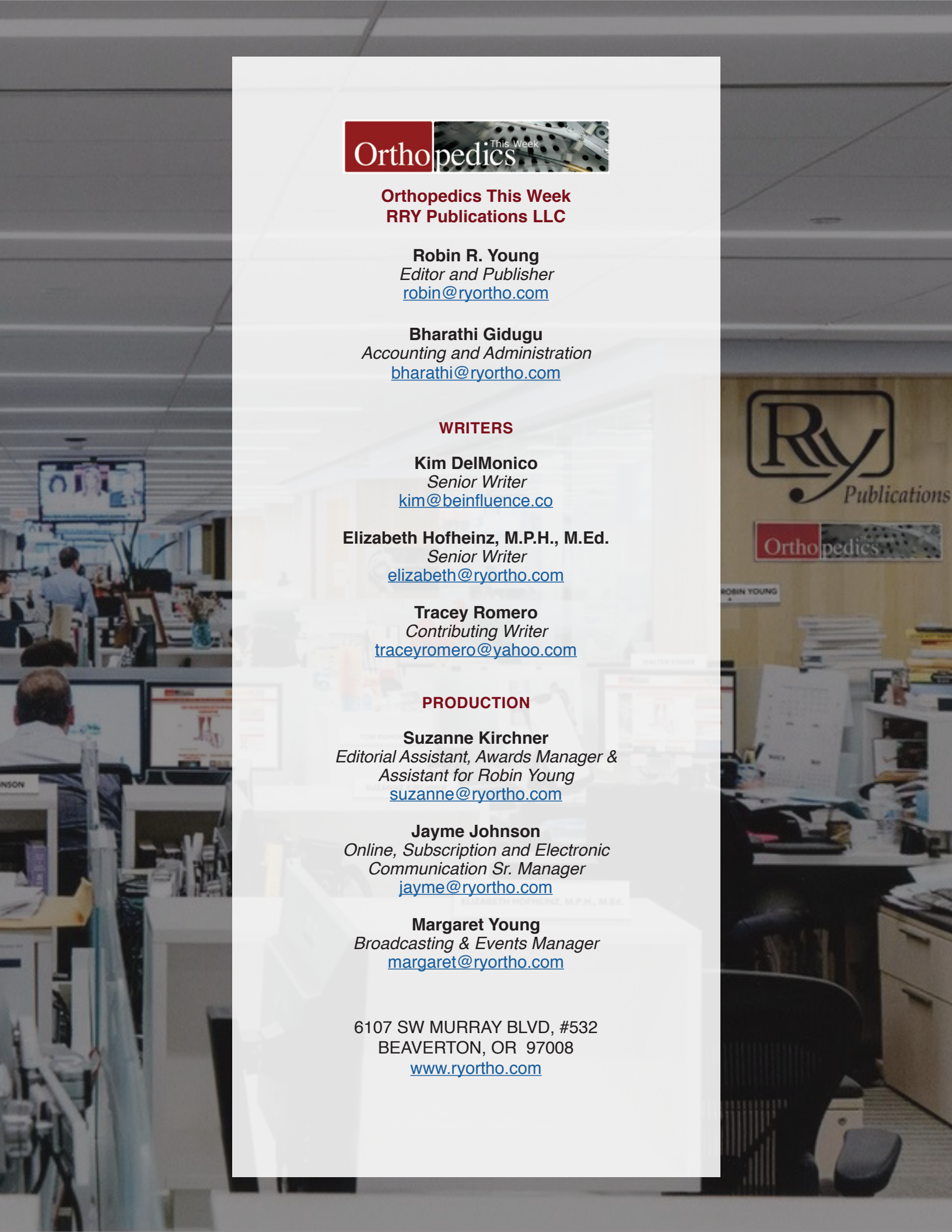
He'd received numerous accolades both from patients and colleagues including Physician of the Month and countless patient-based awards for exemplary surgical patient care.

Earlier this year, he "…was elected chairman of orthopedic surgery of the American Board of Physician Specialties (ABPS) headquartered in Tampa, Florida. He was instrumental in developing board certification and re-certification evaluations and was passionate about promoting national options for physician-led board certification."

"A common theme reiterated by his patients was how much time he would spend with them and their families and how much he genuinely cared for them. He was frequently described as the most down-to-earth doctor anyone had ever met."

Konstantakos was born in Akron, Ohio, to Konstantin Konstantakos and Zoi Konstantakos in 1974. His family later moved to Littleton, Colorado, where he went to high school at Wheat Ridge High School and graduated in 1992. His lifelong love of sports and fitness led him to pursue orthopedics. He excelled in football, track and field, and weight training.

Besides his passion for fitness and medicine, Konstantakos also loved to play guitar at open mic nights and spend time with friends and family. He leaves behind his parents, his brother Anastasios, a large extended family, and many friends. — *TR*



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